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How do doctors make decisions about information disclosure? A moral diagnosis

by

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Abstract

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Matthew Watkins

Alongside diagnosis and treatment, information disclosure is a fundamental legal duty owed by the doctor to the patient during the medical relationship. The duty is based on a longstanding moral responsibility to make decisions in the best therapeutic interests of the patient; by providing them information before, during, and after treatment. Failure to ensure adequate information disclosure is not in the patient's best interests; as it fails to respect the dignity of patients to be informed and denies them the opportunity to make autonomous choices; as the basis of their treatment decisions. Failure to disclose essential information may ultimately lead to patient harm. These failures have been only too well evidenced in several high-profile scandals which have shaken trust in the moral and technical expertise of the medical profession and have led to political and academic calls for stronger ethical and legal regulation, including in relation to medical decision-making about information disclosure.

Academic lawyers and bioethicists have long argued that the sociological nature of the *Bolam* standard has facilitated a culture of deference, within the courts, towards medical paternalism. Since the turn of the century the academic zeitgeist has very much focused on debating the form and structure of normative rules and ethical standards for decision-making around information disclosure. Normativity has been characterised as the solution to future unethical decision-making. The normative rules and standards proposed have prioritised reducing medical discretion, by repurposing information disclosure towards facilitating models of substantive autonomous choice, and in doing so recasting the doctor as a service provider, within a consumer-type medical relationship. This has manifested in the law of negligence through the creation of various patient rights (and corresponding duties), to provide information disclosure to ensure an informed consent to treatment. However, the emphasis on facilitating rights and patient autonomy has often been done without robust empirical reflection, on the impact, rules, and standards of information disclosure on medical decision-making in practice. As such, these rules have failed to alter practices towards the envisaged ethical optimum. This thesis aims to fill that analytical gap by examining the empirical data; to explain how doctors made, and continue to make,

medical decisions (from 1957 to present) about information disclosure and how the various ethical models of the medical relationship, contained within ethical and legal rules, have manifested in practice.

The thesis argues that the lack of empiricism has caused lawyers and ethicists to ignore the axiomatic internal moral norms and processes which have guided and structured medical decision-making within the therapeutic medical relationship, since time immemorial. These moral norms operate in medical decision-making through a process of *circumstantial-moral* reflection - which allowed doctors to facilitate patient information needs by combining learned knowledge, moral norms and patient circumstances, to come to a synoptic decision about materiality and communication, with the teleological aim of acting in the patient's best interests. Legal and ethical normativity has had the effect of restricting the tailored approach to decision-making, by requiring the inclusion of extraneous facts, and that artificial weight be placed on values and principles (such as autonomy), which may be irrelevant to the *actual* patient. As ethical guidance has become more substantive, fear of litigation has created a formulism and rigidity in decision-making about disclosure: a process termed *demoralisation*. The philosophical basis of the rules has also tended to conflate the teleological ends of different types of medical relationships within the law and ethics. This has sometimes confused doctors as to the purpose and process of information disclosure, placing values and principles in conflict with the underlying moral norms of the medical profession. Models of autonomy have also been conflated, within standards of care and ethical rules; requiring doctors to utilise conflicting methods of decision-making to identify material information to ensure an informed consent. The confusion and conflict as to the purpose and process of disclosure has led to a form of moral fracture within the medical profession.

The lack of certainty about the ethical underpinning of rules after *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, has now created uncertainty about the appropriate legal interpretation of the standard of care. This uncertainty has, in turn, led to a process of *blinkered moralism*: where the judiciary arbitrarily pick and choose the characteristics, values and criteria necessary to ensure an informed consent, when deciding liability. The unknowability of the correct form of decision-making, coupled with the fear of liability, has encouraged doctors to adopt practices of exhaustive disclosure. Exhaustive disclosure leads to patients being bombarded with information and requiring a mandatory autonomous choice. This type of defensive practice fails to either provide patients with the information they need (denying them an informed choice) or respect their choices about their preferred role within the medical relationship (causing them a dignitary harm). The thesis concludes by suggesting that the remedy to defensive practices is, first, a recognition of the essential *moral* and *circumstantial* nature of decision-making and, second, a return to a sociological standard of judicial evaluation - which examines the internal logic of a decision, and whether the decision meets the societal standards expected of the medical profession. This thesis therefore suggests the adoption of a revised form of the *Bolam* standard

(*Bolam* 2.0). This standard would avoid the problems of normativity, facilitate the moral method of medical decision-making, and allow doctors to make decisions which are conducive to the therapeutic information needs of the *actual* patient.

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Research Thesis: Declaration of Authorship

Print name: Matthew John Barclay Watkins

Title of thesis: How do doctors make decisions about information disclosure? A moral diagnosis

I declare that this thesis and the work presented in it is my own and has been generated by me as the result of my own original research.

I confirm that:

1. This work was done wholly or mainly while in candidature for a research degree at this University;

2. Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;

3. Where I have consulted the published work of others, this is always clearly attributed;

4. Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;

5. I have acknowledged all main sources of help;

6. Where the thesis is based on work done by myself jointly with others, I have made clear exactly what was done by others and what I have contributed myself;

7. None of this work has been published before submission;

Signature: Date: 21.06.2021

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Glossary

Medical Ethics

Miola rightly critiques the confusing proliferation of medical ethical regulation and commentary as a confusing smorgasbord of competing approaches.[1] Understanding how medical ethics affects decision-making therefore requires more specificity about the sources of rules, discussion, and guidance, and their coercive effect on decision-making in practice.

There are three broad types of *ethics*, to which this thesis will refer (which are delineated because of the form of normative rules in which they manifest): (1) legal normativity, (2) ethical normativity, and (3) moral normativity. All these forms of normative rules are underpinned by philosophical ethical principles and approaches.[2] Philosophical ethics is the substantive ethical language which forms and underpins external normativity, within ethical and legal rules. Philosophical ethical principles become normative rules through a process called *specification*:

> *Specification* is a process of reducing the indeterminacy of abstract norms and generating rules with action-guiding content. For example, without further specification, "do not harm" is too bare a starting point for thinking through problems such as whether it is permissible to hasten the death of a terminally ill patient.[3]

The ethical content of these rules can have:
(1) distinct *teleological* purposes i.e., the purpose of the rules seeks to achieve certain ethical outcomes. For example, acting in the patient's best interests would require a therapeutic model of medical relationship, but the purpose of maximising patient autonomy might require a consumer model of the medical relationship.[4]

(2) distinct *deontic* rules which ensure that the process of medical decision-making is morally acceptable, and/or achieves the aims of a disclosure. For example, disclosure of an objective content of information would be necessary to have a rational form of autonomous choice, as the basis of informed consent.[5]

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[1] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship.* (Hart Publishing, 2007), 38-46
[2] For example, see: T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics* (Oxford University Press, 2013); R. Veatch, *A Theory of Medical Ethics.* (Basic Books, 1981); T. H. Engelhardt, *The Foundations of Bioethics.* (Oxford University Press, 1986)
[3] T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics* (Oxford University Press, 2013), 17. Relying on H. S. Richardson, 'Specifying Norms as a Way to Resolve Concrete Ethical Problems.' (1990) 19 *Philosophy and Public Affairs* 279-310; H.S. Richardson, 'Specifying, Balancing, and Interpreting Bioethical Principles.' (2000) 25 *Journal of Medicine and Philosophy* 285-307
[4] M. Perlman, 'The Modern Philosophical Resurrection of Teleology.' (2004) 87(1) *The Monist* 3-51
[5] A. Larry & M. Moore, "Deontological Ethics," (Stanford Encyclopaedia of Philosophy, 2020)

Legal normativity

Law is the most coercive form of normativity. Philosophical ethics manifest through standards of care in law and through *orbiter dicta*. However, the specialist, regulatory, and fact-specific nature of law, means that philosophical ethics are often unlikely to be directly referenced, nor are the models of the medical-relationship substantively elicited as the basis, or purpose, of legal rules. This opacity can cause conceptual confusion about the appropriate philosophical basis of legal rules, and therefore the purpose of legal standards of care. [6]

Ethical normativity

Miola helpfully divides medical ethical guidance into three typologies. These typologies are distinguished based on their authorship, their coercive force, and their readership.[7]

(1) *Formal sector*: This describes the system of ethics made by legally recognised regulators, or organisations, which have statutory powers to produce guidance, or discipline individuals, within the medical profession. For example, the GMC were established under the Medical Act 1983, and are the sole body with a mandate to provide ethical advice to the medical profession.[8] Moreover, it is the only body with the power to discipline errant doctors.[9] For the purposes of this thesis, I have expanded this definition, to include organisations, or regulators, which have statutory powers to affect systems of care, resource allocation, or infrastructure, which in turn impact medical decision-making. This would include, for example, the Department of Health (DoH),[10] NICE and the Care Quality Commission (CQC),[11] who produce policy, provide advice and/or regulate about the organisation and running of hospitals, resource allocation, and preferred treatment regimes. The rules and guidance produced by these organisations therefore alter the form of diagnosis, treatment, and thus information disclosure that the patient receives. This conceptualisation of doctors within systems of health, corresponds to the description of medical decision-making by the Supreme Court:

> The treatment which [doctors] can offer is now understood to depend not only upon their clinical judgement, but upon bureaucratic decisions as to such matters as resource allocation, cost-containment and hospital administration: decisions which are taken by non-medical

[6] M. A. Jones, 'Informed consent and Other Fairy Stories.' (1999) 7 *Med L Rev* 103-134, 133: "It is difficult to envisage any court, whether applying *Bolam* or any other standards, coming up with such a detailed set of rules by way of guidance. The conclusion might be that there is no place for the law in seeking to develop a proper framework for the doctor-patient relationship through the concept of informed consent. It is simply too blunt an instrument, applied *post hoc*, and too far removed from the practical realities of the consulting room or the hospital ward."

[7] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship*. (Hart Publishing, 2007), 6.

[8] s.35 Medical Act 1983

[9] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship*. (Hart Publishing, 2007), 6

[10] See for example, Department of Health, *Reference Guide to consent for examination or treatment, Second edition* (DoH, 2009)

[11] See for example, National Institute of Health and Care Excellence, *Diabetes in Pregnancy: Management of Diabetes and Its Complications for Preconception to the Postnatal.* (NICE, 2015).

> professionals. Such decisions are generally understood within a framework of institutional rather than personal responsibilities […].[12]

(2) *Semi-formal sector*: This group is made up of organisations which represent doctors. For example, the British Medical Association (BMA) [13] would be a semi-formal organisation, as it is effectively the doctor's trade union. Guidance produced by the Royal Colleges, as a specialist members organisation, and the Medical Defence Union (MDU) and Medical Protection Society (MPS) are also constituted from medical membership and would therefore fall within the semi-formal category. Guidance produced by this sector can more legitimately be characterised as being representative of the standards within the medical profession. As the ethical basis of guidance is drawn democratically; from the technical and moral experience of the profession, it can be considered as more empirically representative of the existing medical *gold-standard*.[14]

(3) *Unofficial sector*: Miola characterised this guidance as composed by those who have no legislative authority, and by those not representative of the medical profession.[15] This thesis is unconcerned with the effect of this sector on medical decision-making.

Moral normativity

Medical morality is often conflated with personal morality i.e. the values and beliefs that doctors hold as an individual.[16] However, normative medical morality is an unwritten, collective, or corporate morality, which is developed through entering the medical profession, and undertaking the act of medical decision-making; it is often referred to as the internal morality of medicine.[17] It is learned through socialisation, for example, as part of the hidden curriculum,[18] and is developed with experience, and sharing of patient narratives.[19] As moral normativity is the least coercive, higher orders of external

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[12] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [75]

[13] See for example, BMA, *The Handbook of Medical Ethics* (BMA, 1980), BMA, *The Philosophy and Practice of Medical Ethics*. (BMA, 1988)

[14] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship*. (Hart Publishing, 2007), 51

[15] *Ibid*, 6

[16] C. Foster & J. Miola, 'Who's in Charge? The Relationship between Medical Law, Medical Ethics, and Medical Morality?' (2015) 23(4) *Med L Rev* 505-530, 514; J. Miola, "Moralising Medicine and Decision-Making." S. Forvargue & A. Mullock (ed.), *The Legitimacy of Medical Treatment: What Role for the Medical Exception?* (Routledge, 2016), 82-85

[17] E.D. Pellegrino & D.C. Thomasma, *The Virtues in Medical Practice*. (Oxford University Press, 1993), 52-54; E.D. Pellegrino, The Internal Morality of Clinical Medicine: A Paradigm for the Ethics of the Helping and Healing Profession.' (2001) 26(6) *Journal of Medicine and Philosophy* 559-579

[18] F.W. Hafferty & R. Franks, 'The Hidden Curriculum, Ethics Teaching, and the Structure of Medical Education.' (1994) 69 *Acad Med* 861-867; F.W. Hafferty, 'Beyond Curriculum Reform: Confronting Medicine's Hidden Curriculum.' (1998) 73 *Acad Med* 403-407; H. Lempp, 'The Hidden Curriculum in Undergraduate Medical Education: Qualitative Study of Medical Students' Perceptions of Teaching.' (2004) 329 *BMJ* 770

[19] A.H. Jones, 'Narrative in Medical Ethics.' (1999) 318 (7178) *BMJ* 253-256; J.E. Paulsen, 'A Narrative Ethics of Care.' (2011) 19(1) *Health Care Anal* 28-40H. Brody & M. Clark, 'Narrative Ethics: A Narrative.' (2014) 44(1) *Hastings Center Report* 7-11

normativity, can reduce the scope for moral decision-making, and as Montgomery argues, de-moralise medicine.[20]

Schools of thought

This thesis uses the term 'schools of thought' to describe a line of thinking that is present within academic commentary and case-law but may not be explicitly recognised within the academic literature. In this thesis, 'schools of thought' will be used to describe how some academic commentators critique the law from one preferred ethical stance: that of the principle autonomy, and patient rights. The terms should be understood as a descriptive mechanism only. It would be a mistake to place too much emphasis on identification and categorisation of individuals, who exclusively fit into these schools. Many individuals, move in and out of the descriptive bracket dependent on the theme of their commentary and/or after reflection on developing law (and rightly so). One, instead, should look to the content of the academic voices which adopt a distinct perspective. This thesis argues, it is enough to conceptualise the collective body of work as a 'school of thought' under a normal dictionary definition of school of thought: "a point of view held by a particular group."[21]

[20] J. Montgomery, 'Law and the Demoralisation of Medicine. (2006) 26(2) *Legal Studies* 185
[21] Free Dictionary:(<https://www.thefreedictionary.com/school+of+thought>)

CHAPTER 1: INTRODUCTION

1.1 Introduction

This thesis aims to further interrogate the question posed by Miola in his seminal monograph:[1] why has law and ethical guidance failed to ensure that doctors make good decisions? This thesis focuses on one particular aspect of medical decision-making: how doctors make decisions about information disclosure. The benefit of focusing on information disclosure, as Miola recognised, is that the law of negligence has come ethically full-circle: it has moved from a model of medical decision-making grounded on therapeutic considerations,[2] to a model of the consumer relationship which privileges patient autonomy as the purpose of information disclosure.[3] This allows the thesis to evaluate both the effectiveness of law as a regulatory mechanism, and the effectiveness of the ethical models which underpin the standards and rules about materiality; to explain the reasons for deviation from normative standards, in practice. This analysis has been achieved through sociological reflection on studies of patient information need and medical decision-making about information disclosure, conducted exclusively within the UK. This analysis builds on and draws inspiration from the work of other socio-legal commentators, both in the UK,[4] and US,[5] by dividing the analysis into periods of time associated, with distinct normative models of medical decision-making, operating within the law and ethics, of the time. Structuring the analysis in this way, allows the author to identify correlation between the content of normative rules, and practical outcomes. Reflection on individual ethical models of normativity is important, as the judiciary adopt a more active approach to standard setting, proactively engage with ethical and philosophical discourse, and create more substantive patient rights.[6] This is particularly true in the law of information disclosure, where after the Supreme Court judgement in *Montgomery v Lanarkshire Health Board*,[7] the judiciary have constructed duties in the law of negligence to ensure that

[1] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship.* (Hart Publishing, 2007).
[2] *Bolam v Friern Hospital Management* Committee [1957] 1 WLR 583; *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871; *Bolitho v City & Hackney Health Authority [1997] 4 All ER 771*
[3] *Pearce v Bristol Healthcare NHS Trust* (1998) 48 BMLR 118; *Chester v Afshar* [2004] UKHL 41; *Montgomery v Lanarkshire Health Board* [2015] UKSC 11
[4] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law.' (1987) 7 *Legal Studies* 169, 174-175; M.A. Jones, Informed Consent and Other Fairy Stories. (1999) 7 *Med L Rev* 103-144; A. Maclean, 'Giving the Reasonable Patient a Voice: Information Disclosure and the Relevance of Empirical Evidence.' (2005) 7(1) *Med L Int.* 1-40; R. Heywood, 'Medical Students' Perceptions of Informed Consent.' (2007) 23 *Professional Negligence* 151-164; R. Heywood, *et al*, 'Patient Perceptions of the Consent Process: Qualitative Inquiry and Legal Reflection. (2008) 24(2) *Professional Negligence* 104-121; R. Heywood, *et al*, 'Informed Consent in Hospital Practice: Health Professional's Perspectives and Legal Reflections.' (2010) 18(2) *Med L Rev* 152-184
[5] For example, A. Meisel & L.H. Roth, 'What We Do and Do Not Know about Informed Consent.' (1981) 246(21) *JAMA* 2473-2477; A. Meisel & L.H. Roth, 'Towards an Informed Discussion of Informed Consent: A Review and Critique of the Empirical Studies.' (1983) 25(2) *Ariz Law Rev* 265-346; B.A. Rich, *Strange Bedfellows: How Medical Jurisprudence Has Influenced Medical Ethics and Medical Practice.* (Kluwer Academic, 2001); C.E. Schneider, *The Practice of Autonomy: Patients, Doctors, and Medical Decisions.* (Oxford University Press, 1998).
[6] J, Miola, "Moralising Medicine and Decision-Making." In, S. Forvargue & A. Mullock (ed.), *The Legitimacy of Medical Treatment: What Role for the Medical Exception?* (Routledge, 2016), 79-82. For example: *Rees v Darlington Memorial Hospital NHS Trust* [2014] 1 AC 309; *Chester v Afshar* [2014] UKHL 14; *Aintree Hospital NHS Foundation Trust v James* [2013] UKSC 67; *Re Y* [2018] UKSC 46; *Darnley v Croydon Health Services NHS Trust* [2018] UKSC 50
[7] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11

patients have an informed consent to treatment.[8] The ethical purpose of these duties, and associated standards of care, are frustrated when they are not achieved (or are not feasibly achievable) in practice.

Asking why decision-making in practice deviates from the law and ethical guidance is also not a trite question. Deviation continues to cause patients' real harm.[9] Miola, rightly, foregrounded his argument in the light of the Bristol Inquiry; which was set up after large discrepancies in paediatric cardiac mortality rates were identified in Bristol Royal Infirmary, and other centres, between 1988 and 1994.[10] During the investigation process, the Inquiry identified evidence of various systemic problems of ethical governance, lack of regulatory overview,[11] and the proliferation of 'silos of bad practice.'[12] What was particularly egregious was that the parents of children, who had suffered brain damage as the result of treatment, were not provided with honest advice about the risks associated with cardiac procedures.[13] Patients were discouraged from asking questions and were only given access to limited, and often confused, advice and information.[14] This trend of poor quality information disclosure was evident throughout the NHS.[15] Kennedy argued that this behaviour resulted from a culture of excessive paternalism; where the importance of patient and parental understanding was not prioritised; instead doctors attempted to protect patients from harm.[16] This moral orientation was not challenged by external ethical guidance, regulators or managers. The lack of overview meant that power was afforded to individual senior doctors undertaking managerial roles, creating exclusive realms of geographical and departmental responsibility.[17] Kennedy problematised the failure of external ethical guidance to safeguard patients by ensuring a reasonable standard of disclosure:

> There does not appear to have been any deep thinking about how to communicate information to parents in advance of surgery, nor any systematised approach to doing so. While some parents felt that they had been significantly helped to understand what the surgery and subsequent intensive care involved, we were also told of doctors and nurses drawing diagrams on scrap paper, or even a paper towel. The sense is gained that informing parents and gaining their consent to treatment was regarded as something of a chore by surgeons.[18]

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[8] See, S. Devaney, *et al*, 'The Far-Reaching Implications of *Montgomery* for Risk Disclosure in Practice.' (2018) 24(1) *Journal of Patient Safety and Risk* 25-29
[9] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship*.(Hart Publishing, 2007), 22-25
[10] I. Kennedy, *Learning from Bristol: The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995.* (Cm 5207, 2001), 2[11], 4[25]
[11] *Ibid*, 5-6
[12] *Ibid*, Introduction
[13] *Ibid*, 6-7
[14] *Ibid*, 122-123
[15] *Ibid*, 268
[16] *Ibid*, 7 [34]: "[…] It should not be a question of the healthcare professional judging what the parent needs to know; it is the parent who should make that decision. At the time, however, the prevailing view was that parents should be protected from too much information."
[17] *Ibid*, Chapter 15
[18] *Ibid*, Introduction. 6-7 [32]

Kennedy also argued that 'guidelines appear from a variety of bodies giving rise to confusion and uncertainty.'[19] Much of the guidance published by regulatory organisations overlapped, was conceptually conflicted, and was usually aimed at systems of care and service provision, rather than decision-making of individual doctors, and their facilitation of ethical duties in the doctor-patient relationship.[20] Thus, one of Kennedy's 200 recommendations included the creation of 'agreed published standards of clinical care for healthcare professionals to follow.'[21] These standards would be agreed between the various associated bodies, such as the Department of Health, and the Royal Colleges, as a sovereign 'gold standard' that would be ensured by a presiding regulator. Kennedy also critiqued medical law for creating barriers to openness.[22]

> The culture of blame is a major barrier to the openness required if sentinel events are to be reported, lessons learned and safety improved. The system of clinical negligence is part of the culture of blame. It should be abolished.[23]

The dominant narrative in the ethical[24] and legal[25] community has been to safeguard patient autonomy; by creating increasingly substantive rules, to ensure patients receive an objective content of information disclosure.[26] This potentially draws decision-making away from the ethical purpose of the standard (to provide information to patients according to their *circumstantial needs*), towards providing information to meet the needs of an (unknowable, hypothetical) judicial construct.[27] As standards of care were enhanced, this increased fear of litigation, which then has an ossifying effect on decision-making. Doctors, then, clung to what they perceived as 'regular' or 'good' practice to avoid liability.[28]

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[19] *Ibid*, 17 [90]-[91].
[20] *Ibid*, 17 & Chapter 14
[21] *Ibid*, 2 [17]
[22] *Ibid*, 2[14], 13 [62]
[23] *Ibid*, 16[86]
[24] T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics*. (Oxford University Press, 2013), 101-149; R. Gillon, 'Medical Ethics: Four Principles Plus Attention to Scope.' (1994) 309(6948) *BMJ* 184-188; R. Gillon, 'Ethics Needs Principles – Four Can Encompass the Rest – And Respect for Autonomy Should Be "First Among Equals".' (2003) 29 *J Med Ethics* 307-312; R. Macklin, 'Applying the Four Principles.' (2003) 29(5) *J Med Ethics* 275-280
[25] I. Kennedy, 'The Patient on the Clapham Omnibus.' (1984) 47(4) *MLR* 457-471; M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 85
[26] C. Foster, *Choosing Life, Choosing Death: The Tyranny of Autonomy in Medical Ethics and Law.* (Hart Publishing, 2009), 5
[27] S.A.M. Maclean, *A Patient's Right to Know: Information disclosure, the Doctor and the Law.* (Dartmouth, 1989), 162
[28] *Ibid*, H. Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship.* (Clarendon Press, 1994), 13-24; R. Heywood, 'Excessive Risk Disclosure: The Effects of the Law on Medical Practice.' (2005) 7(2) *Med L Int* 93-112; J. Montgomery & E. Montgomery, '*Montgomery* on Informed Consent: An Inexpert Decision?' (2015) 42 *J Med Ethics* 89-94, 90-91

Despite recognising the scourge of defensive medicine, the answer from commentators, and indeed the judiciary, has been more law and more ethics, or better law, and better ethics.[29] This has manifested in two schools of thought,[30] set out in Chapter 1 and Chapter 2 respectively:

> (1) the jurisdiction school, argued that the court should reduce the scope of medical discretion and thus avoid paternalism, through creating normative standards of care;[31]
>
> (2) The rights school argued that the correct standard should ensure that patients have enough information to make an autonomous choice.[32]

However, despite more prescription from law and ethics, neither of these *panaceas*[33] has achieved a system of decision-making which prevents harm in practice.[34] This has been exemplified in a number of further national scandals, since the Bristol Inquiry, which continue to exhibit the same trends of poor decision-making in practice.[35] For example, the Francis Report, published in 2013, investigated the Mid Staffordshire Hospital scandal, which took place between 2005-2008. Like Bristol,[36] concerns were raised about the Trust's inexplicably high mortality rates.[37] Unlike Bristol, however, there was an exceptionally high level of systematic regulatory oversight.[38] Doctors and health boards were scrutinised by the Local Strategical Health Authority, the Department of Health, as well as being compliant with the Healthcare Commission and NHS Litigation Authority.[39] The Report argued that oversight was necessary, however, the level of oversight contributed to confusion about best practices and ethical methods of decision-making:

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[29] *Ibid*, Teff, 26-27; S. Maclean, *Old Law, New Medicine: Medical Ethics and Human Rights.* (Rivers Oram Press, 1999), 1-4
[30] See, K. Veitch, *The Jurisdiction of Medical Law.* (Ashgate, 2007), 3-4
[31] For example, J.L. Montrose, 'Is Negligence an Ethical or a Sociological Concept.' (1958) 21(3) *MLR* 259-264; H. Teff, 'Consent to Medical Procedures: Paternalism, Self-determination or Therapeutic Alliance.' (1985) *L Q Rev* 432-453; K. Norrie, 'Common Practice and the Standard of Care in Medical Negligence.' (1985) *Judicial Review* 145
[32] For example, G. Robertson, 'Informed Consent to Medical Treatment.' (1981) 97 *L Q Rev* 102-126; I. Kennedy, 'The Patient on the Clapham Omnibus.' (1984) 47(4) *MLR* 457-471; M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution.' (2000) 8(1) *Med L Rev* 85-114; J. Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas.' (2008) 17(1) *Med L Rev* 76-108
[33] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution.' (2000) 8(1) *Med L Rev* 85-114
[34] C. Foster, *Choosing Life, Choosing Death: The Tyranny of Autonomy in Medical Ethics and Law.* (Hart Publishing, 2009), Chapter 1
[35] R. Gilroy, 'Similarity of NHS Care Scandals 'Sobering' says Nurse Academic.' (*Nursing Times*, 20 November 2019)
[36] R. Francis QC. *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry: Executive Summary.* (HC 974, 2013)23[66]: "Professor Sir Brian Jarman pointed out in his evidence to this inquiry that at the Bristol Inquiry in which he was a member of the Inquiry panel, there were 120 mentions of the word "hindsight" in the evidence. The Bristol Inquiry report contained a section on hindsight. In the Foreword, the panel expressed the hope that the disaster that had been uncovered there would not be repeated: *It would be reassuring to believe that it could not happen again. We cannot give that reassurance. Unless lessons are learned, it certainly could happen again, if not in the area of paediatric cardiac surgery*."
[37] *Ibid*, 12[21]
[38] *Ibid*, 13[25]
[39] *Ibid*, 7-8[4]

> It is because of the fact that not all boards are capable of maintaining acceptable standards or improving services at the required pace, or applying effective stewardship to the resources entrusted to them that healthcare systems regulators and performance managers exist. It is because not all professionals do live up to the high standards expected to them that we have professional regulators. All such organisations have the responsibility to detect and redress deficiencies in local management and performance where these occur. It does not need a public inquiry to recognise that this elaborate system failed dramatically in the case of Stafford.[40]

Despite the level of guidance and oversight the system did not ensure good medical decision-making. There was 'a lack of basic care across a number of wards and departments at the Trust,'[41] and a lack of ethical focus on the needs of the actual patient. Instead, doctors were concerned about following guidelines formulaically[42] and fulfilling targets.[43] Doctors were scared of deviating from these guidelines to ensure good care:

> [t]he culture at the trust was not conducive to providing good care for patients or providing a supportive working environment for staff; there was an atmosphere of fear of adverse repercussions; a high priority was placed on the achievement of targets; the consultant body largely dissociated itself from management; there was low morale amongst staff; there was a lack of openness and acceptance of poor standards.[44]

The large number of targets and regulators created a confused maze of regulatory oversight, which shrouded the central purpose of medicine: to ensure the best interests of the patient.[45] The internal moral orientation of decision-making was lost. Thus, when the regulatory confusion led to gaps in procedures, it produced improvised silos of formulaic and poor practice. When these problems were identified, rather than understanding the sociological and moral root of the problem,[46] guidance was changed, and the structure of the service was shifted, which simply created more confusion about regulatory oversight.[47]

Amongst the many recommendations of the Francis Report was the need for a more fundamental, moral, reorientation back towards the needs and care of the individual patient (irrespective of fulfilling targets

[40] *Ibid*, 8[4]
[41] *Ibid*, 13[24]
[42] *Ibid*, 64-65[1.114] & 6 [1.119]
[43] *Ibid*, 44-45
[44] *Ibid*, 13[24]
[45] *Ibid*, 67[1.121]- [1.124]: "The common values of the service must be enshrined in an effectively communicated by the NHS Constitution and owned and lived by all members of the service. The NHS Constitution should be the first reference for all NHS patients and staff should set out the system's values, and rights, obligations and expectations of patients."
[46] *Ibid*, 62[1.104]- [1.113]
[47] *Ibid*, 64-65 [1.114]

and following processes).[48] There was wider criticism of the huge system of regulators and the confusing mass of guidance, with the recommendation that their roles should be reviewed.[49] Medical ethics was not the solution that Kennedy propounded in the Bristol report, as is evident from the GMC response which states:

> The events at the Trust suggest that the culture of the organisation was severely compromised and, judging by some of the comments made to the Inquiry, this had a negative impact on the way that individuals within the organisation behaved. It is very difficult to measure the impact of cultural change and we are one of a number of organisations who should be helping to drive this change.
>
> It is quite clear, and it is the thing that concerns me, that at Mid Staffs there must have been significant numbers of doctors who metaphorically walked on the other side of the ward. They were not following our advice.
>
> Now, of course, as somebody remarked since the Ten Commandments, people have not always followed guidance and rules. But I think there is a duty on us, as the regulator, to redouble our efforts to try and embed this in the profession, and I know Ian Kennedy remarked, in his evidence to you, that he thought that Good Medical Practice had not been the cultural catalyst that was hoped.[50]

This is not an isolated story. Similar patterns of over regulation leading to fragmentation, or deviance, have occurred even more recently.[51] For instance, Professor Sir Ian Kennedy recently presided over the Solihull Hospital Breast Care Review, which investigated the criminal actions of Mr Paterson, who conducted criminally negligent surgeries on breast cancer patients. The mastectomies carried out differed to the treatment consented to,[52] and the various options for oncology care were not discussed

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[48] *Ibid*, 67[1.125]
[49] *Ibid*, 13-14[25]-[26]
[50] R. Francis Q.C., *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry:* Volume 2. (HC 974, 2013), 1015[12.20-12.2]
[51] For example, B. Kirkup, *The Report of the Morecombe Bay Investigation.* (Stationary Office, 2015) (<https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/408480/47487_MBI_Accessible_v0.1.pdf>); M. Weaver, 'Hundreds More Potentially Avoidable Baby Deaths Found at Shropshire NHS Trust.' (*Guardian*, 21 July 2020): [https://www.theguardian.com/society/2020/jul/21/more-potential-failings-maternity-care-shrewsbury-telford-trust-nhs-trust]; S. Lintern, 'East Kent: Maternity Scandal Trust still had Higher-Than-Average Deaths Last Year, Report Says.' (*Independent*, 14 July 2020) (<https://www.independent.co.uk/news/health/east-kent-maternity-safety-baby-deaths-harry-richford-latest-a9616931.html>); J. Cumberlege, *First Do No Harm: The Report of the Independent Medicines and Medical Devices Safety Review.* (OGL, 2020): (https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf)
[52] I. Kennedy, *Review of the Response of Heart of England NHS Trust to Concerns about Mr Ian Paterson's Surgical Practice: Lessons to be Learned and Recommendations.* (Kennedy Review, 2015) [https://hgs.uhb.nhs.uk/wp-content/uploads/Kennedy-Report-Final.pdf], [10] & 51-55

with patients.[53] The law and ethical guidance relating to consent were ignored both by Mr Paterson, senior managers, and even investigators.[54] However, there was little active follow-up from the medical regulators.[55]

> As regards consent, its central importance was not recognised. This was a major oversight by senior managers and others. Had its importance been recognised, action could have been taken much earlier and in a much more forceful manner. It was not and patients were harmed. Moreover, it is clear that the role of consent, as a means of respecting the rights of patients, was simply not properly understood. Talk of "consenting" patients had no place in the care of patients. By adopting this language and what appears to have been a cavalier approach to consent, patients were let down.[56]

The serious harm caused by deviance from normativity means that the question: "why does this deviance remain?" is imperative to answer, not only to prevent future poor ethical practice, but to ensure that law itself does not cause doctors to deviate from patient centred decision-making.

This thesis demonstrates that more law, and more ethics, have led to more conceptual conflict and confusion. Stronger regulatory oversight by the GMC, and more normative and prescriptive standards, have not solved the original problem, of incidence of poor medical decision-making, identified by Miola in his analysis of the Bristol Inquiry. Instead, the scandals around medical decision-making and patient care continue. Miola argues that this is caused by the problematic relationship between law and ethics.[57] Law has historically delegated the responsibility of rationalising the conceptual foundations of duties, such as information disclosure, to the ethical sector;[58] a process termed *Bolamisation*.[59] However, the ethical sector has not created a universalisable set of ethical principles, which can guide medical decision-making. As Kennedy argues:

> In the context of the disclosure of information, the very notion of a professional standard is something of a nonsense. There simply is no such standard, if only because the profession has

[53] *Ibid*, 52 [6.11 -6.18]
[54] *Ibid*, 53 [6.17]: "Right at the heart of the surgical practice there was an ethical (and legal) flaw: on occasions, patients had not consented to the procedure carried out on them. Though, perhaps, appreciated by some members of the breast team, this situation was not formally recognised. Dr Polson was willing to admit to me that when he conducted his investigation in the autumn of 2007, "We missed an opportunity over consent" […]."
[55] *Ibid*, 148 [14.64]
[56] *Ibid*, 55 [6.25]
[57] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship.* (Hart Publishing, 2007), 18
[58] For a definition of the component parts of the ethical sector, see the Glossary.
[59] M. Davies, 'The New *Bolam*' Another False Dawn for Medical Negligence.' (1996) 12 *Professional Negligence* 10; M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85, 90-95

not got together to establish what risks should be disclosed, to which patients, in which circumstances.[60]

Instead, as Miola argued, the symbiotic relationship between law and ethics is one of regulatory circularity. This has created a normative vacuum, with only medical morality to fill the ethical space when doctors are forced to make medical decisions in practice.[61] Miola characterises medical morality as equivocal to personal morality – and thus arbitrary.[62] However, as Miola recognised: 'more ethics and ethical guidance does not automatically signify better guidance and more ethically appropriate professional practice and behaviour.'[63] Foster and Miola, in a later publication, argue that the way out of this circularity is to assign law and ethics spectrums of responsibility.[64] However, this does nothing to ensure conceptual clarity, or continuity between the realms of authority. The failure of doctors to follow rules cannot be reduced, simply, as a 'failure to regulate.'[65] Instead, this thesis argues that rather than focusing on the structure of rules: as ethically abstracted, and top-down mechanisms of regulation, law should be critiqued and constructed from the bottom-up: using sociology to delineate how doctors make decisions in practice. Medical morality should, instead, be understood as a collective corporate morality, which is integral to the act of medical decision-making.[66] As medical morality flows from being part of the medical profession, it is more fundamental in orientating decisions than the external normative systems of law and ethics.[67] The primary aim of medical morality is to act in the best interests of the patient, in their particular circumstances, bounded within the therapeutic relationship.[68] If law and ethics are conceptually unclear, medical morality steps into the breach to orientate decision-making, it also acts as a base for the interpretation and integration of rules into practice. If rules conceptually conflict with this pre-existing moral orientation, then they either ethically displace medical morality, or are ignored. Thus, in many ways the debate so far, whilst important, has been simply tinkering around the edges of the phenomenologically rules of morality, operating normatively within a therapeutic doctor-patient relationship. When adopting this lens, we can see that poor decision-making does not

[60] I. Kennedy, 'The Patient on the Clapham Omnibus.' (1984) 47 *MLR* 454, 468
[61] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship.* (Hart Publishing, 2007), 209
[62] J. Miola, 'Making Decisions about Decision-making: Conscience, Regulation, and the Law.' (2015) 23(3) *Med L Rev* 263-282; C. Foster & J. Miola, 'Who's in Charge? The Relationship between Medical Law, Medical Ethics, and Medical Morality?' (2015) 23(4) *Med L Rev* 505-530, 511-512
[63] J. Miola, "Moralising Medicine and Decision-Making." In. S. Fovargue & A. Mullock (eds.), *The Legitimacy of Medical Treatment: What role for the Medical Exception?* (Routledge, 2016), 73
[64] C. Foster & J. Miola, 'Who's in Charge? The Relationship between Medical Law, Medical Ethics, and Medical Morality?' (2015) 23(4) *Med L Rev* 505-530
[65] . Miola, "Moralising Medicine and Decision-Making." In. S. Forvargue & A. Mullock, *The Legitimacy of Medical Treatment: What role for the Medical Exception?* (Routledge, 2016), 72
[66] E.D. Pellegrino, The Internal Morality of Clinical Medicine: A Paradigm of the Ethics of the Helping and Healing Professions.' (2001) 26(6) *Journal of Medicine and Philosophy* 559-579
[67] A. MacIntyre, *After Virtue* (Notre Dame University Press, 1981)
[68] E. D. Pellegrino & D.C. Thomasma, *The Virtues in Medical Practice.* (Oxford University Press, 1993), 54. T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics.* (University Press, 2009), 36; L. Frith, "What do we mean by 'Proper' Medical Treatment?" In S. Forvargue & A. Mullock, *The Legitimacy of Medical Treatment: What Role for the Medical Exception?* (Routledge, 2017), 32-50

flow exclusively from problematic corporate norms, but also internal conflict between internal and external normativity. Thus, external normativity (and it's relationship to morality) can then be problemitised. For example, this thesis identifies:

(1) that law and ethics have had an ossifying effect on medical discretion,

(2) that there exists conceptual confusion within legal and ethical rules which confuse practitioners as to the content and purpose of external ethics,

(3) Legal and ethical rules conflict with the teleological aim of medical decision-making within the medical relationship.

The content and increasing prescriptiveness of external normative regimes have now fragmented the methodologies adopted by doctors to make medical decisions. The intention to create a universal ethical method (and content of decision-making) has had the effect of splintering the shared process of decision-making in practice. Consequently, some doctors follow various models of autonomy, some adopt defensive practices, and some ignore law and ethics altogether.[69] This thesis is an essential and novel diagnosis of this moral fracture.

1.2 The Methodology of the Empirical Review

The sociological analysis of medical decision-making initially utilised a structured literature review of studies which investigated methodologies of medical decision-making, the utilisation of law, and patient information need. The initial review was conducted between November 2017 and February 2018. To identify the empirical literature, the author utilised Boolean search connectors[70] and applied them on a number of specialist databases, including: Medline (PubMed),[71] the BMJ, Web of Science,[72] Cochrane Library,[73] BMC Medical Ethics,[74] Science Direct,[75] Medline (Ovid),[76] and Google Scholar (for grey

[69] C. McManus & B. Winder, Duties of a Doctor: UK Doctors and G*ood Medical Practice.' (2000) 9(1) Quality in Health Care 14-22, 18-19.*

[70] The Boolean connectors were tailored to the individual search engines and their various search tools and their article descriptors.

[71] Search terms included: "Informed Consent" AND "United Kingdom" (3199 results); "Informed Consent" AND "United Kingdom" AND "Information Disclosure" (518 results); "Informed Consent" AND "United Kingdom" AND "Information Disclosure" AND "Decision making" (95 results); "Informed Consent" AND "Shared Decision Making" AND "Medical Decision Making" AND "United Kingdom" AND "Law" (276 results).

[72] Search terms includes: "Informed Consent" AND "Empirical" (11394 results).

[73] Search term: "Informed Consent" AND "UK" (187 results)

[74] Search terms: "Informed Consent" (432 results)

[75] Search terms included: "Shared decision making" AND "UK" AND "Informed Consent" [Filter: Research Article, Publication Title: "Patient Education and Counseling"] (97 results); "Shared decision making" AND "UK" AND "Informed Consent" [Filter: Research Article, Publication Title: "Social Science and Medicine") (286 results).

[76] Search terms: 1. "Informed Consent/" (38481 results), 2. "Decision Making/" (81703 results), 3. "DISCLOSURE/" (12275), 4. "1 or 2 or 3" (12275 results), 5. "Exp PHYSICIANS/" (117869 results),6. "Doctors.mp" (61108 results), 7. "Medical practitioner.mp." (1106 results), 8. "5 or 6 or 7", 9. "4 and 8", 10 "limit 9 to legal cases or systematic reviews" (493 results),

literature). The titles were screened to eliminate obviously irrelevant studies, and then the abstracts were read to look for relevance. It was essential that the studies were carried out in the countries of the UK; where the standard of care in law, and various regulatory organisations, equivocally operated. Selected articles were acquired and then read in full for relevance. 85 relevant studies were identified (within books and articles). These were then divided into groups according to the operation of the law at the time of their publication. Having carried out the structured review, and reading the studies, it became clear that a structured approach was too limited; as additional relevant articles were found through interrogation of the references, through searching the grey literature, and through wider academic reading. This was particularly important for the pre-1980's material which was often not uploaded, or was absent from the medical search engines. To ignore the wealth of additional material would weaken the substantive content of the analysis. Widening the inclusion criteria means that this analysis includes data from 155 studies taking place between 1967 and 2020.[77]

(i) Limitations

Some of the studies were not methodologically aimed at delineating the processes of medical decision-making, or patient information need, directly. Instead they captured data on medical decision-making, or patient information need indirectly; for example, by measuring the effectiveness of information leaflets,[78] or by developing a scales to test the efficacy of shared decision-making ("SDM").[79] As such, this thesis can sometimes only illustrate correlation, and not direct causation between law, ethics and practice. Further empirical work is essential to establish a causative link between how doctors understand law and ethics, the extent they use it in everyday practice, and how this affects decision-making about information disclosure.

The process of identifying and filtering studies was undertaken independently by the PhD candidate. The inability to ratify the relevance of the studies, because of a lack of institutional support, weakens the methodological independence of the study's initial inclusion. However, this is not deleterious to the review *per se*, as the structured element and therefore the exclusionary mechanism for the review was abandoned. Studies have since been added through snowballing, iterative research, and footnote reviews.

11. "limit 9 to legal cases" (250 results), 12. "1 and 5" (2254 results), 12. "Exp United Kingdom/" (340356 results); "9 and 13" (859 results), "12 and 13" (239 results).

[77] See Appendices 1-4

[78] O. O' Neil, *et al*, 'The Use of an Information Leaflet for Patients Undergoing Wisdom Tooth Removal.' (1996) 34 *British Journal of Oral and Maxillofacial Surgery* 331-334

[79] G. Elwyn, *et al*, 'Shared Decision Making: Developing the OPTION Scale for Measuring Patient Involvement.' (2003) 12(2) *BMJ Quality and Safety* 93-99

As studies were grouped by their date of publication, the actual data collection of the studies may have taken place sometime before; this means that the study may be representative of decision-making under a different normative regime. To attempt to mitigate this problem, trends have only been identified if a number of studies support the same conclusion. Similarly, it is possible that normative changes in the law and ethics may have not had a direct and immediate effect on medical decision-making, due to a lack of educational training, organisational training, or the doctor's knowledge or preferences.

Whilst the aim of the review was to explain the influences of normativity on decision-making about information disclosure, the scope of the thesis would only allow focus on the most influential systems of normative influences, specifically: regulatory ethics, and the law of negligence. Further investigation is needed to delineate the effect of, for example, criminal law and public law, and unformal ethics on medical decision-making. [80]

The nature of law also means that the interpretation of standards changes over time. This thesis aims to highlight the different interpretative approaches, which could influence medical decision-making, rather than come to a normative conclusion about the preferred interpretation; or even a black-letter interpretation. Indeed, this thesis illustrates those propounding distinct normative interpretations of the law is unhelpful, as it creates confusion about the correct standard of care which should be applied in practice. Instead, this thesis would argue that more focus should be placed on the achievability of legal rules and standards, as the purpose of rules are defeated if they are not implementable. [81]

1.3. The structure of this thesis

The substantive content of this thesis is divided into five chapters, which correspond to the seminal cases in the law of negligence relating to information disclosure between 1957 to present. This division allows the thesis to identify any correlation between the model of decision-making operating in the law and ethics of the time, and the method of decision-making adopted in practice. Further ethical interrogation of law and ethical guidance, allows this thesis to identify potential reasons for deviation.

Chapter 2: The *Bolam* standard and the jurisdiction school of thought[82] (1957-1997):

Chapter 2 investigates medical decision-making during the period where the sociological *Bolam* standard was in operation.[83] The chapter will argue that *Bolam* was conventionally interpreted as a

[80] See for example, M. Kazarian, 'Defective Medical Devices: Analysing the Role of the Criminal Law in the PIP Breast Implants Scandal.' (2016) 13(4) *Contemporary Issues in Law* 1-18; M. Kazarian, 'Who should we blame for Healthcare Failings? Lessons from the French Tainted Blood Scandal.' (2019) 27(3) *Med L Rev* 390-405; A-M. Farrell, *et al*, 'Gross Negligence Manslaughter in Healthcare: Time for a Restorative Justice Approach.' (2020) 28(3) *Med L Rev* 526-548

[81] See for example: O' O'Neil, 'Some Limits of Informed Consent.' (2003) 29(1) *J Med Ethics* 4-7; N.C. Manson & O. O'Neil, *Rethinking Informed Consent in Bioethics.* (Cambridge University Press, 2007)

[82] For a definition of 'schools of thought' see the Glossary

[83] *Bolam v Friern Hospital Management Committee* [1998] A.C. 1 W.L.R. 582. ("*Bolam*")

defence to medical negligence; allowing doctors to use expert evidence to ratify their action, and thus barring judges from interrogating the reasonableness of their decisions about information disclosure. The jurisdiction school-of-thought argued that a sociological standard of care was inappropriate, as it allowed the doctor to control the standard of care in the law of negligence, which in-turn proliferated paternalism within medical decision-making. Instead, the jurisdiction school argued that the law should adopt a normative standard, which fixed the ethical process of decision-making about medical practice. This chapter challenges the presumptions of this line of thinking, by illustrating that the purpose of medical decision-making was to ensure that the patient received information for therapeutic ends i.e. beyond achieving an informed consent. This required doctors to undertake a process of *circumstantial-moral* decision-making: where the typologies of usual patient paradigms, (based on information need) were interpreted and augmented in the *circumstances* of the *actual* patient, to make decisions about what information would most benefit that individual. The chapter argues that a sociological *Bolam* standard was necessary to accommodate the circumstantial nature of decision-making. However, this sociological test, properly understood, invited, rather than barred, rigorous judicial analysis of decision-making. *Bolitho* simply restated the requirement that a decision about the materiality of information should be internally consistent, and ethically reasonable by the standards of an external observer.[84] The chapter concludes that the requirement of a 'logical' basis for decision-making, without further explication as to the form and basis of rational choice, had an ossifying effect. First, it led to the rapid growth of ethical guidance; and second, led to a rigidity of decision-making, which meant that doctors were reluctant to deviate from the patient paradigms of information need, thus eradicating the necessary *circumstantial-moral* approach to individualised patient care.

Chapter 3: *Sidaway*[85] and the rights school of thought (1957-1997):

This chapter sets out the critique of the rights school, who argued that to overcome the paternalism of *Bolam*, normative standards in law and ethics should be constructed to protect patient rights. This reorientated information disclosure, from providing a patient information that they need throughout a therapeutic relationship, towards ensuring that the patient received a content of information necessary to have an informed consent. The rights school argued that this can either be achieved through:

> (1) normative standards of care, which create requirements which must be accommodated within medical decision-making. For example, requiring the doctor to disclose information that a reasonable patient might need, or

[84] *Bolitho v City & Hackney Health Authority [1997] 4 All ER 771("Bolitho")*
[85] *Sidaway v Board of Governors and Bethlem Royal Hospital* [1985] AC 871("*Sidaway*")

(2) through abandoning the therapeutic relationship and adopting a model of the consumer relationship.

The consumer relationship is characterised as the optimum methodology to avoid the harms of increasing technological advancement, and *medicalisation* of areas of decision-making beyond exclusive medical competence.[86] Consumerism reconceptualises the patient, as an empowered consumer, operating within a market of medicine; able to safeguard themselves against medical paternalism by making informed choices. Human rights principles are used as legal mechanisms to construct and extent duties which maximise patient choice in relation to diagnosis and treatment, and provide patients information; so that they can have an informed consent to medical treatment.
The chapter problematises the consumer relationship by:

(1) arguing that there three distinct models of autonomy that can be utilised as the conceptual basis of an informed consent: (i) a libertarian model, (ii) a liberal model, and (iii) an authenticity model of autonomy - all of which are incompatible; as they have both distinct aims and different external and internal criteria which must be facilitated. Only one model of autonomy can be facilitated as the basis of an informed consent at one time. Failure to either explicate which model is being utilised, or conflation of the models, will inevitably lead to confusion about the purpose and standard of information disclosure; thus, undermining the ability of the patient to have an autonomous choice.

(2) The consumer relationship and the therapeutic relationship are incompatible, as they have distinct aims, and therefore cannot exist in one cause of action.

(3) The patient has to reach high standards of understanding, rationality and independence, to be conceptually considered as autonomous. However, these ethical standards are not matched by the law of mental capacity, as such. Patients may be legally capacitous, but might be unable to make an informed consent.

(4) The consumer patient is characterised as atomistic, independent and wishing to have both a high level of information and a central role as decision-maker. However, this model denies the patient the liberty to delegate decision-making authority to the doctor, and thus choose their preferred role within the medical relationship.

[86] D. Pereira Gray, *et al*, 'Medicalisation in the UK: Changing Dynamic, but still ongoing.' (2015) 109(1) *J Roy Soc Med* 7-11

(5) This is justified on empirical data from the US; which indicates that patients want to play a more proactive role in the decision-making process. The chapter argues, that instead, data from the UK shows that the average patient was unwilling and unable to adopt the responsibilities of the consumer patient. Adopting the consumer relationship did not just have the propensity to cause conceptual confusion in decision-making, but ignored actual patient choices and information preferences.

Chapter 4: *Pearce* and the prudent patient (1998-2004):

This chapter argues that *Pearce*[87] is illustrative of legal normativity in action. The requirement to disclose information that the reasonable patient would consider significant, adopted the internal rights approach. However, the legal requirement to disclose a content of information, was not specific about whether a liberal, or authentic, model of autonomy was being serviced. Subsequent case-law was therefore divided between seeking to facilitate a subjective or objective definition of 'significant' risks.[88] The formal sector reacted by straddling the binary between the two models; advising the doctor to disclose both an objective and subjective content of information. The semi-formal sector went further and suggested that the aim of disclosure had be altered to ensure an informed consent (this acted as a precursor for abandoning the therapeutic relationship in chapter 5). Doctors in practice were confused about the purpose of information disclosure. Some doctors reacted by abandoning the *circumstantial-moral* method of decision-making, and instead disclosed either:

(1) an objective content of significant risks based on a percentage threshold of occurrence, or,
(2) followed the GMC guidance, and adopted an exhaustive content of disclosure.

Both options denied patient's the information they needed based on their individual values, needs, or particular circumstances.

Chapter 5: *Chester* and the consumer relationship (2005-2014):

The chapter argues that the *Chester*[89] judgement adopted the consumer relationship into law, so that the purpose of information disclosure was altered, to achieve an informed consent. If the doctor did not provide patients with the necessary content of information, this would deny them the ability to make an autonomous choice, which became an actionable damage. Whilst the *Chester* judgement has since been distinguished, on the basis that it related to a narrow band of factual causation (where failure to provide information has directly led to a harmful decision), it acted as a precursor for the consumer relationship entering law. Subsequent cases were divided between adopting the consumer or the therapeutic

[87] *Pearce v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118 ("*Pearce*")
[88] *Ibid*, 124
[89] *Chester v Afshar* [2004] UKHL 41 ("*Chester*")

relationship, and thus, the purpose of information disclosure. This was important as both types of relationships required different forms of medical decision-making to avoid liability. The standard of care in practice became unknowable, both on a teleological [90] (about the purpose of the disclosure), and deontic, level (about the appropriate model of autonomy to be facilitated).[91] Again, rather than rationalising the confused ethical underpinnings of the law, the formal sector: the DoH [92] and particularly the GMC, obfuscated their duty of delineation; by adopting both the therapeutic and consumer models within the guidance (requiring doctors to adopt a process of 'shared decision-making').[93] The British Medical Association ("BMA"), however, pushed back against this binary model and instead advised the doctor to facilitate the information needs of *actua*l patients, not for a process of consent, but for therapeutic purposes.[94] This fractured the medical morality both horizontally and vertically. Some doctors attempted to provide patients information according to the liberal model, some the authentic model, and some adopted an exhaustive disclosure. Patients themselves also rejected the consumer relationship and their responsibilities to understand, and make, rational decisions. A significant minority of doctors rejected the consumer relationship and disclosed information using *circumstantial-mora*l decision-making.

Chapter 6: *Montgomery* and beyond (2015-2020):

The chapter argues that the *Montgomery*[95] judgement attempted to adopt the consumer relationship into law, by reconceptualising the patient as an independent and informed consumer in a market of healthcare. Doctors were to provide patients with the information they needed to make an autonomous choice. The Supreme Court adopted the Australian formulation of the standard of care, from the case of *Rogers v Whitaker*,[96] into law. This dual standard conflated the incompatible liberal and authentic model of autonomy within one standard of care. The reliance on the GMC's ethical guidance as the justification for the movement to the consumer standard also reintroduced therapeutic considerations back into the decision-making process. Since the Supreme Court judgement, the judiciary have been divided between applying a *Bolam* plus standard of care, which caters to the therapeutic relationship, and an extreme consumer relationship, which sees judges making their own delineations of the materiality of information and comparing them, with hindsight, to the decision the doctor *actually* made. The reliance on the GMC guidance had an ossifying effect on the ability of the regulator to update its guidance; as doing so could have the effect of undermining the justification for the standard of care in law. Rationalising the conceptual confusion of the *Montgomery* judgement, was left to the semi-formal

[90] A. MacIntyre, *After Virtue.* (University of Notre Dame Press, 2007), 187
[91] T.L. Beauchamp, 'Internal and External Standards for Medical Morality.' (2010) 26(6) *Journal of Medicine and Philosophy* 601-619, 609; T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics.* (Oxford University Press, 2013) 3-5
[92] Department of Health, *Reference Guide to Consent for Examination or Treatment, Second Edition*. (DoH, 2009)
[93] GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008), [9]
[94] British Medical Association Ethics Department, *Medical Ethics Today – 3rd Edition*. (BMJI Books, 2012), 65.
[95] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 ("*Montgomery*")
[96] *Rogers v Whitaker* (1992) 175 CLR 479 ("*Rogers*")

sector, however, the Royal Colleges, Medical Defence Union ("MDU") and BMA were divided about the optimum model of autonomy to facilitate. Doctors in practice were therefore forced to choose which *horse-to-back*: some chose an objective content of disclosure, others chose a subjective content, and others chose to undertake a defensive practice. However, a significant minority of mostly senior doctors, experienced in undertaking information disclosure, opted to ignore the law and ethics and instead provided information the patient needed using *circumstantial-moral* decision-making.

The thesis concludes by arguing that normative standards, in law and ethics, have acted to undermine the discretion necessary to make *circumstantial-moral* decisions. Instead, normativity has encouraged defensive disclosure practices to avoid liability. Adopting the consumer relationship, within the law, acted to conceptually confuse the purpose of medical decision-making and forces responsibilities on patients, irrespective of their vulnerabilities or their actual information preferences. Similarly, adopting a binary model introduces confusion into medical decision-making; as the doctor does not know which teleological end to service: the requirement to act in the patient's best interest, or to ensure an autonomous choice. The conflation of multiple models within normative guidance subsequently confuses the processes for identifying material information.

The panacea, as this thesis sees it, is to recognise the essential nature of *circumstantial-moral* decision-making, emanating from a distinct internal morality; which prioritises decision-making in the patient's best interest. This orientation is an axiomatic part of the operation of medical discretion and therefore acts as the moral bedrock for medical decision-making, regardless of the normative rules in operation. The thesis identifies how this moral orientation has been utilised as an interpretative mechanism to both rationalise, and in some cases reject, competing and confused models of the medical relationship, medical duties, and standards of disclosure, within law and ethics. Normativity which acts against, or confuses, this internal orientation has had the effect of fracturing and demoralising medical decision-making. Fear of liability then causes a mechanistic process of defensive disclosure which has the effect of overwhelming and potentially harming patients. The thesis concludes by arguing that the remedy to this moral fracture is a recognition of the moral content of decision-making, and the cure to future moral-fracture is a return to a sociological standard of care in the law of negligence; one that clearly defines the proper methodology for evaluating medical decision-making, on its own moral terms.

CHAPTER 2: THE *BOLAM* STANDARD OF CARE AND THE JURISDICTION SCHOOL OF THOUGHT: 1957-1997

This chapter explains that a key element in the analysis of case law relating to information disclosure has been missed: understanding how doctors actually make decisions about information disclosure in practice. The oft repeated assertion, utilised by academics, to attack the legitimacy of medical decision-making, and thus medical power, is that the methodology of decision-making was arbitrary and based on individual and thus arbitrary moral choices. These choices were characterised as paternalistic and it was claimed that doctors often ignored the values, needs and choices of patients. Consequently, much of the medico-legal commentary critiqued the professional standard set in *Bolam v Friern Hospital Management Committee*[1] ("*Bolam*") as acceding to, or even endorsing, medical paternalism. [2] The critique of the legal standard can be divided into two schools of thought. Chapter 1 deals with the jurisdictions school of thought[3] which argued that the conventional *Bolam* standard prevented the judiciary from either critically analysing medical decision-making, or setting standards of care in law. As such, this school endorsed normative judicial standard setting. Chapter 2 focuses on the rights school which builds on this jurisdiction school by arguing that the form and ethical content of the normative standards should be solely focused on ensuring a form of autonomous patient choice. Autonomy would be facilitated through a purpose of informed consent to medical diagnosis and/or treatment.[4]

This chapter rebuts the presumptions on which the jurisdiction school critique rests, by engaging in a sociological analysis of historical empirical studies (that focused on how doctors made decisions, communicated with the patient, and facilitated patient information need). It demonstrates that rather than being paternalistic, doctors made decisions based on a combination of experiential and scientific knowledge, and technical expertise, which informed the creation of paradigms or typologies of patient information need. These paradigms which are interpreted in individual circumstances of the particular patient (*circumstantial-moral* decision-making), with the wider teleological aim of acting in the patient's best therapeutic interest's. With this knowledge early cases relating to the law of medical negligence, and particularly information disclosure is reinterpreted, to argue that judges were aware of the phenomenological structure of medical decision-making and that *Bolam* invited an analysis which

[1] *Bolam v Friern Hospital Management Committee* [1998] A.C. 1 W.L.R. 582. ("*Bolam*")
[2] For example, H. Teff, 'Medical Models and Legal Categories: An English Perspective.' (1993) 9 *J Contemp Health L Pol'y* 211, 211; A.M. McLean, *A Patient's Right to Know: Information Disclosure, the Doctor and the Law*. (Dartmouth, 1989)
[3] For a definition of "school of thought" see the Glossary
[4] This Thesis does not draw a clear line between commentators who are for the 'jurisdiction' or the 'rights' school. Often commentators for the rights school build on the arguments of the jurisdiction school and visa-versa. Whilst it is important to delineate the two schools of thought as a basis the diagnosis of this thesis, in the legal commentary, the two arguments are often conflated to argue more widely for a right to a standard of information or a right to informed consent, through the mechanism of law.

was tailored to this method of medical decision-making. This form of judicial engagement was later made explicit by *Bolitho*.[5]

However, by explicating the method of judicial analysis and requiring that decisions be made on a 'logical basis'[6] Lord Browne Wilkinson, unintentionally, began a process of ossification of medical decision-making practices. Fear of litigation led to surge in medical ethical regulation in the mid-to-late 1990's, which allowed doctors a source of legitimacy (if not logic) to base their decisions about materiality. Thus, the wishes of the jurisdiction school were fulfilled, albeit through the back door.[7]

The chapter concludes, by problematising the central thesis of the jurisdiction school: that normativity leads to better decision-making. Instead, this thesis argues that the ossification of decision-making processes during this period led to a rigidity in disclosure; which meant patients often did not receive the information they needed. This is because a normative standard, or threshold, of information disclosure, whilst facilitating an external or abstracted ethical model of beneficence or autonomy, is constructed on a single conceptualisation of a hypothetical reasonable patient. Reducing the scope for discretion, undermined the ability of doctor's to circumstantially augment disclosure regimes to individual patient needs. Facilitating disclosure for the hypothetical patient meant that the needs of the actual patients were ignored. Fear of litigation, also meant that information would be supplied to the patient even if it was refused, or harmful. As the process of *circumstantial moral* decision-making was eroded the internal morals of medical decision-making too began to fracture.[8]

2.1. The jurisdiction school of thought

This section sets out the central thesis of the 'jurisdiction' school of thought, by highlighting the sociological assumptions within their primary arguments. It then goes on to rebut these assumptions through normative critique and sociological analysis.[9]

2.1.1. The conventional interpretation of *Bolam*

To understand the problematisation of *Bolam* (which underpins the jurisdiction school of thought) it is necessary to first set out the *conventional* view and highlight the misnomers that allow the school of thought to advance its position. *Bolam v Friern Hospital Management Committee*[10] was an instruction

[5] *Bolitho v City and Hackney Health Authority* [1996] 4 All ER 771
[6] *Ibid*, 778
[7] Although fear of litigation was evident much sooner in practice: M.A. Jones, 'Informed consent and other fairy stories.' (1999) 7 *Med L Rev* 103-134, 130-131; J. Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas.' (2009) 17 *Med L Rev* 76-108, 105-108. 105-106; M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 110-112
[8] See Chapter 4, Section 1 & 3
[9] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treat Me Right – Essays in Medical Law and Ethics*. (Oxford University Press, 1988), 188
[10] *Bolam v Friern Hospital Management Committee* [1998] A.C. 1 W.L.R. 582

to the jury and as such is directive rather than explanatory of a particular decision (which may be the source of confusion about the standard of care). John Hector Bolam received ECT to cure depression without relaxant drugs, or manual restraints, consequently Mr Bolam fell off the bed and fractured his femur, causing it to be driven through the acetabulum (or cup of the pelvis).[11] Mr Bolam alleged that the doctor should have: (1) provided a relaxant drug, (2) supplied sufficient nurses to control the convulsions, (3) provided him information and warn him of the risks.[12] The test for negligence was set out in *Hunter v Hanley.*[13]

> […] whether he has been proved to be guilty of such failure as no doctor of ordinary skill would be guilty of, if acting with "ordinary" care. If that statement of the true test is qualified by the words "in all the circumstances," […][14]

In summing up the law to the jury, McNair J stated that:

> I myself would prefer to put it this way, that he is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art.[15]

He clarified this by saying:

> I do not think there is much difference in a sense. It is just a different way of expressing the same thought. Putting it the other way round, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion would take the contrary view.[16]

Unfortunately, commentators and judges alike have hyper-focused on the summary of the test, which was intended to be a mere explanation of how *not* to evaluate medical decision-making – using the sociological standard of care.[17] However, this was interpreted as the *crux* of the standard, so if the professional could show that they followed, or were supported by, a responsible body of medical opinion, then they would have met the standard of care for information disclosure. A defence could be established by calling expert evidence[18] to attest that the doctor would have made the same decision.

[11] *Ibid*, 588
[12] *Ibid*, 588
[13] *Hunter v Hanley* (1955) S.L.T 213, per Lord Clyde at 217
[14] *Bolam v Friern Hospital Management Committee* [1998] A.C. 1 W.L.R. 582, 587
[15] *Ibid*, 587
[16] *Ibid*, 587
[17] *Ibid*, 587
[18] H. Teff, 'The Standard of Care in Medical Negligence – Moving on from *Bolam*?' (1998) 18 *Oxford Journal of Legal Studies* 473, 474

Critiques found this problematic as experts were often partisan in their analysis of the doctors' decision-making. [19]All that had to be evidenced was the credentials of the responsible expert.[20] This essentially amounted to a *Bolam* defence being adopted as the basis of evaluating decision-making, relating to both diagnosis,[21] and treatment,[22] in the doctor-patient relationship.[23]

Commentators such as Brazier and Miola argued that McNair J conflated the test for reasonableness with responsibleness.[24] This was unsatisfactory from a constitutional point of view, as judges were being prevented from both carrying out their role of reviewing medical decision-making.[25] Judges were not allowed to investigate whether doctors correctly identified or weighed relevant factors, or acted globally in the best interests of the patient.[26] This lack of transparency about the rationale for decisions about materiality led to accusations of arbitrary and paternalistic decision-making.[27] Teff, for example, argued that doctors placed inappropriate weight on the potential psychological harms of disclosure, rather than focusing on the benefits of patients receiving information so that they could make autonomous choices about their health.[28]

2.1.2. Reasons for the professional standard

The jurisdiction school opined that judges felt that they lacked the tools, or expertise, to analyse or criticise a medical decision. As Teff suggests: 'judges often remained ill-equipped to explore and evaluate the inherent 'reasonableness' or 'responsibility; of the practice supported by the medical witnesses on either side.'[29] Judges, particularly, felt unable to engage with the moral content of a decision[30]- whilst judges may have jurisprudential knowledge, they did not have the philosophical training to engage in debates about medical ethics, morality, or the correct interpretation of Kant.[31]

[19] *Ibid*, 481-482; Lord Woolf, *Access to Justice: Final Report* (Department of Constitutional Affairs, 1996), 143.
[20] M. Jones, 'The *Bolam* Test and the Responsible Expert.' (1999) *Tort Law Review* 226, 230-233
[21] *Maynard v West Midlands Regional Health Authority* [1984] 1 WLR 634
[22] *Whitehouse v Jordan* [1981] 1 WLR 246
[23] H. Teff, 'The Standard of Care in Medical Negligence – Moving on from *Bolam*?' (1998) 18 *Oxford Journal of Legal Studies* 473, 474-475; M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 88-90; *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 AC 871, per Lord Scarman at 881
[24] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 87
[25] H. Teff, 'Medical Models and Legal Categories: An English Perspective.' (1993) 9 *J Contemp Health L Pol'y* 211, 213
[26] J. Katz, *The Silent World of Doctor and Patient* (The Free Press, 1984), 165-206.
[27] H. Teff, 'Consent to Medical Procedures: Paternalism, Self-determination or Therapeutic Alliance?' (1985) 101 *L Q Rev* 432-453, 432.
[28] *Ibid*, 432-433.Also, see for example, M. Jones, 'The *Bolam* Test and the Responsible Expert.' (1999) *Tort Law Review* 226, 230-233 & 234
[29] H. Teff, 'The Standard of Care in Medical Negligence – Moving on from *Bolam*?' (1998) 18 *Oxford Journal of Legal Studies* 473, 476.
[30] *Ibid*, 476. Also, H. Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship*. (Clarendon Press, 1994), 9-14. For example, *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 AC 872, per Lord Diplock, at 893
[31] See, J. Montgomery, 'Medicine, Accountability and Professionalism.' (1989) 16(2) *Journal of Law and Society* 319; J. Keown, 'Doctor Knows Best?: The Rise and Rise of "The *Bolam* Test".' (1995) *Singapore Journal of Legal Studies* 342-364, 362.

Instead, judges felt better able to evaluate decisions based on the 'seniority, reputation, and performance' of an expert, than the content of their evidence.[32]

Commentators also argued that there was an irrational deference to doctors, because they were part of a skilled profession;[33] and thus, holders of specialist knowledge.[34] For example, Brazier, and later Maclean, insinuated that this may have been one of the motivating factors in limiting the cause of action in battery – 'to distinguish beneficent doctors who operated with an inadequate consent from muggers and hoodlums.'[35] As a profession, doctors were seen, by the judiciary, as having a unique moral rule in society, and technical expertise in decision-making which should be respected.[36] Being part of a profession invoked an empathy with judges, who had previously been practitioners and may have been placed in similarly compromising positions by their clients.[37] Teff argued that this deference was in line a wider societal problem of 'notoriously low level of accountability demanded of the political system as a whole.'[38]

2.1.3. The conventional *Bolam* standard: examples from the case-law

Teff argued that in practice it was difficult to critique medical decision-making because of the lack of a collectively 'accepted medical practice.'[39] There was simply no scientific or empirical basis, and thus objective stand-point, to counter expert opinion. Experts hid behind this veil of professional expertise. Brazier and Miola, argued that, in practice: '[t]he test became no more than a requirement to find some other expert(s) who would declare that they would have done as the defendant did.' [40] This interpretation of the *Bolam* standard is understandable, both, because there are examples of expert evidence which were clearly negligent and yet unchallenged,[41] and that evidence was more robustly challenged in other

[32] H. Teff, 'The Standard of Care in Medical Negligence – Moving on from *Bolam*?' (1998) 18 *Oxford Journal of Legal Studies* 473, 476

[33] Lord Woolf, 'Are the Excessively Deferential to the Medical Profession?' (2001) 9(1) *Med L Rev* 1-16; S. Devaney & S. Holm, 'The Transmutation of Deference in Medicine: An Ethico-Legal Perspective.' (2018) 26(2) *Med L Rev* 202-224

[34] I. S. Goldrein, '*Bolam*-Problems Arising Out of 'Ancestor Worship.'(1994) 144 *NLJ* 1237-1239, 1248, 1282-1284, 1315-1316, 1415-1416, 1449-1450.

[35] A. Maclean, 'Giving the Reasonable Patient a Voice: Information Disclosure and the Relevance of Empirical Evidence.' (2005) *Med L Rev* 1-40, 2; M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law?' (1987) 7 *Legal Studies* 169, 180. Also, A. Grubb, "Consent to Treatment: The Competent Patient." In I. Kennedy & A. Grubb, (eds.), *Principles of Medical Law*. (Oxford University Press, 2004), 173

[36] For example, Kennedy terms doctors "The New Magicians" I. Kennedy, *The Unmasking of Medicine.* (George Allen and Unwin, 1981), 27-50. See also S. McLean, *Old Law and New Medicine: Medical Ethics and Human Rights.* (Rivers Oram Press, 1998), 3-4. See also, J. Badenock Q.C, 'Brushes with *Bolam.* Where will it lead?' (2004) 72(4) *Medico-Legal Society* 127, 134.

[37] J. Badenock Q.C. *Ibid*, 134; S. Devaney & S. Holm, S. Devaney & S. Holm, 'The Transmutation of Deference in Medicine: An Ethico-Legal Perspective.' (2018) 26(2) *Med L Rev* 202-224.

[38] H. Teff, 'Consent to Medical Procedures: Paternalism, Self-determination or Therapeutic Alliance?' (1985) 101 *L Q Rev* 432-453, 444

[39] H. Teff, 'The Standard of Care in Medical Negligence – Moving on from *Bolam*?' (1998) 18(3) *Oxford Journal of Legal Studies* 473-484, 476.

[40] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 85

[41] See for example, M. Khan & M. Robson, '*Bolam* Rides Again.' (1995) 2(2) *P.I.L.M.R.* 105; N.H. Harris, 'Standards of Practice.' (1997) 141 *S.J. Supp. Exp.* 38; D.K. Feenan, 'Beyond *Bolam*: Responding to the Patient.' (1994) 1 *Med L Int* 177; J. Keown, 'Burying *Bolam*: Informed Consent Down Under.' (1994) 35 *CLJ* 16.

professional spheres.[42] For example, Miola and Brazier argued that the judgement in *Maynard v West Midlands Regional Health Authority*[43] created the perception that all *Bolam* requires is that the defendant fields an expert from his speciality to testify that they would have adopted the same approach as the defendant doctor.[44] In *Maynard*, the trial judge preferred the expert evidence of the claimant, but the House of Lords decided that a judge could not prefer a school of thought;[45] even if the school of thought was limited to only a few individuals.[46] For example, in *De Freitas v O'Brien* only five out of two hundred and fifty consultants were considered a reasonable school of thought.[47] Commentators did note that Sach J in *Hucks v Cole*[48] rejected expert evidence on the basis that there was a lacuna in professional practice - where no school of thought had developed. In this circumstance, the judge could interrogate the logic of the defendant's decisions, so: 'where risks of grave danger are knowingly taken, however small the risk, the court must anxiously examine the lacuna – particularly if the risk can easily and inexpensively be avoided.'[49] However, commentators distinguished this case from the conventional line of *Bolam* case-law.[50] The case was originally conducted in 1968, and had been overruled by the House of Lords (in *Maynard).*[51] The courts have not since differentiated between novel and standard practices – all medical actions were characterised as expert.[52]

Commentators argued the conventional *Bolam* standard was again endorsed by the majority of the House of Lords in *Sidaway.*[53] For example, Lord Diplock was argued to have offered the most conservative approach, accepting expert evidence about whether the medical action amounted to a responsible school of thought,[54] rather than engaging in a normative debate about the underlying medical ethics, or interrogating the doctor's decision-making. Miola argued that Lord Diplock's suggestion that doctors should disclose information in a patient's best interest (e.g., to ensure that they

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[42] See, *Edward Wong Finance v Johnson Stokes & Master* [1984] AC 296
[43] *Maynard v West Midlands Regional Health Authority* [1985] 1 All ER 635
[44] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 88
[45] *Maynard v West Midlands Regional Health Authority* [1985] 1 All ER 635, per Lord Scarman, at 639. See also, *Whitehouse v Jordan* [1981] 1 All ER 267
[46] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 89
[47] *De Freitas v O'Brien* [1993] 4 Med L R 281.
[48] H. Teff, 'The Standard of Care in Medical Negligence – Moving on from *Bolam*?' (1998) 18(3) *Oxford Journal of Legal Studies* 473-484, 477
[49] *Hucks v Cole* [1993] 4 Med L R 393 (CA), 397. See, M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution? (2000) 8 *Med L Rev* 85-114, 98-99
[50] H. Teff, 'The Standard of Care in Medical Negligence – Moving on from *Bolam*?' (1998) 18(3) *Oxford Journal of Legal Studies* 473-484, 477; M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 101. This thesis would argue that the case is similarly distinguished by Brazier and Miola, as they view it as an individual pre-cursor to *Bolitho*, rather than indicative of contemporary legal position.
[51] *Maynard v West Midlands Regional HA* [1984] 1 WLR 634.
[52] H. Teff, 'The Standard of Care in Medical Negligence – Moving on from *Bolam*?' (1998) 18(3) *Oxford Journal of Legal Studies* 473-484, 477
[53] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 90; J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship*. (Hart Publishing, 2007), 57. Also, I. Kennedy, 'Consent to Treatment: The Capable Person." In C. Dyer, *Doctors Patients and the Law.* (Blackwell, 1992), 65
[54] This is because Lord Diplock recognised that there were normative ethical principles intrinsic to medical ethical decision-making about the standard of care that should be adopted, irrespective of the type of decisions that were being made. Thus, the ethics of information disclosure could not be delineated from the wider moral duties of medical practice. See *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 All ER 643, at 657.

are persuaded to consent to an operation) supported an intrinsic medical paternalism.[55] Lord Bridge and Lord Templeman also adopted the sociological standard, albeit, they endorsed the jurisdiction school requirement of utilising formal ethical principles as the basis for decision-making. Lord Bridge recognised the need for judges to be critical of medical practice and encouraged an external critique of decision-making; to see whether it fell within the bounds of reasonability.[56] This approach would allow judges to choose between responsible bodies of medical practice.[57] Lord Templeman also argued that the assessment of medical decision-making was a sociological standard, but encouraged that doctors pay more heed to the information needs of the patient by allowing and supporting the patient to ask questions. In Lord Templeman's view, providing patients with a greater amount of information allowed for a more substantive autonomy, which was also in patient's best interests.[58] Lord Scarman, who was the minority, took a more proactive approach to normative law-making; he argued 'the law imposes the duty of care; but the standard of care is a matter of medical judgement.'[59] The jurisdiction school argued that the lack of critical engagement in the content of a decision was fatal to the role of the judge as decision-maker.[60]

2.1.4. Justifications for normativity

To combat the problems of the conventional *Bolam* standard, the jurisdiction school argued that a normative legal standard of care in negligence should be created to allow the judge to critically evaluate medical decision-making, and thus prevent paternalism. This section sets out the three central pillars of argumentation for judicial normativity. The next section argues that these justifications are empirically unfounded and normatively problematic.

(i) Justification (1): the role of the judge

Montrose argued that the professional standard, in *Bolam*, conflated the ethical role of the law - to set normative standards of practice - with a sociological standard, which tied the judge to simply asking whether the doctor had achieved the standard of the *ordinary* doctor.[61] Teff adopted and updated Montrose's argument,[62] and argued (probably more accurately) that judges were defining what was reasonable *descriptively*. The descriptive standard, as opposed to the sociological standard, was equivocal to the decision that the doctor had actually made, as the standard of care was defined solely

[55] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship*. (Hart Publishing, 2007), 58-59
[56] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 All ER 643, 663
[57] *Ibid*, per Lord Bridge, at 663; J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship*. (Hart Publishing, 2007), 60
[58] *Ibid*, per Lord Templeman at 664
[59] *Ibid*, at 649
[60] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 88
[61] J.L. Montrose, 'Is Negligence and Ethical or Sociological Concept?' (1958) 21(3) *MLR* 259-264, 259.
[62] H. Teff, *Reasonable Care: Legal perspectives on the Doctor Patient Relationship* (Clarendon Press, 1994), 181; H. Teff, 'The Standard of Care in Medical Negligence – Moving on from *Bolam*?' (1998) 18 *Oxford J. Legal Stud* 473; H. Teff, Medical Models and Legal Categories: An English Perspective.' (1993) 9 *J Contemp. Health L & Pol'y* 211

by the individual expert.[63] Teff argued that the judges should first be allowed to evaluate what amounted to 'accepted medical practice in the circumstances' - which would allow judges to critically engage with the content of a medical decision.[64] He agreed with Montrose, who argued that the judge could utilise this analysis to adopt a normative standard (in areas of decision-making which are not explicitly technical).[65] Whilst, the normative judicial standard could be set at the *ordinary* standard, this would not be equivocal to the descriptive approach. Teff took the view that on average doctors made poor ethical decisions[66] and therefore required a higher threshold of disclosure within the law; to avoid paternalism.[67] Informed consent, enacted through a normative standard of information disclosure, within the law of negligence, would, he argued, promote a better balancing of considerations in medical decision-making in practice.[68]

(ii) Justification (2): unethical decision-making

One of the key reasons for the need for legal normativity was the sociological claim that the majority of doctors were arbitrary in their decision-making processes. The intention to act in the patient's best interest. as the overriding aim of medical practice. resulted in paternalism. In the context of disclosure, this meant doctors placed inappropriate weight on protection, and underestimated the therapeutic benefit of providing detailed information.[69]

The rhetoric of paternalism emerged first in the bioethical literature in the US, [70] for example, when defining paternalism, Beauchamp stated: '[t]here are so many individual examples of controversial paternalistic justifications in biomedical and behaviour contexts that only a few selected samples can be treated here.'[71] This rhetorical claim was regularly adopted to justify movements towards normative

[63] *Ibid*, 181; H. Teff, 'The Standard of Care in Medical Negligence – Moving on from *Bolam*?' (1998) 18 *Oxford J. Legal Stud*. 473, 475-477. Also, A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5 *Med L Int* 205, 207. The term *descriptively* is then accurately used by Miola in J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship*. (Hart Publishing, 2007), 11

[64] H. Teff, 'The Standard of Care in Medical Negligence – Moving on from *Bolam*?' (1998) 18 *Oxford J. Legal Stud*. 473, 475

[65] *Ibid*, 475. He suggested: "[…] doctors, in common with professional generally, should be judged by the standards proclaimed by their peers – 'proclaimed' rather than 'adhered to', since, although Bolam itself might have been clearly on the point, 'accepted practice' is to be understood in a normative rather than a descriptive sense."

[66] H. Teff, Medical Models and Legal Categories: An English Perspective.' (1993) 9 *J Contemp Health L & Pol'y* 211, 213

[67] See for example, H. Teff, Medical Models and Legal Categories: An English Perspective.' (1993) 9 *J Contemp Health L & Pol'y* 211, 231-232

[68] H. Teff, Consent to Medical Procedures: Paternalism, Self-Determination of Therapeutic Alliance? (1985) 101 *Law Q Rev* 432-453, 436

[69] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treat Me Right – Essays in Medical Law and Ethics*. (Oxford University Press, 1988), 189

[70] For example, G. Dworkin, "Paternalism." In S. Gorovitz *et al* (eds.), *Moral Problems in Medicine*. (Prentice-Hall, 1976), 185

A. E. Buchannan, Medical Paternalism. (1978) 7 *Phil & Pub Aff* 370,371-372; J.F. Childress, *Who Should Decide? Paternalism in Health Care*. (Oxford University Press, 1982); T.L. Beauchamp, The Promise of the Beneficence Model for Medical Ethics. (1990) 6 *Contemp Health L & Pol'y* 145; O. Corrigan, 'Empty Ethics: the problem with informed consent.' (2003) 25(7) *Social Health* Ill 768-792; R. Veatch, Models for ethical medicine in a revolutionary age. (1972) 2 *Hastings Center Report* 5-7.

[71] T. L. Beauchamp, "Paternalism." In W.T. Reich, (eds.), *Encyclopaedia of Bioethics.* (Macmillan, 1978), 1194-1201: 1194

standards of disclosure within the law in North America.[72] The only legitimate role for beneficence within the materiality paradigm was as a therapeutic privilege,[73] which qualified withholding information only if there was significant and imminent risk of harm.[74]

The rhetoric of paternalism was later adopted into UK bioethics.[75] Commentators argued that paternalism had infected the medical relationship, and acted as a barrier to the proper facilitation of patient's autonomous choices.[76] In *Unmasking Medicine*, for example, Kennedy attacked what he argued was the '19th century approach'[77] to decision-making based on biomedical values. He argued that doctors conceptualised themselves as scientists and patients as biological conduits, on which they performed experiments to fix dysregulated systems.[78] This biomedical construction of disease failed to recognise the individual (the emotional, psychological, societal, environmental and relational factors) within a definition of ill health[79] - thus, the idiosyncracies of the patient were ignored.[80] In relation to information disclosure, if the doctor failed to take account of the individual's values, they were characterised as not providing them with the information they needed to make a decision (and therefore could not be said to have acted in their best interest's).[81]

Medical decision-making was further de-legitimised because the values and principles that were being used to make decisions were not explicated within any formal ethical codes. Instead, deviations were characterised as 'the unfettered autonomy of the individual consultant.'[82] As, Kennedy argued:

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[72] In relation to legal commentary, see: J.H. Swan, The California Law of Malpractice of Physicians, Surgeons, and Dentists (1945) 33 *Calif L Rev.* 248, 251; A.H. McCoid, 'Reappraisal of Liability for Unauthorized Medical Treatment.' (1957) 41 *Minn L Rev* 381; A.H. McCoid, 'The Care Required of Medical Practitioners.' (1959) 12 *V and L Rev* 549; M. Oppenheim, 'Informed Consent to Medical Treatment.' (1962) 11 *Clev Mr. L Rev* 249; W.H. Karchmer, 'Informed Consent: A Plaintiff's Medical Malpractice "Wonder Drug." (1966) 31 *Mo L Rev* 405; Comment, 'Informed Consent in Medical Malpractice.' (1967) 55 *Calif L Rev.* 1396, 1407-10; M.L. Plante, 'An Analysis of "Informed Consent".' (1968) 36 *Ford L Rev* 639; J.R. Waltz & T.W. Scheuneman, 'Informed Consent to Therapy.' (1970) 64 *Nw U L Rev* 628; M. Lieberman, 'The Physician's Duty to Disclose Risks of Treatment.' (1974) 50(8) *Bull NY Acad Med* 943; J.E. Maldonado, 'Strict Liability and Informed Consent: "Don't Say I Didn't Tell You So!".' (1976) 9(4) *Akron Law Review* 609-628; A. Meisel, L.H. Roth & C.W. Lidz, 'Towards a Model of the Legal Doctrine of Informed Consent.' (1977) 134(3) *Am J Psychiatry* 285-289; A. Meisel, 'The Expression of Liability for Medical Accidents: From Negligence to Strict Liability by Way of Informed Consent.' (1977) 56 *Nebraska Law Review* 51; M.L. Plante, 'The Decline of "Informed Consent".' (1978) 35(1) *Wash & Lee L Rev* 91; A. Meisel & L.H. Roth, 'What We Do and Do Not Know about Informed Consent.' (1981) 246 *JAMA* 2473; A. Meisel & L.H. Roth, 'Towards an Informed Discussion of Informed Consent: A Review and Critique of the Empirical Studies.' (1983) 25 *Ariz L Rev* 265; J. Katz, *The Silent World of Doctor and Patient.* (The Free Press, 1984), Chapters 1-2; R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 74-86

[73] For example, I. Kennedy, "Patient on the Clapham Omnibus." In I. Kennedy (eds.), *Treat Me Right: Essays in Medical Law and Ethics.* (Clarendon Press, 1994), 187

[74] For example, M.D. Kirby, 'Informed Consent: What Does It Mean?' (1983) 9 *J Med Ethics* 69-75, 72; H.A. Bassford, 'The Justification of Medical Paternalism.' (1982) 16(6) *Soc Sci Med* 731-739

[75] For example, R. Gillon, 'Paternalism and Medical Ethics.' (1985) 290 *BMJ* 1971

[76] C. Strong, 'Informed Consent: Theory and Policy.' 91979) 5 *J Med Ethics* 196; M.D. Kirby, 'Informed Consent: What does it mean?' (1983) 9 *J Med Ethics* 69; R. Gillon, 'Ethics Needs Principles – Four can encompass the rest – and respect for autonomy should be "first among equals." (2003) 29 *J Med Ethics* 307-313

[77] R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 74-87

[78] I. Kennedy, *The Unmasking of Medicine.* (George Allen and Unwin, 1981), 29-31

[79] *Ibid*, 29-31

[80] *Ibid*, 28-29

[81] *Ibid*, 28-29 & 39-44

[82] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 99-100

> In the context of disclosure of information, the very notion of a professional standard is something of a nonsense. There is simply no such standard, if only because the profession has not got together to establish which risks should be disclosed to which patients in which circumstances.[83]

This rhetoric allowed commentators to argue that by continuing to endorse the *Bolam* defence the judiciary were effectively endorsing poor decision-making.[84] For example, Kennedy powerfully argued:

> That women in the 1980's should not be entitled in law to information about the risks and alternatives to a procedure such as sterilisation without having to ask is, frankly, an appalling state of affairs.
>
> Women patients have put up with this kind of nonsense from doctors for far too long, and it is time that the courts realised this. If courts think that by making such decisions they are saving the medical profession from litigation and thus doing us all a service, they are tragically wrong. Far worse consequences will befall the doctor-patient relationship if patronising paternalism is legitimised as the appropriate mode of communication between doctor and patient.[85]

Teff[86] similarly argued that:

> The nature of medical practice may have changed considerably in recent years, but hospital medicine in particular continues to bear the stamp of Hippocratic tradition. Physicians are generally committed to a principle or duty of beneficence in which "beneficence" is routinely determined by the individual doctor. Similarly, the ancient admonition to conceal most things from patient lest they take a turn for the worse still has many adherents.[87]

Brazier offered a more balanced interpretation[88] but similarly exemplifies this point of view by stating:

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[83] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treat Me Right – Essays in Medical Law and Ethics*. (Oxford University Press, 1988), 189

[84] See for example, S.A.M. McLean, *A Patient's Right to Know: Information Disclosure, The Doctor and The Law*. (Dartmouth Publishing, 1989)

[85] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy (eds.). *Treat Me Right: Essays in Medical Law and Ethics*. (Clarendon, 1991), 211-212

[86] Teff relies on T.L. Beauchamp, The Promise of the Beneficence Model for Medical Ethics.' (1990) 6 *J Contemp Health L & Pol'y* 145; A. Buchanan, 'Medical Paternalism.' (1978) 7 *Phil & Pub Aff* 371-372. In H. Teff, 'Medical Models and Legal Categories: An English Perspective." (1993) 9 *J Contemp Health L & Pol'y* 211, 211

[87] *Ibid*, Teff, 212

[88] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law?' (1987) 7(2) *Legal Studies* 169-193, 173-176

> […] a still considerable body of medical opinion […] consider that patient autonomy is sufficiently respected once the patient, having taken an initial decision to seek treatment, has had explained to him the broad general nature of what his doctors propose to do by way of treatment with perhaps some indication given of any particularly significant risks inherent in treatment […]. The practitioner holding this view may regard himself free, in addition, to withhold any information on the nature of treatment, the risk or even the diagnosis where he judges that non-disclosure is in the patient's best interests. The practitioner's clinical judgement is paramount in determining how much information patients be given about their treatment.[89]

This rhetoric has continued to be operationalised to attack medical decision-making, for example, in their 2015 paper Miola and Foster argued:

> […] Kennedy was correct about the law being overly paternalistic in the 1980s, and the fact that doctors were claiming responsibility for making decisions that were outside of their field of expertise. In this context judicial interventionism and de-medicalisation are entirely reasonable suggestion.[90]

Having delegitimised the process and moral orientation of medical decision-making, commentators could then make a powerful argument for normative rules to ensure that patients were protected. For example, in Kennedy's prolific review of the Court of Appeal judgement, in *Sidaway*, he argued that the:

> […] English law could make a major contribution to the development of a doctor-patient relationship based on shared decision making. It would then be for the educators, the trainers, the doctors, and the patients to ensure that the idea became a reality.[91]

Later commentators made much stronger arguments for law to adopt the biopsychosocial tradition. This was especially pronounced in the law of information disclosure; which was seen as a forum of moral rather than technical decision-making. Whilst:

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[89] *Ibid*, 173-174

[90] C. Foster & J. Miola, 'Who's in Charge? The Relationship between Medical Law, Medical Ethics and Medical Morality?' (2015) 23(4) *Med L Rev* 505-530, 529

[91] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy (eds.), *Treat Me Right: Essays in Medical Law and Ethics.* (Clarendon, 1991), 211-212

> [t]he law alone cannot effect a substantial change in the routine behaviour of doctors, […] it could have some symbolic impact on their perception of what is appropriate in relationships with patients.[92]

Jones agreed.[93] Brazier took the position that law should normatively regulate but that it should be adopted into law through legislation, after analysis by a commission, which would establish an ethics of medical decision-making.[94] With Miola, she argued:

> […] inappropriate deference to medical opinion should be replaced by legal principles which recognise the imperative to listen to both doctors and patients and which acknowledge that the medical professional is just as much required to justify his or her practice as the architect or solicitor.[95]

Brazier, with Cave repeats this position in her textbook(s), albeit that ethical standards should lead the way in specifying the process and content of disclosure. The law should be set at a threshold of bare competence. This legal-ethical relationship would require the Law Commission and the GMC to work together to set normative standards.[96] Miola went further than Brazier and argued that a new body should be set up to seek a complementary relationship between ethics and law.[97] However, the most direct call for normativity was provided by Sheila McLean, who argues that law and particularly human rights should be used as a mechanism to wrestle control of medical decision-making from the medical profession.[98] This critique of Hippocratic paternalism has remained a dominant academic narrative.[99]

(iii) Justification (3): decision-making is not technical

The third justification for normativity is made by suggesting that doctors do not have exclusive competence in relation to areas of medical practice, and aspects of decision-making. As such, they do not have expertise and therefore cannot claim exclusive power. This is particularly true where decisions involve a moral element. Kennedy,[100] for example, argued that the content of decisions about the materiality of information are not exclusively technical.[101] By 'technical', he meant that the content, or

[92] H. Teff, 'Consent to Medical Procedures: Paternalism, Self–Determination or Therapeutic Alliance?' (1985) 101 *L Q Rev* 432-453, 453
[93] M.A. Jones, 'Informed Consent and Other Fairy Stories.' (1999) 7 *Med L Rev* 103-144, 134
[94] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law.' (1987) 7 *Legal Studies* 169, 191-193
[95] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev.* 85-114,114.
[96] M. Brazier & E, Cave, *Medicine, Patient and the Law*. (Penguin, 2003), 485
[97] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship.* (Hart, 2007), 218-219
[98] S. Maclean, *Old Law, New Medicine: Medical Ethics and Human Rights.* (Rivers Oram Press, 1999), 3
[99] For example, J. Katz, *The Silent World of Doctor and Patient.* (John Hopkins University Press, 1984), 28. See also, J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship.* (Hart Publishing, 2007), 23-28
[100] I. Kennedy, *The Unmasking of Medicine.* (George Allen and Unwin, 1981),76-77
[101] This trend has similarly been exposed by Montgomery in: J. Montgomery, 'Time for a Paradigm Shift? Medical Law in Transition.' (2000) 53 *Current Legal Problems* 354-408, 373

methodology, for identifying and weighing and balancing considerations was not a learnt skill, or one that was specific to medicine. The process of decision-making could therefore be distinguished from diagnosis and treatment, which contained more substantive technical content. [102] Kennedy argued that technicality was used as a rhetorical claim to power; which allowed doctors to black-box the moral content of decision-making.[103] In reality, some elements of these decisions were not objective but made utilising the doctor's individual discretion.[104]

> For if doctors claim unique competence it must be in something they are uniquely competent to do. Doctors are not uniquely competent to make ethical decisions. They receive no training to prepare them for such a role. So, put rather bluntly, what I am calling for is a wholesale re-examination of the sphere of alleged competence of the doctor.[105]

Kennedy argued '[…] it is not for professionals to set the moral agenda for their relationship with those they serve. They have only extra duties, not privileges.'[106]As such, he argued that normative rules were necessary to regulate the moral elements of a decision. By doing so, the moral and scientific elements of information disclosure are thus abstracted. This position has been adopted by a number of commentators to justify legal regulation, for example Teff asserts:

> There is growing resentment of claims by professional groups to a monopoly over decision-making in areas which do not self-evidently call for their particular skills, or at least the full range of such skills. And it is the more marked in matters which require insights and judgements of a kind not necessarily associated with the professional group in question.[107]

Jose Miola, who has probably been the strongest proponent of this justification, utilises it in numerous publications.[108] He argued that: '[…] the medical practitioner possesses no special skill that makes her the best person to make decisions of an ethical nature.'[109]This argument was later adopted by the majority in *Rogers v Whitaker*, [110] because they:

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[102] *Ibid*
[103] *Ibid*, 76-77
[104] *Ibid*, 78-80
[105] *Ibid*, 78
[106] I. Kennedy "The Patient on the Clapham Omnibus." In, I. Kennedy, *Treat Me Right.* (Oxford University Press, 1988), 178
[107] H. Teff, 'Consent to Medical Procedures: Paternalism, Self-Determination or Therapeutic Alliance?' (1985) 101 *Law Q Rev* 432-453, 445-446
[108] See also, J. Miola, "Moralising medicine: 'Proper medical treatment' and the role of ethics and law in medical decision-making." In S. Fovargue & A. Mullock, *The Legitimacy of Medical Treatment: What Role for Medical Exception?* (Routledge, 2016), 73-77
[109] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship* (Hart Publishing, 2007), 40-42
[110] *Rogers v Whitaker* (1992) 16 BMLR 148; K. Tickner, '*Rogers v Whitaker* – Giving Patients a Meaningful Choice.' (1995) 15 *Oxford J Legal Studies* 109, 114. As Ticker argues: "[…] the High Court found that the provision of information was different from the provision of medical treatment because the former, in most cases, merely involves communication skills which are not exclusive to medical practitioners and therefore can be judged by non-medical people. Therefore, the rationalise,

> […] recognise that risk disclosure is not an area of practice requiring technical medical skill, and thus distinguished it, as Lord Scarman had done in *Sidaway*, from diagnosis and treatment.[111]

In 2015, Miola repeated Kennedy's technical justification as a basis for judicial interventionism,[112] arguing:

> If we accept Kenney's assertion that many of the decisions made by doctors are not technically medical in nature, we can extrapolate that in many cases this laissez-faire attitude on the part of the law allowed doctors to exercise their consciences to a significant degree. However, things have now changed. The law now concerns itself with patients' rights rather than medical discretion, and this has by definition limited the space available to doctors to use their conscience.[113]

The consistency and virulence of this critique saw this position adopted in the leading case of *Montgomery v Lanarkshire Health Board.*[114] Lord Kerr and Reed, giving a joint majority judgement, stated:

> […] the extent to which a doctor may be inclined to discuss risks with a patient is not determined by medical learning or experience, the application of the *Bolam* test to this question is liable to result in the sanctioning of differences in practice which are attributable not to divergent schools of thought in medical science, but merely to divergent attitudes among doctors as to the degree of respect owed to their patients.[115]

2.1.5. A Rebuttal

(i) Rebuttal (1): the role of the judge

The main critique of Montrose and Teff, in their call for normativity, is that a sociological test bars the judge from critically engaging with the content of the medical decision. This is incorrect, as the following sections will argue; the *Bolam* test invites the judge to assess both the internal basis, and logic

behind the *Bolam* test, that expert matter can only be judged by expert opinion, cannot be used to justify its application to determine the doctor's duty of disclosure."

[111] *Ibid*

[112] J. Miola, 'Making Decisions about Decision-Making: Conscience, Regulation, and the Law.' (2015) 23(2) *Med L Rev* 263-282, 264

[113] *Ibid*, 281

[114] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, particularly, [74]-[89]

[115] *Ibid*, [84].

of a decision, as well as requiring an external evaluation of whether the decision is of a professional standard, and/or ethically appropriate as a function of medicine in a liberal society.[116]

(ii) Rebuttal (2): unethical decision-making

The argument that doctors are, generally speaking, paternalistic in their decision-making process is a sociological claim that requires robust evidence. Instead of providing this evidence, commentators rely on rhetoric or as Kennedy terms it a 'broad brush' approach.[117] Commentators such as McCullough[118] have already begun to dispel this rhetoric, by challenging the arguments sociologically.[119] This chapter would add to this challenge in two ways, first, in this section, by analysing the sociological materials relied on by Kennedy to support his argument that paternalism 'pervade[s] the whole range of medical care.'[120] Second, by presenting a competing conceptualisation of medical decision-making as *circumstantial-moral* decision-making.[121]

In *Unmasking Medicine*, Kennedy relied on three primary sources to support his claim.[122] First, the Royal Commission Survey, which evidenced that disclosure processes were flawed because patients did not receive their preferred level of information: '31 per cent of in-patients and 25 per cent of out-[…] did not consider they were given enough information about their treatment and care.'[123]Whilst this is a significant minority, this would mean that the majority of patients were satisfied. The data presented also does not identify the cause of the failure to satisfy patient need. Other reviews have identified that satisfaction could be impacted by the ability of the patient to understand or recall information.[124] This is a real concern as 40-80% of patients in studies did not recall information.[125] Whilst patient

[116] See Section 3, below
[117] I. Kennedy, *The Unmasking of Medicine.* (George Allen and Unwin, 1981),44
[118] L.B. McCullough, 'Was Bioethics founded on historical and conceptual mistakes about medical paternalism.' (2011) 25(2) *Bioethics* 66-74, 72; Also, see R. Veatch, *Death, Dying, and the Biological Revolution: Our Last Quest for Responsibility.* (Yale University Press, 1976), 206; R.M. Veatch & E. Tai, 'Talking about Death: Patterns of Lay and Professional Change.' In R.C. Fox (ed.) *The Social Meaning of Death*. (American Academy of Political and Social Science, 1980), 30-31
[119] See excellent works rebutting the presumption of paternalism B. Gert & C. Culver, "The justification of paternalism." In W. Robison & M. Pritchard M, (eds.), *Medical responsibility.* (Humana Press, I979), 2: D.C. Thomasma, 'Beyond Medical Paternalism and Patient Autonomy: A Model of Physician Conscience for the Physician-Patient Relationship.' (1983) 98(2) *Annals of Internal Medicine* 243-248; M.S. Komrad, 'A Defence of medical paternalism: maximising patients' autonomy.' (1983) 9 *J Med Ethics* 38-44; O. O'Neil, Paternalism and partial autonomy. (1984) 19 *J Med Ethics* 173-178; L. B. McCullough & A.W. Cross, 'Respect for autonomy and medical paternalism reconsidered.' (1985) 6 *Theoretical Medicine* 295-308; L.B. McCullough, 'Was Bioethics Founded on Historical and Conceptual Mistakes about Medical Paternalism?' (2011) 25(2) *Bioethics* 66-74; R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 60-83
[120] I. Kennedy, *The Unmasking of Medicine.* (George Allen and Unwin, 1981), 86.
[121] See Section 2, below
[122] I. Kennedy, *The Unmasking of Medicine.* (George Allen and Unwin, 1981), 86.
[123] Royal Commission on the NHS, *Report of the Royal Commission on the National Health Service.* (HMSO, 1979) ("Merrison Commission")
[124] See, E. Christalle, 'Assessment of Patient Information Needs: A Systematic Review of Measures.' (2019) 14(1) *PloS One* e0209165. See for also, Y. Godwin, 'Do They Listen: A Review of Information Retained by Patients Following Consent for Reduction Mammoplasty.' (2000) 53 *Br J Plast Surg.* 121-125; J.L. Anderson, *et al*, 'Patient Information Recall in a Rheumatology Clinic.' (1979) 18 *Rheumatol Rehabil* 245-255
[125] L.C. McGuire, 'Remembering what the Doctor said: Organisation and Older Adults' Memory for Medical Information.' (1996) 22 *Exp Aging Res* 403-428; C.R.B. Joyce, 'Quantitative Study of Doctor-Communication.' (1969) 38(150) *Quarterly Journal of Medicine* 183-194; P. Ley, 'Memory for Medical Information.' (1979) 18(2) *Br J Soc Clin Psychol* 245-255

information need is an indicator of the extent to which the doctor has identified and appropriately weighed factors and values, the statistic decontextualises the circumstances of the decisions. To make the assessments 'that on average doctors were improperly weighing patient needs', would require a number of measures.[126] Further, the data relied upon by Kennedy does not indicate whether the patients communicated their choices about information (which would be necessary to evaluate whether a decision amounted to paternalism).[127] Even if it could be argued that these statistics were indicative of a failure to address patient information need, there were similar indications that doctors were focused on centring the patients values and needs in decision-making.[128] For example, Stewart *et al*, identified that the doctors' awareness of complaints, discomforts, worries and disturbances of daily living could be described as 'moderately high.'[129]

Kennedy's second example is probably his most compelling; there was some evidence that doctors made blanket decisions to withhold information about cancer diagnoses. [130] Relying on McIntosh,[131] Kennedy, argued:

> […] uncertainty over diagnosis was not the reason for withholding information, though it was used to justify it. The better explanation for non-communication, […] was uncertainty […] over how much each patient wished to know, an uncertainty largely produced by the doctor's own anxieties. All the doctors in the study firmly believed that the great majority of patients should not be told that they had cancer, nor be given their prognosis unless it was favourable. The patients were to be given only as much information as was compatible with the retention of hope, whether justified or not.[132]

However, this presumptive approach is not indicative of arbitrary paternalism when it is contextualised.[133] McIntosh found that patients with a positive prognosis were routinely told

[126] M.A. Stewart *et al*, 'The Doctor/Patient Relationship and its Effects upon Outcome.' (1979) 29(199) *J Royal College of General Practitioners* 77-82, 79. The systematic review by Christalle *et al*, (2019) casts doubt on the reliability of measures used to identify patient information need: E. Christalle, *et al*, 'Assessment of Patient Information Needs: A Systematic Review of Measures.' (2019) 14(1) PloS *ONE*: (<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0209165>)

[127] The reader may argue that the patient should not be obliged to activate a duty by asking additional questions. However, these risks cognitive overload and thus harm. See Z. Fritz *et al*, 'Patient engagement or information overload: patient and physician views on sharing the medical record in the acute setting.' (2019) 19(5) *Clinical Medicine* 386-391

[128] *Ibid*, P. Ley & M. Spelman, 'Communications in an Out-Patient Setting.' (1965) 4(2) *Br J Soc Clin Psychol* 114-116

[129] *Ibid*

[130] I. Kennedy, *The Unmasking of Medicine.* (George Allen and Unwin, 1981), 86

[131] J. McIntosh, "The Routine Management of Uncertainty in Communication with Cancer Patients." In A. Davies (ed.), *Relationship between Doctors and Patients.* (Saxon House, 1978), 106-131

[132] I. Kennedy, *The Unmasking of Medicine.* (George Allen and Unwin, 1981), 86

[133] J. McIntosh, "The Routine Management of Uncertainty in Communication with Cancer Patients." In A. Davies (ed.), *Relationship between Doctors and Patients. (*Saxon House, 1978), 109-110: "The routinisation of communication provided ways of managing uncertainty in accordance with the doctors' beliefs about patients' desire for information and probable reactions to being told. The routines were geared to avoiding disclosure to patients. There were routine procedures pertaining

information; it was only the patients with a poor prognosis who might not be told.[134] For the doctors that adopted presumptive approaches to withholding negative information, this was not arbitrary, or borne solely out of personal anxiety, but on experience. Instead, participants to the study suggested that withholding information occurred in relation to patients who had previously been told bad information, had reacted badly to the disclosure, and this affected their physical prognosis.[135] Subsequently, the participant doctor's approached disclosure sensitively to avoid causing significant harm.[136] McIntosh identified that whilst doctors in this group might avoid the word 'cancer' and 'malignancy' the patient would gain a fundamental understanding of the disease and the treatment.[137] Studies indicated that patients often did not want to be explicitly told about their diagnosis,[138] and could instead read between the lines.[139] McIntosh recognised, however, these presumptions could be *circumstantially* rebutted, by the individual needs of patients:

> while holding the view that patients in general did not want to be told, the doctors did acknowledge that some patients would genuinely want to know and expressed the view that, where they could be counted upon to not react unfavourably, they should be informed.[140]

Whilst there is some evidence that doctors adopted presumptive positions for withholding diagnosis in the 1960's,[141] there are other studies which indicated (as early as the 1950's)[142] that doctors recognised

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to what was volunteered to patients and a separate set of routine responses to specific types of patient demand. These routines were differentially appropriate for different categories of conduction, in terms of severity, at different stages of their treatment."

[134] *Ibid*, 107

[135] *Ibid*, 107

[136] *Ibid*, 108: "The doctors believed that patients who were told would become extremely anxious and depressed (even mentally unstable) and might withdraw completely and simply await death. Above all, though, it was anticipated that patients who were informed of their condition would lose all hope. Leaving patients with hope of recovery was one of the main concerns of medical staff […]."

[137] *Ibid*, 110

[138] D.H. Novak, 'Changes in Physicians' Attitudes Towards Telling the Cancer Patient.' (1979) 241 *JAMA* 897-900; J. Spencer Jones, 'Telling the Right Patient.' (1981) 283 *BMJ* 291-292, 291.

[139] J. Spencer Jones, 'Telling the Right Patient.' (1981) 283 *BMJ* 291-292, 292; H.C. Shands & J.E. Finesinger, 'Psychological Mechanism in Patients with Cancer.' (1951) 4 *Cancer* 1159-1170; J. McIntosh, "The Routine Management of Uncertainty in Communication with Cancer Patients." In A. Davies, *Relationship between Doctors and Patients. (*Saxon House, 1978), 128; J.T. Ptacek & T.L. Eberhardt, 'Breaking Bad News. A Review of Literature.' (1996) 276(6) *JAMA* 496-502; L. Witzel, 'Behaviour of the Dying Patient.' (1975) 2 *BMJ* 81-82; M. Watson *et al*, 'Reaction to a Diagnosis of Breast Cancer Relationship between Denial, Delay and Rates of Psychological Morbidity.' (1984) 53(9) *Cancer* 2008-2012; S. Greer *et al*, 'Psychological Responses to Breast Cancer: Effect on Outcome.' (1979) 314(8146) *The Lancet* 785-787; M. Watson, 'Influence of Psychological Response on Survival in Breast Cancer: A Population-Based Cohort Study.' (1999) 354(9187) *The Lancet* 1331-1336; S. Sepplet & M. Neuses, 'Cortisol, Immune Status and Patients' Coping with Primary Breast Cancer.' (1998) 21 *Onkologie* 496-502; P.E. Schofield, *et al*, 'Psychological Response of Patients Receiving a Cancer Diagnosis of Cancer.' (2003) 14(1) *Annals of Oncology* 48-56; M. Watson, *et al*, 'Influence of Psychological Response on Breast Cancer Survival: 10 Year Follow-Up of a Population-Based Cohort.' (2005) 41(12) *European Journal of Cancer* 1710-1714

[140] J. McIntosh, "The Routine Management of Uncertainty in Communication with Cancer Patients." In A. Davies (ed.), *Relationship between Doctors and Patients. (*Saxon House, 1978), 108

[141] For example, W.T. Fitts, 'What Philadelphia Physicians Tell Patients with Cancer.' (1953) 153 *JAMA* 901-904; D. Oken, 'What to Tell Cancer Patients. A Study of Medical Attitudes. (1961) 175 *JAMA* 1120-1128

[142] R. Paterson, 'An Experiment in Cancer Education.' (1954) 2(4898) *BMJ* 1219-1220; J. Aiken-Swan & R. Paterson, 'The Cancer Patient Delay in Seeking Advice.' (1955) 1 *BMJ* 623; R. Paterson, *et al*, 'Public Opinion on Cancer: Changes following Five Years of Cancer Education.' (1958) 272(7050) *The Lancet* 791-793; J. Aitken-Swan & R. Easson, 'Reaction of Cancer Patient on Being Told their Diagnosis.' (1959) 1 *BMJ* 288

the individual information needs of patients. By the 1970's-1980's there is substantial evidence that disclosing diagnosis was the norm.[143] Despite the empirical realities, the rhetoric of paternalism in the diagnosis of cancer has continued.[144]

Finally, Kennedy relied on Maclean's[145] article to argue that 88% of doctors (n=219) regularly withheld information from patients. This article, itself, relied on the Oken study, conducted in the US some years earlier (1961), which Maclean relied upon to improperly suggested that paternalism had metastasised in western medical practice - including within the UK.[146] This claim is unreliable, not only because of the distinct population and medical context. The Oaken study was a convenience sample of physicians from one city hospital in Chicago, Illinois, which methodologically reduces its reliability. Oken found that 88% of his respondents (n=219) reported that they withheld the truth about patient's conditions and prognosis, and suggested that this was as evidence of paternalism. However, on close analysis the data does not support the conclusions reached by the Oaken. The study stated that: '32% said that they would make exceptions often or occasionally, and 47% said very rarely. Only 8% reported that they would never tell a patient […].' Oken went on to state: '[a]greement was essentially unanimous that some family member must be informed if the patient is not made aware of the diagnosis.'[147] Despite this clear flaw in the conclusion of the study, it is relied on by Maclean (and subsequently Kennedy). The more representative pole by Marmor (of 23'000 doctors within the UK, with a response of 2707, found that 32% of doctors always told patients if they were dying, 21% did it but seldom, and only 21% said never) was characterised by Maclean as 'superficial.'[148] On this basis, one can at least questions the basis of the continued accusations of paternalism within Kennedy's writing.

(iii) Rebuttal (3): Decision-making is not technical

This thesis would argue that the distinction between technical and moral content within medical decision-making is unconvincing. To draw a distinction, one would need to provide a defensible definition of 'technical' decision-making which contains no 'moral' considerations. Decisions about which diagnostic tests to provide, contain a moral content – based on what symptoms to include, or disregard, in a differential diagnosis.[149] So too is the provision, or withdrawal, of treatment;[150] hence

[143] See specifically for the UK: B. Hogbin & L. Fallowfield, 'Getting it Taped: the 'Bad News' Consultation with Cancer Patients.' (1989) 41(4) *Br J Hosp Med* 330-333. For a general indication of the movement of practices in Western Medicine see, for example: K.M. Taylor, "Physicians and the Disclosure of Undesirable Information." In M. Lock & D. Gorden, (eds.), *Biomedicine Examined: Culture Illness and Healing, Vol. 13* (Springer, 1988), 441-463; R.J. Sullivan, *et al*, 'Truth-Telling and Patient Diagnosis.' (2001) 27 *J Med Ethics* 192-197

[144] See Chapter 3-4. For example, R. Gillon, 'Telling the Truth and Medical Ethics.' (2085) 291(6508) *BMJ* 1556-1557

[145] U. Maclean, 'Learning about Death.' (1979) 5(2) *J Med Ethics* 68-70

[146] D. Oken, 'What to Tell Cancer Patients: A Study of Medical Attitudes.' (1961) 175 *JAMA* 1120-1128.

[147] L.B. McCullough, 'Was Bioethics Founded on Historical and Conceptual Mistakes about Medical Paternalism.' (2011) 25(2) *Bioethics* 66-74, 72

[148] U. Maclean, 'Learning about Death.' (1979) 5(2) *J Med Ethics* 68-70, 69; Relying on J. Marmor, "The Cancer Patient and His Family." In E. Lief & V.F. Lief, *The Psychological Basis of Medical Practice*. (Harper Row, 1963).

[149] *Penney v East Kent Health Authority* [2000] PNLR 323; *Muller v Kings College Hospital* [2017] EWHC 127

[150] E.D. Pellegrino, 'Decisions to Withdraw Life-Sustaining Treatment: A Moral Algorithm.' (2000) 283(8) *JAMA* 1065-1067

the call for legitimacy through 'shared decision-making.'[151] As Montgomery and Montgomery argue, requiring *technicality* reduces decision-making to algorithms; which is itself a sign of a novice, rather than an expert.[152] An expert requires integration of knowledge, technical skill, and moral insight into the purpose of the medical profession and needs of the patient.

If the division between technical and moral content can be convincingly made, then one may ask: on what ethical basis do medical professionals owe a duty to patients to provide information (or care). If the moral content of the medical relationship, and thus the decision are removed, without normativity, the doctor is not obliged to act in the patients best interests. As a matter of ontology, one cannot have a standard of care, without an initial duty. As Kennedy argues, 'medical ethics are not separate from, but part of, the general moral ethical office by which we live.'[153] Doctors would be ethically limited to simply carrying out their legal or regulatory function – yet society relies on doctors acting beneficently (and sometimes saintly),well beyond their normative obligations.[154] This problem is powerfully illustrated by Lord Mustill, in *Wilsher v Essex Area Health Authority*:

> The doctors and nurses worked all kinds of hours to look after her baby. They safely brought it through the perilous shoals of its early life. For all we know, they far surpassed on numerous occasions the standards of reasonable care. Yet it is said that for one lapse they (and not just their employers) are to be found to have committed a breach of duty. Nobody could criticise the mother for doing her best to secure her son's financial future. But has not the law taken a wrong turning if action of this kind is to succeed.[155]

Similarly, requiring law to replace morality would eradicate medical discretion. If a lacuna manifests in common law rules then there would be no moral requirement for the doctor to provide any information.[156] As Montgomery argued, in *demoralising* medicine in this way,[157] the values underpinning medical decision-making are moved from an interpretative art, to formulistic science, which has the propensity to focus on biomedical, rather than biopsychosocial factors (in antithesis to Kennedy's intention).[158] Finally, if the doctor is not an expert, in the natural sense, one must question

[151] C. Charles, 'What Do We Mean by Partnership in Making Decisions About Treatment?' (1999) 319 *BMJ* 780
[152] J. Montgomery & E. Montgomery, '*Montgomery* on Informed Consent: An Inexpert Decision?' (2016) 42 *J Med Ethics* 89-94, 93
[153] I. Kennedy, *The Unmasking of Medicine.* (George Allen and Unwin, 1981), 78.
[154] T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics.* (Oxford University Press, 2013), 204-209; P.D. Hopkins, 'Viral Heroism: What the Rhetoric of Heroes in Covid-19 Pandemic Tells Us About Medicine and Professional Identity.' (2021) *HEC Forum* 2-16
[155] *Wilsher v Essex Area Health Authority* [1986] 2 All ER 801, at 810. Taken from J. Montgomery, 'The Demoralisation of Medicine.' (2006) 26(2) *Legal Studies* 185-210, 201.Also see this point made in *Sidaway v Bethlem Royal Hospital Governors* [1985] 1 All ER 643, per Lord Diplock at 656 & 659. J. Montgomery, 'Medicine, accountability and professionalism.' (1989) 16 *JLS* 319
[156] *Hucks v Cole* [1993] 4 Med L R 393 (CA), 397
[157] J. Montgomery, 'The Demoralisation of Medicine.' (2006) 26(2) *Legal Studies* 185-210, 200-201
[158] I. Kennedy, *The Unmasking of Medicine.* (George Allen and Unwin, 1981), 5

why normative rules place such high moral demands on medical decision-making? Surely, if a reasonable patient can determine their own best interests, technical or moral, then the correct standards of disclosure should be the (moral) man on the Clapham Omnibus.[159]

Even if the technical/moral distinction could act as a positive reason for adopting normative standards, the potential problems must be balanced against the benefits to see whether the imposition of standards is proportionate. An objective, or prudent patient standard, within law would potentially limit the discretion of the doctor, and require the doctor to fulfil the information need of the hypothetical patient, rather than disclosing information based on *actual* patient needs or choices.[160] If a subjective, or particular patient standard, was applied this may lead to uncertainty about materiality in practice – so the standard becomes unknowable.[161] There is also the potential for the doctor to disclose information to follow the letter and not the ethos of the rule.[162] For example, if the doctor was required to disclose an objective standard of information, so that the patient has the ability to make an autonomous choice, the doctor could communicate this in a way that the patient may not understand, or at a time that was inappropriate to the patient. As the doctor had complied with the rule this would bar the judge from finding the doctor liable. The requirement of disclosure to an objective standard may also bar the judge from interrogating the reasoning or logic of a decision – and thus reintroducing the central critique of the conventional *Bolam* standard. The law, to-date, has also failed to manifest transparent safeguards to circumstantially override the requirement to give patients information to avoid serious harm i.e., a therapeutic privilege.[163]

If normative standards are proportionate, this also does not necessarily mean that standards should be set by the judiciary. Doctors may be better placed to make these moral determinations because they have experience of patient information need.[164] As Foster and Miola recognised, judge-made law lacks the legitimacy of primary legislation, if not simply because the court does not have the time or resources to examine how the law would impact medical decision-making, the patient, or the function of medicine in society.[165] Whilst judge-made law is more dynamic, as Jones argues, it is reactive, in the sense that it can only manifest in response to a claimant issuing a claim when there has been some breach, or

[159] I. Kennedy, 'The Patient on the Clapham Omnibus.' (1984) 47 *MLR* 454
[160] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of the Law?' (1987) 7(2) *Legal Studies* 169, 189
[161] *Ibid*, 189-191
[162] J. Raz, 'The Rule of Law and Its Virtue.' (1977) 93 *L Q Rev 195*, 211
[163] E. Cave, 'The Ill-Informed: Consent to Medical Treatment and the Therapeutic Exception.' (2017) 46(2) *Common Law World Review* 140-168; R. Mulheron, 'Has *Montgomery* Administered the Last Rites to Therapeutic Privilege? A Diagnosis and a Prognosis.' (2017) 70(1) *Current Legal Problems* 149-188
[164] C. Foster & J. Miola, 'Who's in Charge? The Relationship between Medical Law, Medical Ethics, and Medical Morality?' (2015) 23(4) *Med L Rev* 505-530, 529
[165] *Ibid*, 524

where there is a lacuna in the rules.[166]It is also uncertain whether common law can reach the level of *specificity* necessary to act as a regulatory mechanism,[167] due to the wide diversity of medical practice, the circumstantial nature of decision-making, and variation of individual patient needs.[168]

Whilst, principlism could be used as the ethical basis of standards, and therefore provide some orientation for decision-making, unless these ethical concepts are clearly defined, they may be used inconsistently, and therefore become contested;[169] which undermines the ability of this ethic to act as a certain basis of medical decision-making. It is also uncertain whether the common law is an appropriate conduit for this sort of philosophical analysis – as principles would flow from individual cases, rather than from empirical or deontic maxims.[170]If the definition of the principles was linked to the circumstances of the case, this would mean that the exact philosophical definitions of the ethics of law would be applied differently dependent on the situation. For these reasons a principled approach was strongly rejected by the Court of Appeal in *Burke v GMC*, on these policy grounds.[171] Requiring judges to effectively legislate proactively would also place them in a compromising constitutional position, which may lead to accusations of surpassing the separation of powers.[172] On a practical level, if a senior court came to a faulty interpretation of the law then this would bind lower courts to apply the letter of the law, irrespective of the inequity and potential harm caused.[173] The only way to change rules would be to appeal to the higher courts, with the associated costs; this is likely to create a barrier to justice for the most vulnerable.

If rules were to be enacted through the common law, it is not obvious that they would be followed by doctors: first, because 'the law is not widely known and probably even less well understood by the medical profession.'[174] As Lord Diplock in *Sidaway* warned normative standards could lead to an

[166] M.A. Jones, 'Informed Consent and Other Fairy Stories.' (1999) 7 *Med L Rev* 103-134, 106: "Although the case law can gradually fill in some of the areas of doubt it can never be a comprehensive framework, in contrast to the guidance provided by the medical profession itself which can be both more specific and more likely be read and acted upon by doctors."
[167] T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics. (*Oxford University Press, 2013), 14-24
[168] R.M. Veatch, 'The Impossibility of a Morality Internal to Medicine.' (2001) 6 *Journal of Medicine and Philosophy* 621-642, 629
[169] J. Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism?' (2007) 15(3) *Health Care Analysis* 235-255.
[170] R. Downie, "Cases and Casuistry." In S. Maclean, *First Do No Harm: Law Ethics and Healthcare*. (Routledge, 2006), 21-28; R.G. Lee & D. Morgan, 'Regulating Risk Society: Stigmata Cases, Scientific Citizenship & Biomedical Diplomacy.' (2011) 23 *Sydney L Rev* 297
[171] *Burke v GMC* [2005] EWCA Civ 1003, [20]-[21]
[172] J. Montgomery *et al*, 'Hidden Law-Making in the Province of Medical Jurisprudence.' (2014) 77(3) *MLR* 343-378
[173] See, J. Miola and J. Coggon, 'Autonomy, Liberty and Medical Decision-Making.' (2011) 70(3) C*ambridge Law Journal 523*-547; C.E. Schneider, *The Practice of Autonomy: Patients, Doctors, and Medical Decisions.* (Oxford University Press, 1998), 17
[174] M. Jones, 'Informed Consent and Other Fairy Stories.' (1999) 7 *Med L Rev* 103-134, 106.

ossification of medical practice.[175] As Black recognised, any normative infringement on the 'art of medicine' may have a distorting effect on decision-making. [176]

The next section uses the studies identified by the empirical review to illustrate that the distinction between technical and moral content in a decision is illusory. Further, there is no need to make this distinction,[177] as the *Bolam* standard, properly understood, invites the judge to analyse the internal content of medical decision-making. Expertise has not acted as a barrier to external critique.[178]

2.2. How do doctors make decisions about information disclosure?

Jones pioneered the socio-legal approach[179] in relation to information disclosure.[180] This section will use this empirical approach to answer the question posed by this thesis: "how do doctors make decisions in practice?" This section sets out the internal methodological processes used by doctors to make decisions about information disclosure. The failure of previous commentators to fully develop a sociological model of how doctors make decisions in practice has lent weight to the jurisdiction school of thought, by allowing them to assume that there is no substantive normative content internal to medical decision-making; thus, doctors needed normative legal standards, and formal ethical rules, to ethically orientate their decisions. Instead, this section posits a model of axiological decision-making which has been identified continuously, irrespective of the various legal regimes. Setting out this model not only rebuts the claims of the jurisdiction school but acts as a foundation to examine the effect of law on medical decision-making in the following chapters. It also acts as a basis for arguing, in the next section, that the operation of the *Bolam* standard within case-law was structured around a dual-stage model of medical decision-making.

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[175] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 All ER 643, 657

[176] D. Black, "Guidelines or Gumption? The Role of Medical Responsibility: A View from the Profession." In S.R. Hirsch and J. Harris (eds.), *Consent and the Incompetent Patients: Ethics, Law and Medicine* (Royal College of Psychiatrists, 1988). See also, J. Warden, 'NICE to Sort out Clinical Wheat from Chaff.' (1999) 318 *BMJ* 416. More recently, this has been persuasively argued in K. Montgomery, *How Doctors Think: Clinical Judgement and the Practice of Medicine*. (Oxford University Press, 2006). And the dangers of judicial cherry-picking guideline to follow are exposed by J. Montgomery & E. Montgomery, 'On Informed Consent an Inexpert Decision?' (2016) 42 *J Med Ethics* 89-94

[177] J. Montgomery, 'The Demoralisation of Medicine.' (2006) 26(2) *Legal Studies* 185-210, 200. Montgomery posits that the reason that the jurisdiction school may cling to this terminology: "The individuality of the professional duties of doctors (and other health workers) is [a] key feature of what might be described as an integrated model of the relationship between technical skill and moral reasoning. On this model, moral reasoning is seen as an essential part of the practice of health care not some external process applied to it. This leads naturally to an integrated model of the relationship between health care law and morality in which it is assumed the professional practice already takes into account the moral dimension and approaches its regulation of that basis. Thus, reinforcing prevailing professional standards is also to reinforce moral practice."

[178] See, this position in A. MacIntyre, *After Virtue*. (Notre Dame Press, 1981), 176. See an excellent rebuttal in E.D. Pellegrino, 'The Internal Morality of Clinical Medicine: A Paradigm for the Ethics of the Helping and Health Profession.' (2001) 26(6) *Journal of Medicine and Philosophy* 559-579, 562-563. Also R.M. Veatch, 'The Impossibility of a Morality Internal to Medicine.' (2001) 26(6) *Journal of Medicine and Philosophy* 621-642, 622-624

[179] M.A. Jones, 'Informed Consent and Other Fairy Stories.' (1999) 7 *Med L Rev* 103-134

[180] Also see, A. Maclean, 'Giving the Reasonable Patient a Voice: Information disclosure and the Relevance of Empirical Evidence.' (2005) 7(1) *Med Law Int* 1-40; R. Heywood, *The Law and Practice of Consent to Medical Intervention*. (PhD Thesis, Sheffield Hallam University, 2006)

This section argues that the methodology of decision-making utilised an undelineable combination of moral, technical and sociological processes; to construct patient architypes, or paradigms, which doctors used to identify material information.[181] These paradigms assist the doctor in deciding what factors may be relevant to a decision, and how various circumstantial factors are to be weighed. However, these archetypes are augmented according to the individual needs of the actual patient i.e. according to their particular circumstances and values. The inner morality of the doctor-patient relationship requires the doctor to structure the decision so that she would be disclosing information in the patients' best interests. The doctor's experience with patients fed back into the conceptualisation of the patient archetype; in a cyclic relationship between patient and paradigm, termed *reflexive equilibrium*.[182]

2.2.1. Decision-making in practice

Establishing how doctors made decisions about information disclosure between 1957 -1997 has been a process akin to constructing a jigsaw with mismatched pieces. No single study has asked the seminal questions of how, and why, doctors in England and Wales make decisions about information disclosure? Instead, the patterns of practice have been gleaned from a rich range of specialist and general studies,[183]and interpreted in light of the legal, ethical, political and social context in which the studies took place, and the wider empirical data on how doctors make decisions.[184] The push towards normativity has meant that many of the studies are focused on identifying patient information need as the basis of prospective normativity.[185]However, patterns identified in numerous studies (their literature reviews, methodology, results section and analysis) provide a robust evidence base to posit the structure of medical decision-making about information disclosure in practice, during the *Bolam* era.

(i) Patient paradigms

The doctor has a continuous therapeutic duty, within the doctor-patient relationship, to provide information. This is not limited to a specific place or time, or for example, to the purpose of providing an informed consent to treatment; it is a duty undelineable from the wider duty to act in the patient's best interests.[186] The first phase of any medical decision is identifying the important factors, and values, to place into a wider decision about materiality. This involves consideration of both biomedical

[181] See for example, S.C. Mahood, 'Medical Education: Beware the Hidden Curriculum.' (2011) 57(9) *Can Fam Physician* 983-985; F. Hafferty & R. Franks, 'The Hidden Curriculum, Ethics Teaching, and the Structure of Medical Education.' (1994) 69(11) *Academic Medicine* 861-871

[182] T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics*. (Oxford University Press, 2013), 404-410; J. Rawls, *A Theory of Justice*. (Harvard University Press, 1999), 46-50, 579-580; J. Rawls, *Political Liberalism.* (Columbia University Press, 1996), 8, 381, 384, 399

[183] See Appendix 1

[184] See for example, J. Dowie & A. Elstein, *Professional Judgement: A Reader in Clinical Decision-Making.* (Cambridge University Press, 1988); H. Arkes & K. Hammond, *Judgement and Decision Making: An Interdisciplinary Reader*. (Cambridge University Press, 1987); D. Kahneman *et al*, *Judgement under Uncertainty: Heuristic and Bias.* (Cambridge University Press); A. Elstein *et al*, *Medical Problem Solving: An Analysis of Clinical Reasoning.* (Harvard University Press, 1978)

[185] See Appendix 1

[186] See, *Sidaway v Board of Governors of the Bethlem Royal Hospital NHS Trust* [1985] AC 871, per Lord Diplock at 893, per Lord Bridge 894-895, per Lord Templeman at 904

(scientific) factors, which relate to the nature of the disease, its progression, options, and prognosis, and wider biopsychosocial considerations, such as the patients' symptoms, persona, communication, values and wider circumstances. The in-depth sociological analysis of Stimson and Webb identified that doctors worked from paradigmatic processes as a basis to begin investigating the important factors related to diagnosis and advice.[187] The paradigms were built around generally adopted images of the patient and 'their sick role.'[188] Importantly, these conceptualisations were not exclusively biomedically, or biopsychosocially defined, but conceptualised using a combination implicit and explicit indicators.[189] For example, Ford *et al*, found that three of the clinicians in their study altered their behaviour according to the age, and the prognosis, of oncology patients.[190] This paradigmatic approach was effective in triaging patients into decision-making trees associated with hypothetical objective information needs delineated experientially, from patients in the same position.

This process of identifying material elements of a decision about materiality is similar to the dual stage model of the diagnostic process.[191] The development of these 'patient constructs' are indicative of expertise.[192] This paradigm is learned through experience with individual patients, and their preferred positionality or communication style,[193] and more generally is augmented over time, according to the doctors' experience, training, and conversation with colleagues.[194] As such these paradigms are constantly changing. In disclosure this leads the doctor to construct communicative regimes to investigate areas of importance, as well as make assumptions about the important factors that will play into the wider materiality decision. For example, Stimson & Webb identified that, in terms of communication:

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[187] G. Stimson & B. Webb, *Going to See the Doctor: The Consultation Process in General Practice*. (Routledge & Kegan Paul. 1975), 61-66. For example, the Royal College of General Practitioners advised that doctors ask himself questions: "What must I tell this patient? How much of what I learned about him should he know? What words shall I use to convey this information? How much of what I propose to tell him will he understand? How will he react? How much of my advice will he take? What degree of pressure am I entitled to apply?" Royal College of General Practitioners Working Party, *The Future General Practitioners* (RCoGP, 1972), 17

[188] *Ibid*, 2-8

[189] *Ibid*, 2-9.

[190] S. Ford, *et al*, 'Doctor-Patient Interactions in Oncology.' (1996) 42(11) *Soc Sci Med* 1511-1519, 1518.

[191] See generally, Committee on Diagnostic Error in Health Care *et al*, *Improving Diagnosis in Health Care*. (National Academies Press, 2015), Chapter 2: (https://www.ncbi.nlm.nih.gov/books/NBK338593/)

[192] A. Baerheim, 'The Diagnostic Process in General Practice: Has it a Two-Phase Structure?' (2011) 18 *Family Practice* 243-245, 245

[193] G. Stimson & B. Webb, *Going to See the Doctor: The Consultation Process in General Practice*. (Routledge & Kegan Paul. 1975), 38-39: "The consultation does not take place in a vacuum. First, both doctor and patient may have met before and will have foreknowledge of each other. This, as we have seen, allows the patient to anticipate the consultation and rehearse the strategies. Where the doctor and illness condition are well known and the patients feels certain of the encounter and able to predict its probable course, we suggest that presentation and control strategies may have less of a persuasive content and the effort may be concentrated on reinforcing a common understanding and following the usual pattern of activity."

[194] *Ibid*, 8-10; M. Balint, *The Doctor, his Patient and Illness.* (Pitman Medical, 1957, 1971); L.H. Blum, *Reading Between the Lines: Doctor-Patient Communication.* (International Universities Press, 1972); J. P. Recordon, 'Communication in the Doctor-Patient Relationship.' (1972) 22(125) *J Royal College of General* Practitioners 818-827, 826: "I have already mentioned that I belong to a group of doctors who meet once a week. There, we learn to scrutinise what is going on in our relationships with patients. We can learn also from the scrutiny of our staff, our patients, our partners and not least of our family. Through others I am slowly acquiring the skills to communicate and the knowledge of how to deal with the communication therapeutically."

> The doctor is able to develop 'routines' because much of the work is routine. The doctor at practice A made a written record of the consultation for thirty-five of the people we interviewed prior to the consultation. […] Part of the information contained on this record sheet gave a description of the complaints brought by the patient. In only one of these cases could the patient's problem be described as involving an illness episode with imminent threat to life. […] [T]he list shows from the point of view of the doctor, most of the problems he sees are minor ones. Furthermore, many of the patients consult frequently over the same problem; at the two practices we interviewed a total of ninety-six patients and of these, only twenty-four (25 per cent) were consulting the doctor with a problem that was being brought to him for the first time. [195]

Similarly, the Verby *et al* study identified:

> In very many consultations general practitioners appear to develop a pattern of consulting behaviour that is singularly consistent. In our study few interviews were recorded but there was no indication that the clinical material of the consultations differed substantially between the control and the experimental groups or between individual doctors' first and second recordings.[196]

(ii) Facilitation of the particular patient's information needs

The doctor does deviate from the paradigm's dependent on the individual needs of the particular patient.[197] If the doctor failed to do so, he would not be acting in the patient's best interests.[198] Doctors recognise that patients are not passive entities; consultations are a 'negotiation' of the values which should enter the determination on the materiality of information. [199] Both the patient and the doctor have power associated with the information they exclusively hold – and thus have duties and responsibilities to each other. Stimson and Web argued that the patient has power over their symptoms, circumstances and values, and the doctor over technical information and considerations about the hypothetical patients' best interests. Both typologies of information are necessary to make a medical decision.[200]

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[195] *Ibid*, 61-63
[196] J.E. Verby, *et al*, 'Peer Review of Consultations in Primary Care: The use of Audiovisual Recordings.' (1979) 1 *BMJ* 1686-1688, 1688.
[197] G. Stimson & B. Webb, *Going to See the Doctor: The Consultation Process in General Practice*. (Routledge & Kegan Paul. 1975), 62
[198] E. D. Pellegrino & D.C. Thomasma, *The Virtues in Medical Practice*. (Oxford University Press, 1993), 54
[199] *Ibid*, 62
[200] G. Stimson & B. Webb, *Going to See the Doctor: The Consultation Process in General Practice*. (Routledge & Kegan Paul. 1975), 40-63

> Very often all information is not given at the outset, almost as though the patient is not sure what is relevant. During the course of the interaction, the patient may select and introduce other topics in response to the doctor's own interpretation and approach to the problem. For example, at a late stage in the presentation of her daughter's symptoms, a mother said 'She has had a lot of injections lately.' Although this was phrased as a statement rather than a question, it was offered in a way that seemed to raise the question of whether the injections could have had anything to do with the child's present symptoms.[201]

Verby *et al*, similarly, recognised that doctor's prioritised patient psychosocial values during consultations, as a basis for asking questions and providing information.[202] The doctors focused discussion on issues dependent on the needs of the particular patient. For example, in follow-up consultations, for both the experimental (n=15) and control (n=47) groups, the doctors were found to have good communication (answered questions) [203] and placed less emphasis on psychosocial matters ((1)1.5/3 and (2) 0.96/3); which reflected patient reluctance to discuss personal issues ((1)1.3/3 and 1.04/3 v (2) 0.9/3 and 0.42/3, respectively). [204] Ford *et al*, similarly found that doctors (n=117) allowed the patients the ability to communicate their needs and issues within the consultation and provided information which met that patient need (whether it is biomedical or biopsychosocial). In the first consultation, the patient's spoke about biomedical information 41% of the time, and asked biomedical questions in 5%. The doctor, similarly, spent 31% of their time on providing biomedical information, 11% asking closed questions, and 3% asking open biomedical questions.[205]

The doctor is obliged to make decisions about information disclosure, as an ongoing process through the consultation, and indeed, the wider medical relationship. The data indicated that doctors incorporated circumstantial considerations (relating to the presentation of the patient, their condition, and the place, and time of the consultation) when evaluating patient information need. If, for example, the patient is seeing a GP, and treatment is likely to be a simple prescription (with little significant side-effects) the explanation remained generalised, selective and controlled.[206] In secondary care, if the

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[201] *Ibid*, 42

[202] J.E. Verby, *et al*, 'Peer Review of Consultations in Primary Care: the use of Audiovisual Recordings.' (1979) 1 *BMJ* 1686-1688, 1686; relying on A.R. Fienstein, *Clinical Judgement.* (Williams and Wilkins, 1967) the author describes this circumstantial decision-making as an art.

[203] *Ibid*, 1687

[204] *Ibid*, 1687. This is unlikely to be caused by overt paternalism, as the general approach of the doctor in the consultation remained the same: they retained good body posture ((1)1.8/3 and 1.71/3 v (2) 2.5/3and 2.0/3), they had generally appropriate eye contact ((1)1.2/3 and 1.5/3 v (2) 2.2/3 and 1.75/3), they gave the patient more silence, and thus space to think in the second consultation (1.8/3 and 2.0/3 v (2) 2.1/3 and 1.63/3), and were generally warm in both consultations ((1) 1.7/3 and 2.00/3 v (2) 2.7/3 and 1.96/3)

[205] S. Ford, *et al*, 'Doctor-Patient Interactions in Oncology.' (1996) 42(11) *Soc Sci Med* 1511-1519, 1514

[206] G. Stimson & B. Webb, *Going to See the Doctor: The Consultation Process in General Practice*. (Routledge & Kegan Paul, 1975), 121-122: "From the observations we made we noted that when the doctor is giving advice or reassuring the patient that the condition is not a cause for concern, explanatory statements may also be made, but they are secondary in emphasis.

diagnosis is significant and patient's may struggle to engage and communicate with the doctor,[207] especially during the early stages of the medical relationship, disclosure will again remain general.[208] For example, patient's usually ask less questions in the first consultation (5% biomedical), compared to second consultations (9% biomedical). In second consultations patients are more talkative (+9%), ask more biomedical questions and exert more control over the conversation (+42%).[209] As Dawes *et al* [210] and Beaver *et al*[211] identified, patients prefer specific, or further information in pre-operative consultations. The gap between the first (outpatient) and second (inpatient) phase, allows the patient the ability to reflect on information, and form follow-up questions.[212] At the in-patient stage, for example, before surgery, the disclosure process is focused on signing a consent form, and achieving a legal consent.[213] At this stage, some patients want details of post-operative landmarks and serious risks,[214] to ask follow-up question, and have a more active decision-making role.[215] This means to continue to act in their best interests, doctors must provide specific information about rare or significant risks. This is important as some lawyers conceptualised the purpose of disclosure, exclusively, as consent to treatment (and evaluate decision-making from this narrow perspective) when in reality, decision-making is a longitudinal and iterative process throughout the entirety of the medical relationship.[216]

(iii) Weighing identified factors: paradigms and circumstances

With regard to treatment, information given by the doctor is even more restricted in its explanatory context. It is rare for the doctor to name the drug […] other than in blanket descriptive terms: 'Take these lozenges' and, 'I'll give you something to calm your nerves down.' Nor does the doctor generally supply information about the way in which the drug acts or what its constituents are. If the doctor does tell the patient anything about the treatment he is thinking of prescribing, this is usually in terms of what the prescription is for – a referral back to the diagnosis – or what it will do in terms of the desired effect the drug is being used to achieve."

[207] For example, see D.J. Bryne, *et al*, 'How Informed is Signed Consent.' (1988) 296 *BMJ* 839. Also P.J.D. Dawes *et al*, 'Informed Consent: The Assessment of Two Structured Interview Approaches Compared to the Current Approach.' (1992) 106 *The Journal of Laryngology and Otology* 420-424, 420; relying on amongst others R.N. Villar & A.C. Hume, 'Informed Orthopaedic Consent: Fact or Fallacy?' (1988) 4 *Journal of the Medical Defence Union* 32-33. Also, A.P. Armstrong *et al*, 'Informed Consent: Are We Doing Enough?' (1997) 50 *Journal of Plastic Surgery* 637-640, 638

[208] P. Meredith, 'Patient Participation in Decision-making and Consent to Treatment: The Case of General Surgery.' (1993) 15(3) *Sociology of Health and Illness* 315, 319-321.

[209] S. Ford, *et al*, 'Doctor-Patient Interactions in Oncology.' (1996) 42(11) *Soc Sci Med* 1511-1519, 1518 & 1515

[210] P.J.D. Dawes, *et al*, 'Informed Consent: Using a Structured Interview Changes Patients' Attitudes Towards Informed Consent.' (1993) 107 *The Journal of Laryngology and Otology 775*-779, 775-777.

[211] K. Beaver *et al*, 'Treatment Decision Making in Women Newly Diagnosed with Breast Cancer.' (1996) 19(1) *Cancer Nursing* 8-19, 8

[212] P. Meredith, 'Patient Participation in Decision-Making and Consent to Treatment: The Case of General Surgery.' (1993) 15(3) *Sociology of Health and Illness* 315, 324-326; S. Ford *et al*, 'The Influence of Audiotapes on Patient Participation in the Cancer Consultation.' (1995) 31A *European Journal of Cancer* 2264-2269

[213] *Ibid*

[214] M. Lonsdale, & M. Hutchinson, 'Patients' Desire for Information about Anaesthesia.' (1991) 46 *Anaesthesia* 410-412. For example, information about pain relief (77%), when they can eat and drink (75%) and when they are allowed up (75%), (40%) wanted information about dangerous complications, and 43% wanted information about all possible complications

[215] P. Meredith, 'Patient Participation in Decision-Making and Consent to Treatment: The Case of General Surgery.' (1993) 15(3) *Sociology of Health and Illness* 315, 324-326

[216] See this argued more fully in Chapter 3. The purpose of this section is to set out the model of medical decision-making. Without this model, the thesis cannot answer the central question.

Doctors utilise a bank of pre-constructed decision-making paradigms, aimed at making decisions in the best interests of the patient populations they usually serve. These paradigms rest on technical knowledge and experience, and moral assumptions about the characteristics of the patient, and thus what information the average patient needs. These paradigms are initially constructed pedagogically through role-play during training,[217] and develop as doctor's increase in experience, and knowledge, when communicating with actual patients.[218] The archetype of patient information need is then shared through informal means such as conferences, professional conversations,[219] formal training and workplace policy.[220] This reassessment of assumptions may occur due to the development in medical knowledge, for example, through reading a study, through the development of normative rules, or potentially fear of litigation.[221]

The development and operationalisation of internal moral presumptions are thus complex, circumstantial and interactional. These decisions are not value neutral and the presumptions contain an internal moral content which orders the importance of factors according to these constructed values. However, this deontic ordering is aimed at constructing paradigms that can best meet the needs of the patients which the doctor is making decisions about. In attempting to meet these aims, the doctors must deal with the conflict between the application of ethical optimums, and the realities of the patient population, in constructing these information archetypes. For example, Meredith identified that doctors were aware that:

> […] the majority of patients were not equipped with knowledge to assess alternative therapies; tended to overestimate the risk of common complications; found it difficult to retain accurately what was told to them; and, some patients had little interest in choice, while others were too emotionally compromised.[222]

[217] G. Stimson & B. Webb, *Going to See the Doctor: The Consultation Process in General Practice.* (Routledge & Kegan Paul), 124-125
[218] D.J. Rothman, *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision-making.* (Basic Books, 1991), 9
[219] J.E. Verby, 'Peer Review of Consultations in Primary Care: The Use of Audiovisual Recordings.' (1979) 1 *BMJ* 1686-1688, 1687
[220] See, D.L. Sackett & W.C Rosenberg, 'Evidence Based Medicine: What It Is and What It Isn't.' (1996) 312 *BMJ* 71-72; T. Greenhalgh & B. Hurwitz, 'Narrative Based Medicine: Why Study Narrative?' (1999) 318 *BMJ* 48-50; T. Greenhalgh, 'Intuition and Evidence – Uneasy Bedfellows?' (2001) 52 *BMJ* 48-50; T. Greenhalgh, *How to Read a Paper: The Basics of Evidence-Based Medicine*. (BMJ Books, 1997); T. Greenhalgh, *How to Implement Evidence-Based Healthcare.* (Blackwell, 2018)
[221] H. Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship.* (Clarendon Press, 1994), 17-29 & 57-60
[222] P. Meredith, 'Patient Participation in Decision-Making and Consent to Treatment: The Case of General Surgery.' (1993) 15(3) *Sociology of Health & Illness* 315, 331

However, balanced against this was the therapeutic benefit of ensuring the patient had a sufficient level of understanding, was supported in their decision-making, and thus had an autonomous choice.[223] In making these determinations, the doctor had to balance the autonomy interests of the patient, as well as their information preference, when making a wider decision about what was in the patient's best interests. For example, in the Bunker *et al* study doctors usually provided patients information according to their preferred level of detail.[224] Doctors overrode some patient's preferences and told them more information because patient understanding was sometimes seen as essential to their therapeutic interests.[225] The construction of patient paradigms is orientated towards the therapeutic interests of the patient population.[226]

(iv) *Circumstantial-moral* decision-making

Potential conflicts are usually mitigated because the doctor must reinterpret the archetypes and thus, the order of moral content, in light of the circumstances and values of the actual patient. [227] Numerous studies indicated that patients deviate from the norm of information need. For example, Wallace found that when patients in Scotland were asked about how much information they wanted, 39% wanted to know all the details, 25% wanted a good description, 28% wanted just a 'rough idea,' and 7% wanted to know nothing. [228] Lavelle-Jones *et al*, found that patient's (n=887), deviated in their information need according to their preferred 'locus of control' i.e. those who had an internal locus wanted more information, and those who had an external locus, wanted less information so they doctor could decide.[229] One could identify a locus of control depending on patient actions.[230] For example, 69% of patients admitted to not reading the consent form before signing it; this was indicative of an external locus.[231]

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[223] L.M. Louise, 'Informed Consent to Elective Surgery: The 'Therapeutic' Value?' (1986) 22(1) *Soc Sci Med* 29, 29; C. Strong, 'Informed Consent: Theory and Policy.' (1979) 5 *J Med Ethics* 196; D.A. Rockwell & F.P. Rockwell, 'The Emotional Impact of Surgery and the Value of Informed Consent.' (1979) 64 *Med Clin N Am* 1341

[224] T.D. Bunker, *et al*, 'An Information Leaflet for Surgical Patients.' (1983) 65 *Annuls of the Royal of Surgeons of England* 242-243, 242

[225] *Ibid*, 242: thus, the doctors told 73% of patients that they would have a catheter and 73% of patient how long they would have it, when only 68% wanted to know.

[226] E.D. Pellegrino, 'The Internal Morality of Clinical Medicine: A Paradigm for the Ethics of the Helping and Healing Profession.' (2001) 26(6) *Journal of Medicine and Philosophy* 559-579; F.G. Franklin & H. Brody, 'The Internal Morality of Medicine: An Evolutionary Perspective.' (2001) 26(6) *Journal of Medicine and Philosophy* 581-599; X. Symons, 'Pellegrino, MacIntyre, and the Internal Morality of Clinical Medicine.' (2019) 40 *Theoretical Medicine and Bioethics* 243-251

[227] D.A. Schon, "From Technical Rationality to Reflection-in-action." In J.D. Dowie & A. Elstein, *Professional Judgement: A Reader in Clinical Decision Making*. (Cambridge University Press, 1988), 75-76.

[228] L.M. Wallace, 'Informed Consent to Elective Surgery: The 'Therapeutic' Value?' (1986) 22(1) *Soc Sci Med* 29, 29

[229] C. Lavelle-Jones, *et al*, 'Factors Affecting Quality of Informed Consent.' (1993) 306 *BMJ* 885-890, 889: "The assessment of health locus of control showed that patients who thought that they had control over their health were better informed than those who thought external forces shaped their destiny. The observation that the latter group of patients seemed uninterested in the details of surgery is a factor that may influence recovery from surgery. Thus, as well as targeting these patients for extra effort in communication, special measures may be needed to optimise their recovery."

[230] *Ibid*, 888-889: "Immediately after the consent form was signed 21% of patients considered that most information, they possess on their surgical treatment had been obtained from sources other than the hospital. This worrying finding required further evaluation."

[231] C. Lavell-Jones, *et al*, 'Factors Affecting Quality of Informed Consent.' (1993) 306 *BMJ* 885, 889. In support in the US context: B.R. Cassileth *et al*, 'Informed Consent – Why are its Goals Imperfectly Realised? (1980) 302 *N Engl J Med* 896-900

A *circumstantial-moral* approach allowed doctors to choose between perspectives by prioritising the preferences of the patient and/or their information need, in their best interests, within the actual circumstances.[232] Disclosure in practice therefore deviated along a continuum of providing a general prudent patient standard, to a highly specific particular patient standard of information. [233] Regular deviation from the circumstantial *archetype* caused the doctor to alter their conception of information need. The archetype is therefore in constant renegotiation, and is constantly reorientated towards the needs of patient group that the doctor is serving, in a process of phenomenological empiricism, or *reflexive equilibrium.*[234] The professional standard of care is therefore inevitably a patient standard of care. Rothman terms this decision-making as a biographical approach or 'bedside ethics.'[235] In the sociological literature, Katheryn Montgomery, terms this *narrative rationality,*[236] Schon termed it *reflection-in-action.*[237] For the purpose of information disclosure, it can be more plainly understood as *circumstantial-moral decision-making*. Kathryn Montgomery rightly argued that this form of decision-making is inevitable:

> […] objects of knowledge, health and morals differ from physical phenomena, about which certainty is available. For moral questions, as for questions about the care of patients, absolute or invariant answers are unobtainable. For this reason, scientific reasoning, or episteme, is inappropriate in fields like medicine, ethics, law […] disciplines that are interpretative because they are radically uncertain. Episteme belongs, instead, to stable physical phenomena that can be known through necessary and invariant laws. Medicine and morals […] call for phronesis or practical reasoning, the ability to determine the best action to take in particular circumstances that cannot be distilled into universally applicable solutions. While scientific reasoning has precision and replicability as its goal, practical reasoning seeks the best answer possible under the circumstances. It enables the reasoner to distinguish, in a given situation, the better choice from the worse. The form is law-like and generalizable to every similar instance, while the

[232] G. Stimson & B. Webb, *Going to See the Doctor: The Consultation Process in General Practice.* (Routledge & Kegan Paul), 124; J. McIntosh, "The Routine Management of Uncertainty in Communication with Cancer Patients.' In A. Davies, *Relationship Between Doctors and Patients. (*Saxon House, 1978), 128

[233] See for example, T. Greenhalgh, 'How to Read a Paper: The Basics of Evidence-Based Medicine. (Blackwell, 2006), 5-6

[234] T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics*. (Oxford University Press, 2013), 404-410; J. Rawls, *A Theory of Justice*. (Harvard University Press, 1999), 46-50, 579-580; J. Rawls, *Political Liberalism.* (Columbia University Press, 1996), 8, 381, 384, 399

[235] D.J. Rothman, *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision-making.* (Basic Books, 1991), 9: "This type of approach, which I call bedside ethics, essentially meant teaching by example, by role modelling, by students taking cues from practicing physicians. Students were not to learn ethics by studying principles but by watching senior physicians resolve individual situations and then doing likewise. It is as though medical decision making begins and ends (or more precisely, should begin and end) with the dyad of the doctor and the patient alone in the examining room."

[236] K. Montgomery, *How Doctors Think: Clinical Judgement and the Practice of Medicine.* (Oxford University Press, 2006), 43

[237] See, D.A. Schon, "From Technical Rationality to Reflection-in-action." In J. Dowide & A. Elstein (ed.), *Professional Judgement: A Reader in Clinical Decision Making.* (Cambridge University Press, 1988), 60

latter is inescapable particular and interpretable, applicable to only a small set of more richly detailed circumstances.[238]

This thesis has found robust evidence for the existence and use of *circumstantial-moral* decision-making throughout all periods of inquiry, which leads this author to believe that the phenomenon is axiomatic, irrespective of normative change. For example, the early study of Stimson and Webb[239] identified that doctors altered the content and method of communication to suit the actual patient. Doctors would provide information in a simple way, so that patients could understand; Reynolds[240] found this variation led to high patient satisfaction.[241] Doctors relied on patients to ask further questions and indicate a need for more information.[242] This passive approach was adopted because some patients, particularly the elderly (10%), did not want to know information.[243] Chee Saw *et al*, found in general, this mode of decision-making had ensured information disclosure which allowed good understanding of their treatment, whilst respecting information choices.[244] For example, 90% of the patients knew the position of the prostate gland, the purpose of the operation, and were able to give a good description of the operation. However, a large minority of patients did not want to be engaged in making decisions about treatment, or did not want to hear about material information. For example, 41% stated that they did not mind what happened to them, provided that the doctor acted in their best interests to make them better, 54% of them trusted their doctor would do the right thing, and therefore did not think that detailed information was necessary.[245] Whilst 53% thought that consent was respecting a patient's right to autonomy, 62% of patients felt that it had the dual purpose of protecting the doctor. Thus, a therapeutic, rather than formulaic, approach to consent was more important to patients.[246]

(v) Patient choice is presumed to be in the patient's best interests

[238] K. Montgomery, *How Doctors Think: Clinical Judgement and the Practice of Medicine*. (Oxford University Press, 2006), 43-44

[239] G. Stimson & B. Webb, *Going to See the Doctor: The Consultation Process in General Practice.* (Routledge & Kegan Paul, 1975), 123: "It was evident from what [doctor at practice A] said that he decided upon the amount and type of information to give patients according to his assessment of how much they were able to understand. Referring to a woman whom he defined as having a low IQ, he said of such people: It's no good trying to explain anything to them, you have to be authoritarian.' On the other hand, a patient whom the doctor thought asked intelligent questions and who appeared to him sensible and receptive, was given a lengthy explanation in the consultation about her forthcoming operation. A patient's approach may be seen by the doctor as meriting the giving of information, whether or not it is asked for."

[240] M. Reynolds, 'No News is Bad News: Patients' Views about Communication in Hospital.' (1978) *BMJ* 1673, 1674

[241] *Ibid.* Also, P. Meredith, 'Patient Participation in Decision-Making and Consent to Treatment: The Case of General Surgery.' (1993) 15(3) *Sociology of Health & Illness* 319.

[242] *Ibid*

[243] *Ibid*, 1675

[244] K. Chee Saw *et al*, 'Informed Consent: An Evaluation of Patients' Understanding and Opinion (with Respect to the Operation of Transurethral Resection of Prostate).' (1994) 87 *J R Soc Med* 143

[245] *Ibid*

[246] *Ibid*, 144. Similar to the finding of B.R. Cassileth *et al*, 'Informed Consent - Why Are its Goals Imperfectly Realised.' (1980) 302 *N Engl J Med* 896-900

One of the main critiques of the jurisdiction school is that patient choice is given little weight in medical decisions.[247] However, the studies identified for this period indicate that limited disclosures were a consequence of patient preference. The majority of patients during this period did not want to play an active role in making healthcare choices and therefore defining their information need. For example, Stimson and Webb identified that 'patients do not ask questions' and 'they do not wish for explanations.'[248] Similarly, Lonsdale and Hutchinson indicated that, generally, patients during this early period did not want an 'active voice', and were not willing to take the lead in defining their values or making a decision.[249] For example, when Meredith asked patients (n=30) whether they wanted to be involved in decision-making, 'immediate reactions were guarded, in some cases, […] patients shied away from the suggestion that decisions about 'which kind of surgery they needed could be left to them."[250] Whilst doctors allowed time for patients to ask questions, and indicate the information that they needed to make an autonomous choice, patients trusted doctors, and wanted them to be proactive in their decision-making.[251]As doctors are reliant on individual patients to rebut presumptions, if a patient fails to display their preference for active decision-making, there is little evidence with which the doctor can utilise to reorientate information from the reasonable patient paradigm.[252] If, on the other hand, patients asked about a treatment, or a relevant alternative option, then doctors often offered the treatment to the patient, after evaluating whether it would be therapeutically beneficial.[253]

The studies identified found that there was a general presumption that disclosure was in the best interests of the patient, as it allowed patient's the ability to make a balanced decision.[254] For example, Morris *et al* found a significant proportion of doctors, (n=375) almost always gave patients a choice between a mastectomy and wide excision with axillary clearance, or axillary clearance; (12% would always give a choice, whilst 51% would give it in most cases).[255] There was a presumption that patients wanted self-determination and this principle was weighed heavily within the decision-making

[247] Decisions around providing patients the liberty of choice, and decisions around providing patients the ability to make autonomous decisions are two different concepts and should not be conflated. J. Coggon & J. Miola, 'Autonomy, Liberty, and Medical Decision-Making.' (2011) 70(3) *Camb L J* 523-547
[248] G. Stimson & B. Webb, *Going to See the Doctor*. (Routledge, 1975), 123
[249] As Chapter 3 will argue, ensuring a substantive type of autonomous choice was problematic because of the psychological capacities of ordinary patients. M. Lonsdale & G.L. Hutchinson, 'Patients' Desire for Information about Anaesthesia.' (1991 46 *Anaesthesia* 410-412, 410; S.M. Miller & C.E. Mangan, 'Interacting Effects of Information and Coping Style in Adapting to Gynaecological Stress: Should the Doctor Tell All?' (1983) 45 *Journal of Personality and Social Psychology* 223-236
[250] P. Meredith, 'Patient Participation in Decision-Making and Consent to Treatment: The Case of General Surgery.' (1993) 15(3) *Sociology of Health & Illness* 315, 319
[251] *Ibid*, 320
[252] *Ibid*, 323
[253] *Ibid*
[254] *Ibid*, 322-323
[255] J. Morris, *et al*, 'Changes in the Surgical Management of Early Breast Cancer.' (1989) 82 *J R Soc Med* 12, 14

paradigm.[256]Fallowfield *et al*, 1990[257] and 1994[258] studies also provides evidence (albeit more limited) of this presumption in favour of providing patient choice in breast cancer treatment. Out of 22 surgeons interviewed, 8 would usually solely recommend mastectomy, 10 surgeons would favour breast conservation, and four surgeons preferred to give no advice and let the patient decide based solely on their preference.[259] Doctors were happy to provide options if the patient was able to understand information or when there was equipoise between options.[260] Ensuring patient understanding was necessary so individuals could safeguard themselves from the potential harms inherent in the available options.[261] As Fallowfield argued, '[m]uch is written about patients' rights, and adequate information about options, side effects, and realistic therapeutic benefits are crucial; but women also have a right to decline the opportunity to participate in decision-making.'[262]

(vi) Autonomous choices are presumed to be in the patient's best interests

Patient autonomy was assumed to be in a patient's best interests, and thus acted as the starting point of medical decision-making about materiality. [263] For example, Verby *et al* identified that GP's made significant efforts to communicate information to a standard that allowed patients to understand the content of information (experimental group: 1.9/3 and 2.0/3 and control: 1.54/3 and 1.17/3 respectively).[264] Dunkelman (1979) argued that:

> […] it is only right that he is told what is being done – for example, when an intravenous infusion is being sited he should be told why it is necessary, its duration, and what the fluid is. Similarly, when a patient is prepared for theatre he should understand exactly what the operation consists of and the reasons for the necessary preparations.[265]

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[256] *Ibid*, 14. Also see, P. Meredith, 'Patient Participation in Decision-Making and Consent to Treatment: The Case of General Surgery.' (1993) 15(3) *Sociology of Health & Illness* 315, 324

[257] L.J. Fallowfield, *et al*, 'Psychological Outcomes of Different Treatment Policies in Women with Early Breast Cancer outside a Clinical Trial.' (1990) 301(6725) *BMJ* 575-580

[258] L.J. Fallowfield, *et al*, 'Psychological Effects of Being Offered Choice of Surgery for Breast Cancer.' *(1994) 309 BMJ 448*

[259] L.J. Fallowfield, *et al*, 'Psychological Outcomes of Different Treatment Policies in Women with Early Breast Cancer outside a Clinical Trial.' (1990) 301(6725) *BMJ* 575-580. Also see, P. Meredith, 'Patient Participation in Decision-Making and Consent to Treatment: The Case of General Surgery.' (1993) 15(3) *Sociology of Health & Illness* 315, 323

[260] *Ibid*

[261] L.J. Fallowfield, 'Psychological Effects of Being Offered Choice of Surgery for Breast Cancer.' (1994) 309 *BMJ* 448, 448: "Although no evidence exists to support the notion that choice prevents psychological morbidity, the data show the importance of effective communication when diagnosis and treatment options are discussed to the long-term adjustment to treatment of breast cancer. A person's desires for autonomy may be less strong than the need for clear and accurate information. A study of 150 women with recently diagnosed breast cancer showed that only 20% wanted an active role in deciding their treatment; 28% preferred to share decision making, and 52% wished the surgeon to decide." Relying on K. Luker *et al*, *Preference for Information and Decision Making in Women Newly Diagnosed with Breast Cancer: Final Report.* (Research and Development Unit, University of Liverpool Department of Nursing, 1993)

[262] *Ibid*

[263] C. Lavell-Jones, *et al*, 'Factors Affecting Quality of Informed Consent.' (1993) 306 *BMJ* 885, 886

[264] J.E. Verby, *et al*, 'Peer Review of Consultations in Primary Care: The Use of Audiovisual Recordings.' (1979) 1 *BMJ* 1686-1688, 1687

[265] H. Dunkelman, 'Patients' Knowledge of Their Conditions And Treatment: How It Might Be Improved.' (1979) 2(6185) *BMJ* 311-314, 312

Meredith identified that doctors provided information that was tailored to the practical needs of the patient, moving from strictly clinical terms, to 'practical discourse which addressed more mundane daily life management issues of which (positive or negative assurance was sought).'[266] One doctor stated: '[a]s we operate we have to take into account how what we do will affect their daily lives afterwards. You have to do a good job because your patient always comes back to you in the end.'[267] This does not, however, mean that the weight placed on patient values was always correct in the circumstances, and there is certainly evidence that patients wanted more information, and some doctors took an overly paternalistic approach.[268] However, individual cases of paternalism are not necessarily representative. Presumptions had to be reflective of patient populations, and paternalism may be caused by a failure to readjust paradigms, rather than a purposeful ignorance of patient values.

(vii) Non-maleficence

Medical decision-making was seen to contain an internal moral content which structured the attribution of weight to relevant factors and considerations. One of the structural principles was that the doctor should do no harm.[269] Doing the patient harm would be the antithesis of acting in the patient's best interests, so it would defeat the purpose of the therapeutic medical relationship. This principle requires *circumstantial* decision-making to ensure that information is not forced on patients through the rigid use of paradigms.[270] The identified studies characterised the principle as integrated within the wider therapeutic decision about materiality.[271] For example, in Lankton *et al*, 7/12 patients who were provided information about risks indicated that they did not welcome more detailed information, and 4 indicated that they had been frightened by the explanation.[272] Meredith *et al*, similarly, identified that some doctors felt that knowledge of 'cancer' would depress and alarm some patients, impacting their quality of life[273] It was recognised that disclosure had the potential to cause patients psychological injury; psychological harm was likely to undermine their capacity to make an autonomous choice.[274]

[266] P. Meredith, 'Patient Participation in Decision-Making and Consent to Treatment: The Case of General Surgery.' (1993) 15(3) *Sociology of Health & Illness* 315, 331
[267] *Ibid*
[268] See for example, S. Gibbs, *et al*, 'Communicating Information to Patients about Medicine: Prescription Information Leaflets: A National Survey.' (1990) 93(5) *J R Soc Med* 292-297
[269] See, T. L. Beauchamp & J. F. Childress, *Principles of Biomedical Ethics*. (Oxford University Press, 2013), 150-178
[270] M. Wallace, 'Informed Consent to Elective Surgery: The 'Therapeutic' Value?' (1986) 22(1) *Soc Sci Med* 29-33, 30-32; D.J. Byrne, *et al*, 'How Informed is Signed Consent?' (1988) 296 *BMJ (Clin Res Ed*), 840
[271] Those studies which investigated informed consent conceptualised this element of decision-making as an additional step, or a therapeutic privilege, after the decision-making about materiality. K. Hodkinson, 'The Need to Know – Therapeutic Privilege: A Way Forward.' (2013) 21 *Health Care Analysis* 105-129; M. Wallace, 'Informed Consent to Elective Surgery: The 'Therapeutic' Value?' (1986) 22(1) *Soc Sci Med* 29-33, 30
[272] J. Lankton *et al*, 'Emotional Responses to Detailed Risk Disclosure for Anaesthesia: A Prospective, Randomised Study.' (1977) 46 *Anaesthesiology* 294
[273] C. Meredith, *et al*, 'Information Needs of Cancer Patients in West Scotland: Cross Sectional Survey of Patient Views.' (1996) 313 *BMJ* 724-726, 725
[274] G. Stimson & B. Webb, *Going to See the Doctor: The Consultation Process in General Practice.* (Routledge & Kegan Paul, 1975), 124; D.D. Kerrigan, 'Who's afraid of informed consent.' (1993) 306 *BMJ* 29; R. Lemaire, 'Informed consent – a contemporary myth?' (2006) 88(1) *The Journal of Bone and Joint Surgery* 1-7; C.K. Pager, 'Randomised controlled trial of preoperative information to improve satisfaction with cataract surgery.' (2005) 89 *Brit J Opthalmol* 10-13. Also see R. Macklin, 'Understanding Informed Consent.' (2009) 38(1) *Acta Oncologica* 83-87; J. Bester, 'The Limits of Informed Consent

Hawkins, for example, identified that doctors provided 74% of patients with a satisfactory explanation of diagnostic tests (n=295/399),[275] however, in some circumstances the doctor decided not to provide patients with information: 10% (n=42) had partial explanation and 16% (n=62) had no explanation, which correlated with those that were fearful (n=57).[276] Morris identified:

> Some 30% of patients (n=312), for example, welcomed receiving frightening information themselves, but they would not advise giving that information to a friend in the same position. Rather, these patients would advocate giving fellow patients emotional support, rather than specific information.[277]

For other patients, providing too little information will similarly deprive them of the ability to make a more substantive autonomous choice; which would, again, amount to a type of dignitary harm.[278]

2.3. *Bolam*: not that bad?

This section argues that the conventional understanding of *Bolam* is incorrect. The judgement of McNair J invited detailed analysis of both internal and external elements of the medical decision.[279] The accusations of judicial deference to the medical professions, which supported the movement to normative standards is therefore rebutted.[280] The first part of this section will argue that the *Bolam* judgement, instead, established a two stage analysis. First, the internal test required the judge to analyse the factual issues that are identified as relevant to the decision, the scientific basis of the disclosure (i.e. the frequency and magnitude of risk), and then assess whether the weighing and balancing of these factors, to decide on materiality, is logical. The second phase invited an external analysis of the decision and asks: whether the information disclosed is at the standard expected by the medical profession, in combination with whether it met the standard of care expected of a doctor, carrying out their moral role within society. The section concludes that judicial normativity is non-essential, and that that the sociological test is complementary to the proper functioning of *circumstantial-moral* decision-making. As Montgomery argues: 'the integrated model of law and professional activity working together to secure a common end of moral practice can be seen as a deliberate project to promote moral values.'[281]

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for an Overwhelmed Patient: Clinicians' Role in Protecting Patients and Preventing Overwhelm." (2016) 18 *AMA Journal of Ethics* 869-886; J.E. Barnett, *et al*, 'Informed Consent: Too Much of a Good Thing or Not Enough?' (2007) 38(2) *APA PsyNet* 179-186.

[275] C. Hawkins, 'Patients' Reactions to their Investigations: A Study of 504 Patients.' (1979) 2 *BMJ* 638-640, 639

[276] *Ibid*

[277] L.M. Louise, 'Informed Consent to Elective Surgery: The 'Therapeutic' Value?' (1986) 22(1) *Soc Sci Med* 29, 30

[278] See this argument in, A. Meisel, 'A "Dignitary Tort" a Bridge between the Idea of Informed Consent and the law of Informed Consent." (1988) 16(3-4) *Law Medicine and Health Care* 210-218. Also see, E. Sheley, 'Rethinking Injury: The Case of Informed Consent.' (2015) 1(4) *BYU Law Review* 63

[279] *Bolam v Friern Hospital Management Committee* [1998] 1 W.L.R. 582

[280] Lord Woolf, 'Are the Courts Excessively Deferential to the Medical Profession?' (2001) 9(1) *Med L Rev* 1-16

[281] J. Montgomery, 'Law and Demoralisation of Medicine.' (2006) 26(20 *Legal Studies* 185-210, 206

2.3.1. The Internal Test

(i) *Bolam*

McNair J set the standard of care in information disclosure, as the standard expected of reasonably 'competent medical men at the time.'[282] To identify whether the decision not to use restrains, or relaxant drugs, was *reasonable* required the judge to analyse the internal process of decision-making. McNair J was clear that 'a mere personal belief that a particular technique is best is no defence unless that belief is based on reasonable grounds.'[283] If the decision was not logical or was materially incorrect then it could not reach the standard expected of a competent medical man. Judicial analysis under the *Bolam* standard can be separated into three steps, to:

(a) Identify and evaluate the scientific evidence-base

McNair J first identified, and then evaluated, the scientific evidence-base on which the doctor was making their decision. The doctor failed to disclose the risk of acetabular fracture, as a result of unrestrained and non-medicated ECT, was between 1 in 10'000 - 50'000.[284] McNair J made clear that reliance on *any* science was not enough, it had to be contemporary and responsible: a medical man cannot 'obstinately and pig-headedly carry on with some old technique if it has been proved to be what is really substantially the whole of informed medical opinion.'[285]

(b) To identify the relevant factors that should be included in the decision

The defendant in *Bolam* gave evidence that the purpose of the ECT was to cure Mr Bolam who was currently residing in a mental institution, and 'suffering from one of the most terrible ills from which a man can suffer, he had very little hope of recovery.'[286] The aim of the treatment was therefore to act in the claimant's best interest's and was potentially lifesaving. Against the benefit of cure was balanced the risk of acetabular fracture, which was one in '50'000 involving a quarter of a million treatments.'[287] The use of manual restraints carried with it a similar risk of fractures, to fractures resulting from convulsions.[288] The use of relaxant drugs carried with it the risk of death and was weighed against a small risk of fractures. In the patients' particular circumstances there were no symptoms which would place him at a higher chance of fractures if he was not given drugs, and the claimant had expressed no particular preferences which would have caused the doctor to deviate from standard practice. [289] The

[282] *Bolam v Friern Hospital Management Committee* [1998] 1 W.L.R. 582, 586
[283] *Ibid*, 587
[284] *Ibid*, 585 & 589
[285] *Ibid*, 587
[286] *Ibid*, 585
[287] *Ibid*, 585
[288] *Ibid*, 586
[289] *Ibid*, 584

defendant, therefore, adopted the approach of 'saying very little and waiting for questions from the patient.'[290]

(c) Assess whether the weighing and balancing of competing considerations are logical and, in the patient's, best interest's

McNair J recognised that it was a presumption in practice that the patient should attain an autonomous choice: 'it is not right to give no warning of the risk to a person who can understand the warning.'[291] However, on the balance, it was in the patients best interests to ensure that the patient was not harmed: 'there was some danger in emphasizing to a patient who *ex hypothesi* is mentally ill, any dangers which in the doctor's view were minimal, because, if he does so, the patient may deprive himself by refusal of a remedy which is the only available hopeful remedy open to him.'[292] The weighing and balancing of factors cannot be arbitrary, and must be based on a reasonable weighing of the potential benefits and harms, as McNair J recognised:

> Mr Fox-Andrews also was quite right, in my judgement, in saying that a mere personal belief that a particular technique is best is no defence unless that belief is based on reasonable grounds. That again is unexceptionable.[293]

The evidence illustrates that the doctor was making *circumstantial* decisions i.e. altering his treatment and disclosure choices to suit the needs of the *actual* patient. Indeed, the defendant expert argued that if the patient had asked questions this would have necessitated the disclosure of a greater amount of information in his best interests.

> I do not warn as a technique. […] If the patient asks me about risks, I say there is a very slight risk to life, less than in any surgical operation. Risk of fracture, 1 in 10'000. If they do not ask me anything, I do not say anything about the risk.[294]

Similarly, the Dr Page, the Deputy Superintendent of the Three Counties Hospital stated:

> I say that every patient has to be considered as an individual. I ask them if they know of the treatment. If they are unduly nervous, I do not say too much. If they ask me questions, I tell them the truth. The risk is small, but a serious thing when it happens; and it would be a great mistake if they refused to benefit from the treatment because of fear. In the case of a patient

[290] *Ibid*, 590
[291] *Ibid*, 589
[292] *Ibid*, 589-590
[293] *Ibid*, 587
[294] *Ibid*, 589

> who is very depressed and suicidal, it is difficult to tell him of things you know would make him worse.[295]

The claimant's expert recognised that:

> I can believe that there would be circumstances in which it could be considered that it would not be beneficial at all to tell the patient of possible dangers and mishaps […].[296]

McNair J directed the jury to analyse the logic of the defendant's decision to withhold the information i.e., whether non-disclosure of the minute harm from a mentally ill patient, when the treatment would likely save his life.[297]

> Members of the jury, though it is a matter entirely for you, you may well think that when dealing with a mentally sick man and having a strong belief that his only hope of cure is E.C.T. treatment, a doctor cannot be criticised if he does not stress the dangers which he believes to be minimal involved in that treatment.[298]

It was not enough for the doctor to provide expert evidence, that another doctor would have made the same decision; the judge/jury must interrogate the position to see whether it stood up to scrutiny. If the defendant's position was illogical, then the doctor could prefer the expert evidence of the claimant. [299] Lord Scarman later, in *Maynard v West Midlands Healthcare Authority*, made clear that the role of the judge was not to make an independent normative assessment, of what the doctor should have disclosed, but whether the actual decision was reasonable. [300]

(ii) Post-*Bolam* examples

There are numerous examples, of judges engaging in similar scrutiny of the doctor's medical decision-making,[301] for example in *Chatterton v Gerson*, Bristow J analysed the practice of Dr Gerson to see whether the failure to warn about the risk of chronic intractable pain, which manifested as a result of an

[295] *Ibid*, 590
[296] *Ibid*, 589
[297] *Ibid*, 590
[298] *Ibid*, 590
[299] H. Teff, 'The Standard of Care in Medical Negligence – Moving on from *Bolam*?' (1998) 18 *Legal Studies* 473, 479; *Bolam v Friern Hospital Management Committee* [1957] 1 W.L.R. 582, 587-588: "[…] it is not essential for you to decide which of two practices is the better, as long as you accept that what the defendants did was in accordance with a practice accepted by responsible persons; if the result of the evidence is that you are satisfied that his practice is better than the practice spoken of on the other side, then it is really a stronger case."
[300] *Maynard v West Midlands Regional Health Authority* [1985] 1 All ER 635, per Lord Scarman at 638.
[301] See also, *Well v Surrey AHA*, Times (29 July 1978, unreported) (Croom-Johnson J); *Sankey v Kensington and Chelsea and Westminster Area Health Authority* [1982] Lexis Citation 458; *O'Malley-Williams v Board of Governors of the National Hospital for Nervous Diseases* [1975] 1 BMJ 635 (Bridge J)

intrathecal phenol solution injection, was reasonable. [302] The judge found that it was the usual practice of the defendant to disclose the possibility of injections interrupting the nerve signals to the brain, which could result in numbness and muscle weakness (although he did not usually disclose the particulars, or extent, of the weakness). The claimant received two such injections to cure pain. During the first injection, there was no circumstantial or individual factors that would cause Dr Gerson to alter his disclosure practice. The judge also found that the patient was 'charming, sensible, [and] intelligent' and thus capable of complaining or asking if they needed more specific information.[303] The treatment failed, and the doctor provided another intrathecal block (albeit that the patient was now in desperate pain).[304] The doctor again provided the same level of information disclosure before administering the injection, which resulted in damage to the patient. The claimant argued that the doctor should have disclosed a prudent patient standard of information, so that she could have an informed consent. [305] Bristow J said that: 'the duty of a doctor is to explain what he intends to do and its implication, in a way a careful and responsible doctor in similar circumstances would have done.'[306] In coming to a decision about materiality, the doctor properly weighed and balanced the biomedical risks of the procedure, the likelihood of misfortune, the method of warning and the particular patient's welfare; [307] on this basis Bristow J found the disclosure reasonable.

A similar judicial method of evaluation occurred in *Hills v Potter*.[308] The claimant argued that the doctor had failed to ensure that her consent was real or effective, by not disclosing the risk of anaesthetic complications, risks of paralysis (spasmodic torticollis), or death, resulting from cervical anterior rhizotomy surgery.[309] The claimant argued that a failure to disclose these serious risks meant that she could not appropriately weigh the benefits (70-80% chance of success) and harms (1-2% risk of injury resulting from any surgery), and thus make an informed decision.[310] To identify whether it was reasonable to disclose these serious risks, Hirst J interrogated the scientific evidence, and found that: '[p]rior to 1974 there were no recorded cases of paralysis as a result of the operation such as the plaintiff suffered.'[311] The judge also found that in deciding what information to tell the patient the doctor would 'always explain what the operation involved, though the detail varied by reference to the particular patient's ability to understand.'[312] The doctor, in this case, provided more than his usual disclosure by answering the claimant's questions, and providing details of the surgery.

[302] *Chatterton v Gerson* [1981] 1 All 257, 264
[303] *Ibid*, 267
[304] *Ibid*, 267
[305] *Ibid*, 264
[306] *Ibid*, 286
[307] *Ibid*, 286
[308] *Hills v Potter* [1984] 1 WLR 641,
[309] *Ibid*, 642-643
[310] *Ibid*, 650-651
[311] *Ibid*, 643
[312] *Ibid*, 642

> She asked what it consisted of, and he said that he would have to cut the muscles on the righthand side of her neck to stop them pulling her neck down. It was a major operation with a small risk, but he did not say what the risk was or give detail of it. After the operation she would have to wear a collar and would never be able to turn her head or look over her shoulder either way.[…] She confirmed that the first defendant had said that the proposed operation was major surgery which should not lightly be undertaken.[313]

The doctor also stated that the operation was irreversible and explained the risks if the operation went wrong. The doctor reassured the claimant because she seemed to be overestimating the dangers; he therefore stated: 'that if his wife were in a similar condition, he would advise her to have the operation.'[314] As this was an elective surgery, the doctor advised her to take some time to think. Hirst J made clear that the *Bolam* standard does not abdicate power to the doctor. In deciding whether the actions were reasonable, the court must evaluate the logic of the decision to see if they were 'respectable and responsible.'[315] Hirst J found that the first instance judge was correct, in finding that the doctor provided information which would give the claimant a proportionate sense of the seriousness of the operation, and that she would likely be worse off if it was not performed.[316] He could not have provided a disclosure of the precise risk which occurred, as it had never occurred before, and was not present in the medical literature.[317] On this basis the disclosure was reasonable.

(iii) *Sidaway*

The House of Lords judgement in *Sidaway* set the standard of care for medical decision-making in the law of negligence.[318] At first instance, Skinner J considered whether Mr Falconer had been negligent in failing to disclose the risk of damage following an operation on the cervical vertebrae of the patient.[319] The judge found that the surgeon, who was deceased at the time of trial, told the claimant of the possibility of disturbing the nerve root, and the consequences, however, he did not tell her of the potential damage to the spinal cord.[320] On this basis, the doctor was found not to be negligent. This decision was then appealed to the House of Lords, on the basis that an incorrect test was applied. In assessing whether the failure to do so fell below the standard of the 'responsible body of skilled and

[313] *Ibid*, 642
[314] *Ibid*, 642 & 645
[315] *Ibid*, 652
[316] *Ibid*, 644
[317] *Ibid*, 645
[318] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 AC 871
[319] *Ibid*, 871-872
[320] *Ibid*, per Lord Bridge at 896

experienced neuro-surgeons' the majority in the House of Lords applied the sociological *Bolam* test.[321] As Lord Diplock argued, the judge:

> […] has to rely upon and evaluate expert evidence, remembering that it is no part of its task of evaluation to give effect to any preference it may have for one responsible body of professional opinion over another, provided it is satisfied by the expert evidence that both qualify as responsible bodies of medical opinion.[322]

However, as Lord Bridge argued:

> […] that the judge might in certain circumstances come to the conclusion that disclosure of a particular risk was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it.[323]

If expert evidence is factually contradictory, the judge can also decide between evidence, as to whether the decision amounts to a responsible body of medical opinion.[324] In coming to their conclusions on liability, the Lords demonstrated the internal and external methodology of evaluation:

(a) Identify and evaluate the scientific evidence-base

The judges had to assess whether the statistical basis on which doctors were identifying risks were factually sound. Lord Bridge, for example, identified from expert evidence, that the risk of any damage to the nerve root site or the spinal cord was between 1-2%.[325] The harm that actually manifested was at 'less than 1 in a hundred,'[326] which both the claimant and defendant's experts agreed, was below the threshold of general disclosure.[327] Lord Bridge went on to argue that the *prima facie* threshold at which doctors must disclose simple and general risks[328] is around 10%:

> […] for example, the ten per cent risk of a stroke from the operation which was the subject of the Canadian case of *Reibl v. Hughes* […]. In such a case, in the absence of some cogent clinical reason why the patient should not be informed, a doctor, recognising and respecting his patient's right of decision, could hardly fail to appreciate the necessity for an appropriate warning.[329]

[321] *Ibid*, 871
[322] *Ibid*, per Lord Diplock at 895
[323] *Ibid*, per Lord Bridge at 900
[324] *Ibid*, per Lord Bridge at 900
[325] *Ibid*, per Lord Bridge at 895-896
[326] *Ibid*, per Lord Diplock at 891
[327] *Ibid*, per Lord Bridge at 901
[328] *Ibid*, per Lord Templeman at 902
[329] *Ibid*, per Lord Bridge at 900

Lord Templeman, similarly, argued that the significance of 10% chance of stroke and 4% chance of death from an operation would necessitate disclosure; otherwise, the patient could not make a balanced decision.[330] The specific threshold of negligent disclosure would be altered in the particular circumstances of the actual case. As Lord Diplock argued:

> Statistically, the chances of any risk of the proposed treatment going awry at all may be small - but particularly if surgery is involved (though this is by no means confined to surgery) it is never totally absent and the degree of possible worsening involved may cover a whole spectrum of disabilities from mild occasional discomfort to what might justify the epithet catastrophic. All these are matters which the doctor will have taken into consideration in determining, in the exercise of his professional skill and judgment, that it is in the patient's interest that he should take the risk involved and undergo the treatment recommended by the doctor.[331]

(b) To identify the relevant factors that should be included in the decision

Lord Bridge recognised that evaluating the reasonableness of a decision required the court to identify and assess the factors that entered into the decision-making paradigm. Whether the process of identification was correct was based on evidence of the pertinent factors arising from the doctor-patient relationship, at the time.

> A very wide variety of factors must enter into a doctor's clinical judgment not only as to what treatment is appropriate for a particular patient, but also as to how best to communicate to the patient the significant factors necessary to enable the patient to make an informed decision whether to undergo the treatment.[332]

However, in *Sidaway*,

> […] your Lordships' House have all been denied the advantage of what would clearly have been vital evidence on the issue of liability, not only the surgeon's account of precisely what he had told this appellant, but also his explanation of the reasons for his clinical judgement that, in her case, the information he gave about the operation and its attending risks was appropriate and sufficient.[333]

[330] *Ibid*, per Lord Templeman at 903; *Reibl v Hughes* (1980) 114 D.L.R. (3d) 1
[331] *Ibid*, per Lord Bridge at 900
[332] *Ibid*, per Lord Bridge at 899
[333] *Ibid*, per Lord Bridge at 896

As the particular circumstance and decision-making of the defendant could not be identified, the trial judge had to make delineations from evidence and inferences from his usual disclosure practices. The judges were denied knowledge of the circumstantial element of decision-making. Instead, they had to make an assessment of liability simply on the moral assumptions and paradigms of the defendants medical practice. Thus,

> […] liability fails to be considered, in effect, in relation to that customary practice, independently of the vitally important individual doctor/patient relationship which must play so large a part in any discussion of a proposed operation with a patient. That introduces an element of artificiality into the case which we may deplore but cannot avoid.[334]

Lord Diplock, similarly, recognised that the decision on reasonability of a disclosure must be based on the idiosyncracies of the individual patient:

> We know nothing of the emotional idiosyncracies of the plaintiff, Mrs. Sidaway ("the patient"), even in ordinary health let alone under stress of ill-health and the prospects of waiting for surgical treatment at the hands of Mr. Falconer ("the neuro-surgeon"); and yet a doctor's duty of care, whether he be general practitioner or consulting surgeon or physician is owed to that patient and none other, idiosyncracies and all.[335]

Lord Templeman noted:

> We do not know how Mr Falconer explained the operation to Mrs. Sidaway and we do not know the reasons for the terms in which he couched his explanation.[336]

Lord Scarman, providing a dissenting judgement, also recognised that:

> Whatever be the correct formulation of the applicable law, the issue cannot be settled positively for or against the doctor without knowing what advice, including any warning of inherent risk in the operation, he gave his patient before she decided to undergo it and what was his assessment of the mental, emotional, and physical state of his patient.[337]

And that:

[334] *Ibid*, per Lord Bridge at 896
[335] *Ibid*, per Lord Diplock at 890
[336] *Ibid*, per Lord Templeman at 902
[337] *Ibid*, per Lord Scarman at 876

> Where the court lacks direct evidence as to the nature and extent of the advice **and** warning (if any) given by the doctor **and** as to his assessment of his patient the court may well have to conclude that the patient has failed to prove her case.[338](author's emphasis)

On this basis the *Sidaway* case, whilst leading, is a poor case on which to illustrate the analysis of *circumstantial-moral* decision-making; which is possibly why the conventional view of *Bolam* became ossified in the zeitgeist. Instead, as the Lords noted, they had to hypothetically identify characteristics of the patient which might indicate the *circumstantial* deviation from a general disclosure, or baseline, which would be offered to all patients in the circumstances. Both Lord Bridge[339] and Lord Diplock, [340] argued that if the patient had the capacity to make an informed consent, evidenced, for example, by their profession, then this would be a reason to provide an enhanced disclosure:

> […] the kind of training and experience that a judge will have undergone at the Bar makes it natural for him to say (correctly) it is my right to decide whether any particular thing is done to my body, and I want to be fully informed of any risks there may be involved of which I am not already aware from my general knowledge as a highly educated man of experience, so that I may form my own judgement as to whether to refuse the advised treatment or not.[341]

> *(c) Assess whether the weighing and balancing of competing considerations are logical and, in the patient's, best interest's*

Lord Scarman argued that the moral presumptions, adopted by the medical profession, created an overriding requirement on doctors to provide patients a content of information so that they could make an autonomous choice as the basis of consent.[342] However, Lord Bridge, for the majority, found that whilst there was a medical presumption that information was therapeutically beneficial, there was no evidence that this was a therapeutic maxim, and had no support as a standard of care in law:

> If the law is to impose on the medical profession a duty to warn of risks to secure "informed consent" independently of accepted medical opinion of what is appropriate, neither of these explanations for confining the duty to special as opposed to general surgical risks seems to me wholly convincing.[343]

[338] *Ibid*, per Lord Scarman at 876
[339] *Ibid*, per Lord Bridge at 897
[340] *Ibid*, per Lord Diplock at 895
[341] *Ibid*, per Lord Diplock at 895
[342] *Ibid*, per Lord Scarman at 877
[343] *Ibid*, per Lord Bridge at 897

Instead, Lord Bridge rightly recognised that the doctor must balance the *circumstantial* harms of information disclosure, against the presumed benefits, based on the needs of the patient, and circumstances of the actual case.[344] If providing information would alarm the patient, causing them distress, this should be weighed against the potential benefits of disclosure.[345] For example, Lord Templeman argued that:

> Mr Falconer may reasonably have taken the view that Mrs Sidaway might be confused or frightened or misled by more detailed information which she was unable to evaluate at a time when she was suffering from stress, pain and anxiety.[346]

Another important factor in weighing and balancing harms was the values and information choices of the actual patient. If the patient requested more information, for example, by asking a question, then the doctor would be obliged to provide that information - as disclosing this information would be circumstantially in their best interests.[347] Lord Bridge, for example, recognised:

> […] when questioned specifically by a patient of apparently sound mind about risks involved in a particular treatment proposed, the doctor's duty must in my opinion be to answer both truthfully and as fully as the questioner requires.[348]

Lord Templeman, similarly, argued:

> In my opinion if a patient knows that a major operation may entail serious consequences, the patient cannot complain of lack of information unless the patient asks in vain for more information or unless there is some danger which by its nature or magnitude or for some reason requires to be separately taken into account by the patient in order to reach a balanced judgement in deciding whether or not to submit to the operation.[349]

For the patient to show that a specific disclosure was required, they needed to evidence that that particular information would have affected their decision-making.[350] On the other hand, '[a] patient may prefer that the doctor should not thrust too much detail at the patient'[351] doing so would require the doctor to limit the amount of information in the patient's best interests. As Lord Diplock noted, in

[344] *Ibid*, per Lord Bridge at 897-898
[345] *Ibid*, per Lord Diplock at 891, Lord Bridge at 897-898
[346] *Ibid*, per Templeman at 891
[347] *Ibid*, per Lord Diplock at 895, Lord Bridge at 898, per Lord Templeman at 902
[348] *Ibid*, per Lord Bridge at 898
[349] *Ibid*, per Lord Templeman at 902
[350] *Ibid*, per Lord Templeman at 902-903
[351] *Ibid*, per Lord Templeman at 902

the present case, there was no indication that the patient wanted information beyond the general disclosure provided. [352] Adopting a normative approach to the law would mean that patient choices would not alter the content of information that would be provided: undermining patient liberty. Lord Bridge therefore, rightly, argued that:

> I cannot believe that contemporary medical opinion would support this view, which would effectively exclude the patient's right to decide in the very type of case where it is most important that he should be in a position to exercise that right and, perhaps even more significantly, to seek a second opinion as to whether he should submit himself to the significant risk which has been drawn to his attention.[353]

(iv) Post-*Sidaway* examples

The post-*Sidaway* cases,[354] similarly, recognised the phenomenological method of medical decision-making, required to evaluate the internal methods of medical decision-making on its own terms. For example, in *Knight v Home Office,* Pill J stated that '[t] he reasons given by the doctor for their decision, however, should be examined by the court to see if they stand up to analysis. [355]In *Joyce v Merton, Sutton and Wandsworth HA*, Roch LJ argued that expert evidence would be accepted '[p]rovided that clinical practice stood up to analysis and was not unreasonable in the light of medical knowledge at the time.' This 'is very important because without it, it leaves the decision of negligence or no negligence in the hands of the doctors, whereas the question must at the end of the day be one for the courts.'[356] Also, in *Wiszniewski v Central Manchester,* the judge stated that 'it is clearly necessary for me to analyse whether the course of the treatment […] put the patient unnecessarily at risk.'*[357]*

The post-*Sidaway* case law is more illustrative of the analytical steps necessary to evaluate whether disclosure amounted to a reasonable decision.[358] For example in *Huck v Cole*, the patient developed puerperal fever, due to the doctor's failure to prescribe penicillin. The defendant, provided expert evidence that other doctors would have adopted a similar treatment regime. However, Sach LJ found that the scientific basis of the decision was outdated, and therefore the reliance on the procedure was illogical.[359] A decision- which relied on incorrect or out-dated science, would be open to judicial critique, under the internal analysis.[360] Even on a common sense weighting of the decision, the risks of

[352] *Ibid*, per Lord Diplock at 895
[353] *Ibid*, per Lord Bridge at 898
[354] See similar assessments of expert evidence at first instance in *Smith v Tunbridge Wells Health Authority* [1994] 5 Med LR 334, at 339
[355] *Knight v Home Office* [1990] 3 All ER 237 per Pill J at 244
[356] *Joyce v Merton, Sutton and Wandsworth HA* [1996] 7 Med LR 1, per Hobhouse LJ at 13-14
[357] *Wiesniewski v Central Manchester HA* [1998] Lloyd's Rep Med 223, at 260.
[358] See for example, Blyth *v Bloomsbury Health Authority* [1993] 4 Med LR 151, at per Lord Kerr at 157: per Neil LJ at 160
[359] *Huck v Cole* [1993] 4 Med LR 393, per Sach L.J. at 397
[360] I. Goldrein, 'Exploding the *Bolam* Myth, Part Two.' (1994) 144 *NLJ* 1283.

providing antibiotics did not outweigh the very serious risk of death, as a result of non-treatment. Thus, Sach LJ stated that:

> When the evidence shows that a lacuna in professional practice exists by which risks of grave danger are knowingly taken, then, however small the risks, the court must anxiously examine the lacuna – particularly if the risks can be easily and inexpensively avoided. [361]

A similar approach was adopted in *Loveday v Renton*[362] where Stuart-Smith LJ stated that:

> [t]he mere expression of opinion or belief by a witness, however eminent, that the vaccine can or cannot cause brain damage, does not suffice. The court has to evaluate the witness and the soundness of his opinion. Most importantly this involves an examination of the reasons given for his opinions and the extent to which they are supported by the evidence. […].[363]

2.3.2. The External Test

This section argues that the second part of the sociological *Bolam* test required an external analysis about whether the decision met the objective standards of the reasonable medical practitioner. Particularly, the standard integrates the question: whether the doctor reached the standard expected by the medical profession, then, whether the doctor reached the standard expected by society.

The external test can therefore be divided into two stages: first, the judge evaluated whether the best interest's decision fell within the spectrum of reasonable medical practice (expected by the professional, in relation to their expertise, and in the particular circumstances).[364] McNair J expressed this requirement as: 'the standard of the ordinary skilled man exercising or professing to have that special skill'[365] and 'that there may be one or more perfectly proper standards; and if he conforms with one of those proper standards, then he is not negligent.'[366] Whether the decision falls within a spectrum of reasonable medical practice could be evidenced utilising expert evidence, so 'he is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art.'[367] The expert should be of the same specialism as the doctor,

[361] *Huck v Cole* [1993] 4 Med LR 393, per Sach L.J. at 397, per Sach LJ at 397
[362] *Loveday v Renton* [1990] 1 Med LR per Stuart-Smith LJ, at 98
[363] *Ibid*
[364] *Bolam v Friern Hospital Management Committee* [1998] A.C. 1 W.L.R. 582, 587; *Hunter v Hanley* (1955) SLT 213, per Lord Clyde P. at 638 *Whitehouse v Jordan* [1981] 1 WLR 246, per Lord Edmund-Davies at 258; *Maynard v West Midlands Regional Health Authority* [1984] 1 WLR 634, per Lord Scarman at 638
[365] *Bolam v Friern Hospital Management Committee* [1998] 1 W.L.R. 582, 586
[366] *Ibid*, 587
[367] *Ibid*, 587

and if giving an opinion on the reasonableness of the approach, should use the same facts available to the doctor at the time the decision was made.[368]

> The language of the *Bolam* test clearly requires a different degree of skill from a specialist in his own special field than from a general practitioner. In the field of neuro-surgery it would be necessary to substitute for Lord President Clyde's phrase "no doctor of ordinary skill," the phrase "no neuro-surgeon of ordinary skill." All this is elementary and, in the light of the two recent decisions of this House referred to, firmly established law.[369]

This expertise is necessary. Only an expert will be providing insight into whether first; the construction of the internal moral paradigms of patient need, were within reasonable boundaries of the specialism,[370]and second, whether in the circumstances of the case, deviation from those moral paradigms were medically or rationally justified. As Badenoch argued, the judge must evaluate the supporting expert evidence, to see if it is logical.[371] If the internal logic of the doctor's decision-making was sound, and he followed a practice that fell within the boundary of that expected by his specialism, he would not be negligent. As Lord Bridge states:

> […] the issue whether non-disclosure in a particular case should be condemned as a breach of the doctor's duty of care is an issue to be decided primarily on the basis of expert medical evidence, applying the *Bolam* test. But I do not see that this approach involves the necessity "to hand over to the medical profession the entire question of the scope of the duty of disclosure, including the question whether there has been a breach of that duty."[372]

Lord Templeman agreed:

> […] if the practice of the medical profession is to make express mention of a particular kind of danger, the court will have no difficult in coming to the conclusion that the doctor ought to have referred expressly to this danger as a special danger unless the doctor can give reasons to justify the form or absence of warning adopted by him.[373]

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[368] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 AC 871, per Lord Bridge at 896
[369] *Ibid*, per Lord Bridge 897; *Whitehouse v Jordan* [1981] 1 WLR 246, 258, per Lord Edmund-Davies and in *Maynard v West Midlands Regional Health Authority* [1984] 1 WLR 634, per Lord Scarman at 638
[370] *Ibid*, per Lord Bridge 899
[371] J. Badenock Q.C., 'Brushes with *Bolam*. Where Will it Lead?' (2004) 72(4) *Medico-Legal Society* 127, 137-141
[372] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 AC 871, per Lord Bridge at 900
[373] *Ibid*, per Lord Templeman at 903

Lord Diplock, similarly, indicated that the judge must not simply accept evidence, but must 'evaluate expert evidence' and be satisfied that the expert evidence 'qualify as responsible bodies of medical opinion.'[374] For example, in *De Freitas v O'Brien* Otton LJ analysed the expert's qualification to see whether they are sufficiently experienced, qualified, and part of the specialist group, before relying on their opinion of whether the defendant's actions fell within a reasonable spectrum of medical practice.[375] The Court of Appeal found that the size of the school of thought was irrelevant, if the internal elements of the decision were sound.[376] This process of assessing the status and thus competence of the expert can be seen throughout the case-law.[377] However, this goes to the construction of the reasonable standard, not purely as a justification for deference.

Second, the judge then had to consider whether the decision about information disclosure reached the standard expected of a doctor, carrying out their function of medicine within society. This includes considerations of human rights, and principles of justice, equality and liberty. Of particular importance is whether proper weight is afforded to patient choice and values. Whilst liberty is not a paramount principle within a beneficently orientated decision, it is afforded more epistemic weight when medical decision-making is operating within a democratic society. As Lord Denning MR commentated: '[t]he common law can and should keep pace with the times'[378] which meant both requiring, and limiting, forms of legitimate medical action; which may have been traditionally acceptable. To ensure that decision-making is contemporarily, ethically, appropriate the judge must sometimes take an interpretive approach to update the law. For example, in *Gillick v West Norfolk and Wisbech AHA*, Lord Fraser and Lord Scarman updated the law on consent for minors, to afford competent children the ability to consent to treatment.[379] As Lord Scarman argued:

> The law ignores these developments at its peril. The House's task, therefore, as the supreme court in a legal system largely based on rules of law evolved over the years by the judicial process is to search the overfull and cluttered shelves of the law reports for a principle, or set of principles recognised by judges over the years but stripped of the detail which, however appropriate in their day, would, if applied today, lay the judge open to a justified criticism for failing to keep the law abreast of the society in which they live and work.

[374] *Ibid*, per Lord Diplock at 895
[375] *De Freitas v O'Brien* (1995) 25 BMLR 51, 61
[376] *Ibid*, 60-61. Although this approach has been criticised: M. Brazier & E. Cave, *Medicine, Patients and the Law*. (Penguin, 2011), 163; M. Khan & M. Robson, 'What is a responsible group pf medical opinion?' (1995) 11 *Professional Negligence* 4
[377] For example, see, *Ratty v Haringey Health Authority* [1994] 5 Med LR 413, per Kennedy L.J, at 416; *Sankey v Kensington and Chelsea and Westminster Area Health Authority* [1982] Lexis Citation 458
[378] *Hewer v Bryant* [1970] 1 Q.B. 357, per Lord Denning M.R. at 369.
[379] *Gillick v West Norfolk and Wisbech AHA* [1985] 3 WLR 830, per Lord Fraser at 842; per Lord Scarman at 853

> It is, of course, a judicial common place to proclaim the adaptability and flexibility of the judge-made common law. But this is more frequently proclaimed than acted upon. The mark of the great judge from Coke to Mansfield to our day has been the capacity and will to search out principle, to discard the detail appropriate (perhaps) to earlier times, and to apply principle in such a way as to satisfy the needs of their own time. If judge-made law is to survive as a living and relevant body of law, we must make the effort, however inadequately, to follow the lead of the great masters of the judicial art.[380]

In *Sidaway*, the claimant argued that this element of the analysis required the judge to protect patient's societal rights, by constructing a normative duty to ensure that the patient received an informed consent.[381] As Lord Bridge surmised, this external test could be utilised to create 'criterion of the doctor's duty to disclose the risks inherent in a proposed treatment […] independently of any medical opinion or practice'.[382] However, this was rejected by the majority, as it created an objective test which ignored the relevant factors of the medical relationship of the time, it would make medical evidence about the reasonableness of a decision irrelevant, and a judicial test would 'be so imprecise as to be almost meaningless.'[383]As Lord Diplock argued, the movement to a normative standard was unnecessary, as the sociological approach required by *Bolam* 'brings up to date and re-expresses in light of modern conditions in which the art of medicine is now practiced, an ancient rule of common law.'[384]

2.3.3. Backing *Bolam*

The *Bolam* standard is therefore conceptually compatible and facilitative of medical decision-making in practice – as it is self-updating, in line with contemporary best practice, whilst still being orientated towards ensuring that the doctor makes decisions in the best interests of the patient, whilst in the therapeutic relationship.[385] For example, Lord Templeman, in *Sidaway*, recognised that '[t]he doctor, obedient to the high standards set by the medical profession impliedly contracts to act at all times in the best interests of the patient.'[386] To act in the best interests of the patient, the doctor must aim towards: 'the prolongation of life, the restoration of the patient to full physical and mental health and the alleviation of pain.'[387]The majority of the House of Lords recognised that all the component elements

[380] *Ibid*
[381] *Ibid*, per Lord Bridge at 897 & 899
[382] *Ibid*, per Lord Bridge at 898. Relying on *Canterbury v Spence* (1972) 464 F 2d 772, Per Robinson J at 784
[383] *Ibid*, per Lord Bridge at 899; per Lord Templeman at 903
[384] *Ibid*, per Lord Diplock at 892
[385] *Bolam v Friern Hospital Management Committee* [1998] A.C. 1 W.L.R. 582, 587; *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 AC 871 Per Lord Diplock at 893, Per Lord Bridge at 896 & 899, Per Lord Templeman 904-905
H. Teff, 'Medical Models and Legal Categories: An English Perspective.' (1993) 9 *J. Contemp. Health L. & Pol'y* 211, 221-224
[386] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 AC 871, per Lord Templeman at 905
[387] *Ibid*, per Lord Templeman at 903

of medical decision-making: advice, diagnosis and treatment, were undelineable; and all serviced the beneficent ends of medicine.[388] For example, Lord Diplock argued:

> In English jurisprudence the doctor's relationship with his patient which gives rise to the normal duty of care to exercise his skill and judgment to improve the patient's health in any particular respect in which the patient has sought his aid, has hitherto been treated as a single comprehensive duty covering all the ways in which a doctor is called upon to exercise his skill and judgment in the improvement of the physical or mental condition of the patient for which his services either as a general practitioner or specialist have been engaged. This general duty is not subject to dissection into a number of component parts to which different criteria of what satisfy the duty of care apply, such as diagnosis, treatment, advice (including warning of any risks of something going wrong however skilfully the treatment advised is carried out).[389]

In *Gold v Haringey Health Authority*, the judge found that even when the treatment was elective, the doctor was still acting within the therapeutic relationship.[390]

The benefit of the *Bolam* standard is that that standard of care improves, in line with the development of practice, and the increase in knowledge and technology; the law is therefore reflective and facilitative of practice. The reasonableness of the medical decision evaluated according to the knowledge of the time, so doctors cannot simply repeat a content of information in perpetuity, and instead, must update their practices in line with contemporary medical knowledge.[391] It also avoids the potential problem of the stagnation of patient paradigms (and development of defensive process-driven decision-making).[392] As Lord Diplock, for the majority, argued:

> Those members of the public who seek medical or surgical aid would be badly served by the adoption of any legal principle that would confine the doctor to some long-established, well-tried method of treatment only, although its past record of success might be small, if he wanted to be confident that he would not run the risk of being held liable in negligence simply because he tried some more modern treatment, **and** by some unavoidable mischance it failed to heal but did some harm to the patient. This would encourage "defensive medicine" with a vengeance."[393]

[388] *Ibid*, per Lord Diplock at 893, per Lord Bridge 896-897, per Lord Templeman at 903
[389] *Ibid*, per Lord Diplock 893
[390] *Gold v Haringey Health Authority* [1988] Q.B. 481, 491
[391] *Bolam v Friern Hospital Management Committee* [1957] 1 W.L.R. 582, 587
[392] *Ibid*, per Lord Scarman at 887; Lord Diplock at 893
[393] *Ibid*, per Lord Diplock at 982-893

At the same time, the sociological standard also provides the necessary discretion for *circumstantial-moral* decision-making:[394] This allows appropriate weight to be placed on providing information so that patients can have an autonomous choice,[395] others can be protected from harm,[396] and appropriate weight can be given to their individual preferences and their healthcare circumstances.[397]

2.4. *Bolitho:* restating the obvious

The *Bolitho* judgement was seen by some commentators as marking a paradigm shift towards the senior courts analysing medical decision-making (and thus endorsing normativity).[398] This thesis argues, instead, that the judgment was simply restating the existing two-step judicial evaluation of *circumstantial-moral* decision-making. [399] *Bolitho* made the evaluatory framework explicit, as James Badenoch QC argued:

> If *Bolam* had been strictly applied very few if any of those cases would ever have been won, but a good proportion were won. There were always judges who applied their critical and intellectual faculties to the arguments, and invoked what is now called the *Bolitho* principle long before *Bolitho* had been decided. They did so even in the dark ages of medical negligence litigation when there was no exchange of expert reports prior to trial and defences could be no more than a bare denial - although it is the notorious fact that in front of certain judges the Plaintiffs did invariably fail.[400]

Normative standards of care in information disclosure were therefore unnecessary to avoid paternalism.

This section illustrates how making the *Bolam* test explicit encouraged a movement towards ethical normativity, which altered how doctors made decisions about information disclosure. First, requiring judges to evaluate medical decision-making, without explicitly setting out the mechanism for doing so, encouraged judges to abandon the internal analysis, and independently reach a conclusion about materiality, as the basis of assessing liability. Second, it led to the ossification of decision-making in practice, by fixing patient paradigm (and the associated content of disclosure) through formal and semi-formal medical ethics, in an attempt to ensure that the basis of medical decisions were 'logical.' This discouraged *circumstantial* movement from these paradigms.

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[394] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] 1 AC 871, per Lord Templeman at 904; per Lord Bridge 899 & 900

[395] *Ibid*, per Lord Bridge 897, Lord Templeman at 904

[396] *Ibid*, per Lord Bridge 898, Lord Templeman at 904

[397] *Ibid*, per Lord Bridge 899-900; Lord Templeman at 904

[398] M. Brazier & J. Miola, Bye-Bye *Bolam*: A Medical Litigation Revolution? (2000) 8 *Med L Rev* 85-114, 100; I. Kennedy & A. Grubb, Principles *of Medical Law* (Oxford University Press, 1998), 173; A. Grubb, 'Negligence: Causation and *Bolam*.' (1998) 6 *Med L Rev* 378

[399] J. Badenock Q.C., 'Brushes with *Bolam*. Where Will it Lead?' (2004) 72(4) *Medico-Legal Society* 127, 131

[400] J. Badenoch Q.C., *Bolam – Let's Kill It Off a Heretics View*. (<http://connect-avma.public-i.tv/document/The_Continum_Relevance_of_the_Bolam_Test.pdf>), [18]. See also, J. Badenoch Q.C., 'Brushes with *Bolam*. Where Will it Lead?' (2004) 72(4) *Medico-Legal Society* 127, 131-132

2.4.1 The *Bolitho* judgement:

The case revolved around a two-year-old boy who was discharged from hospital after treatment for croup and was later readmitted with respiratory difficulties. The senior paediatric registrar failed to attend, and the boy suffered respiratory collapse and cardiac arrest resulting in brain damage, from which he eventually died. The claimant alleged that the failure to attend and intubate the child was negligent. It was agreed that intubation was the only procedure that would have avoided harm.[401] The defendant accepted negligence for failure to attend, but argued that she would not have intubated, thus, breaking the chain of causation between the negligent act and the harm.[402] She attempted to rely on the conventional *Bolam* approach, arguing that other doctors would not have intubated and relied on three expert witnesses in support of her assertion that intubation was contrary to acceptable medical practice.[403] The first tier judge accepted that the opinion of the defendant was reasonable;[404] this was upheld by the Court of Appeal.[405] The House of Lords found that the *Bolam* test was applicable to hypothetical actions.[406] Lord Browne Wilkinson made transparent:

> […] in my view, the court is not bound to hold that a defendant doctor escapes liability for negligent treatment or diagnosis just because he leads evidence from a number of medical experts who are genuinely of the opinion that the defendant's treatment or diagnosis accorded with sound medical practice.[407]

Lord Browne-Wilkinson, instead, argued that the decision must be analysed in two stages.[408] First, the decision had to be internally logical and consistent.[409] This required the decision to be based on the relevant factors as hand, which had to rationally weigh by the doctor.[410]

> The use of the adjectives - responsible, reasonable and respectable – all show that the court has to be satisfied that the exponents of the body of opinion relied on can demonstrate that such opinion has a logical basis. In particular, in cases involving, as they so often do, the weighing of the risks against benefits, the judge before accepting a body of opinion as being responsible, reasonable, respectable, will need to be satisfied that, in forming their view, the experts have

[401] *Bolitho v City and Hackney Health Authority* [1997] 4 All ER 771, at 776
[402] *Ibid*, 776-777; *Joyce v Merton Sutton and Wandsworth HA* (1996) 27 BMLR, per Hobhouse LJ, at 156.
[403] *Ibid*, 775
[404] *Ibid*, 777. M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 97
[405] *Bolitho v City and Hackney Health Authority* [1994] 1 Med L.R. 381, (Simon Brown LJ dissenting)
[406] *Bolitho v City and Hackney Health Authority* [1997] 4 All ER 771, at 778
[407] *Ibid*
[408] *Ibid*, 777
[409] *Ibid*, 776-779. See also, Joyce *v Merton Sutton and Wandsworth HA* (1996) 27 BMLR 124; *Hucks v Cole* (1993) 4 Med L Rev 393; *Edward Wong Finance Co Ltd v Johnson Stokes & Master (a firm*) [1984] AC 296.
[410] *Ibid*, 778

> directed their minds to the question of comparative risks and benefits and have reached a defensible conclusion on the matter.[411]

Expert evidence would have a persuasive role in the reasonability of the method and content of medical decision-making. If the decision was supported by a well credentialed school of thought, this would add weight to the external analysis i.e., that the decision is socially acceptable, and thus responsible. However, Lord Browne-Wilkinson made clear that expert evidence in itself was not determinative.[412] Upon analysis, the judge found that a hypothetical refusal to intubate fell within the bounds of reasonable practice.

(i) The logic of *Bolitho*

For those commentators who had previously adhered to the conventional approach to *Bolam*, *Bolitho* was initially interpreted as a paradigm shift; it was the first time that the Court of Appeal had explicitly stipulated that the judge could engage with the content of a medical decision about materiality.[413] For example, Kennedy and Grubb argued that *Bolitho* required the courts to cast aside *Sidaway* (as a flawed interpretation of *Bolam*) and instead construct normative standards which could guide information disclosure.[414] Other commentators took a more revisionary approach - re-analysing pre-*Bolitho* case-law, particularly at first instance, to argue that a trend of judicial analysis was identifiable as early as the 1990's.[415] Miola and Brazier, and later Grubb, for example, argued that the professional standard was not without redemption and that *Bolam* had simply been misapplied.[416] Jurisdiction orientated commentators argued that this judicial engagement sparked the potential for normative law making. Teff, for example, claimed that: '[a]lthough there remains a strong argument for jettisoning *Bolam*, in whatever form, it is unclear whether such a move would substantially alter outcomes.'[417] Miola went

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[411] *Ibid*, 778

[412] *Ibid*, 779: "[…] In the vast majority of cases the fact that distinguished experts in the field are of a particular opinion will demonstrate the reasonableness of that opinion. In particular, where there are questions of assessment of the relative risks and benefits of adopting a particular medical practice, a reasonable view necessarily presupposes that the relative risks and benefits have been weighed by the experts in forming their opinions. But if, in the rare case, it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible."

[413] A. Grubb & I Kennedy, "Consent to Treatment: The Competent Patient" In, I. Kennedy & A. Grub (eds.), *Principles of Medical Law* (Oxford University Press, 1998), 173

[414] I. Kennedy & A. Grubb, *Medical Law: Text with Materials.* (Butterworths, 2000), 440-441

[415] *Ibid*, H. Teff, 'The Standard of Care in Medical Negligence - Moving on from *Bolam*?' (1988) 18(3) *Oxford J Legal Stud* 473-484, 477-478: "[i]n the last decade, there has been a pronounced shift in the rhetoric of medical negligence case law favouring a more interventionalist stance. Commentators speak of a new Dawn, 'new *Bolam*', and a 'hard look at the evidence'."

[416] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 98-99; Brazier and Miola admit that: '[…] *Bolitho* is not the first judgement which seeks to correct misinterpretations of the *Bolam* test.' Could this not simply be that the correct *Bolam* test was being utilised correctly before? Relying on *Hucks v Cole* [1993] 4 Med L.R. 393; *Joyce v Merton, Sutton & Wandsworth HA* [1996] 7 Med L.R. 1; *Clarke v Adams* (1950) S.J. 599; *Jones v Manchester Corp* [1952] 2 All E.R. 125; *Wisznieski v Central Manchester Health Authority* [1996] 7 Med L R 245. See also, A. Grubb, 'Negligence, Causation and *Bolam*.' (1998) 6 *Med L Rev* 378, 380.

[417] H. Teff, 'The Standard of Care in Medical Negligence - Moving on from *Bolam*?' (1988) 18(3) *Oxford J Legal Stud* 473-484, 483

further arguing that *Bolitho* offered an opportunity for the creation of normative standards if the judge determined that insufficient weight was being regularly placed on patient autonomy.[418]

However, other commentators initially took a more reserved approach,[419] recognising that the potential for normative change 'should not be oversold.'[420] Indeed, the House of Lords argued that the requirement for logic did not apply to information disclosure (probably because of the primarily moral nature of the determination)[421] although it was later applied in *Pearce*.[422] Mulheron comments, *Bolitho* simply became a gloss on *Bolam* – that expert evidence was accepted as credible and then evaluated for its logic.[423] In terms of jurisprudence, the conservative commentators were correct - Lord Browne-Wilkinson made clear overriding the doctor should only happen in circumstances, where ' a judge can be satisfied that the body of expert opinion cannot logically be supported at all.'[424] Dillon LJ went as far as to say that this needed to be the standard of Wednesbury unreasonable.[425]

Jurisprudential conflict about how *Bolitho* would be applied in practice had a confusing effect on how doctors should make medical decisions in practice to avoid litigation.[426] The heavy moral content of the decision meant that doctors were exposed to attack from the jurisdiction school about the empirical legitimacy of presumptions, compared to diagnosis and treatment which had (at the time) more

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[418] J. Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas.' (2009) 17(1) *Med L Rev* 76-108.

[419] J.K. Mason & R.A. McCall Smith, *Law and Medical Ethics* (Butterworths, 1999), 283. See also, J. Montgomery, 'Time for a Paradigm Shift? Medical Law in Transition.' (2000) 53 *Current Legal Problems* 363, 375; P.D.G. Skegg, 'English Medical Law and 'Informed Consent': An Antipodean Assessment and Alternative.' (1999) 7 *Med L Rev* 135, 145-146; M.A. Jones, 'Informed Consent and Other Fairy Stories.' (1999) 7 *Med L Rev* 103, 117-118.

[420] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85,114, 100-101. See a similar interpretation by J. Herring, *Medical Law and Ethics*. (Oxford University Press, 2010), 108.

[421] *Bolitho v City and Hackney Health Authority* [1997] 4 All ER 771, at 778.

[422] *Pearce v United Bristol Healthcare NHS Trust* [1998] EWCA Civ 865; M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85,114, 105.

[423] R. Mulheron, 'Trumping *Bolam*: A Critical Legal Analysis of Bolitho's "Gloss".' (2010) 69(3) *Camb L J* 609-638, 617-618; J. Montgomery, *Health Care Law*. (Oxford University Press, 2003), 176; A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5 *Med L Int* 205, 222-224:

[424] *Bolitho v City and Hackney Health Authority* [1997] 4 All ER 771, at 779: "I emphasise that, in my view, it will seldom be right for a judge to reach the conclusion that views genuinely held by a competent medical expert are unreasonable. The assessment of medical risks and benefits is a matter of clinical judgement which a judge would not normally be able to make without expert evidence. As the quotation from Lord Scarman makes clear, it would be wrong to allow such assessment to deteriorate into seeking to persuade the judge to prefer one of two views both of which are capable of being logically supported. It is only where a judge can be satisfied that the body of expert opinion cannot be logically supported at all that such opinion will not provide the bench mark by reference to which the defendant's conduct to be assessed." See commentary by R. Mulheron, 'Trumping *Bolam*: A Critical Legal Analysis of *Bolitho*'s "Gloss".' (2010) 69(3) *Camb L J 609*-638, 617. Referring to: *Re B (A Child)* [2000] 1 W.L.R. 790 (Fam. Ct.), at 796, per Otter L.J.; *E v. Castro* [2003] EWHC 2066, 80 B.M.L.R. 14, at [99]. In *Bolitho*, Lord Browne-Wilkinson argued that judges would only "very seldom" reject the evidence of the defendant - this was reiterated in: *M v. Blackpool Victoria Hospital N.H.S. Trust* [2003] EWHC 1744 (Q.B.), at [42]. Also, *French v Thames Valley Strategic H.A.* [2005] EWHC 459 (Q.B.), at [112]; *Calver v Westwood Veterinary Group* (2000) 58 B.M.L.R. 194, per Simon Brown L.J., at [31]-[34]; *AB v Leeds Teaching Hospital N.H.S. Trust* [2004] EWHC 644 (Q.B.), 77 B.M.L.R. 145, at [226]

[425] *Bolitho v City and Hackney Health Authority [1993] 4 Med L.R. 381, 392.* Also, *Kushnir v Camden & Islington H.A.* (Q.B., 16 June 1995). Although there has been much academic and judicial criticism of confusion the public law term with negligence: I. Kennedy & A. Grubb, *Medical Law: Cases and Commentary* (Butterworths, 2000), 442: "it does not assist to introduce concepts from administrative law such as the Wednesbury test; such tests are directed to very different problems and their used, even by analogy, in negligence case can […] only serve to confuse." *Joyce v Merton Sutton and Wandsworth H.A.* (1995) 27 BMLR. 124

[426] A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5 *Med L Int* 205, 210

scientific content.[427] Teff identified that this exacerbated medical fears about litigation because doctors were unsure about what element of the medical decision had to be *logical*.[428] The logic test could be applied to any of the elements of medical decision-making: identification of factors, the assumptions about patient information needs, the identification of circumstantial needs, the weighing of factors and the harm threshold. Maclean undertook a review of case-law (64 cases) which utilised *Bolitho*'s gloss and found irregularity in judicial application. However, the number of doctors found liable post-*Bolitho* did increase:[429] in the Court of Appeal, nine defendants (out of 18) were found liable (50%). Four of the cases involved non-disclosure allegations and two defendants were found liable (one referred only to *Bolam*, the other to *Bolitho*).[430] At first instance sixteen defendants (out of 45 cases) were found liable (36%). Liability was more likely when *Bolitho* was specifically applied.[431]

Mulheron undertook a similar review of the substantive case-law and also found that judges applied *Bolitho* in a range of different ways to find liability:[432]

> (1) Ignoring a clear precaution to avoid adverse outcomes;
> (2) Lack of resources or conflict of duties;
> (3) Failure to weigh the comparative risks and benefits of the chosen course of conduct;
> (4) Where the accepted medical practice contravenes widespread public opinion;
> (5) Where the doctor's peer medical opinion cannot be correct when taken in the context of the whole factual evidence;
> (6) Where the doctor's expert medical opinion is not internally consistent; and
> (7) The peer professional opinion had adhered to the wrong legal test.

Logic has been used to interrogate every aspect of the medical decision.[433] Of particular concern was the requirement of a formal evidence-base for the identification of material factors, and presumptions about patient information need. Whereas the *Bolam* standard required deductive reasoning to assess the

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[427] M. A. Jones, 'Informed Consent and Other Fairy Stories.' (1999) 7 *Med L Rev* 103-134, 117-118: Also, F.A. Trindade, 'Disclosure of Risks in Proposed Medical Treatment.' (1993) 109 *L Q Rev* 352; M.A. Jones, '"Informed Consent" in the High Court of Australia.' (1994) 2 *Tort L Rev* 5; D.K. Malcolm, 'The High Court and Informed Consent: The *Bolam* Principle Abandoned.' (1994) 2 *Tort L. Rev* 81

[428] Teff, H. 'The Standard of Care in Medical Negligence – Moving on from *Bolam*?' (1998) 18 *Oxford J. Legal Stud* 43 at 481

[429] A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5 *Med L Intl* 205, 211

[430] *Ibid*

[431] *Ibid*, 212

[432] R. Mulheron, 'Trumping *Bolam*: A Critical Legal Analysis of Bolitho's "Gloss".' (2010) 69(3) *Camb L J* 609-638, 620-634

[433] Items 1-3 could roughly be considered the internal analysis, and 4-7 could roughly be considered the external analysis (see above).

internal logic of a decision, the jurisdiction school encouraged judges to make an independent assessment of this decision-making from scientific data.[434] For example, Maclean argued that:[435]

> (1) Where there is conflict about the clinical evidence, i.e., the material factors, the judge should decide this based on the balance of probabilities. This should be decided based on credibility alone.
> (2) Where the clinical evidence and interpretation are considered reasonable by experts, but the claimant claims it was not the right choice, he argues that the Judge should make an independent assessment, and could find the practice unreasonable, despite universal acceptance.

In relation to the external analysis, if there is conflict between experts about whether it amounts to a reasonable school of thought, the Judge can:

> (3) Decide that one expert is not credible, and reject their evidence, meaning that there is no supporting school of thought.
> (4) Accept one is illogical and thus both the expert and the defendant's decision are internally flawed.
> (5) Find that the internal logic and credibility of both experts is sound, and thus the decisions of the doctor fall into the spectrum of reasonability.[436]

The lack of a substantial content of sociological evidence to support the existence and utilisation of patient paradigms (beyond experience) meant that decisions appeared arbitrary to those not expert in a given field.[437] However, requiring a fixed method for the evaluation of patient needs necessarily requires a dynamic approach (which combines technical and moral content) through communicativeness and responsiveness to the patients' needs over the course of a consultation. This can require very many augmentations to decision-making to identify and weigh material factors appropriately.

If scientific data of risks, or sociological data of information need, was presented to the judge, this allowed them scope to critique the medical interpretation if it deviated from this seemingly objective data. However, judges received no formal training in scientific, or sociological methods, which meant that the specialist nature of the data could easily be misinterpreted.[438] Studies often focus on individual

[434] J. Keown, 'Reining in the *Bolam* test.' (1998) 57 *Camb L J* 248, 249.
[435] A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5 *Med L Int* 205, 211-222.
[436] *Ibid*, 211-222.
[437] See, N.M. Priaulx & M. Weinel, 'Behaviour on a Beer Mat: Law, Interdisciplinarity & Expertise.' (2014) *U.Ill.J.L. Tech & Pol'y* 361
[438] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85,114, 101

elements of the medical decisions, which are distinct from the complex combination of risks and benefits, circumstances, and needs and wishes of the patient which form the actual medical judgement. Abstracting interpretation from the *circumstantial* evidence would inevitably allow judges to make independent decisions with the benefit of hindsight. For example, the first instance judge, in *Bolitho*, found that intubation and resuscitation seemed like the only 'logical' option.[439] The process is of course infinitely more gruesome and indeed harmful than the lay person would imagine.[440] Maclean, identified a number of cases where judges rejected expert evidence, and instead, embarked on an independent decision-making process utilising the scientific data.[441] For example, in *Marriott West Midlands HA*, Bedlam LJ came to the conclusion that neither the defendant nor the claimant's expert position amounted to a responsible school of thought.[442] Pill LJ agreed, suggesting that as the defendant expert had based his opinion on the circumstances of the defendant, his opinion was invalidated. On this basis 'the judge is entitled to form her own view upon the logic of the medical evidence.'[443] The problem was more widespread at first instance. A trend emerged where judges independently assessed the factors in a decision, came to their own conclusion, and rejected expert evidence.[444] For example, in *Wisniewski v Central Manchester HA*, the judge utilised *Hucks v Cole*[445] to assert that doctors should have performed an artificial rupture on a pregnant woman whose foetus was in distress. The Court of Appeal reversing the decision made clear that whilst the judge can come to their own conclusion: '[a] judge has to be conscious of his own lack of medical knowledge and the fact that clinical decisions are often difficult to make.'[446] Similarly, in *Mirza v Birmingham HA*[447], the claimant suffered ischaemic damage of the spinal cord following a redo repair of the aorta. Eady J found for the defendant but criticised the lack of scientific rigour of the published literature on the subject.[448]

[439] *Bolitho v City and Hackney HA* [1997] 3 WLR 1151 at 1160: "Intubation is not a routine, risk-free process. Dr Robertson described it as 'a major undertaking – an invasive procedure with mortality and morbidity attached."
[440] A.M.G. Cordeiro, *et al*, 'Possible Risk Factors Associated with Moderate or Severe Airway Injuries in Children who Underwent Endotracheal Intubation.' (2004) 5(4) *Paediatric Critical Care Medicine* 364-368.
[441]A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5 *Med L Int* 205, 218-221
[442] *Marriott v West Midlands HA* [1999] Lloyd's L.R. Med. 23 (CA), 27; A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5 *Med L Int* 205, 211.212 As Maclean describes the process: "If there is no evidence as to what would be accepted as reasonable by a responsible body of opinion then the judge is required to approach the circumstances from first principles by assessing the relevant risks and deciding whether the defendant's course of action was reasonable."
[443] *Marriott v West Midlands HA* [1999] Lloyd's L.R. Med. 23, 30
[444] See also A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5 *Med L Int* 205; relying on cases where judges rejected expert evidence that the practice formed a respectable body of medical opinion: *Zinzuwadia v The Home Office* (2000) Transcript No. CV703426; 2000 WL 33148757; *Drake v Pontefract HA* [1998] Lloyd's L.R. Med 425; *Hutchinson v Leeds HA* (2000) Transcript No 1994 H No 08392; Hunt *v NHS Litigation Authority* (2000) Transcript No. 1998 H No. 800 per Hunt J, at [30]-[34]
[445] *Wiesniewski v Central Manchester HA* [1998] Lloyd's Rep Med 223, per Brooke LJ, at 235
[446] *Ibid, per* Brooke LJ at 235-236. Also, at 237: "it is quite impossible for a court to hold that the views sincerely held by Mr Macdonald ("an eminent consultant and an impressive witness") and Professor Thomas cannot logically be supported at all."
[447] *Mirza v Birmingham HA* [2001] EWHC QB 1.
[448] *Ibid*, [52]-[55], [100]-[103] & [107].

This 'common sense'[449] approach was not value-neutral. Unlike doctors, who could rely on corporate morality, independent assessments by judges were actually derived from their individual personal morality.[450] As Mulheron argued, this is problematic as a trend of superiority analysis in important areas of scientific research could have the effect of barring essential medical discoveries;[451] by ossifying old, or poor practices, as standards in law, by side-lining new research, or by creating incoherence in technical medical approaches.[452] Important to this thesis, however, is that this superiority assessment makes the actual standard of care in information disclosure unknowable. This legal or factual incoherence may go undetected for some time and my be proliferated due to the rapid increase in litigation.[453]

2.4.2. Normativity in ethical guidance

The requirement that the scientific and interpretative basis of decisions must be logical, encouraged the formalisation of medical decision-making processes in medical ethical guidance.[454] It was hoped that the formulisation of evidence-based standards would provide judges with a 'gold standard' which could act as the basis for evaluating the logic of medical decision-making; whilst still being compatible with the level of discretion necessary to act in the patients best interests.[455] As Miola argued, guidance which had been previously discursive in nature, and endorsed circumstantial decision-making, moved to objective rules and processes, which set the parameters by which the logic of medical decision-making could be judged (thus avoiding the risk of arbitrary judicial decision-making).[456] For example, in 1995, the GMC published *Good Medical Practice*, which contained a description of the appropriate conditions for the therapeutic doctor-patient relationship. It required medical relationship operated on trust, and the doctor had moral duties to the patient. However, there was scant advice about the content of information disclosure.[457] The 1998 guidance was much more prescriptive, and required that the doctor

[449] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85, 103. Indeed, Brazier and Miola argue: "*Bolitho* has set in train a process whereby judges scrutinise medical evidence, using the same mixture of common sense and logical analysis that they use to scrutinise other expert evidence in negligence claims against professionals such as architects and accountants."

[450] *Bolitho v City and Hackney Health Authority* [1997] 4 All ER 771, at 777-778 & 779-780.

[451] R. Mulheron, 'Trumping *Bolam*: A Critical Legal Analysis of Bolitho's "Gloss".' (2010) 69(3) *Camb L J* 609-638, 614; R. Heywood, 'The Logic of Bolitho.' (2006) 22(4) *Professional Negligence* 225-235, 230

[452] Hoffmann LJ, 'The Reasonableness of Lawyers 'Lapses.' (1994) 10 *Professional Negligence* 481: who argues that the judicial tendency to "rest upon well-worn formulae rather than to puzzle out the reason why one case was different from another' should be displaced."

[453] R. Mulheron, "Trumping *Bolam*: A Critical Legal Analysis of Bolitho's "Gloss"." (2010) 69(3) *Camb L J* 609-638, 617: "[…] more than a decade after *Bolitho* was handed down, there has been no judicial (or academic) undertaking of the type of close analytical exercise – of identifying "*Bolitho* factors"."

[454] S.R. Hirsch & J. Harris, *Consent and the incompetent patient: ethics, law and medicine*. (Gaskell, 1988), 33

[455]A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5 *Med Law Intl* 205, 218-221, 223; M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85, 99-100.

[456] See J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship*. (Hart Publishing, 2007), 48.

[457] GMC, *Good Medical Practice.* (GMC, 1995), [15]: "Because the doctor-patient relationship is based on trust you have a special responsibility to make the relationship with your patients work. If the trust between you and a patient breaks down either of you may end the relationship. If this happens, you must do you r best to make sure that arrangements are made promptly for the continuing care of the patient. You should hand over records or other information for use by the new doctor as soon as possible."

must 'give patients the information they ask for or need about their condition, its treatment and prognosis' and ensure that 'patients be fully involved in decisions about their care.' [458]

A similar increase in ethical content occurred in the semi-formal sector during the 1980's, the BMA updated the 1974 ethical guidance, [459] in 1980[460], 1981[461] and 1984[462] in *The Handbook of Medical Ethics*, along with specific advice sheets and guidance notes on a variety of areas.[463] However, like the GMC, the guidance contained little prescriptive content for information disclosure (other than providing a framework so that individuals could discover their own ethical solutions to dilemmas). [464] After *Bolitho*, the BMA published *The Philosophy and Practice of Medical Ethics.*[465] This guidance recommended that doctor's made ethical decisions using a principled approach, which it was hoped would lead to more substantive: 'arguments and counter-arguments which lead either to universally accepted ethical principles or consensus views.'[466] Miola argued that this changed the 'emphasis towards direction rather than debate.'[467] As Kessel argued, doctors in the UK moved towards decision-making grounded on weighing and balancing principles, rather than circumstances;[468] this encouraged the development of a more explicit moral consensus about how principles, and more specifically about how autonomous should be facilitated by the medical profession.[469] The Blue Book, published in 1993 [470] was, again, more explicit in requiring the doctor to disclose all the information that the patient 'needs or desires' and that Lord Scarman's judgement was the appropriate ethical, if not legal, position.[471] Later editions encouraged more substantive recording of ethical decision-making, for example, by recommending doctors make decisions using flow-charts.[472]

[458] GMC, *Good Medical Practice.* (GMC, 1998), [12]
[459] BMA, *Medical Ethics*. (BMA, 1974)
[460] BMA, *The Handbook of Medical Ethics*. (BMA, 1980)
[461] BMA, *The Handbook of Medical Ethics*. (BMA, 1981)
[462] BMA, *The Handbook of Medical Ethics*. (BMA, 1984)
[463] V. Nathanson, *Report to the Penrose Enquiry*. (Penrose Enquiry, 2012),3: "In addition the BMA has always produced specific advice sheets and guidance notes on a variety of areas. The areas on which specific advice is seen as necessary are spotted either by clusters of requests for advice or because the ethics staff observe a clinical development that might lead to ethical questions. Such guidance can be on broad issues, including how ethical constraints should apply to a new scientific development, or on the very specific ethical elements applied to individual care and the individual patient doctor relationship."
[464] Ibid, 2
[465] BMA, *The Philosophy and Practice of Medical Ethics*. (BMA, 1988)
[466] I. Kessel, 'Book Review.' (1988) 14 J*ournal of Medicine and Philosophy* 709-710, 709
[467] J. Miola, *Medical Law and Medical Ethics: A Symbiotic Relationship*. (Hart Publishing, 2007), 50
[468] I. Kessel, 'Bool Review.' (1989) 14 *Journal of Medicine and Philosophy*, 709-710, 709: "[…] there is a real need in Britain for thoughtful discussion of these issues, and especially for one that can reach Britain's doctors. For despite the work of the London Medical Group, and its progeny around the country, and of the efforts of the Institute of Medical Ethics and its Journal, doctors and their patients are very rarely exposed to principles arguments concerning issues such as the status of the foetus, informed consent and treatment decisions, human experimentation, or the allocation of the NHS resources (all topics mentioned in the BMA Book)."
[469] J. Miola, *Medical Law and Medical Ethics: A Symbiotic Relationship*. (Hart Publishing, 2007), 50
[470] BMA, *Medical Ethics Today: Its Practice and Philosophy*. (BMJ Publishing Group, 1993)
[471] See Chapter 3, Section 1; BMA, *Medical Ethics Today: Its Practice and Philosophy*. (BMJ Publishing Group, 1993), 10
[472] J. Miola, *Medical Law and Medical Ethics: A Symbiotic Relationship.* (Hart Publishing, 2007), 52-53; BMA, *Medical Ethics Today: The BMA's Handbook of Ethics and Law* (BMA, 2004), 8.

As medical guidance moved towards normativity, as a way to ensure that decision-making could stand-up to 'logical' scrutiny, any deviation from these norms in practice could be attacked using the *Bolitho* judgement.[473] For example, Samanta *et al* undertook an empirical study which found that guidance was used as either a 'sword or shield' in litigation.[474] This encouraged doctors to follow processes rather than meet the ends of medicine; by providing information that patients needed according to their particular circumstances.[475]

2.4.3. Effect of *Bolitho* in practice

The last section argued that *Bolitho* encouraged the development of medical ethical guidance which formalised the medical decision-making process, and required the doctor to place emphasis on patient autonomy as the paramount principle to judge patient information need.[476] Whilst *Bolitho* did not create normative standards, per se, the combination of *Bolam* and *Bolitho* meant that normativity within ethical rules could be adopted, as part of the external test, to find doctors liable. This fear was exacerbated by the transatlantic spectre of a litigation-crisis, which encouraged the adoption of rigid processes of decision-making.[477] This fear is not altogether unfounded, as Jones and Robertson[478] argued, as whilst litigation on the basis of information disclosure was not often successful, it became common to addendum allegations on to other negligence claims.[479]

This fear of litigation was recognised in many of the identified studies, and acted as an impetus to construct an objective checklist for the disclosure process to ensure legal compliance.[480] Some senior doctors would refuse to undertake the consent process; leaving duties to junior colleagues and house officers, who lacked experience and would undertake 'routinised' processes.[481] Doctors became reluctant to circumstantially deviate from patient paradigms. Several studies were undertaken to create statistically supported decision-analysis frameworks, which doctors could utilise to justify their decision-making methodologies.[482] Some commentators advocated disclosure from a 'comprehensive

[473] H. Teff, 'The Standard of Care in Medical Negligence - Moving on from *Bolam*?' (1988) 18(3) *Oxford J Legal Stud* 473-484, 484

[474] A. Samanta, *et al*, 'The Role of Clinical Guidelines in Medical Negligence Litigation: A Shift from the *Bolam* Standard?' (2006) 14(3) *Med L Rev* 321-366, 340-343; J.E. Pelly, Clinical Practice Guidelines Before the Law: Sword or Shield?' (1998) 169(9) *MJA* 330-333

[475] See, B. Hurwitz, 'How Does Evidence Based Guidelines Influence Determinations in Medical Negligence?' (2004) 329(7473) *BMJ* 1024-1028; A. Samanta, *et al*, 'Legal Considerations of Clinical Guidelines: Will NICE Make a Difference?' (2003) 96(3) *J R Soc Med* 133-138

[476] P. Meredith, 'Patient Participation in Decision-Making and Consent to Treatment: The Case of General Surgery.' (1993) 15(3) *Sociology of Health & Illness* 315, 315-316; A. L. Caress, *et al*, 'Patient-Sensitive Treatment Decision-Making? Preferences and Perceptions in a Sample of Renal Patients.' (1998) 3(5) *Journal of Research in Nursing* 364-372, 364.

[477] *Ibid*, 329

[478] G. Robertson, 'Informed Consent Ten Years Later: The Impact of *Reibl v Hughes*.' (1991) 70 *Can Bar Rev* 423

[479] M.A. Jones, 'Informed Consent and Other Fairy Stories. (1999) 7 *Med L Rev* 103-114, 121.

[480] See for example, L.M. Wallace, 'Informed Consent to Elective Surgery: The 'Therapeutic Value?' (1986) 22(1) *Soc Sci Med* 29-33, 29-30

[481] P. Meredith, 'Patient Participation in Decision-Making and Consent to Treatment: The Case of General Surgery.' (1993) 15(3) *Sociology of Health & Illness* 315, 328

[482] D. J. Mazur, 'Influence of the Law on Risk and Informed Consent.' (2003) 327 *BMJ* 731

list of post-operative complications.'[483] This checklist of objective information changed the focus from the actual patient to fulfilling the needs of the hypothetical legal patient.

> On the one hand, for surgeons the consent form was merely a bureaucratic affirmation of the implicit consent which stemmed from the patients willingness to be admitted to the ward […]. However, it could also on occasion constitute a threat to their clinical freedom to judge what was in the patient's best interests. Thus, there was also awareness of the increasing incidence of patients resorting to legal action in cases where surgery was performed which was not explicitly agreed to via the form. […].[484]

Dawes *et al* found that structured disclosure increased patient anxiety, as they were not able to direct consultations in the way they required.[485] Morris *et al* similarly found that requiring the disclosure of a prudent patient standard of information did nothing to reduce the anxiety of 63% of patients (n=312).[486] Requiring a normative standard of information, potentially undermined the actual process of medical decision-making, first, by preventing the experiential development of patient archetypes according to patient need. Second, reducing discretion prevented the doctor from making a *circumstantial-moral* decision, to act in the individual patient's best interest.[487]Communications also became more formalised, through increasing amounts of documentation[488] and structured interview techniques.[489] Consent forms became the norm. However, '[…] consent forms [were] viewed by many doctors as a substitute for talking to patients, and by many patients as nothing but paperwork.'[490] Doctors were also encouraged to formalise the timeline of the consent process, despite patients understanding, and thus information need, developing at different rates. Doctors often dumped information on patients in a tick-boxing process to evidence a legal consent.[491] Patients also complained of the artificiality of signing a

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[483] D.D. Kerrigan, *et al*, 'Who's Afraid of Informed Consent?' (1993) 306 *BMJ* 298-300, 298

[484] P. Meredith, "Informed Consent: Court Viewpoints and Medical Decision-Making." In J. Dowie & A. Elstein, *Professional Judgement: A Reader in Clinical Decision Making.* (Cambridge University Press, 1988), Chapter 28; P. Meredith, 'Patient Participation in Decision-Making and Consent to Treatment: The Case of General Surgery.' (1993) 15(3) *Sociology of Health & Illness* 315, 327

[485] P.J.D. Dawes, *et al*, 'Informed Consent: The Assessment of Two Structured Interview Approaches Compared to the Current Approach.' (1992) 106 *The Journal of Laryngology and Otology* 420-424, 423-424

[486] L.M. Louise, 'Informed Consent to Elective Surgery: the 'Therapeutic' Value?' (1986) 22(1) *Soc Sci Med* 29, 30

[487] K. Montgomery, *How Doctors Think: Clinical Judgement and the Practice of Medicine.* (Oxford University Press, 2006), 43; K. Montgomery, 'Narrative, Literature, and the Clinical Exercise and Practical Reason.' (1996) 21 *Journal of Medicine and Philosophy* 21.

[488] T.D. Bunker, 'An Information Leaflet for Surgical Patients.' (1983) 65 Annals of the Royal College of Surgeons 242, 243. Relying on Nuffield Working Part on Communication with Patients, *Talking with Patients.* (Kings Fund Survey, 1977); P.J.D. Dawes, *et al*, 'Informed Consent: Using a Structured Interview Changes Patients' Attitudes Towards Informed Consent.' (1993) 107 *The Journal of Laryngology and Otology 775*-779, 775-777; A.P. Armstrong *et al*, 'Informed Consent: Are We Doing Enough?' (1997) 50 *Journal of Plastic Surgery* 637-640

[489] See for example, P.J.D. Dawes, 'Informed Consent: The Assessment of Two Structured Interview Approaches Compared to the Current Approach.' (1992) 106 *The Journal of Laryngology and Otology* 420-242

[490] Anonymous, 'Adequately Informed Consent.' (1985) 11 *J Med Ethics* 115-116, 116

[491] P. Meredith, 'Patient Participation in Decision-Making and Consent to Treatment: The Case of General Surgery.' (1993) 15(3) *Sociology of Health & Illness* 315, 327

consent document. The therapeutic purpose of disclosure was abandoned, and as such the process of consent, and therefore disclosure, was interpreted by patients as a barrier to receiving treatment.[492]

[492] *Ibid*, 329

CHAPTER 3: *SIDAWAY* AND THE RIGHTS SCHOOL OF THOUGHT: 1957-1997

The rights school monopolised on the success of the jurisdiction school by arguing that the content of normative rules, in law and ethics, should be focused on providing patients information so that they could have an autonomous consent to treatment. It is important to set-out these distinct arguments as they act as the theoretical basis for the attack on *circumstantial moral* decision-making. Recognising how the attack on medical morality has developed, allows the thesis to reflect on how, and why, medical decision-making has deviated from legal standards in later chapters; thus, answering the central question posed by this thesis.

The rights-based arguments have attacked *circumstantial moral* decision-making from two perspectives:[1]

Section 1 identifies the *internal critique* of medical decision-making within the therapeutic doctor-patient relationship. The rights school argued that doctors paid insufficient regard to the therapeutic benefits of autonomy and thus did not attribute patient needs, values and choices with appropriate weight. Autonomy should therefore be seen as therapeutically essential. As a result, it was argued that the courts should impose a normative ethics that enshrined self-determination and various models of patient autonomy as supreme in the hierarchy of bioethical principles.[2] The paradigm of patient needs should therefore be externally constructed.

Section 2 deals with the theoretical foundations of the *external critique,* which argued that a process of *medicalisation*[3] had stretched medical discretion into areas of societal decision-making; where the therapeutic teleology of the medical relationship was illegitimate. Instead, rights commentators argued that the therapeutic relationship should be abandoned, and instead, principles which define and limit the boundaries of medical discretion should be derived from a common morality, or societal norms.[4] These arguments manifest in the law through the adoption and incorporation of supra-national human rights instruments into domestic legislation and common-law. The consumer model of the medical relationship allowed the proliferation of patient rights: as it afforded patients increased power and control.[5] This model placed autonomy as the teleological purpose of disclosure. To facilitate and

[1] These distinct normative positions are seldom recognised by the judiciary or within the academic literature. Instead, the deontic and teleologic arguments are conflated in a global argument for the adoption of informed consent.
[2] *Sidaway v Board of Governors and Bethlem Royal Hospital* [1985] AC 871, per Lord Scarman at 884. See, R. Gillon, 'Ethics Needs Principles – Four Can Encompass the Rest – and Respect for Autonomy Should Be "First Among Equals."' (2003) 29 *J Med Ethics* 307-312
[3] D. Pereira Gray, 'Medicalisation in the UK: Changing Dynamics, but Still Ongoing.' (2016) 109(1) *J R Soc Med* 7-11; C. Piciocchi, 'The Definition of Health and Illness and Between Juridification and Medicalisation: A Private/Public Interest Perspective.' (2018) 25(2) *European Journal of Health Law* 177-195.
[4] T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics*. (Oxford University Press, 2013), 2-5
[5] See for example, I. Kennedy, 'Consumerism in the Doctor-Patient Relationship.' (1980) 11 *The Listener* 777-780; H. Teff, *Reasonable Care: Legal Perspectives on the Doctor-Patient Relationship.* (Clarendon Press, 1994) 94-116

safeguard patient choices, patients had to provide an informed consent to treatment. Informed consent ensured that patients had a form of autonomous choice; however, the appropriate model of autonomy was contested.[6]

Section 3 sets out the internal, and external, requirements of each model of autonomous choice which have since acted as the theoretical foundation for normative duties and standards within the law of medical negligence. It is important to set out the contents of these conceptual models so later chapters can draw attention to the conflation and incompatibility of requirements within the law and formal ethics. It is argued that these conceptual conflations are a root cause of many of the major problems experienced by doctors in their decision-making practices, and thus, deviation from normative rules.

Section 4 is concerned with the manifestation of informed consent in common law. Both the therapeutic and consumer relationship requires that the doctor disclose information to patients. As Chapter 2 argued, the therapeutic relationship required that doctors disclose information in the patient's best interests, and this requirement was accommodated in the law of negligence, which operated under the *Bolam* standard. The consumer relationship requires the disclosure of information to ensure an autonomous choice, as the basis of informed consent. The requirement to achieve an autonomous choice has been traditionally housed within the law of battery. However, the judiciary prevented the development of a duty of information disclosure under this cause of action, due to policy considerations.[7] This meant that the requirement of information, to achieve an informed consent, has to also be accommodated within the law of negligence. However, the teleological aim of the therapeutic and consumer relationships are incompatible. This will inevitably create confusion as to why doctors are disclosing information to patients, and thus, what information is material.

Section 5 examines the development of the patient-consumer and rebuts the empirical claim of the rights school: that patients could and/or wanted to be consumers of medicine, by problematising the capacities necessary to have an informed consent and the creation of a capacity-gap. It goes on to argue that most patients wanted to take a passive role in the medical relationship. The creation of normative duties, which require the doctor to ensure an informed consent, are therefore both potentially unachievable in practice, and harmful to patients who can't, or refuse, to make autonomous choices.

3.1. Internal critique

The extent to which the aims of the rights school of thought should be implemented occurred on a spectrum, dependent on the extent to which it was thought that doctor should hold decision-making

[6] See, section 2.3
[7] *Chatterton v Gerson* [1981] QB 432

power within the medical relationship.[8] At one end of the spectrum, commentators argued that moral medical decision-making should be orientated to place more weight on patient autonomy, as the foundation of a patient's best interests. Here, the provision of information would still ultimately be determined by therapeutic ends, but a normative rule in law, or ethics, would create a presumption within the operation of medical discretion, that a content of information was in the patients best interests.[9] At the other end, the therapeutic relationship was displaced completely, and replaced by a system of patient rights to information and treatment.[10] This section deals with the less ambitious rights based argument, which focused on reorienting the internal ethics of medical decision-making and how this has manifest within law.

Within the area of medical discretion, the principle of autonomy and beneficence are not incompatible; if, as McLean argued, they point in the same direction:

> […] it is unhelpful to characterise what is going on as a conflict between individual rights and collective beneficence. A collective 'good' is the sum of its constituent parts – in this case, the respect accorded to patients by their medical advisers is the core element in the general beneficence of the medical enterprise.[11]

Similarly, Lord Scarman, speaking extra-judicially, stated:

> The sovereignty of the patient – let us say, his or her right to make the ultimate decision – is in fact completely consistent with the common law. It is also consistent with the medical ethics, because the duty of the doctor has always been recognised as being to conduct himself in his relationship with his patient in a way which in his judgement conduces to further the best interests of the patient; to restore the patient to health, if possible, to relieve pain, and if possible to eradicate or minimise illness.[12]

Kennedy adopted this position in his analysis of the Court of Appeal decision in *Sidaway,*[13] arguing that to meet the duty in negligence required a positive content of information to protect the patient's

[8] J. Montgomery, 'Time for a Paradigm Shift? Medical Law in Transition.' (1988) 51(2) *MLR* 245-251, 249-250; J. Montgomery, 'Power/Knowledge/Consent: Medical Decision-making.' (2000) 53(1) *Current Legal Problems* 363-408, 363 & 387

[9] See for example, Lord Scarman, 'Consent, Communication and Responsibility.' (1986) *79 J Roy Soc Med* 697-700, 698

[10] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy (eds.), Treat *Me Right: Essays in Medical Law and Ethics*. (Oxford University Press, 1988), 178-180

[11] S.A.M. McLean, *A Patient's Right to Know: Information disclosure, the Doctor and the Law*. (Dartmouth, 1989), 7

[12] Lord Scarman, 'Consent, Communication and Responsibility.' (1986) *79 J Roy Soc Med* 697-700, 698

[13] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treat Me Rights: Essays in Medical Law and Ethics.* (Clarendon Press, 1988)

right to self-determination. This was grounded in a principled, Kantian, conception of autonomy,[14] which required a positive content of information to ensure an understanding, rather than limiting this duty to a negative[15] or Millian[16] concept of autonomy.[17] In this way a presumption that it was in the patients' best interests to have a standard of understanding as the basis of consent to treatment was created, meaning that there was a presumed standard of disclosure that would meet this basic information need, irrespective of the circumstances.[18] Relying on the battery case of *Freeman v Home Office,*[19] Kennedy argued that the circumstances of consent to treatment inserted these presumptions as relevant factors for consideration by the doctor.[20] These presumptions were recognised at common law, as the doctor was required to ensure that a consent was voluntary, and the patient was informed of the nature of a choice.[21] Robertson, similarly, argued that to ensure self-determination this model required freedom from interference, so the decision to undergo medical treatment should ultimately be that of the patient and that the patient should be given sufficient information to provide him with an opportunity of making this decision in a rational manner.[22] Robertson and Brazier argued that the extent to which information is necessary to protect autonomy can be determined by a professional standard; whereby, doctors decide the extent of the additional information need. Alternatively, the standard of information could be set as a prudent patient standard, where the information is defined by some metric (empirically, experientially, or by utilising the material characteristics of the actual patient) to fulfil the need of a hypothetical reasonable patient.[23] Or, the doctor can simply utilise the characteristics of the *actual* patient (similar to the model of *circumstantial-moral* decision-making), to decide what additional information is material and necessary for patient understanding (i.e. the particular patient standard).[24]

[14] See for example, O'O Neil, *Autonomy and Trust in Bioethics*. (Cambridge University Press, 2002), 73-95
[15] I. Berlin, "Two Concepts of Liberty." In I. Berlin, *Four Essays on Liberty*. (Oxford University Press, 2002)
[16] J. S. Mill, *On Liberty.* (Penguin Books Ltd, 1974)
[17] See a similarly distinction made by J. Coggon and J. Miola, 'Autonomy, Liberty and Medical Decision-Making.' (2011) 70(3) *Camb L J* 523-547, 526
[18] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kenned, *Treat Me Rights: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 177. Respectfully, this is a flawed argument, as it assumes that the level of understanding is universally achievable. As I will argue in Section 4, this is demonstrably false. This thesis would also reject the argument that a Kantian conception of autonomy required a type of understanding as the basis of a categorical imperative. Instead, autonomy under Kant should be understood as the absence of any substantive requirements and instead the freedom form external control or validation to use pure rationality as the basis of decision-making. I. Kant, *Metaphysics of Morals.* (1797), 4:433. A similar argument about the conflation of liberty and autonomy has been made by J. Coggon & J. Miola, 'Autonomy, Liberty, and Medical Decision-Making.' (2011) 70(3) *Camb L J* 523-547
[19] *Freeman v Home Office* [1984] 1 All ER 1036; *Freeman v Home Office (No. 2)* [1984] QB 524
[20] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treatment Me Rights: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 177
[21] *Ibid*
[22] Although Robertson recognises that other commentators add additional requirements of informed consent, such as intentionality, and freedom control. G. Robertson, 'Informed Consent to Medical Treatment.' (1981) 97 *L Q Rev* 102-126, 108
[23] G. Robertson, 'Informed Consent to Medical Treatment.' (1981) 97 *L Q Rev* 102-126, 108; M. Brazier, Patient Autonomy and Consent to Treatment: The Role of the Law.' (1987) 7 *Legal Studies* 169, 181-191.
[24] *Ibid*. Relying on D.E. Seidelson, 'Medical Malpractice: Informed Consent in 'Full-Disclosure' Jurisdictions.' (1976) 14 *Duq L Rev* 309

3.1.1. Justification for a normative standard in law

Kennedy argued that the need to protect autonomous choice should compel the senior courts in England and Wales to enshrine these internal maxims of decision-making as standards in law. [25] He therefore strongly attacked the policy basis on which the Court of Appeal rejected the prudent patient standard of care in *Sidaway*, and instead endorsed a libertarian model of autonomy i.e. where the patient should be entitled to a choice about the information that they would receive.[26] It is necessary to, briefly, review these arguments, as they have acted as the backbone of judicial reasoning, for both the adoption of informed consent, and later redefining the purpose and standards of information disclosure within law.[27]

The Court of Appeal recognised that providing an objective standard of information had the potential to cause patients psychiatric harm; if providing the information made them overly anxious or altered their ability to make a rational choice, because they would overweigh elements of the information. It would also be a dignitary harm if patients did not want to receive information,[28] and may not fulfil the information need for the actual patient because of their values. Kennedy argued, first, that the requirement of an objective standard would not cause patient harm because of the existence of a therapeutic privilege. Specifically, he argued that this would not undermine the standard of care, as it would not be a 'wide doctrine and probably only applies when to disclose the information would cause recognized physical and mental harm to the patient.'[29] Kennedy argued, that legal support for the therapeutic privilege could be found in the judgement of Browne-Wilkinson LJ, who stated that information could be withhold from a patient where it might potentially cause significant harm.[30]

Mulheron, in a more recent analysis of the case-law surrounding therapeutic disclosure, supports Kennedy's contention that the therapeutic defence has been established in the Law on England and Wales.[31] Mulheron posits that since the Court of Appeal judgement, *Pearce v United Kingdom Healthcare NHS Trust* (dealt with below), could be considered a case which is illustrative of the proper application of the therapeutic privilege. This was because Lord Woolf decided that: '[p]articularly when

[25] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treatment Me Rights: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 179; *Sidaway v Board of Governors and Bethlem Royal Hospital* [1984] 1 All ER 1018, per Dunn J, at 1036
[26] *Ibid*, 183-184
[27] See Chapter 4, Section 1; *Pearce v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118
[28] For example, *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1984] 2 WLR 778, per Lord Browne-Wilkinson, at 799-800
[29] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treatment Me Rights: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 187; Law Reform Commission of Canada, *Consent to Medical Care* (1980), 16
[30] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treat Me Rights: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 185. Referring to *Sidaway v Board of Governors and Bethlem Royal Hospital* [1984] 1 All ER 1018, per Browne-Wilkinson LJ, at 1034.
[31] R. Mulheron, 'Has *Montgomery* Administered the Last Rites to Therapeutic Privilege? A Diagnosis and a Prognosis.'(2017) 70(1) *Current Legal Problems* 146-188, 157-160

one bears in mind Mrs Pearce's distressed condition, one cannot criticise Mr Niven's decision not to inform Mrs Pearce of that very, very small additional risk.'

However, this author would reject the contention that the therapeutic privilege acts as an adequate safeguard. Whilst, on the face of it, one might very well argue that this seems to be a judgement made on the basis of the harmful impact of information on the claimant.[32] The statement must be placed into context. First, this was an orbiter comment, made in the context of a previous finding, that the information disclosed was not material to a prudent patient standard. Second, the therapeutic defence was never argued in *Pearce*, so the judge would not be entitled to make legal findings on that basis. Third, the comments were a finding in relation to medical decision-making operating in a therapeutic relationship. The doctor was therefore entitled to weigh up the pros and cons of disclosing information in the patients best medical interests – using a process of *circumstantial-moral* decision-making.[33] Indeed, this is illustrated by the quotation of Lord Woolf's judgement - which Mulheron uses to support her contention.[34]

> The obstetrician was entitled to take account of the effect that disclosure might have on the 'state of the patient at the particular time, both from the physical point of view and an emotional point of view.'[35]

The therapeutic privilege defence, on the other hand (as Mulheron and Kennedy seem to understand it) would apply as a stand-alone test used to mitigate the excesses of a model of informed consent. As will be argued below, informed consent is a manifestation, or requirement, that forms part of a consumer-type medical relationship. Indeed, Kennedy makes his claim on the basis that Browne-Wilkinson LJ was endorsing the requirement of an informed consent i.e. that 'there is a prima facie duty to inform.'[36] A therapeutic defence would seek to balance the principle of autonomy, operating through a standard of care in information disclosure, with a principle of non-maleficence, again, operating through a corresponding therapeutic privilege. This is a distinct operationalisation of the principle of non-maleficence, rather than the integrated approach adopted in therapeutic decision-making. The relationship specific nature of the therapeutic privilege, is similarly demonstrated in Mulheron's

[32] *Ibid*, 159.
[33] See Chapter 2, Section 2
[34] R. Mulheron, 'Has *Montgomery* Administered the Last Rites to Therapeutic Privilege? A Diagnosis and a Prognosis.'(2017) 70(1) *Current Legal Problems* 146-188, 159.
[35] *Pearce v United Kingdom Healthcare NHS Trust* [1999] PIQR P53, P60
[36] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treatment Me Rights: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 185-186; *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1984] 1 All ER 1018, per Browne-Wilkinson LJ at 1034

reliance on cases (to illustrate the existence of the therapeutic defence) which endorse a consumer-type of medical relationship and often a model of informed consent.[37]

Even if Mulheron is correct, as Cave argues, a detailed model of the therapeutic exception has not emerged in the Law of England and Wales. As such, the theoretical content and application of the therapeutic privilege remains legally contested.[38] Resultantly, doctors have never explicitly relied on it as a legal defence to justify a decision to restrict the content of disclosure.[39] Indeed, Mulheron recognises that despite the *Pearce* judgement, use of the therapeutic privilege is a 'rarity' and that 'all three comparator jurisdictions to avoid the tricky problem of articulating why, when, and to whom, the defence of therapeutic privilege should apply.'[40] She goes on to argue that this lack of specificity could have a significant impact on medical practice, arguing for:

> […] clearer guidance to doctors who are conducting appointments under often pressurised and difficult schedules, as to when the defence could excuse non-disclosure, is urgently required. It is also a question of fairness – if this defence is to persist, then the medical profession surely deserved a better explanation of it than has been judicially provided thus far.[41]

At the time, Kennedy too failed to deal with the potential problem of constructing a distinct (and corresponding) threshold, or test, for the therapeutic privilege defence. A test within law which attempts to define a threshold of material harm, would lead to the same type of problems created by the requirement to disclose a content of information to ensure an autonomous choice. For example, it might create, or lead to, assumptions about types of information which are deemed harmful to a reasonable, or prudent patient (objectively defined). These presumptions also have the potential to undermine the disclosure necessary for either an autonomous choice, according to the patient's subjective informational needs, or to fulfil the therapeutic needs of the actual patient.[42] This is problematic as

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[37] R. Mulheron, 'Has *Montgomery* Administered the Last Rites to Therapeutic Privilege? A Diagnosis and a Prognosis.'(2017) 70(1) *Current Legal Problems* 146-188, 159-160, for example: *Sidaway v Governors of Bethlem Royal Hospital* [1985] AC 871, per Lord Scarman at 889; *Thake v Maurice* [1986] QB 644 (CA); *McAllister v Lewisham and North Southwark Health Authority* [1994] 5 Med LR 343; *Poynter v Hillingdon HA* (1997) 37 BMLR 192 (QB); *Wyatt v Curtis* [2003] EWCA Civ 1779, per Kay LJ at [21]; *Chester v Afshar* [2004] UKHL 41, [16], [42] & [50]; *Deriche v Ealing Hospital NHS Trust* [2003] EWHC 2104 (QB), [40];

[38] E. Cave, 'The Ill-Informed: Consent to Medical Treatment and the Therapeutic Exception.' (2017) 46(2) *Common Law World Review* 140-168. See the contested definitions in M.A. Somerville, 'Therapeutic Privilege: Variation on the Theme of Informed Consent.' (1984) 12(1) *Law, Medicine and Health Care* 4-12; A.K. Edwin, 'Don't Lie but Don't Tell the Whole Truth: The Therapeutic Privilege – Is it Ever Justified?' (2008) 42(4) *Ghana Med J.* 156-161; K. Hodkinson, 'The Need to Know-Therapeutic Privilege: A Way Forward.' (2013) 21 *Health Care Analysis* 105-129; S. Menon, 'How Should the 'Privilege' in Therapeutic Privilege be Conceived When Considering the Decision-Making Process for Patients with Borderline Capacity?' (2021) 47 *J Med Ethics* 47-50.

[39] E. Cave, 'The Ill-Informed: Consent to Medical Treatment and the Therapeutic Exception.' (2017) 46(2) *Common Law World Review* 140-168.

[40] R. Mulheron, 'Has *Montgomery* Administered the Last Rites to Therapeutic Privilege? A Diagnosis and a Prognosis.'(2017) 70(1) *Current Legal Problems* 146-188, 187

[41] *Ibid*, 188.

[42] See Chapter 2, Section 4

individuals may be psychologically triggered, or harmed, by even mundane issues because of their personal circumstances.[43]

Secondly, Kennedy argued that a legal standard would not undermine confidence and trust in medical decision-making; instead, trust in the medical relationship would improve if the law requires an objective standard of information.[44] Kennedy relied on the President's Commission, which identified that individuals in the US wanted more information. He argued that this trend was also identified by the Royal Commission.[45] However, his references only indicate information preference, rather than evidencing the link between meeting information preferences and increasing trust or confidence.[46] To the contrary, as O'Neil argues, the triumph of informed consent has 'constrained, formalised and regulated the ways' that doctors communicate, and 'may erode patients' reasons for trusting.[47] This bureaucratisation of the medical relationship seems to be in antithesis to Kennedy's intention to construct a relationship where the 'patient can become a friend', which encourages 'openness and sharing of information.'[48] Nor, does Kennedy show why this type of relationship can only be achieved, or indeed, is more effectively achieved, through a standard in law, rather than perhaps orbiter, or ethical guidance.

Third, Kennedy rebuts the suggestion that a normative standard would open the floodgates of litigation, and lead to defensive medicine.[49] However, as Robertson[50] and later Teff[51] evidence, defensive practices did emerge as a result of objective standards in the US. Kennedy argued that the communitarian nature of healthcare in the UK would mitigate the potential harms of a litigation revolution.[52] This reliance on the public and utopian nature of the NHS is undermined, due to contemporary movements to towards marketisation of health within policy, organisation and infrastructure under consecutive conservative governments.[53] Indeed, this is a curious distinction to

[43] A. Abu-Rus, 'Informed Consent Content in Research with Survivors of Psychological Trauma.' (2018) 29(8) *Ethics & Behaviour* 595-606
[44] In opposition see *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1984] 2 WLR 778, per Sir John Donaldson MR, at 795
[45] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treat Me Rights: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 185-188; President's Commission for the Study of Ethical and Legal Problems in Medicine, *Making Health Care Decisions*. (US Government, 1982), 36, 43-44; Royal Commission, *Report of the Royal Commission on the National Health Service*, (HMSO, 1979), Chapter 5
[46] He also argues that I.E. Thompson, *et al*, 'Learning About Death: A Project Report from the Edinburgh University Medical School.' (1981) 7(2) *J Med Ethics* 62-66, shows this trend, but this student study propounds no such claim and fails to mention 'trust' at all.
[47] O. O'Neil, *Autonomy and Trust in Bioethics.* (University of Cambridge Press, 2002), 39
[48] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kenned, *Treat Me Rights: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 188
[49] *Ibid*, 186-191
[50] G. Robertson, 'Informed Consent to Medical Treatment.' (1981) 97 L Q Rev 102-126, 109
[51] H. Teff, Legal Perspectives on the Doctor/Patient Relationship' (Oxford University Press, 1994), 17-26
[52] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treatment Me Rights: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 189
[53] J. Harrington, *Towards a Rhetoric of Medical Law*. (Routledge,2017), Chapter 5

make in relation to health systems, when his substantive argument is drawn from legal principles operating within the private market of healthcare within the US. Kennedy[54] goes on to argue that commentators[55] like Robertson[56] 'may have been too persuasive' and their warnings may have become the cause of litigation panic. However, this argument is unpersuasive. Kennedy backs down from this assertion when he attempts to minimise the litigation revolution, within the US, by arguing that 'the number of cases has settled down.'[57] He seems to concede the argument when he states a number of state legislatures have intervened to reassert the professional standard in the US, because of the influx of litigation.[58]

Failing in his previous argument, Kennedy instead made the empirical claim that the judiciary must set an objective standard, because without any normative standards doctors made arbitrary decisions.[59] As the previous chapter illustrated, this claim lacks robust empirical foundation – doctors made decisions using patient paradigms and collective moral norms.[60]

3.1.2. The prudent patient standard

Despite the faults in Kennedy's critique, his approach was almost fully adopted within the judgement of Lord Scarman in the appeal to the House of Lords.[61] To understand how this rights argument has developed and proliferated as the template for judicial normativity in later chapters, it is important to briefly set out the content of this judgement, here.

Lord Scarman drew on the jurisdiction arguments, and adopted the conventional *Bolam* approach to critique McNair J, for creating an exclusive jurisdiction of medical decision-making.[62] Adopting Kennedy's argument, Lord Scarman suggested that the purpose of consent to treatment is to facilitate a human right of self-determination, which, Lord Scarman argued, has positive obligations that require

[54] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treatment Me Rights: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 189
[55] For example, H. Teff, 'Consent to Medical Procedures, Paternalism, Self-determination or Therapeutic Alliance.' (1985) 101 *L Q Rev* 432, 433-439. As Brazier argues, some commentators argue that informed consent opens up the doorway to strict liability; M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law.' (1987) 7 *Legal Studies* 169, 172. See A. Meisel, 'The Expansion of Liability for Medical Accidents: From Negligence to Strict Liability by Way of Informed Consent.' (1977) 56 *Nebraska Law Review* 51.
[56] G. Robertson, 'Informed Consent to Medical Treatment.' (1981) 97 *L Q Rev* 102, 109-112.
[57] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treatment Me Rights: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 189
[58] *Ibid*, 189. This was a point made in *Sidaway v Board of Governors and Bethlem Royal Hospital* [1985] AC 871, per Lord Scarman at 887. Indeed, in the five years since the explicit introduction of the prudent patient standard in *Montgomery*, there has been a staggering increase in published cases, with no less than 41 cases between 2015 and the beginning of 2020. See Chapter 6, Section 1 and Appendix 5.
[59] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treatment Me Rights: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 189
[60] See Chapter 2, Section 2
[61] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, per Lord Scarman at 886-887
[62] *Ibid*, 882

the doctor to provide information so that the patient can understand the collateral implications of treatment. [63]

> Known as the "doctrine of informed consent," it amounts to this: where there is a "real" or a "material" risk inherent in the proposed operation (however competently and skilfully performed) the question whether and to what extent a patient should be warned before he gives his consent is to be answered not by reference to medical practice but by accepting as a matter of law that, subject to all proper exceptions (of which the court, not the profession, is the judge), a patient has a right to be informed of the risks inherent in the treatment which is proposed.[64]

This common law right would require a distinct standard of information in the law of negligence, to ensure consent occurred with an adequate understanding.[65] However, Lord Scarman rejected the argument that there was a distinct equitable fiduciary relationship,[66] and instead, found that the duty was grounded on the moral requirements emerging from the therapeutic medical relationship.[67] Consequently, Lord Scarman required the doctor to provide information that would ensure proper respect for the patient's right to an autonomous choice as the basis of consent.[68] This was justified on Kennedy's contention that facilitating patient rights were in the patient's best interests.

> The root principle of common law negligence is to "take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour" […].[69] If it be recognised that a doctor's duty to care extends not only to health and well-being of his patient but also to a proper respect for his patient's rights, the duty to warn can be seen to be part of the doctor's duty of care.[70]

Thus, Lord Scarman argued that the doctor should have an additional duty to 'be required to exercise care in respecting the patient's right of a decision.'[71] The construction of the patient's rights was a matter for the court, leading to a duty for the court to investigate the methodology adopted by the doctor

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[63] *Ibid*
[64] *Ibid*
[65] *Ibid*, 883. Although, he recognised, if negligence could not accommodate this distinct right, then, the common law could create duties resulting from other types of moral relationship; *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, per Lord Scarman at 884. For example, the Appellant relied on *Nocton v Lord Ashburton* [1914] AC 932 per Viscount Haldane LC at 947 and *Derry v Peek* (1889) 14 App Cas 337, per Lord Haldane LC at 947: "There are other obligations besides that of honest the breach of which may give a right to damages. These obligations depend on principles which the judges have worked out in the fashion that is characteristic of a system where much of the law has always been judge-made and unwritten."
[66] *Ibid*
[67] *Ibid*
[68] *Ibid*, 885
[69] *Donoghue v Stevenson* [1932] AC 562, 580 per Lord Atkins
[70] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, per Lord Scarman at 885
[71] *Ibid*, 885-886

in making decisions.[72] As the patient had rights irrespective of the circumstances, a content of information would always be provided as was presumed to always be in their best interests; *vis a vi*, there is therefore a right to informed consent.[73]

Lord Scarman relied on *Canterbury v Spence* to argue that all patients should receive an objective level of information, or a prudent patient standard of understanding, as the basis of their consent to treatment.[74]

> a risk is […] material when a *reasonable person*, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy. (Emphasis supplied).[75]

He recognised the draw of requiring the doctor to provide information to a particular patient standard,[76] but accepted that it was unworkable as a standard in practice as '[t]he law does not operate in Utopia.'[77] Lord Scarman therefore adopted a prudent patient standard of materiality which he defined as 'the degree of likelihood of it occurring' according to some objective percentage threshold, in combination, with an objective view of the seriousness of the possible injury if it should occur, both of which 'can in most, if not all, cases be assessed only with the help of medical evidence.'[78] However, the doctor would also be compelled in some circumstances to provide additional information beyond this standard. For example, if the patient asked questions which required disclosure of additional information.[79] The doctor could hypothetically limit the right by utilising the therapeutic privilege, if he 'reasonably believed it to be against the best interests of the patient to disclose it.'[80]

Lord Scarman, perhaps recognising the weakness in Kennedy's empirical arguments, did not deal substantively with the risk of defensive medical practice developing. Instead, he argued that the role of the judge is to implement the law i.e., to define patient rights, and the effects of law 'are best left to the legislature.'[81] This is a curious position when Lord Scarman has adopted his approach based on the policy implications of a black-letter interpretation of *Bolam*. Indeed, Lord Scarman later argued on

[72] *Ibid*, 885
[73] *Ibid*, 885-886
[74] *Canterbury v Spence* 464 F.2d 772, 787 (DC Cir. 1972), 786. See Section 2.3, which argues that this standard is facilitative of a liberal model of autonomous choice.
[75] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, per Lord Scarman at 887
[76] *Ibid*, 886
[77] *Ibid*, 888. See Section 2.3, which also argues that this standard is facilitative of an authenticity model of autonomous choice, which is not compatible with a liberal model of autonomous choice, as they require the patient to have different threshold of understanding as the basis of their decision.
[78] *Ibid*, 888- 889
[79] *Ibid*
[80] *Ibid*, 889
[81] *Ibid*, 887

policy terms that his approach to the prudent patient standard was the leading judgement.[82] This was and remains manifestly incorrect, despite Kennedy's hyperbolic *postscript* to his earlier article.[83] Concerningly, his approach was adopted by first instance judges in a number of cases such as *McAllister v Lewisham & Norther Southwark HA*[84], *Smith v Tunbridge Wells*[85] and *Gold v Haringey.*[86] Rouiger J. in *McAllister*, for example, quoted the majority judgements in support of Lord Scarman. [87] This interpretation has subsequently acted as a template for judicial normativity in *Pearce*[88] and *Montgomery*.[89] This thesis argues that this type of revisionism is, and remains, problematic when the internal critique lacks empirical substantiation.[90] As Chapter 4 will argue, the lack of sociological reflexivity on medical decision-making has encouraged defensive practices, which undermine the purpose of an objective standard; as patients do not receive the information they need to make an informed consent; as a result, patient trust in the therapeutic medical relationship is damaged.[91]

3.2. The External critique

The previous section set out the internal rights critique: that decision-making should be orientated around facilitating the patient's right to autonomous choices, within the context of the therapeutic relationship. As this was not successful in the *Sidaway* judgement, rights advocates argued that the concept of the therapeutic relationship should itself be abandoned, advancing their argument through an external critique on the function of medicine in society, and the legitimacy of doctors to make decisions about the materiality of information outside their historical boundaries.[92] This is because the function of the doctor has extended into areas of decision-making where they do not have unique technical, or ethical, knowledge: a process called *medicalisation*.[93] This extension allows them to apply the technical moral distinction identified in the previous Chapter. Rights commentators, first in North America,[94] then the UK,[95] argued that, instead, decision-making in this area required the adoption of a

[82] Lord Scarman, 'Consent, Communication and Responsibility.' (1986) 79 *J Roy Soc Med* 697, 697.
[83] I. Kennedy, "Postscript." In I. Kennedy, *Treat Me Rights: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 210-211
[84] *McAllister v Lewisham and North Southwark HA* [1994] 5 Med L Rep 343
[85] *Smith v Tunbridge Wells HA* [1994] 5 Med L Rep 334
[86] *Gold v Haringey HA* [1987] 2 All ER 888
[87] J. Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas.' (2009) 17 *Med L Rev* 76-108, 96; *McAllister v Lewisham and North Southwark HA* [1994] 5 Med L Rep 343, 351
[88] *Pearce v United Bristol Healthcare NHS Trust* [1998] EWCA Civ 865
[89] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11
[90] J. Montgomery, 'Time for a Paradigm Shift? Medical Law in Transition.' (2000) 53(1) *Current Legal Problems* 363-408, 389-390
[91] See Chapter 2, Section 3
[92] See for example, I. Kennedy, *The Unmasking of Medicine*. (George Allen & Unwin, 1981), 130-139; J. Katz, *The Silent World of Doctor and Patient.* (John Hopkins University Press, 1984), 121-129; S.A.M. McLean, A *Patient's Right to Know*. (Dartmouth, 1989), 102-139
[93] See, P. Conrad, 'The shifting engines of medicalization.' (2005) 46 J *Health Soc Behav* 3-14; L. Frifth, "What do We Mean by 'Proper' Medical Treatment?" In S. Forvargue & A. Mullock (ed.), *The Legitimacy of Medical Treatment: What Role for the Medical Exception?* (Routledge, 2010), 34-36
[94] R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 86-100; J.W. Berg, *Informed Consent: Legal Theory and Clinical Practice*. (Oxford University Press, 2001), 41-52
[95] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law.' (1987) 7 *Legal Studies* 169, 170-172.

higher order of societal moral norms: termed a common morality,[96] to both limit medical discretion, and provide institutional safeguards for patients against the potentially arbitrary use of power by doctors. The medical relationship was turned on its head so the patient gained power to make decisions as a consumer who operated within a market of medicine.[97] The UK approach utilised human rights concepts as a way to legitimise the consumer relationship, forge fiduciary duties, and particularly, to enshrine the supremacy of the principle of autonomy, within medical decision-making.[98] Information disclosure was re-purposed to ensure an informed consent, rather than to provide information that facilitated the therapeutic needs of the patient.[99] The last sub-section illustrates the conceptual pit-falls of utilising existing principles within human rights law as a method for constructing a proactive ethics of autonomy through judge-made law.

3.2.1. The problem of *medicalisation*[100]

In the academic debates about informed consent, patient rights commentators argued for a distinct type of medical relationship; by problematising the role of the doctor within society, rather than problematising the internal content of medical decision-making, within the doctor-patient relationship.[101] As Kennedy argued, the internal morals of medicine, used for medical decision-making, were no longer suited to the types of social, ethical and political decisions required by the medical profession.[102] Smith explains that this occurred due to a definitional expansion around concepts of illness and disease. Doctors were using biomedical values, and scientific methodologies, in areas of life which required the weighing and balancing of biopsychosocial values, and the utilisation of societal ethics.[103] This extension also took place because of the rapid growth of novel biomedical technologies; for example, genetics, embryology, artificial reproductive technologies and life support.[104] The review of the regulation of cosmetics and human enhancement, for example, explicitly recommended that

[96] T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics.* (Oxford University Press, 2013), 2-10
[97] H. Teff, 'Medical Models and Legal Categories: An English Perspective.' (1993) 9 *J Contemp Health L & Pol'y* 211, 215-216
[98] M. Donnelly, *Healthcare Decision-Making and the Law: Autonomy, Capacity and the Limits of Liberalism.* (Cambridge University Press, 2010), 50-52, 77-78, 211-224
[99] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law.' (1987) 7 *Legal Stud* 169, 170-172; M. Jones, 'Informed Consent and Other Fairy Stories.' (1999) 7 *Med L Rev* 103-134, 104-105
[100] D. Pereira Gray, *et al*, 'Medicalisation in the UK: Changing Dynamic, But Still Ongoing.' (2015) 109(1) *J Roy Soc Med* 7-11.
[101] I. Kennedy, *The Unmasking of Medicine*. (George Allen & Unwin, 1981), Chapter 2
[102] I. Kennedy, "What is Medical Decisions?" In I. Kennedy (eds.), *Treat Me Right: Essays in Medical Law and Medical Ethics.* (Clarendon Press, 1988), 22-25. Also see, A. Frawley, "Medicalisation of Social Problems." In T. Schramme & S. Edwards (eds.), *Handbook of Philosophy of Medicine.* (Springer, 2015), 1-18
[103] R. Smith, "Bodily Integrity Identity Disorder: A Problem of Perception?" In A. Alghrani, *et al*, (eds.), *Bioethics, Medicine and the Criminal Law Volume 1: The Criminal Law and Bioethical Conflict: Walking the Tightrope* (Cambridge University Press, 2013); T. Elliot, 'Body Dysmorphic Disorder, Surgery and the Limits of Consent.' (2009) 17 *Med L Rev* 149; D. Meyers, *The Human Body and the Law: A Medico-Legal Study.* (Edinburgh University Press, 1970)
[104] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship.* (Hart Publishing, 2007), 36; R.H. Ebert, "A Twentieth Century Retrospective." In E. Ginzberg (ed.), *Medicine and Society – Clinical Decisions and Societal Values* (Westview Press, 1987), 15-18

doctors be co-opted as the sole providers and thus, regulators, of cosmetic medicines.[105] Commentators of the rights school articulated unease with medical professionals being automatically adopted as gatekeepers of this technology, as many of these roles went beyond their historical competence and ethical experience. In these areas, the medical profession, lacked a clear collective vision of what amounted to responsible medical practice.[106] As the boundaries of medicine expanded, the base-line of what amounted to reasonable or proper medical decisions inevitably changed. [107]

This is important, because as the parameters of medical decision-making expand, so do the values inherent within *circumstantial moral decision-making*.[108] If the doctor cannot understand, internalise and weigh values which are epistemically foreign to the medical enterprise, they cannot necessarily make decisions in the therapeutic interests of the patient.[109] As Kennedy argued, the legitimate scope of medicine and thus its function within society is a political question.[110] Even today, the political nature of medicine within society is demonstrated by debates over mask wearing during the Covid-19 pandemic, or the provision of puberty blockers to minors.[111] Values and principles external to medicine, however, are not necessarily compatible with the internal morality or teleology of medicine. For example, providing cosmetic enhancement to the patient may maximise the values of the patient, but it also requires abandoning exclusively therapeutic aims.[112] Miola argued that as technology grows and experimentation increases, the telos of the medical relationship shifts, which risks conceptualising the patient as no longer an *end* but as a *utility*.[113]

> In other words, while the new questions posed by medical technology are of concern to non-doctors, who therefore become involved in ethical debate, the medical profession paradoxically claims such issues as its own, and society's instinct is similarly to abrogate responsibility to it.

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[105] Sir Brue Keogh, *Review of the Regulation of Cosmetic Interventions: Final Report*. (Department of Health, 2013). A similar co-option occurred in relation to circumcision: M. Fox & M. Thomson, ''Short Changed?' The Law and Ethics of Male Circumcision.' (2005) 13 *International Journal of Children's Right* 161

[106] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law.' (1987) 7 *Legal Studies* 169, 173; I. Kennedy, "What is Medical Decisions?" In I. Kennedy (eds.), *Treat Me Right: Essays in Medical Law and Medical Ethics.* (Clarendon Press, 1988), 22-25

[107] P.D.G. Skegg, *Law Ethics and Medicine: Studies in Medical Law.* (Clarendon Press, 1984), 31.

[108] See Chapter 2, Section 2

[109] This creates its own epistemic and legitimacy problems as the role of the doctor becomes indistinct from other professions. See, M.O. 'Role Obligations.' (1974) 91(7) *Journal of Philosophy* 333-363; A.J. Simmons, 'External Justifications and Institutional Roles.' (1996) 93(1) *Journal of Philosophy* 28-36; K. Gibson, 'Contrasting Role Morality and Professional Morality: Implications for Practice.' (2003) 20(1) *J App Philos* 17-29; P. Cane, 'Role Responsibility.' (2016) 20(1-3) *J Ethics* 279-298; A. Baril, The Ethical Importance of Roles. (2016) 50(4) *J Value Inq* 721-734

[110] I. Kennedy, *Unmasking Medicine.* (George Allen & Unwin, 1981), 2-25 & 142: "I have already referred to the irritating and singularly ill-conceived argument of some scientists and engineers – that they are neutral researchers, seekers after knowledge. Their motives are solely concerned with truth, they argue. They cannot be held responsible for the mess mortals make of their innovation"

[111] K. Abbasi, 'Covid-19: Politicisation, "Corruption," and Suppression in Science.' (2020) 371 *BMJ* 4425; A. Walker, *et al*, *The Great Barrington Declaration* (2020): (https://gbdeclaration.org/)

[112] S.R. Mousavi, 'The Ethics of Aesthetic Surgery.' (2010) 3(1) *J Cutan Aesthet Surg* 38-40

[113] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship.* (Hart Publishing, 2007), 36; A. Jonsen, *The Birth of Bioethics.* (Oxford University Press, 1998)

> Medicine and the medical profession can be seen to not only not be value-neutral, but, through the medicalisation of social problems, very much involved in any debates that society finds it hard to talk about.[114]

Similarly, Brazier and Miola argued that the proliferation of *medicalisation* was exacerbated by the judiciary in England and Wales, as they actively handed over the jurisdiction of ethical decision-making about societal issues to the medical profession.[115] This surrender of jurisdiction is recognised as a distinct species of *Bolamisation* (widening the *Bolamite* spectrum).[116] For example, in *Airedale NHS Trust v Bland*[117] the judiciary allowed the medical profession to define the requirements for the withdrawal of artificial nutrition and hydration from a PVS patient.[118] Commentators such as Katz rightly problematised the lack of both consensus, and normative guidance, in this novel area, because: '[g]ranting professionals such sweeping powers [are] dangerous for one obvious reason: the human proclivity to abuse power.'[119]As Maclean argued, in areas of novel practice, doctors have not acquired the collective experience to form moral norms, to ensure consistency.[120] As Siglar argued doctors cannot rely purely on medical ethics to make these decisions because as society becomes more a-religious and morally diverse the shared moral norms held between the profession and society evaporate.[121] Lack of a shared ethics between the profession and society raises questions about legitimacy and decision-making power.

Brazier and Forvargue rightly warn that the *Bolamisation* of areas of societal competence have extended the medical privilege into novel areas. In criminal law this privilege allowed doctors to make decisions which had the potential of severely harming the patient or even ending their lives.[122] Lord Mustill argued in *Airedale NHS Trust v Bland* : '[i]f one person cuts off the hand of another it is no answer to say that the amputee consents to what was done',[123] however, 'bodily invasions in the course of proper medical treatment (if that treatment reaches a reasonable standard) is completely outside the 'criminal law.'[124]

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[114] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship.* (Hart Publishing, 2007), 36
[115] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 91
[116] *Ibid*, 91-93; *Re F (Mental Patient: Sterilisation)* [1990] 2 A.C. 1, per Lord Goff, at 567: "No doubt, in practice, a decision may involve others bedsides the doctor. It must surely be good practice to consult relatives and others who are concerned with the care of the patient. Sometimes of course, consultation with a specialist or specialists will be required; and in others, especially where the decision involves more than purely medical opinion, an inter-disciplinary team will in practice participate in the decision."
[117] *Airedale NHS Trust v Bland* [1993] All ER 821 (HL), per Lord Keith at 861 & per Lord Goff at 871
[118] *Ibid*, 92-93
[119] J. Katz, *The Silent World of Doctor and Patient.* (The John Hopkins University Press, 2002), 89
[120] S. Maclean, *Old Law, New Medicine: Medical Ethics and Human Rights.* (Rivers Oram Press), 1-2: "Without a healthy scepticism, and in absence of an informed debate, the process of empowering the profession can only continue. Moreover, in an increasingly secular Western world, the temptation to trust – indeed the need to trust – some body of people who are almost magical in what they appear to be able to achieve is even stronger."
[121] M. Sigler, 'Searching for Moral Certainty in Medicine: A Proposal for a New Model of the Doctor-Patient Encounter.' (1981) 57 *Bull NY Acad Med* 56, 61
[122] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law.' (1987) 7 *Legal Studies* 169, 173
[123] *Airedale NHS Trust v Bland* [1993] AC 789, 891
[124] *Ibid*, 889

Similarly, in *R v Brown* Lord Mustill noted that 'surgical treatment requires a degree of bodily invasion well on the upper side of the critical level will nevertheless be legitimate if performed in accordance with good medical practice and with the consent of the patient.'[125] Consequently, commentators such as Jones argued that blind or deferential trust to ensure patient safety can 'no longer provide the primary model of interaction between the doctor and patient.'[126]

3.2.2. Medical decision-making and the panacea of patient rights.

The potential harm of decision-making based on conscience, coupled with a *legal* medical privilege, provides a compelling argument for the limitation of medical discretion to pre-defined functions.[127] The extension of medical discretion also upsets the therapeutic relationship, as the internal morality becomes experientially diluted, through the cyclic re-creation of internal moral paradigms.[128] To save the legitimacy of medical decision-making an area of medical competence either had to be strictly defined, or safeguards put in place to prevent abuse.[129] Katz, and later Kennedy, for example, argued that the development of medical technology and techniques are both necessary, and inevitable, normativity would act to ossify the necessary development of medical practice. The therapeutic model which relied on medical expertise did not provide the safeguards necessary to prevent harm, it should therefore be abandoned and a consumer relationship should be adopted which reorientates power towards patient choice.[130] As the principles of the therapeutic relationship had to be abandoned, the theoretical underpinnings of this novel relationship had to be drawn from a higher layer of societal values.[131] Bioethicists, moral philosophers, and lawyers, began to forge a distinct normative paradigm as the basis for regulating the role of medicine within society, and thus, the conduct of professionals (globally)[132] who carry out those functions.[133] Miola, for example, termed this phenomenon as the proliferation of medical ethics.[134] It is important to recognise that this 'medical ethics' was distinct from medical (moral) ethics used to describe forms of professional *circumstantial-moral* decision-making, used to

[125] *R v Brown* [1994] 1 AC 212 per Lord Mustill at 259, per Lord Jauncey, at 245 and per Lord Templeman, at 231
[126] M.A. Jones, 'Informed Consent and Other Fairy Stories.' (1999) 7 *Med L Rev* 103-134, 104
[127] For example, S. Forvargue & A. Mullock, *The Legitimacy of Medical Treatment: What Role for the Medical Exception?* (Routledge, 2017); J. Montgomery, 'Patient No Longer? What Next in Healthcare Law?' (2017) 70(1) *Current Legal Problems* 73-109
[128] See, Chapter 2, Section 2; O' O'Neil, Accountability, Trust and Informed Consent in Medical Practice and Research.' 4(3*) Clin Med (London)* 269-276
[129] This thesis would argue that Brazier and Forvargue set out the best synopsis of arguments defining and therefore legitimising the scope of the medical privilege. See, M. Brazier & S. Forvargue, 'Transforming Wrong into Right. What is 'Proper Medical Treatment'?" In. S. Forvargue & A. Mullock (eds.), *The Legitimacy of Medical Treatment: What role for the Medical Exception?* (Routledge, 2016), 19
[130] J. Katz, *The Silent World of Doctor and Patient.* (John Hopkins University Press, 2002), 85-103; I. Kennedy, *Unmasking Medicine.* (George Allen & Unwin, 1981), 141-166
[131] *Ibid*
[132] S. Holm, 'Global Bioethics – Myth or Reality?' (2006) 7 *BMC Med Ethics* 10
[133] See for example, M. Schlesinger, 'A Loss of Faith: The Sources of Reduced Political Legitimacy for the American Medical Profession.' (2002) 80(2) *The Milbank Quarterly* 185-235; M. Davies, 'The Future of Medical Self-Regulation in the United Kingdom – Renegotiating the State-Professional Bargain?' (2014) 14(4) *Med L Int* 236-265; J. Montgomery, 'Patient No Longer? What Next in Healthcare Law?' (2017) 70 *Current Legal Problems* 73; T.T. Arvind & M. McMahon, 'Responsiveness and the Role of Rights in Medical Law: Lessons from *Montgomery*.' (2020) 28(3) *Med L Rev* 445-447
[134] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship*. (Hart Publishing, 2007), 38-40

regulate medical decision-making through the therapeutic framework. This new, external, and supposedly universalisable, medical ethics attempted to regulate medical decision-making, from debate outside the profession, utilising principles found axiomatically in liberal societies: such as dignity, freedom, and autonomy.[135] Whilst principles are shared between the relationships, a clear line should be drawn between an ethics which is internal and external to the therapeutic relationship, and a normative medical ethics which is drawn from an universalisable common morality.[136] Beauchamp and Childress, for example conceptualised the common morality, relating to medicine, as four principles: autonomy, beneficence, non-maleficence and justice.[137] Others, such as Gert *et al*, argued that there were up to 10 principles of medical ethics.[138] These principles can be interrogated in different contexts to form rules, through a process called *specification.*[139] These rules then formed the basis of an explicit ethics, which can be used by the consumer to enforce their rights within the consumer relationship. External ethics therefore explicitly shift the locus of power.[140]

It is important to draw-out, and differentiate, the content of this medical ethics; as it is made up of very different substance than that of therapeutic ethics, and thus requires a different deontic form of decision-making. Unfortunately, these two species have often been conflated, but unless one identifies the content of this medical ethics, and later its adoption in law, one cannot accurately recognise the effect that law has had on medical practice, and therefore how doctors make decisions.

3.2.3. The growth of patient rights

This section sets out how rights arguments developed, first, in the North American context, then, in the Law of England and Wales. As Harrington argues the dominant account of medical law is normatively and conceptually subordinate to medical ethics, or bioethics.[141] Understanding the history and context of the normative arguments within bioethics, and how they have been rhetorically utilised to support rights arguments in the US, exposes how patient rights have proliferated, transplanted, and become the

[135] I. Berlin, "Two Concepts of Liberty." In I. Berlin (ed.), *Four Essays on Liberty.* (Oxford University Press, 1969)
[136] See, B. Gert, *Common Morality: Deciding What to Do*. (Oxford University Press, 2004), 9, 19-20; T.L. Beauchamp & J. F. Childress, *Principles of Biomedical Ethics.* (Oxford University Press, 2013), 25-26; R.M. Veatch, 'Is There a Common Morality? (2003) 13(3) *Kennedy Institute of Ethics Journal* 189-192
[137] T. Beauchamp and J.F. Childress, *Principles of Biomedical Ethics*. (Oxford University Press, 2013), 6-8. See also an interesting argument by Rosamond Rhodes, where she argues that medical ethics needs to be delineated from the common morality, and advocates for a black-letter or closed ethics grounded on a normative ethical certainty: R. Rhodes, 'Why Not Common Morality' (2019) 45(12) J *Med Ethics* 770-777
[138] B. Gert, *et al*, *Bioethics: A Systematic Approach*. (Oxford University Press, 2006), 43
[139] T.L. Beauchamp and J.F. Childress, *Principles of Biomedical Ethics*. (Oxford University Press, 2013), 16. Also, T.L. Beauchamp, 'Methods and Principles in Biomedical Ethics. (2003) 29 *J Med Ethics* 269-274
[140] L.G. Reeder, 'The Patient-Client as a Consumer: Some Observations on the Changing Professional-Client Relationship.' (1972) 13(4) *Journal of Health and Social Behaviour* 406-412; S. Little, 'Consumerism in the Doctor-Patient Relationship.' (1981) 7 *J Med Ethics* 187-190; T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics.* (Oxford University Press, 2013), 7
[141] J. Harrington, *Towards a Rhetoric of Medical Law*. (Routledge, 2007), 1; K. Veitch, *The Jurisdiction of Medical Law*. (Ashgate, 2007), 13

dominate legal perspective in common law jurisdictions; particularly the UK.[142] Specifically, the spread of consumerism, as a model of healthcare, required the adoption of the ethical principles of liberalism, autonomy and patient-power. This process of ethical transference, laid the conceptual ground-work, for the adoption of right-concepts, and language, to be transplanted from the US, into other common law jurisdictions. However consumerism (and the ethical principles which underpin this model), and therefore legal 'rights' may be practically and conceptually inconsistent with the underlying values which structure and orientate nationalised or social healthcare systems. Patient rights have the potential to operate effectively in private health systems, predicated on contracts and fiduciary duties, but not social healthcare systems which operate on moral duties: such as the NHS. This thesis therefore argues that *consumerism* is in ethical antithesis to the values underpinning a nationalised health service. Thus, the creation of legal rules to maximise patient choice, by requiring a normative standard of information disclosure, has the potential to create conceptual inconsistency between, not only existing causes of action, but the shared understanding of the purpose and values of health in practice.

(i) Patient rights within the US

The consumer relationship first appeared as a method to limit the potential harms of *medicalisation*, in the US context.[143] The private structure of the healthcare system encouraged the growth of markets, where patients could choose from a range of treatments – from the conventional to the experimental. Patient rights were constructed from interpretative approaches to constitutional documents, made by academics, by lawyers who challenged medical decisions within Senior Courts, and judges themselves. For example, the Supreme Court relied on patient rights to require doctors to provide certain treatment choices such as abortion in (*Roe v Wade).*[144] Rights were similarly used to limit medical action. For example, the negative liberty right of privacy[145] was extended outwards, to create substantive duties of confidentiality, and bodily integrity,[146] in the cases of *Quinlan* and *Saikewicz,* respectively.[147] Extension of rights concepts, beyond their historical boundaries, began to manifest as a distinct content of medical law: formed from actionable duties and standards which were owed by doctors, as state actors, to patients, as rights-holding citizens.[148]

[142] For example, Canada: Australia, New Zealand and the United Kingdom.
[143] H. Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship.* (Clarendon Press, 1994), 96-106
[144] *Roe v Wade*, 410 US 113 (1973)
[145] R.R. Faden and T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 40
[146] H. Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship.* (Clarendon Press, 1994), 97
[147] *Re Quinlan*, 70 N J 10, 355 A.2d 647 (Del. 1980); *Superintendent of Belchertown State School v Saikewicz*, 370 N E 2d 417 (Mass. 1977)
[148] R.R. Faden and T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 32; relying on S. Warren & L. Brandeis 'The Right to Privacy' (1980) 4 *Harvard Law Review* 193-220; W.L. Prosser, 'Privacy.' (1960) 48 *California Law Review* 383-423; E.J. Bloustein, 'Privacy as an Aspect of Human Dignity: An Answer to Dean Prosser.' (1964) 39 *New York Law Review* 962-1007

The concept of informed consent similarly arose as a theoretical extension of an existing constitutional right. In 1969, Waltz & Scheuneman argued that a liberty right of consent to treatment required a right to a standard of information, to ensure an informed consent:[149]

> A risk is thus material when a reasonable person, in what the physician knows or should know to be the patient' position, would be likely to attach significance to the risk in deciding whether or not to forego the proposed therapy.[150]

These commentators were relied on by Robinson J, in *Canterbury v Spence*, to extend the duty of disclosure, to ensure that patients have an autonomous choice.[151] This was perceived as a doctrinal rather a substantive legal extension. [152] Robinson J argued that:

> True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risk attendant upon each. The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision. From these almost axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible.[153]

This required that the patient have access to a content of information so that they can make a rational choice.[154] The benefit of this conceptual extension was that the right to information became a proactive duty, and thus the standard of care became regulatory: '[i]t is an axiom of constitutional theory that preventing constitutional violations is preferable to assessing damages after violations take place.'[155]

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[149] J.R. Waltz & W. Scheuneman, 'Informed Consent to Therapy.' (1969-1970) 64(5) *NW U L Rev* 628-650, 637. Also relied on see, A.H. McCoid, 'A Reappraisal of Liability for Unauthorized Medical Treatment.' (1957) 41 *Minn LR* 381, 434. And student analysis in Comment, 'Informed Consent in Medical Malpractice.' (1967) 55 *California Law Review* 1396; Note, 'Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship.' (1970) 79 *Yale Law Review* 1533. R.R. Faden and T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 148 - as Faden and Beauchamp argue: "Perusal of the references in *Canterbury* paints a good picture of the influence of legal scholarship."
[150] J.R. Waltz & W. Scheuneman, 'Informed Consent to Therapy.' (1969-1970) 64(5) *NW U L Rev* 628-650, 640
[151] *Canterbury v Spence* 464 F.2d 772, 787 (DC Cir. 1972), 786
[152] *Ibid*, 782-783
[153] *Ibid*, 780
[154] *Ibid*, 787, quoting from: J.R. Waltz & W. Scheuneman, 'Informed Consent to Therapy.' (1970) 64 *NWUL Rev.* 628,640. See, G.J. Annas, *et al*, *Informed Consent to Human Experimentation: The Subject's Dilemma*. (Ballinger Publishing Co, 1977); C. Strong, 'Informed Consent: Theory and Policy.' (1979) 5(4) *J Med Ethics* 196-199
[155] R.R. Faden and T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 42. Relying on A. Meisel, 'The 'Exceptions' to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decision-making.' (1979) 2 *Wis L Rev* 413-488; L.L. Riskin, 'Informed Consent: Looking for Action.' (1975) 4 *University of Illinois Law Review* 603

(ii) Rejecting rights

The development and propagation of the *consumer* model of health, as the (conceptually) optimum type of healthcare provision, to some extent, explains why the rights-based arguments, utilised to extend medical duties and standards in the US, were so successful.[156] Healthcare in the US is privatised, and provision of coverage occurs through private insurance with only very limited public assistance.[157] The private health system axiomatically empowers the individual, as a patient as a chooser: they are required to choose between a range of providers which accept their particular insurance. Patients as a matter of course are required to be informed, and accept the economic burden and responsibility of their choice; as they are required to pay a premium on services. The private system of healthcare also works through contracts and business principles. Patients, then, are understandably concerned about standards of health provision; as failure to ensure contractual entitlements potentially affects their individual health, financial health, and potentially health outcomes for their families. Individual consumers (rather than patients) must have an *a priori* form of actionable power to both enter a contractual relationship, be facilitated in making informed choices about health provision, attain a decent standard of service, and have their choices respected. The fundamental and universal nature of rights, imbued through the status of citizen (or human), act as a useful framework to facilitate these basic a priori requirements needs. The functioning of a privatised market system requires an ethical orientation towards liberty, and maximisation of patient autonomy, to facilitate choice within the healthcare market (as well as ensure that the patient is able to safeguard themselves from exploitation and harm). This libertarian approach chimes with, and is explicitly supported, by constitutional liberty rights. As well as a wider political commitments within parts of the US political community who view self-sufficiency as a virtue.

The concepts of rights, and political and ethical principles of liberty, are however, historically and legally alien to the UK. Indeed, one could go as far as to state that they are conceptually and politically in direct conflict with the 'utopian' socialist ideals and organisational structure of the Nationalised Health System.[158] As Harrington argues, Aneurin Bevan[159] envisaged the NHS as removing health from the market; in the sense that access to healthcare would no longer depend on income, and clinical relationships would not be medicated by money.[160] Similarly, Titmuss, who wrote about commercial markets in human blood, recognised that the national health system politically, and ideologically,

[156] J. Harrington, *Towards a Rhetoric of Medical Law*. (Routledge, 2017), Chapter 3-4. Also, J. Harrington, 'Time and Space in Medical Law: Building on Valverde's Chronotopes of Law.' (2015) 23(3) *Feminist Legal Studies* 361-367

[157] For example, the Social Security Amendments Act 1965, (signed by President Johnson), created the Medicare insurance program (for Americans over 65), and Medicaid (a health insurance program for low-income Americans). The Health Insurance Portability and Accountability Act (HIPAA) which added protections for individuals with pre-existing conditions, and The Medicare Drug, Improvement, and Modernization Act 2003, which creased prescription drug benefits. In 2010 President Barak Obama made significant changes to the health care system through the Affordable Care Act 2010 ("Obamacare") which required that everyone have either private or public insurance.

[158] Department of Health & Social Care, *Guidance: The NHS Constitution for England*: (<The NHS Constitution for England - GOV.UK (www.gov.uk)>)

[159] A. Bevan, *In Place of Fear*. (Quartet Books, 1990)

[160] J. Harrington, *Towards a Rhetoric of Medical Law*. (Routledge, 2017), 98-99

rejected markets and commercialisation as the optimum form of health care. Instead, health was orientated towards principles of collectively and communitarianism. With this ideology, the patient was situated within a wider social system of health: they were a patient within a community, rather than a patient consumer.[161] The medical relationship, between the patient and doctor, was therefore grounded on moral obligations to society and mutually philanthropic motivations.[162]

What one can see from this brief synopsis is that the social and political values of a given society, affect the organisation and principles which define the role of a health services.[163] The content of the law relating to health, both in the structure of the care-systems, and regulation of the profession, inevitably reflect the political value-commitments,[164] as well as the dominant moral values of given society.[165] As Harrington argues,

> […] anti-market arguments instantiate and extend certain utopian aspirations shared by the founders of the National Health Service. Their rhetorical plausibility depended significantly on the resonance with the general vision of the health service as an enclave, an exemplary zone of non-commodified human relationships.[166]

To fulfil this conceptualisation of health care, and to appropriately regulate practice, the law too must adopt the same, or complementary, values as the basis of legal duties and standards. In the context of a socialised health system, this means rejecting *laissez-fare* patient choice, and thus the legal constructs of rights, which facilitate the consumer model. Harrington,[167] draws on the report into the regulation of commercial surrogacy conducted by Brazier *et al*. to exemplify how this value-commitment to community, shared-obligations and prevention of harm, can be appropriately managed.[168] Brazier refused to rescind the criminalisation of commercial surrogacy under the Surrogacy Arrangements Act 1985, and instead argued that payments to surrogates needed to be more tightly regulated.[169] This was justified on three ground: (1) that commercialisation of surrogacy had the potential to cause psychological harm to children,[170] (2) that payment for surrogacy could lead to exploitation of surrogate mothers from lower socio-economic backgrounds,[171] (3) that the law would be permitting the

[161] R.M. Titmuss, *The Gift Relationship: From Human Blood to Social Policy*. (New Books, 1997); B. Abel-Smith & K. Titmuss, *The Philosophy of Welfare. Selected Writings of Richard M Titmuss*. (Allen and Unwin, 1987), 269
[162] See, E.D Pellegrino, 'The Internal Morality of Clinical Medicine: A Paradigm for the Ethics of the Helping and Healing Professions.' (2001) 26 *Journal of Medicine and Philosophy* 559=579
[163] J. Harrington, *Towards a Rhetoric of Medical Law*. (Routledge, 2017), Chapter 1
[164] See, J. Montgomery, *et al*, 'Hidden Law-Making in the Province of Medical Jurisprudence.' (2014) 77(3) *MLR* 343-378
[165] See, J. Harrington, 'Time as a Dimension of Medical Law.' (2012) 20(4) *Med L Rev* 491-515
[166] J. Harrington, *Towards a Rhetoric of Medical Law*. (Routledge, 2017), 90
[167] *Ibid*, 91-95
[168] M. Brazier, A. Campbell & S. Golombok, *Surrogacy: Review For Health Ministers of Current Arrangements for the Payments and Regulation*. (Department of Health, 1999)
[169] Ibid, 71-72
[170] Ibid, 33
[171] Ibid, 35

'commodification of child bearing' and thus viewing foetuses, or children, as property, or having a monetary value.[172] This legal position reflected a value dedication to non-commodification, trust and beneficent goals of the British system of healthcare.[173] Commentators who adopted the rhetorical arguments of patient rights, implicitly (if not explicitly), support the rejection of the axiomatic values of the NHS, when they argued for patient choice or dismiss the potential harms of commercial surrogacy.[174] Harrington, identifies a similar ethical commitment to reflective principles in Titmus's work on the regulation of blood donation. Like Brazier, Titmus adopted the same ethical position that to use parts of the human body can only be justified on the basis of informed gifting, and fraternal relationships - rather than a financial transactions, which can lead to exploitation.[175]

> If human blood be legitimated as a consumption good […] [a]ll policy would become in the end economic policy, and only values that would count are those that can be measured in terms of money and pursued in the dialectic of hedonism.[176]

Teff goes further and argues that the values of collectively, communitarianism, and beneficence, were axiomatic to the operation and structure of the NHS. The operation of a nationalised healthcare system created practical barriers to the creation of free-market of healthcare; which might maximise patient liberty, or indeed, their autonomy.

> The "internal market," for example, is a "proxy market" to the extent that the doctor is the effective consumer. It threatens to restrict rather than enlarge patient choice where doctors feel unduly constrained in treatment decisions by considerations of cost, or where the treatment available is dictated by NHS "contracts" negotiated on a batch referral basis.[177]

If extraneous values and principles are applied to a nationalised health service, this can manifest through a number of ethical and operational pathologies. Teff in his analysis of the movement to a market in health, under the Thatcher government, identified that the requirement to commission services through collective service agreements means that patients only have access to pre-defined services and treatments, rather than being able to purchase according to their needs. Those with chronic disabilities are potentially neglected, as well as the ability to recognise or deal with the broader environment or

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[172] *Ibid*, 39
[173] M. Brazier, 'Regulating the Reproductive Business?' (1999) 7 *Med L Rev* 166
[174] For example, see M. Freeman, 'Does Surrogacy Have a Future after Brazier?' (1999) 7(1) *Med L Rev* 1-20, 5-10; H.V. McLachlan & J.W. Swales, 'Babies, Child Bearers and Commodification: Anderson, Brazier *et al*., and the Political Economy of Commercial Surrogate Motherhood.' (2002) 8 *Health Care Analysis* 1; S. Wilkinson, Bodies for Sale. Ethics and Exploitation in the Human Body Trade. (Routledge, 2003), Chapter 8
[175] J. Harrington, *Towards a Rhetoric of Medical Law*. (Routledge, 2017), 101; B. Abel-Smith & K. Titmuss, *The Philosophy of Welfare. Selected Writings of Richard M Titmuss*. (Allen and Unwin, 1987), 237
[176] R.M. Titmuss, *The Gift Relationship: From Human Blood to Social Policy*. (New Books, 1997), 191
[177] H. Teff, 'Medical Models and Legal Categories: An English Perspective. (1993) 9 *J Contemp Health L & Pol'y* 211, 220

social factors which affect health outcomes. The use of contracts in this way perpetuates the biomedical construction of modern medicine – exacerbating, rather than solving, the problem of (managerial) paternalism.[178] As Sorell goes further and argues, the orientating values of consumerism, are axiomatically alien to the culture and methods of the caring profession. Thus, the structures of consumerism may inevitably to conflict with, and undermine, attempts to ensure good patient care.[179]

Black letter lawyers, who reject the existence of an internal moral content, or ethical orientation of legal constructs, drawn from politics and society, are blind to the potential problems of legal splicing. For them, law is simply a mechanism to ensure effective regulation. However, the construction and operation of rights-concepts, duties and standards are particular to the tradition, values and thus context in which they have arisen. The values used to construct rights such as liberty and autonomy have specific roles within a given society, and cannot be blindly transplanted into jurisdictions which have distinct value-commitments. Worse, for those who are aware of the moral commitments underpinning jurisprudential mechanisms; law should not be used as a top-down mechanism to lobby, or to augment systems, of health. Indeed, this seems to be the approach adopted by Kennedy, in his clear rejection of collectively and beneficence as the touch-stones of health care. Instead, these are characterised as social coercion, seen through the lens of consumerism. From this position, informed consent becomes a mechanism to limit the reach of the state (manifest through the NHS), and ensure individuals have *prima facie* powers of choice.[180] Kennedy, suggests that one can ignore the value conflict, and potential conceptual confusion, created by this transplant, because informed consent, as a legal mechanism, would have a distinct role within litigation in the UK, as opposed to the US. Litigation, in the US, he argued, was required due to the private nature of their healthcare system to ensure that victims of negligence, continued to have financial means of ongoing support, to supplements social care. The socialised nature of the health system in the UK, would avoid the potential negative impacts of a medical litigation revolution, by ensuring that informed consent remained symbolic, rather than a mechanism for recouperation.[181] Respectfully, this argument was, and remains, unconvincing.

Despite the ethical incompatibility between consumerism and the communitarian core principles of a nationalised system of health, the market approach, with its liberal ethics, was lorded by some as the optimum model for health.[182] Liberty and autonomy were therefore adopted as the paramount principles for interpretating, constructing and expanding patient rights, as the basis of medical law, within the

[178] *Ibid*, 220-221
[179] T. Sorrell, 'Morality, Consumerism and the Internal Market of Health Care.' (1997) 23 *J Med Ethics* 71-76
[180] I. Kennedy, 'Consumerism in the Doctor-Patient Relationship.' (1980) Dec 11 *The Listener* 777-780, 778
[181] *Ibid*, 777-778. Also see, J.W. Berg, *et al*, *Informed Consent: Legal Theory and Clinical Practice*. (Oxford University Press, 2001), 52
[182] See, D. Hughes, 'The Reorganisation of the National Health Service: The Rhetoric and Reality of the Internal Market. (1991) 54 *MLR* 88

UK.[183] These rights sought to entitle individuals to access a *faux* health market, by establishing normative duties and standards within medical practice to ensure choice. However, this thesis maintains that the imposition of the market model, through constitutional type-rights, like an undiagnosed cancer, continued to metastasise within academic commentary, and later common law.

(iii) Resilient Rights within the UK

The unwritten nature of the constitution and the nationalised health service, in the UK, made the conceptual basis of the consumer relationship more difficult to fashion from existing common law.[184] Teff argues that rights commentators were forced to ground their rights-based arguments on legal principles arising from supra-national instruments;[185] particularly, human rights;[186] which have vertical effect on state bodies.[187] For example, the Nuremberg Codes, the Universal Declaration of Human Rights[188], and later the Declaration of Helsinki, were used as a framework to delineate axiomatic principles which existed as basic rules of non-maleficence; universally applicable to humans.[189] Properly understood, these rights were negatively framed, and could be utilised only when state actors had infringed upon the dignity of persons. For example, in *Glass v United Kingdom* the Strasbourg court held that a child's right under Art 8 was breached when the child was given diamorphine against the wishes of his mother and the doctors failed to gain a court order.[190] This was repeated in *Pretty v United Kingdom*, where the Grand Chamber stated:

> In the sphere of medical treatment, the refusal to accept a particular treatment might, inevitably, lead to a fatal outcome, yet the imposition of medical treatment, without the consent of a mentally competent adult patient would interfere with a person's physic, al integrity in a manner capable of engaging the rights protected under Art 8(1) of the convention.[191]

[183] See, T. Latimer, *et al*, 'Patient-centredness and consumerism in healthcare: an ideological mess.' (2017) 110(11) *Journal of the Royal Society of Medicine* 425-427; A. Mold, 'Making British Patients into Consumers.' (2015) 385(9975) *The Lancet* 1286-1287

[184] H. Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship*. (Clarendon Press, 1994), 102-103.

[185] *Ibid*

[186] See, I. Kennedy, "Patient, Doctors and Human Rights." In R. Blackburn and J. Taylor (eds.), *Human Rights for the 1990's* (Mansell, 1991), Chapter 9. I. Kennedy, "Patients, Doctors, and Human Rights." In, I. Kennedy (eds.) *Treat Me Right: Essays in Medical Law and Ethics*. (Oxford University Press, 1994), 385-415

[187] L. Gostin, 'Dedicatory Essay: Honouring Ian McColl Kennedy.' (1997) 14(5) *J. Contemp Health L & Pol'y* v-xiii, viii. As Gostin notes, Kennedy applied the same framework of analysis to product liability, research and human tissue and other areas of professional liability not historically within the lexicon of medical practice.

[188] For example, Universal Declaration of Human Rights 1948, Art 25 which protects an individual's 'right to standard of living adequate for the health and well-being of himself and of his family.'

[189] For example, The Convention on the Right to Child 1989 (incorporated into law in Rights of Children and Young Persons (Wales) Measure 2011, section 1) and the Convention on the Rights of Persons with Disabilities 2006, and the optional protocol, ratified in 2009. See an excellent synopsis of the rights movement in: H. Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship.* (Clarendon Press, 1994), 96

[190] *Glass v United Kingdom* (2004) ECHR 341. Also see *Re OT (A Baby)* [2009] EWHC 635 (Fam)

[191] *Pretty v United Kingdom* (2002) 35 EHRR 1, [63]

Kennedy and Grubb thus posited that law relating to medical matters should be understood as a form of human rights law.[192] This reconceptualisation of medical law, afforded rights commentators a lens to critique previous case-law which failed to explicate and define distinct normative rights, or adopt their existing value-commitments.[193]

> As with all areas of English law, the central core of medical law is easier to identify than its boundaries. We see it as essentially concerned with the relationship between doctors (and to a lesser extent hospitals or other institutions) and patients. It is made up of, borrows from and reflects other areas of law, in particular tort, crime and family law. It is, however, more than the sum of these parts. It is not in our view, a subject defined merely by reference to a set of factual circumstances. This is, of course, the traditional approach of the pragmatic common law, but it is an approach which is always intellectually unsatisfying. This is not least because it leaves unstated the criteria for deciding whether any particular factual circumstance falls within or outside a given subject area. […]
>
> There are common issues which permeate all the problems which arise: respect for autonomy, consent, truth-telling, confidentiality, respect for personhood and persons, respect for dignity and respect for justice. All of those ethical issues run throughout the field. Until these common themes are recognised and reflected in legal thinking and analysis, a coherent approach to the emerging problems in medical law will be difficult. Thus, we see medical law as having some conceptual unity. The unifying legal theme is, to us, that of human rights. In our view, therefore, medical law is a subset of human rights law. This is what provides its intellectual coherence.[194]

The benefit of constructing medical law on the architecture of human rights principles was that they could act as a regulatory mechanisms which proactively limited the potential harms emanating from *medicalisation*. These principles also had the benefit of tying together the disparate content of law that related to medical practice, as well as structuring future common law advances.[195] As Lady Hale argued in *Nicklinson*, determinations become: 'one of principle rather than fact: once the principle is established, the question for the judge or other tribunal which is asked […] would be one of fact.'[196]

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[192] I. Kennedy & A. Grubb, *Medical Law: Text with Materials* (1994), Introduction
[193] For example, I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy (eds.), *Treat Me Right: Essays in Medical Law and Ethics.* (Clarendon Press, 1988). Also, see for example: S.A.M. McLean, *Autonomy, Consent and the Law.* (Routledge, 2010), 71-97
[194] I. Kennedy & A. Grubb, *Medical Law: Text with Material*. (Butterworths, 1989), 3.
[195] I. Kennedy, "Emergent Problems of Medicine, Technology, and the Law." In I. Kennedy (eds.), *Treat Me Right: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 3-5
[196] *R (Nicklinson) v Ministry of Justice* [2014] UKSC 38, [318].

Once introduced, the Human Rights Act 1998 ("HRA") catalysed this form of revisionism;[197] as section 2 required the judge to interpret statute law in line with ECtHR jurisprudence, and thus, to re-examine pre-HRA case law.[198] As the HRA is a 'living instrument' and conceptualisations of rights change either through direct effect (by interpretation in the ECtHR), or through domestic judicial decision-making,[199] as rights were applied in different context, the content was extended outwards. From Article 8 ECHR, one could therefore begin to construct more substantive duties of informed consent, with more robust requirements for the identification of material information, communication and disclosure.[200]

Drawing from the North American test cases, rights advocates, within the UK, took what were essentially negative liberty rights and argued that these concepts should be conceptually extended to create actionable duties and responsibilities which were required to be fulfilled by state actors.[201] This was not a value neutral extension of the law, but a political endeavour to nudge the zeitgeist along, using the 'fudge-and-nudge' method to develop of English law.'[202] As Teff argued:

> Exposure to European legal analysis, with its strong attachment to the vindication of personal liberties, is beginning to have its effect on English legal thinking as, little by little, the legislature is required to implement and courts are asked to take account of specific provision of the European Convention of Human Rights. […] In addition to external pressures to enunciate specific rights and make administrative discretion more justiciable, there is now new impetus for a 'rights perspective' in domestic law generally because of the more expansive system of judicial review which, as we have seen, could in principle have repercussions in the medical sphere.[203]

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[197] C. Newdick, "The Positive Side of Healthcare Rights." In S. Maclean, *First Do No Harm, Law, Ethics and Healthcare.* (Ashgate Publishing, 2006), 575

[198] This becomes obvious from a careful reading of the reinterpretation of *Sidaway* in *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [39]-[62]. Also see Lord Scarman who writing extra-judicially stated that he was in the majority in the *Sidaway* judgement: Lord Scarman, 'Consent and communication and responsibility.' (1986) 79 *J Roy Med Soc* 697, 697. This rights framework for analysis is expanding outwards into tort law, more generally. See D. Nolan & A. Roberson, "The Conflict of Rights." In A. Robertson & H. Tang (eds), *The Goals of Private Law.* (2009); R. Stevens, "The Conflict of Rights." In A. Robertson & H.W. Tang (ed.), *The Goals of Private Law*. (Hart Publishing), 139-141. Also, A. Beever, *Rediscovering the Law of Negligence* (Hart Publishing, 2007)

[199] The living instrument doctrine was first articulated in *Tyrer v United Kingdom* [1978] EHRR 1; (1978) (application No. 5856/72). Also see, *Dudgeon v United Kingdom* [1981] 4 EHRR 149; (1981) (application no. 7525/76); *Demir and Baykara v Turkey* [2008] ECHR 1345

[200] I. Kennedy, 'Emerging Problems of Medicine, Technology and Law.' In I. Kennedy (eds.), *Treat Me Right: Essays in Medical Law and Ethics*. (Oxford University Press, 1988), Chapter 1

[201] C. Newdick, "The Positive Side of Healthcare Rights." In S. Maclean, *First Do No Harm, Law, Ethics and Healthcare.* (Ashgate Publishing, 2006), 578-579

[202] J. Montgomery, C. Jones & H. Biggs, 'Hidden Law-Making in the Province of Medical Jurisprudence.' (2014) 77(3) *MLR* 343-378, 346; Kennedy, "Emerging Problems of Medicine, Technology, and the Law." In I. Kennedy, *Treat Me Right: Essays in Medical Law and Ethics.* (Oxford University Press, 1988), 10-11

[203] H. Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship*. (Clarendon Press, 1994), 99

Montgomery *et al* rightly identify barristers who were socialised into utilising rights arguments as a mechanism to ensure judges analysed the decision from the perspective of the patient, during trial, or at appeal.[204] Section 6 HRA, for example, required the courts to consider human rights concepts to ensure determinations were compatible with ECtHR principles. These lines of rights-based thinking were then adopted as the basis for judgements as barristers entered the judiciary. Sir James Munby, for example, utilised these arguments during his time as the Official Solicitor, and during his time as the President of the Family Division. Giving a first instance judgement, in *Burke v GMC*[205] he decided that Art 8 ECtHR[206] created a common law right to medical treatment. A similar progression can be delineated from the work of Baroness Hale, who utilised rights-based perspectives, and equality arguments in her early academic work relating to women,[207] and later during her time has head of the Law Commission.[208] Her focus on rights-based arguments persisted as she became Lady of Appeal[209] and during her reign as President of the Supreme Court.[210] As she argues extra judicially:

> […]in the past, we may have thought that the Convention represented what was already UK law but of course it did not always do so and there was nothing to prevent Parliament from limiting them or even taking them away. Second, our courts can now address Convention questions in the same terms that Strasbourg will address them. So if we find that there has not been a violation, Strasbourg is more likely to understand our reasoning. We can have a real debate about it. [211]

Lady Hale went on to argue in favour of judicial legislation to ensure compatibility with ECtHR:

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[204] J. Montgomery, C. Jones & H. Biggs, 'Hidden Law-Making in the Province of Medical Jurisprudence.' (2014) 77(3) *MLR* 343-378, 366-367. Also see, H. Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship.* (Clarendon Press, 1994), 100

[205] Although it was later overturned, the judgement of Mr Justice Munby drew on Articles 2, 3 and 8 of the Human Rights Act 1998, to argue that the patient should have *laissez faire* choice of treatment options, see *R (on the application of Burke) v GMC* [2004] EWHC 1879

[206] See Mr Justice Munby, "Chapter 12: A Duty to Treat? – A Legal Analysis." In S.W. Smith (ed.), *The Legal, Medical and Cultural Regulation of the Body: Transformation and Transgression.* ((Routledge, 2016)

[207] For example: B. Hale, *Parents and Children: The Law of Parental Responsibility* (1977); B. Hoggett, *Family Law and Society: Cases and Materials* (1983); S. Atkins & B. Hoggett, *Women and the Law* (Blackwell, 1984), Chapter 5. More recently, B. Hale, 'The Human Rights Act and Mental Health Law: Has it Helped?' (2007) 15 *International Journal of Mental Health and Capacity Law* 7-18, 16.

[208] The Law Commission, *Family Law: Review of Child Care Law: Custody* (Stationary Office, 1986), 180-181, 192, 218; White Paper, *The Law Relating to Child Care and Family Service.* (Cmnd 62, 1987). See, B. Hale, '30 Years of the Children Act 1989.' (Scarman Lecture 2019, *Law Commission*, 13 November 2019).

[209] For example: *R (Wilkinson) v Broadmoor Hospital* [2002] 1 WLR 419.

[210] For example, *Aintree University Hospitals NHS Foundation Trust v James* [2013] EWCA Civ 65, [26], [43]-[45]; *Greater Glasgow Health Board v Doogan and another* [2014] UKSC 68; *R (on the application of Nicklinson and another) v Ministry of Justice* [2014] UKSC 38; *Montgomery v Lanarkshire Health Board* [2014] UKSC 11. [109]-[115]; *An NHS Trust and others v Y and another* [2017] EWHC 2866, [66]-[74]; *Evans & Another v Alder Hey Children's NHS Foundation Trust & Alfie Evans* [2018] UKSC

[211] Lady Hale, *Celebrating 70 years of the Universal Declaration and 20 years of the Human Rights Act.* (British Institute of Human Rights Annual Lecture, 2019), 8: (https://www.supremecourt.uk/docs/speech-181107.pdf)

> It is fair to say that there has been a range of views within the Supreme Court on [what extent] is it for the courts, rather than the primary decision-makers within government, to assess the proportionality of interferences with qualified Convention rights? We eventually go to the position that it is for the courts to do this – public authorities have to act compatibly with the Convention rights and this includes the court's ruling on the legality of actions of other public authorities.[212]

Medical Law most often poses questions which engage Art 8 as they touch upon the patients' right to have a private life.[213] However, within the Treaty, Art 8 was framed as a negative liberty right to prevent state interference;[214] which, properly understood, enshrines a right to self-determination.[215] This right to liberty of choice is most often expressed by quoting the judgement of Judge Cardoza in *Scholendorff v Society of New York:*

> Every human being of adult years and sound mind has a right to determine what shall be done with his own body.[216]

However, as the Supreme Court in America noted:

> A phrase begins life as a literary expression; its felicity leads to its lazy repetition; and repetition soon establishes it as a legal formula, indiscriminately used to express different and sometimes contradictory ideas.[217]

Rather than continuing to use this limited understanding of self-determination, as liberty of choice, the concept was repeated and extended to justify a range of more substantive requirements necessary to facilitate choices within an individual's private life.[218] In the context of medical law, the purpose of disclosure was re-invented to ensure patient self-determination,[219] which then morphed into a right to

[212] *Ibid*, 9. See for example, *R (Nicklinson) v Ministry of Justice* [2014] UKSC 38, [299]- [325]
[213] See for example, *Pretty v UK* (2002) 35 EHRR 1, at [61]; *Ternovszky v Hungary* (Application no. 67545/09, Judgement of 10 December 2010, at [22]; *KH and Others v Slovakia* (Application no.32881/04), Judgement of 28 April 2009; *Jehovah's Witnesses of Moscow and Others v Russia* (Application no. 302/02), Judgement of 10 June 2010; *Schneiter v Switzerland* (Application no. 63063/00), Judgement of 31 March 2005; *X v Finland* (Application no. 34806/04), Judgement of 3 July 2012
[214] See, *A, B, C, v Ireland* [2010] ECHR 25579/06
[215] J. Coggon & J. Miola, 'Autonomy, Liberty, and Medical Decision-Making.' (2011) 70(3) *Camb L J* 523-547; H. Hannum, 'The Right of Self-Determination in the Twenty-First Century.' (1998) 55 *Wash & Lee L Rev* 773, 773-779
[216] *Scholendorff v New York Hospital*, 211 N.Y. 125(1914)
[217] *Tiller v Atlantic Coast Line Railroad Co* 318 US 54 (1943), per Frankfurter J. at [68]
[218] See, this iterative conceptual extension in R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), Chapter 4
[219] See for example, I. Kennedy & A. Grubb, *Medical Law.* (Butterworths, 2000).575-583; S.A.M. McLean, *Autonomy, Consent and the Law.* (Routledge, 2010), 40-68

an autonomous choice,[220] termed *informed consent*, to treatment.[221] In this model, the content of the autonomous choice was divorced from the therapeutic concerns of the medical relationship, and was constructed solely through the specification of an ethical (rather than therapeutic) principle of autonomy.[222] Adopting this ethical, rather than medical approach, supposedly avoided patients being exposed to the arbitrary moral choices.[223] Informed consent, as the Rosetta stone of the consumer relationship, with repeated with felicity, proliferated into the consciousness of common law judges. For revisionary judges, the uncertain nature of informed consent, allowed the refocusing of rules away from evaluating, and thus regulating, medicine, towards defining minimum standards of practice, through the mechanism of patient rights. This conceptual paradigm shift[224] was adopted by the Supreme Court of Canada in *Reibl v Hughes*[225] to require the disclosure of an objective standard of information.[226] This was legitimate as:

> [t]he issue under consideration is a different issue from that involved where the question is whether the doctor carried out his professional activities by applicable professional standards. What is under consideration here is the patient's right to know what risks are involved in undergoing or forgoing certain surgery or other treatment.[227]

Commentators in the UK used the example of Canada to argue for an objective standard of information in the Law of England and Wales.[228] For example, Robertson suggested that:

> It is to be regretted that the law should seek to restrict the doctrine of informed consent in this way, since this belies the importance to be attached to the patient's fundamental right to decide whether to undergo proposed medical treatment. The informed consent ought to be accepted and developed by the courts in this country so as to ensure that patients are given the

[220] L.B. Jaeckel, 'New Trends in Informed Consent?' (1975) 54 *Neb L Rev* 66
[221] For an excellent overview of the philosophical foundations and implications of informed consent, see: E, Nir, "Informed Consent", (*The Stanford Encyclopaedia of Philosophy*, 2019), Edward N. Zalta (ed.): (https://plato.stanford.edu/archives/spr2019/entries/informed-consent/)
[222] T.L. Beauchamp, 'Methods and Principles in Biomedical Ethics.' (2003) 29(5) *J Med Ethics* 269-274
[223] I. Kennedy & A. Grubb, *Medical Law: Text and Materials*. (Butterworths, 1989), 229. Kennedy and Grubb seem to agree with the conclusion of The President's Commission, *Making Health Care Decisions: The Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship*. (1982), 31-35
[224] This was a significant doctrinal development in Canada, see: M. Goschnauer & D.J. Flemming, New Directions for Medical Disclosure.' (1981) 15 *U B C L Rev* 475, 495; S. Rogers-Magnet, 'Recent Developments of Informed Consent to Medical Treatment. (1981) 14 *CCLT* 61, 76
[225] *Reibl v Hughes* [1980] 2 SCR 880, per Laskin CJ, at 895
[226] But interestingly, not in Battery (see discussion below); in *Scholendorff v Society of New York Hospital* 105 N.E. 92 (N.Y. 1914), 129-30
[227] *Reibl v Hughes* [1980] 2 SCR 880, 890
[228] G. Robertson, 'Informed Consent to Medical Treatment.' (1981) 97 *L Q Rev* 102-126; I. Kennedy, 'The Patient on the Clapham Omnibus.' (1984) 47 *MLR* 454.

> information which they require to exercise their right to decide whether to undergo proposed medical treatment.[229]

These commentators were then relied on by Lord Scarman, in his dissenting judgement, to argue for positive autonomy rights:

> The existence of the patient's right to make his own decision, which may be seen as a basic human right protected by the common law, is the reason why a doctrine embodying a right of the patient to be informed of the risks of surgical treatment has been developed in some jurisdictions in the U.S.A. and has found favour with the Supreme Court of Canada. Known as the "doctrine of informed consent," it amounts to this: where there is a "real" or a "material" risk inherent in the proposed operation (however competently and skilfully performed) the question whether and to what extent a patient should be warned before he gives his consent is to be answered not by reference to medical practice but by accepting as a matter of law that, subject to all proper exceptions (of which the court, not the profession, is the judge), a patient has a right to be informed of the risks inherent in the treatment which is proposed.[230]

Mason CJ, giving the leading judgement in the High Court of Australia, relied on Lord Scarman to argue that the patient had a right to an autonomous choice, in *Rogers v Whitaker.*[231] This again required the extension of the concept of a right to decide, to a right to be provided information:

> In legal terms, the patient's consent to the treatment may be valid once he or she is informed in broad terms of the nature of the procedure which is intended. But the choice is, in reality, meaningless unless it is made on the basis of relevant information and advice.[232]

Jose Miola then went on to reinterpret the *Sidaway* judgement as compatible with *Rogers,*[233] a revisionist view that was adopted into the zeitgeist and utilised as the reasoned basis of the current leading judgement in *Montgomery.*[234] As Lady Hale argued:

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[229] *Ibid*, 126
[230] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, per Lord Scarman at 882
[231] *Rogers v Whitaker* (1992) 109 ALR 625, 630
[232] *Ibid*, 633
[233] J. Miola, 'On the Materiality of Risk: Papers Tigers and Panaceas.' 92009) 17 *Med L Rev* 76-108, 99-105
[234] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [39]-[62].

> It is now well recognised that the interests which the law of negligence protects is a person's interest in their own physical and psychiatric integrity, an important feature of which is their autonomy, their freedom to decide what shall not be done with their body […].[235]

The Supreme Court also used this mercurial principle of autonomy to require NHS doctors to provide a market of reasonable treatment choices[236] for the consumer patient.[237] Agreeing with the judgement of Lord Scarman in *Sidaway*, Brazier and Cave argued that even if 'no remedy for violation of Article 8 (right to privacy) appears to exists, the court must in effect develop a remedy, or the court acts unlawfully in failing to implement Art 8.'[238] The problems of trying to shoehorn distinct theoretical human rights concepts into existing torts which regulate medical decision-making is discussed more fully in Section 4. It has led some commentators,[239] such as Purshouse, to question whether a distinct tort of harm for lost autonomy should be developed.[240] Even when these legal arguments do not lead to substantive change in the law, they have a coercive effect on policy-makers to develop statutory, or ethical, guidance to appear more progressive.[241] For example, after the judgement of *R (on the application of Purdy) v DPP*[242] the DPP introduced new guidelines in relation to assisted suicide.[243] Legal conflations between positive and negative rights have profound practical implications when they emerge in standards of care in law.[244] If law is to adopt an ethics of autonomy, it must be conceptually certain. As the remainder of this chapter will argue, this paradigm shift creates various conceptual and practical difficulties.

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[235] *Ibid*, per Lady Hale, at [108]

[236] J. Herring, *et al*, 'Elbow Room for Best Practice? *Montgomery*, Patients' values, and Balanced Decision-Making in Person-Centred Clinical Care.' (2017) 25(4) *Med L Rev* 582-603.

[237] J. Montgomery, 'Patient No Longer? What next in Health Care Law?' (2017) 70(1) *Current Legal Problems* 73-109

[238] M. Brazier & E. Cave, *Medicine, Patients and the Law.* (Manchester University Press, 2016), 37. Relying on *Campbell v Mirror Group Newspaper* [2004] UKHL 22. Although see *Wainwright v Home Office* [2003] UKHL 53, where the Court decided that any responsibility of the creation of a distinct tort of privacy should be left to Parliament.

[239] A. Meisel, 'A "Dignitary Tort" as a Bridge between the Idea of Informed Consent and the Law of Informed Consent.' (1988) 16(3-4) *Law Med Health Care* 210-218; E.L. Sheley, 'Rethinking Injury: The Case of Informed Consent.' (2015) 1(4) *BYU Law Review* 63-120

[240] C. Purshouse, Liability for Lost Autonomy in Negligence: Undermining the Coherence of Tort Law?' (2015) 22 *Torts Law Journal* 226-254. For a wider discussion see C.J. Purshouse, *Should Lost Autonomy be Recognised as Actionable Damage in Medical Negligence Cases?* (PhD Thesis, University of Manchester, 2016)

[241] For example, the House of Lords in *R(Purdy) v DPP (Purdy)* UKHL 45 required the DPP produce new guidance in relation to prosecutions for assisted suicide. For an excellent commentary see, K. Greasley, '*R (Purdy) v DPP* and the Case for Wilful Blindness.' (2010) 3(2) *Oxford J Legal Stud* 301-326

[242] *R (on the application of Purdy v DPP* [2009] UKHL 45

[243] The ECtHR indicated that the DPP had breached Purdy's Art 8(1) rights (but it was proportionate and necessary under Art 8(2)). See, Director of Public Prosecution, *Policy for Prosecutors in respect of Cases of Encouraging or Assisting Suicide.* (2010).

[244] See, J. Coggon and J. Miola, 'Autonomy, Liberty and Medical Decision-Making.' (2011) 70(3) *Camb L J* 523-547; See also Takala, who argues that appeals to positive liberty presupposes a particular value system and therefore rights are problematic in multicultural societies: T. Takala, 'Conception of "Person" and "Liberty," and their Implications to our Fading Notions of Autonomy.' (2007) 33(4) *J Med Ethics* 225-228.

3.2.4. The problem with rights: legitimacy, ossification and blinkered moralism

This section sets out the conceptual problems with expanding rights concepts as a way to regulate medical decision-making. As Miola and Coggon rightly argue, examples of this conflation between negative liberty rights, and positive rights are littered throughout the Law.[245] Montgomery *et al* argue that this is intentional:

> Medical and health care lawyers have long seen the law as a tool for promoting their interpretations of the requirements of bioethics and patients' rights - and hence their focus has often been on what the law 'should' be – but, in contrast, they have shown comparatively little interest in whether it matters that reform is introduced via the judiciary rather than through the legislature, despite the constitutional issues raised by judicial 'lawmaking'. Indeed, the dominance of legal positivism in Anglo-American jurisprudence in the latter half of the Twentieth Century led to considerable discomfort over the role of judges in making law.[246] The development of Ronald Dworkin's influential account of adjudication as the expression of deep principles, on which the integrity of law is based,[247] can be seen as an attempt to rescue judges from the criticism that they lack constitutional legitimacy. Rather than 'legislating' in such cases, as H.L.A. Hart suggested (because they concern issues on which the voice of Parliament is silent), Dworkin argued that they use the resources of the law to determine the solutions that best fit the authority of the legal tradition that has been handed to them. Hence, the legitimacy of judicial pronouncements is derived from the authority of law, not from that of the individual judges, and adjudication is based on the application of legal principle rather than development of political policy.[248] […] Judicial anxiety about the possibility that they might go beyond their legitimate role in dealing with controversial medico-legal issues indicates that the Dworkinian thesis has clear resonances with the thinking of judges in this area.[249]

Similarly, Mason and Laurie, rightly noted, that the concept of autonomy 'is fast becoming conflated with egotistical hedonism' however, it is a 'legal and ethical area where the great majority of persons want certainty.'[250] More conservative judges have recognised that this form of interpretative law-reform is illegitimate.[251] For example, in *Nicklinson*, Judge CJ stated 'the process of necessary law reform has

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[245] *Ibid*

[246] J. Austin, *The Province of Jurisprudence Determined* (Cambridge University Press, 1995) and H.L.A. Hart, *The Concept of Law* (Oxford University Press, 1961)

[247] R. Dworkin, *Law's Empire* (Fontana, 1986)

[248] R. Dworkin, "Hard cases" In R. Dworkin (ed.), *Taking Rights Seriously* (Duckworth, 1977), 81-130

[249] J. Montgomery, *et al*, 'Hidden Law-Making in the Province of Medical Jurisprudence.' (2014) 77(3) *MLR* 343-378, 344

[250] J.K. Mason & G.T. Laurie, 'Personal Autonomy and the Right to Treatment: A Note on *R (on the Application of Burke) v General Medical Council*: Analysis (2004) 9 *Edinburgh Law Review* 123, 130

[251] J. Montgomery, 'Guarding the Gates of St Peter: Life, Death and Law-Making.' (2011) 31 *LS* 644. Also see, more recently: *R (on the application of Conway) v Secretary of State for Justice* [2018] EWCA Civ 1431. As Montgomery argues, Parliament had expressly considered and rejected reform in this precise area of law which was recognise by the House of Lords in:

been subsumed in prosecutorial guidance. In short, prosecutorial guidance is in danger of expanding into a method of law reform (if only by way of non-enforcement of the criminal law) which is outside the proper ambit of the DPP's responsibilities.'[252] This extension of rights into a form of 'law-making' obviously raises questions of constitutional legitimacy (especially if in doing so one is forming a distinct type of 'medical law'[253]).[254]Judicial law-making is also inevitably circumstantial (in the sense it relies on examples drawn from singular cases) and thus iterative; so extension of rights concepts occur in a haphazard way. This is problematic, as the extension of principles into different areas of law have not been conceptually, or jurisprudentially, aligned. This has meant that different areas of law (such as the law of capacity, and the law of negligence) have adopted conceptually conflicting models of autonomy, as the basis of rules. [255] This is problematic when both areas of law have to be applied synchronously within medical practice.[256] As Lord Hoffmann recognised in *Bland*, this creates difficulties for professionals to understand the basis for respecting patient choices:

> No one, I think, would quarrel with these deeply rooted ethical principles. But what is not always realised, and what is critical in this case, is that they are not always compatible with each other. Take, for example, the sanctity of life and the right of self-determination. We all believe in them and yet we cannot always have them both. The patient who refuses medical treatment which is necessary to save his life is exercising his right to self-determination. But allowing him, in effect, to choose to die, is something which many people will believe offends the principle of the sanctity of life. […][257]

Conflicts between rights concepts also create difficulties for weighing and balancing autonomy, against other values and principles.[258] Teff argued that this problem has manifested more in the law of England and Wales; as judges are not working from a conceptual spreadsheet; unlike US lawyers who have a

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R(Purdy) v DPP (Purdy) [2009] UKHL 45, per Lord Phillips, at [16]; per Lord Hope, at [56]; per Baroness Hale, at [86]-[87]; per Lord Neuberger, at [101]

[252] *R (Nicklinson) v Ministry of Justice* [2013] EWCA Civ 961, [169]

[253] I. Kennedy & A. Grubb, *Medical Law: Text with Material*. (Butterworths, 1989), 3

[254] J. Montgomery, *et al*, 'Hidden Law-Making in the Province of Medical Jurisprudence.' (2014) 77(3) MLR 343-378, 361. Quote from *R (Nicklinson) v Ministry of Justice* [2013] EWCA 961, at [60]; per Judge CJ at [153]-[156]. The Court of Appeal in *Nicklinson* similarly recognised: "Parliament as the conscience of the nation is the appropriate constitutional forum not judges who might be influenced by their own particular moral perspectives; the judicial process which has to focus on the particular facts and circumstances before the court is not one which is suited to enabling the judges to deal competently with the range of conflicting considerations and procedural requirements which a proper regulation of the field may require; and there is a danger that any particular judicial decision, influenced perhaps by particular sympathy for any individual claimant, may have unforeseen consequences, creating unfortunate precedent."

[255] I. Berlin, *Four Essays on Liberty*. (Oxford University Press, 1975); R. Plant, *Modern Political Thought* (Blackwell, 1991). Seem H. Fenwick, 'Clashing Rights, the Welfare of Child and the Human Rights Act.' (2004) 67(6) *MLR* 889-927

[256] J. Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism? (2007) 15(3) *Health Care Analysis* 235-255

[257] *Airedale NHS Trust v Bland* [1993] 1 All ER 821, per Lord Hoffman, at 826-827

[258] *Ibid*, 826-827: "We may adopt a paternalist view, deny that his autonomy can be allowed to prevail in so extreme a case, and uphold the sanctity of life. Sometimes this looks an attractive solution, but it can have disturbing implications. Do we insist upon patients accepting life-saving treatment which is contrary to their strongly held religious beliefs? Should one force-feed prisoners on hunger strike?"

more thorough grounding in constitutional rights, rights theory is not constitutionally native to UK institutions.[259] This leaves the law in an unsatisfactory position: rights cannot be relied on by doctors to guide medical action, and cannot be relied on by patients, with certainty, to ensure access to treatment, or a standard of care, when a breach occurs.[260] As McLean argues, '[p]atients seeking to make decisions that are given legal weight must be able to trust […] that their autonomous choice is respected; that they are, as Hoffmaster puts it, 'self-sufficient'.'[261]

Rather than having consistent principles, as the basis of normativity, variation in their construction and content meant that judges, lawyers, doctors are often reliant on interpretative approaches to define what rights mean, in particular circumstances.[262] In litigation, this moves legal arguments from important discussions, over the correct construction of legal rules, to evidential arguments about whether the circumstances of the case are similar enough to justify the invocation of forms, or categories, of rights. John Coggon, for example, identified that judges were using this circumstantial methodology, to define the test for legal capacity. Judges would pick and choose whether individuals had autonomy, as the basis to respect decisions, often in relation to life-changing, or saving, treatment.[263] Coggon rightly criticises this approach as a type of *blinked moralism;* where autonomy is used as a rhetoric which masks what are essentially personal moral preferences for the exact criteria and standards to be applied. A lack of ethical certainty within the ethics of law risks producing the same paternalism that the consumer relationship was touted to cure.[264]

Irrespective of the model of autonomy on which one settles, an unlimited, or consequential approach to achieving the aims of that principle (through duties and standards) also has the potential to cause harm in practice, if the needs of the patient, their circumstances and context, are not considered. One must therefore recognise a threshold of harm, or non-maleficence, beyond which disclosure is not ethically justifiable. Previous to the rights school of thought, human rights, as negative rights, acted as a societal framework of non-maleficence; that limited the actions of state actors; particularly the liberty right to refuse information or treatment.[265] However, the extension of these principles to create positive duties

[259] H. Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship.* (Clarendon Press, 1994), 97-99
[260] S.A.M. Mclean, *Autonomy and Consent the Law.* (Routledge, 2010), 37
[261] *Ibid*, B. Hoffmaster, 'What Does Vulnerability Mean?' (2006) *Hastings Center Report* 38-45, 42.
[262] For example, the Court of Appeal in *R (on the application of Purdy) v Director of Public Prosecutions* [2009] EWCA Civ 92, could not override the House of Lords decision in *R (Pretty) v Director of Public Prosecutions (Secretary of State for the Home Department Intervening)* [2001] UKHL 61, where was found that Art 8(1) rights were not engaged. This led to an application to the European Court of Human Rights which found that Art 8(1) was engaged (in *Pretty v United Kingdom* (Application No 2346/02) (2002)). The Supreme eventually allowed the appeal and found that the failure of the Secretary of State to provide guidance on assisted dying was in fact incompatible with the Human Rights Act: (*R (on the application of Purdy) v Director of Public Prosecutions* [2009] UKSC 14. For an excellent explanation of this problem see S. Pattinson, 'The Human Rights Act and the Doctrine of Precedent.' (2015) 35(1) *Legal Studies* 142.
[263] J. Coggon, 'Varied and Principled understandings of autonomy in English law: justifiable inconsistency or blinkered moralism?' (2007) 15(3) *Health Care Analysis* 235-255.
[264] S. Devaney, *et al*, 'The Far-Reaching Implications of *Montgomery* for Risk Disclosure in Practice.' (2018) 24(1) *Journal of Patient Safety and Risk Management* 25-29.
[265] See, *A, B, C, v Ireland* [2010] ECHR 25579/06

to provide information, for example, to achieve an informed consent, blurs the purpose of rights. Whereas before, a doctor would be under a duty to ensure patients could have a free choice (e.g. without duress), and that the patient is not harmed (physically, mentally and emotionally), positive rights require the facilitation of a specific form, or content, of understanding to have a type of autonomous choice. This autonomous choice then, becomes the locus of respecting patients decisions.[266] In some constructions of patient rights, the patient is forced to have a mandatory autonomy:[267] where the law denies the patient the ability to choose unless they adopt the role of the consumer patient.[268] Whilst an informed patient could, hypothetically, make choices which safeguard themselves from harm, not all individuals, especially those who are ill, want to play the role of the rational, reasonable and inquisitive patients.[269] The role of consumer patient discriminates against those most at need; exposing them to the power of the doctor, without clear boundaries of unacceptable harm. Constructing duties and models grounded on a mandatory model of substantive autonomy, which are unachievable in practice, also risks moving the focus of decision-making from substance to form. As Montgomery[270] argues:

> […] this promotes autonomy only in a very unsatisfactory sense. For drug companies, informed consent to the transfer of information is by far the preferable route. It absolves them of any requirement to protect the privacy of research participants. Participants know what is happening, the argument goes, if the drug companies have met their legal responsibilities. The participants' ability to control what is happening to their data may be feeble, but they have been informed and can therefore exercise a choice. Their choice is, however, strictly limited.[271]

To understand how autonomy, as a principle, and purpose of the consumer relationship, has affected medical decision-making, it is essential to unpick the models of autonomy which have operated (and continue to operate) as the basis of normative rules in information disclosure.

3.3. The contested models of autonomy in informed consent

The previous section problematised the expansion of liberty rights, into substantive models of autonomy, due to the potential for conceptual conflation, when applied as the basis of normative rules and standards which are used to construct the requirement to have an informed consent.[272] This

[266] J. Coggon & J. Miola, 'Autonomy, Liberty, and Medical Decision-Making.' (2011) 70(3) *Camb L J* 532-547
[267] See for example, E.H. Morreim, *Balancing Act: The New Medical Ethics of Medicine's New Economics.* (Georgetown University Press, 1995), 139-141; J. Katz, *The Silent World of Doctor and Patient.* (Free Press, 1984), 122-123; M. Davies, & G. Elwyn, 'Advocating Mandatory Patient 'Autonomy' in Healthcare: Adverse Reactions and Side Effects.' (2008) 16 *Health Care Analysis 315-328*
[268] C.E. Schneider, *The Practice of Autonomy: Patients, Doctors, and Medical Decisions.* (Oxford University Press, 1998), 11; C E. Schneider, 'After Autonomy.' (2006) 2 *Wake Forest L Rev* 411-444, 416
[269] J. Montgomery, 'Law of Demoralisation of Medicine.' (2018) 26(2) *Legal Studies* 185-210, 186-189
[270] *Ibid*, 187-188
[271] *Ibid*, 188
[272] O. O'Neil, 'Some Limits of Informed consent.' (2003) 29 *J Med Ethics* 4-7, 4

conflation has occurred so readily, both within law, and formal ethic, that the definition of informed consent is now uncertain.[273] The Supreme Court of Canada in *Reibl v Hughes*[274] and the High Court of Australia in *Rogers v Whitaker*[275] encouraged lawyers to abandon the term, due to the potential for confusion. Despite these judicial warnings, the term remains prevalent in the judicial lexicon and thus the conceptual conflation has proliferated.[276] This section defines the content of the models of autonomy that have been utilised to justify the adoption of particular standards of information disclosure, within law of negligence, to ensure an informed consent. It will point out differences in the internal and external requirements of the models, and highlight the areas of conceptual incompatibility, which has led to *blinkered moralism* within both judicial, and thus medical, decision-making.[277]

3.3.1. Delineating the internal and external content of autonomy[278]

Autonomy is descriptive of internal positionalities which allow one to recognise, and respect, the epistemic worth of a decision. As such, it requires certain criteria, or phenomenon, to have occurred for an autonomous choice to have been made. Internal components occur as psychological processes in the mind of the patient, and as the act of autonomous choice is internal to a patient, it is both facilitated and recognised by words and actions externally. External components occur outside of the patient's mind, but act to influence or facilitate the patient's internal positionality. Both internal and external components come together to allow one to identify and therefore respect autonomous patient choices (see Figure 1). The more internally substantive the model of autonomy one is utilising the more onerous the external requirements necessary to facilitate this mental state. As the consumer relationship requires that the patient have an autonomous consent to access information, the doctor (as a state actor) has moral duties to facilitate that choice. The models of autonomy utilised by the law can be categorised along a spectrum dependent on their internal thickness. As the internal content of the model increases, the number of duties, and standards of those duties increase, to facilitate the internal state. The law is therefore descriptive of the duties and standards necessary to have an ethical autonomous choice.[279]

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[273] A.R. Maclean, 'The Doctrine of Informed Consent: Does it exist and has it Crossed the Atlantic?' (2004) 24(3) *Legal Studies* 386-413, 390-404

[274] *Reibl v Hughes* (1980) 114 DLR (3d) 1 SCC

[275] *Rogers v Whittaker* (1992) 16 BMLR 148, 157

[276] A.R. Maclean, 'The Doctrine of Informed Consent: Does it exist and has it Crossed the Atlantic?' (2004) 24(3) *Legal Studies* 386-413

[277] See Chapter 6, Section 1 & 3

[278] No commentators this author has identified uses the simplifiers internal or external to delineate between the types of requirements and duties. Other terms or generalisations such as 'self-government' and 'self-determination' have been used to describe essential elements of autonomy: C. Mackenzie & W. Rogers, 'Autonomy, Vulnerability and Capacity: A Philosophical Appraisal of the Mental Capacity Act.' (2013) 9 *Int'l J.L. Context* 37, 42

[279] See, R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 277-287

Internal (psychological duties)	**External (physical duties)**
A threshold of mental capacities	**Gatekeeping through Mental Capacity Law**
Understanding	**Information Disclosure, and a Subjective Standard of Communication**
Authentic values	**Non-control, Communication, and a Medical Relationship of Trust**
Rational decision-making	**Communication of a Decision and the Testing of Logic**
Authentic decision-making	**Communication of a Decision and the Testing of values**

Figure 1: Examples of Internal and their equivalent External Components of Autonomy.

All models of autonomy share the same basic framework of internal and external content, but place emphasis on different elements of the internal decision. Maclean's political lexicon is an apt way of describing the typologies of autonomy; as the more substantive the internal requirements placed on the patient, the more duties are placed on the state to facilitate them. The modes span the continuum between an 'extreme libertarian view of autonomy as atomistic, independent self-determination to the communitarian extreme in which the importance of individual autonomy is subjugated to the needs and interests of the community.'[280] In the Law of England and Wales three broad models are used: a libertarian approach, a liberal approach and an authenticity approach. Whilst no direct legal examples are provided in this section, the remainder of this thesis will provide numerous examples the models

[280] A. Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge*. (Cambridge University Press, 2009), 10-11.

within law, the operationalisation of their internal and external content (within law and ethics), and their associated conceptual incompatibility. For the purpose of this thesis, a relational approach can be disregarded; as it has not been utilised as the foundation of the law of consent for those adults recognised to have capacity.[281]

2.3.2. The libertarian model

At one end of the spectrum is a model of autonomy which seeks to maximise liberty of choice and the right to self-determination.[282] This model of autonomy only requires that a recognisable choice or agreement is made to treatment, as the basis of consent. The internal content of the actual decision is opaque and does not require any distinct psychological components, or standards. This type of choice is grounded on the Millian notion that the patient is best placed to decide what is in their best interest.[283] As such, the form, and substantive content, of the actual choice is constructed without interference, or requirements placed on the individual, by the state.[284] As Mill argues:

> […] Liberty, as a principle, has no application to any state of things anterior to the time when mankind have become capable of being improved by free and equal discussion. [….] But as soon as mankind has attained the capacity of being guided to their own improvement by conviction or persuasion (a period long since reaches in all nations with whom we need here concern ourselves), compulsion, either in the direct form or in that of pains and penalties for non-compliance, is no longer admissible as a means to their own good, and justifiable only for the security of others.[285]

This is not to suggest that Mill, or indeed, other authors mentioned in this section are politically libertarian (although some are) just that their theories of consent adopt this structural approach. Indeed, although Mill is discussing the relationship between the individual and the state, this is equally applicable between the individual patient, and the doctor, who is a state actor in the context of human

[281] Although relational approaches are becoming more widely adopted in relation to best interest decision-making for those patients who lack capacity, particularly those in a minimally conscious state. See, Art 12 and Art 13 of The UN Convention on the Rights of Persons with Disabilities (CRPD). See C. Kong, 'The Convention for the Rights of Persons with Disabilities and Article 12: Prospective Feminist Lessons against the "Will and Preferences" Paradigm.' (2015) 4(4) *Laws* 709-728. Also see, R. Gilbar & C. Foster, 'It's arrived! Relational Autonomy Comes to Court: *ABC v St George's Healthcare NHS Trust* [2017] EWCA 336. (2018) 26(1) *Med L Rev* 125-133. For a more general normative argument about the use of relational autonomy in medical law see, J. Herring, Forging a Relational Approach: Best Interest's or Human Rights?' (2013) 13(1) *Med L Int* 32-54, 34.

[282] I. Berlin, "Two Concepts of Liberty." In I. Berlin, *Four Essays on Liberty*. (Oxford University Press, 1969), 155-156, 158; T.L. Zutlevics, 'Libertarianism and Personal Autonomy.' (2010) 39(3) *The Southern Journal of Philosophy* 461-471; R. Nozick, *Anarchy, State and Utopia*. (Basic Books), 48

[283] J. S. Mill, *On Liberty*. (Penguin Books Ltd, 1974), 68: "[the individual] cannot rightfully be compelled to do or forbear because it will be better for him to do so, because it will make him happier, because, the opinion of others, to do so would be wise or even right. These are good reasons for remonstrating with him, or reasoning with him, or persuading him, or entreating him, but not compelling him or visiting him with any evil in case he does otherwise."

[284] *Ibid*, 68-69

[285] J. S. Mill, *On Liberty*. (Penguin Books Ltd, 1974), 69

rights law.[286] According to Mill, politicians have no legitimate basis to create external duties and standards, through the law, which require the doctor to provide a content of information - as doing so may have the effect of influencing the patient's values, understanding or methodology for deciding, either implicitly or explicitly, against their will. This conceptualisation of consent, however, places corresponding positive duties on doctors: first, that the doctor must ensure that the patient is free from external control which could affect their liberty to choose.[287] For example, the requirement that the patient is not coerced in the construction of their choice, is similarly, a legal requirement when assessing a patient's consent to treatment[288] in the law of battery.[289] A similar prohibition from coercion can be seen in case-law relating to mental capacity.[290] However, under a libertarian model the doctor is also prohibited from influencing the patient. As the state is prohibited from looking behind a patient's choice, particularly, at their rationale, the doctor cannot retroactively check whether the patient is influenced, or correct their understanding;[291] therefore the doctor must ensure that all information the patient received is value-neutral.[292] The doctor may still obliged to provide the patient with the option of information; if they freely choose to have a type of understanding as the basis of consent. However, this would be a requirement operating between the doctor and the state, rather than the doctor and the patient. Such a requirement may be activated, for example, by the patient asking specific questions.[293] In a more abstract sense, the patient could be characterised as purchasing a distinct content of specialist information (in the form of a consultation with a specialist), or the state purchasing that expertise. The obvious downside being that the expert may not have a holistic overview of the particularities of the patient's condition or their need, and would not be obliged to do so, because of the lack of therapeutic obligations.[294] As the patient is provided a large amount of structural power (i.e. in how they shape the relationship), a theoretically pure libertarian model may only be feasibly accommodated within a model

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[286] *Ibid*, 63

[287] See *Freeman v Home Office* [1984] 1 All ER; *Re T (Adult: Refusal of Treatment)* [1992] 3 WLR 782, 797; *Mrs U v Centre for Reproduction Medicine* [2002] EWCA Civ 565, [22]; C. Stewart & A. Lynch, 'Undue influence, consent and medical treatment.' (2003) 96(12) *J R Soc Med* 598-601.

[288] *Re F (Mental Patient: Sterilisation)* [1990] 2 AC 1, at 77, argued that the law was based on "the libertarian principles of self-determination", and in *Airedale v Bland* [1993] AC 789, at 864 as "the principle [which] requires that respect must be given to the wishes of the patient."; *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, per Lord Scarman at 882: "what is no more or no less the right of the patient to determine for himself whether he will or will not accept the doctor's advice […] the patients right to make his own decision […] may be seen as a basic human right protected by the common law."; *In re T (Adult: Refusal of Treatment)* [1993] Fam 95, per Butler Sloss P, at 116 (relying on *Malette v Shulman* (1990) 67 DLR 321, 336); *Re C* [1994] 1 All ER 819; *Secretary of State for the Home Department v Robb* [1995] Fam 127; *Re MB (Medical Treatment)* [1997] 2 FLR 426, per Butler Sloss LJ at 432; *Re JT (Adult: Refusal of Medical Treatment)* [1998] 1 FLR 48; *St George's Healthcare NHS Trust v S, R v Collins ex p S* [1999] Fam 26; *Re AK (Medical Treatment: Consent)* [2001] 1 FLR 129; *Re B (Consent to Treatment: Capacity)* [2002] EWHC 429 (Fam).

[289] *Chatterton v Gerson* [1981] 1 All 257

[290] *Re F (Mental Patient: Sterilisation)* [1990] 2 AC 1

[291] O' O'Neil, 'Some limits on informed consent.' (2003) 29 *J Med Ethics* 4-7, 5

[292] R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 337-373

[293] J. Coggon & J. Miola, 'Autonomy, Liberty, and Medical Decision-Making.' (2011) 70(3) *Camb L J* 523-547, 539, 547

[294] G. J. Annas, *Some Choice: Law, Medicine, and the Market*. (Oxford University Press, 1998), i-xi, 55-62; L. G. Reeder, 'The Patient-Client as Consumer: Some Observations on the Changing Professional-Client Relationship.' (1972) 13(4) *Journal of Health and Social Behaviour* 406-412; P. Bartlett, 'Doctors as Fiduciaries: Equitable Regulation of the Doctor-Patient Relationship.' (1997) 5(2) *Med L Rev* 193-224

of a consumer relationship; where the patient, once regarded as being competent, has unfettered freedom to engage in the market of medicine.[295]

In the consumer relationship, the doctor would be obliged to assume that the patient had made a self-determined choice to seek out information at the point where the patient requested information. As such, the act of consent could be understood as a waiver: a negative liberty right to allow (in specific circumstances) the patient to disregard their bodily and mental integrity.[296] Manson and O'Neil argue that other models of autonomy, which contain thicker internal requirements, are practically unachievable because understanding and communication are opaque concepts and cannot be accurately identified or measured in the context of normative rule systems.[297] They make a compelling argument, for a return to the negative liberty conceptualisation of consent as a bare right to *self-determination*.[298] Fundamentally, though, a libertarian choice is respected because the patient has the capacity to make a decision which could be *hypothetically* perfectly autonomous.[299] Libertarian autonomy, therefore, awards a status of respect to the individual if they are deemed to have a global capacity to make autonomous choices. As such, it is necessary to define the threshold of capacity to be recognised as a consumer under this model.

(i) Capacity and the status of autonomous person(s)

As the substantive content of individual choices is bare, libertarian autonomy safeguards patients from potential exploitation by ensuring that patients have the capacities necessary to have a more substantive autonomous choice. In this sense a model of patient autonomy is conceptually compatible with other models of autonomy, if those models act as the basis of normative rules in relation to mental capacity. If the law of consent is libertarian in nature, and the rules of capacity are libertarian i.e., that there is a

[295] O. O'Neil, *Autonomy and Trust in Bioethics.* (Cambridge University Press, 2002), 43 & 47. See also, P.R. Wolpe, "The Triumph of Autonomy in American Bioethics: A Sociological View." In R. DeVries & J. Subedi (eds.), *Bioethics and Society: Sociological Investigations on the Enterprise of Bioethics*. (Prentice Hall, 1998), 49: "In a world where medicine has become a good to be consumed, and where patients are customers to be wooed, informed consent becomes the disclosure of the contents on the back of the box. Informed consent involves discussion of the nature of the procedure, its risks and benefits, and alternative treatments, and is enacted through the modern ritual of free assent, the signing of a contract."

[296] N.C. Mason & O. O'Neil, *Rethinking Informed Consent in Bioethics.* (Cambridge University Press, 2003); O' O'Neil, 'Some limits on informed consent.' (2003) 29 *J Med Ethics* 4-7, 5. Although, as Dr Pursehouse commented, when the content of this section were presented as a paper at SLSA 2019, O'Neil may refute the claim that her theory is libertarian in nature: M. Watkins, *Rationalising the Autonomy in Montgomery: clarifying the legal standard of care in information disclosure*. (SLSA Conference, Leeds University, 2019)

[297] O. O'Neil, *Autonomy and Trust in Bioethics.* (Cambridge University Press, 2002), 44.

[298] It is beyond this Thesis to argue whether a consent, or autonomous choice, without any internal processes – for example an arbitrary choice, with only first order reflection can be classed as self-determined or mere (re)action. By this definition must animals, insects, or even bacteria would be deemed autonomous.

[299] N. C. Mason & O. O'Neil, Rethinking Informed Consent in Bioethics. (Cambridge University Press, 2007), ix-x: "In successful informed consent transactions, communication is used to waive specific ethical, legal or other rights, obligations or prohibitions. Such transactions therefore presuppose the rights, obligations and prohibitions that are to be waived. So the obligations of medical practitioners and researchers to inform patients and research subjects, and to seek their consent to specific interventions are always *secondary* obligations. Our rethinking informed consent sets out standards that communicative transactions must meet if they are to be used to waive obligations, rights and prohibitions in specific ways. Properly used, informed consent can render action permissible that would otherwise constitute (for example) assault, false imprisonment, deception, or some other breach of significant ethical requirements."

presumption of capacity that cannot be easily rebutted, then patients may not be able to make more substantive autonomous choices, as a way to safeguard themselves from both medical exploitation and from making unwise decision.[300] The potential for harm is exacerbated if this combination occurs outside the moral medical relationship, as the intrinsic ethical requirements of beneficence are absent. A libertarian model, however, bars the professional from assessing whether the decision made was actually rational and thus whether the patient had capacity. Recognising a patient as capacitous must therefore be a global determination; affording that individual the status of *autonomous person*.[301] If an individual is considered an *autonomous person* their actions and choices are automatically recognised as autonomous and therefore worthy of respect,[302] regardless of whether it is based on actual understanding, or is irrational.[303] The status of *autonomous person* is afforded to the individual if they are recognised as passing a threshold of psychological competence.[304] The obvious problem is finding a threshold that ensures the psychological ability to make medical decisions, to a level where the patient can universally make informed choice, whilst also making the requirement so substantive that the majority of patients are barred from making self-determined choice. Mental capacity can only too easily eat into the libertarian principles which underpin the model, and as Clough argues, achieving this binary distinction may not be possible.[305]

(ii) Limiting liberty through a concept of harm

It is unsurprising, then, that the primary critique of the libertarian model is that once capacity is recognised, the model abandons the patient to the harms of their decisions.[306] Particularly, that within normative rules, consent is reduced to a 'legal flak-jacket'[307] which protects the doctor without ensuring that a more substantive, or rational, choice is made. However, as Mill argued, liberty can be restricted by a concept of *harm*: "That the only purpose for which power can be rightfully exercised over any member of the civilised community, against his will, is to prevent harm to others."[308] This concept of a limiting threshold of inappropriate harm, has for example, been conceptualised by Beauchamp and

[300] K. Keywood, 'Vulnerable Adults, Mental Capacity and Social Care Refusal.' (2010) 18(1) Med L Rev 103-110
[301] R. Gillon, *Philosophical Medical Ethics.* (John Wiley & sons, 1985), 60. See, J. S. Mill, *On Liberty.* (Penguin Books, 1974), 69.
[302] A. Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge*. (Cambridge University Press, 2009), 12: "If autonomy is equated with freedom of action then the relevance of any distinction between an autonomous person and an autonomous act disappears since every act of the autonomous person will, by definition, be autonomous."
[303] s.1(1) Mental Capacity Act 2005. See, *Re MB (An Adult: Medical Treatment)* [1997] 2 EWCA Civ 3093
[304] M. Donnelly, *Healthcare Decision-Making and the Law: Autonomy, Capacity and the Limits of Liberalism*. (Cambridge University press, 2010), 90.
[305] B. Clough, Disability and Vulnerability: Challenging the Capacity/Incapacity Binary.' (2017) 16(3) *Social Policy and Social Justice* 468-481
[306] J. Montgomery, 'Law and the Demoralisation of Medicine.' (2006) 26(2) *Legal Studies* 185-210, 186-187; A. Maclean, 'Autonomy, Consent and Persuasion.' (2006) 13 *European Journal of Health Law* 321
[307] *Re W (A Minor) (Medical Treatment)* [1992] 4 All E.R. 627. See also, H. Teff, 'Consent to Medical Procedures: Paternalism, Self-Determination or Therapeutic Alliance?' (1995) 101 *L Q Rev* 432
[308] J. S. Mill, *On Liberty.* (Penguin Books Ltd, 1974), 68

Childress as the principle of non-maleficence. This principle should be balanced against autonomy.[309] Unfortunately, neither Mill, nor subsequent commentators posited a universally defensible relationship between the two principles[310] which properly balances the competing requirements of both providing information and ensuring that this does not undermine the ability of the patient to make an autonomous choice.[311] This has led to, what Foster has called, a 'tyranny of autonomy':[312] where autonomy trumps other principles without rational justification.[313] As the requirement of non-control prevents doctors from interrogating the reasons for decisions retroactively; both judges[314] and commentators[315] have recognised the need to have a therapeutic privilege which acts as proactive justification to limit information which has a high chance of leading to serious harm. The therapeutic privilege could be used to either: (1) limit the amount of treatment choices, so that decision-making is simplified. This reframing of healthcare choices is termed libertarian paternalism.[316] (2) A doctor might be justified in refusing to provide the patient with information, at their request. For example, if the provision of information would cause the patient psychological harm and injure the patient's capacity to provide a future autonomous choice.[317] However, allowing the doctor to make a decision about harm would invite paternalism into the relationship, which has the potential to gut autonomy of its substantive content, and deprive the patient of being actually self-determined. Similarly, without a facilitative duty to offer a suite of treatments, or a broad content of disclosure, a patient is denied any real choice. As O' Neil rightly warns:

> What is grandly called 'patient autonomy' often amounts simply to a right to choose or refuse treatments on offer, and the patients' corresponding obligation of practitioners not to proceed without patients' consent. Of course, some patients may use this liberty to accept or refuse

[309] T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics.* (Oxford University Press, 2013), 158-162; R. Macklin, 'Applying the Four Principles.' (2003) 29 *J Med Ethics* 275-280
[310] R. Gillon, '" Primum non nocere" and the Principle of Non-Maleficence.' (1985) 291(6488) BMJ 130-131; R. Gillon, 'Medical ethics: four principles plus attention to scope.' (1994) 309(6948) BMJ 184-188.
[311] S. Holm, 'Not Just Autonomy – The Principle of American biomedical ethics.' (1995) 21 *J Med Ethics* 332-338
[312] C. Foster, *Choosing Life, Choosing Death: The Tyranny of Autonomy in Medical Ethics and Law.* (Hart Publishing, 2009), 98-104
[313] R. Gillon, 'Ethics needs principles – four can encompass the rest – and respect for autonomy should be "first among equals" (2003) 29 *J Med Ethics* 307-312.
[314] *Canterbury v Spence* (1972) 464 F 2D 772, per Robinson J at 789; *Sidaway v Board of Governors of the Bethlem Royal Hospital* (1985) AC 871, at 889); *Rogers v Whitaker* (1992) 16 BMLR 148, 153.
[315] R. Mulheron, 'The defence of therapeutic privilege in Australia.' (2003) 11(2) *J Law Med* 201-213; N. Grignoli, *et al,* 'Hope and Therapeutic Privilege: Time for Shared Prognosis Communication.' (2020) *J Med Ethics*:(https://jme.bmj.com/content/early/2020/10/14/medethics-2020-106157). Although other commentators argue that the therapeutic privilege is illegitimate: C.J.G. Holt, 'The Legal and Ethical Implications of Therapeutic Privilege – Is It Ever Justified to Withhold Treatment Information from a Competent Patient?' (2006) 1(3) *Clinical Ethics* 146-151
[316] R.H. Thaler & C. Sunstein, C. *Nudge: Improving Decisions about Health, Wealth and Happiness.* (Yale University Press, 2008); T. Plough & S. Holm, 'Informed Consent, Libertarian Paternalism, and Nudging: A Response.' (2015) 15(12) *The American Journal of Bioethics* 10-13. Although other commentators say that this is an illegitimate limitation on choice: W. Simkulet, 'Informed Consent and Nudging.' (2018) 33(1) *Bioethics* 169-184
[317] J. S. Mill, *On Liberty.* (Penguin Books Ltd, 1974), 70

> treatment with a high degree of reflection and individuality, hence (on some accounts) with a high degree of individual or personal autonomy. But this need not generally be the case.[318]

However, this thesis would argue that decision-making inevitably requires a level of discretion which invites value judgements about limiting information, in the simplest sense, to make a decision about materiality, the doctor will need to interpret the science.[319] This process of interpretation, however, is not value-neutral, neither is interpretation of applicable circumstances, even if one is utilising an objective threshold, and content of information.[320] As O'Neil argues, patients can never have the utopian level of control over the medical relationship envisaged by libertarian ethicists.[321]

3.3.3. A liberal model

A liberal theory of autonomy requires a more substantive content of internal processes to recognise, and thus respect, the autonomous nature of a choice. Unlike a libertarian view, it is not enough that the individual is free from external control and thus, has the liberty to choose the methodology, and values, which enter a decision. The liberal model require, understanding, agency and rationality to be externally recognised. Agency is recognised when a patient exercises the psychological capacities necessary to ensure that they can make a rational decision. This is a distinct type of capacity assessment which is carried out in synchronically; when the decision is actually made, rather than on the capacities necessary to prospectively make a decision. Thus, capacity would be afforded to the individual not as a status as an *autonomous person* but on the basis of an individual *autonomous choice*; as every choice must be autonomous according to the criteria necessary for agency.[322] To have capacity is therefore, to make an autonomous choice.

Requiring any internal requirements necessitates that a doctor interrogate the decision the patient actually makes. This type of interrogation would be seen as illegitimate from the perspective of the ethical libertarian; therefore, the two models are not compatible within normative rules about mental

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[318] O. O'Neil, *Autonomy and Trust in Bioethics.* (Cambridge University Press, 2002), 37

[319] E. Engebretsen, 'Uncertainty and Objectivity in Clinical Decision Making: A Clinical Case in Emergency Medicine.' (2016) 19 *Medicine, Health Care and Philosophy* 595-603

[320] See for example, H.J. Wilson, 'The Myth of Objectivity: Is Medicine Moving towards a Social Constructivist Medical Paradigm?' (2000) 17(2) Family Practice 203-209; T.V. Cunningham, "Objectivity, Scientificity, and the Dual Epistemology of Medicine." In P. Huneman, *et al*, *Classification, Disease and Evidence: Essays in the Philosophy of Medicine*. (Springer, 2014), 1-17

[321] O. O'Neil, *Autonomy and Trust in Bioethics.* (Cambridge University Press, 2002), 37 & 151-154: "[…] the choices that patients are required to make are typically quite limited. It is not as if doctors offer patients a smorgasbord of possible treatments and interventions, a variegated menu of care and cure. Typically, a diagnosis is followed with an indication of prognosis and suggestions for treatments to be undertaken. Patients are typically asked to choose from a smallish menu – often a menu of one item – that others have composed and described in simplified terms. This may suit us well when ill, but it is a far cry from any demanding exercise of individual autonomy."

[322] This gap obviously creates huge problems for those who cannot bridge the divide between a libertarian autonomy model within the Mental Capacity Act 2005 and the threshold of capacity for models of liberal autonomy, which are used as the basis for standards of care in information disclosure. For an excellent argument and analysis see: J. Herring & J. Wall, 'Autonomy, capacity and vulnerable adults: filling the gaps in Mental Capacity Act (2015) 25(4) *Legal Studies* 698-719

capacity.[323] As capacity assessments are context specific psychological thresholds necessary to have a choice shift in accordance with the complexity and/or the objective seriousness of the decision at hand.[324] This circumstantial approach to assessing capacity (once the presumption of capacity has been rebutted)[325] has been the primary methodology adopted by the law of England and Wales, first in the judicial test emanating from *Re C,*[326] where Thorpe J required that P, who was a paranoid schizophrenic, be able to:

(1) Take in information;
(2) Retain information;
(3) Believes the information;
(4) Weighs the information;
(5) Makes a decision.

This was enshrined in the Mental Capacity Act 2005, which required that the doctor rebut the presumption of autonomy, if P suffered from an impairment or disturbance in the functioning of the mind or brain so that they could not:

(a) Understand the information relevant to the decision
(b) Retain that information
(c) Use or weight that information as part of the process of making the decision,
(d) To communicate his decision [327]

Once the patient is seen to have capacity, then her particular choice is seen as automatically autonomous. However, if the requirements of capacity are set too high, this could have the effect of barring people from the ability to make autonomous choices, and as Meisel *et al* argued, introduce medical paternalism by the back-door.[328]

In pure philosophical terms, then, the liberal autonomous choice model requires distinct internal elements to a patient decision, which can be summarised as: (1) intentionality, (2) an actual understanding of a substantive content of objective knowledge,[329] (3), that there is a threshold of

[323] See Section 2.4. C. Mackenzie & W. Rogers, 'Autonomy, Vulnerability and Capacity: A Philosophical Appraisal of the Mental Capacity Act.' (2013) 9(1) *International Journal of Law in Context* 37-52, 42-44
[324] *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 3 WLR 830, per Lord Fraser at 844 & per Lord Scarman at 858; *PC v City of York Council* [2014] 2 WLR 1, [55]
[325] L.H. Roth & C.W. Lidz, 'Tests of Competency to Consent to Treatment.' (1977) 134 *Am J Psychiatry* 279
[326] *Re C* [1994] 1 All ER 819
[327] s.2(1) & s.3(1) Mental Capacity Act 2005
[328] L.H. Roth, A. Meisel & C.W. Lidz, 'Test of Competency to Consent to Treatment.' (1977) 134 *Am J Psychiatry*, 279
[329] I. Kennedy & A. Grubb, *Medical Law; Text with Materials.* (Butterworths, 1994), 106-107.

substantial non-control.[330] The purpose of these requirements is to ensure that the decision is internally rational[331] and flows from a threshold of material knowledge. The doctor has a duty to ensure that the patient receives an objective content of information which can be characterised as the 'informed' element of an informed consent.[332] This requirement for understanding is important for two reasons: first, it ensures that the patient has intentionally accepted the consequences of a decision, creating an identifiable transfer of the moral burden from the doctor to the patient (if said consequences occur),[333] second, understanding allows the patient to make a rational choice, which is perceived to be the ethical optimum (as it allows the patient to make decisions in their own best interests). Rationality can be identified through a process of deductive reasoning to see whether the choice made could logically have flowed from the information given. If the patient does not make a decision which appropriately balances the information provided, this may be because they have not actually understood information, or that they have been unable to use that information in a logical way.[334] Inability to utilise information in a discernible way would be indicative of a lack of capacity. This obviously creates a narrow spectrum for types of decision-making, and therefore types of choices which could be considered autonomous. This has the potential to introduce a type of paternalism if the doctor only recognises choices which he would agree with.[335] If this occurred the core purpose of the autonomy model (i.e. a right to self-determination) would be undermined.[336]

(i). Internal and external requirements

(a) Intentionality:

Intentionality is by its nature binary i.e. either an act is intentional (and potentially autonomous), or non-intentional (and therefore non-autonomous).[337] Faden and Beauchamp argue that to be intentional, requires the patient to choose to consent to treatment. To do so, they must know the nature of the act that is going to be committed, and how it is going to happen as a 'blueprint for action.'[338] The patient

[330] T. L. Beauchamp & J F. Childress, *Principles of Biomedical Ethics.* (Oxford University, 2013), 104; R. R. Faden & T. L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), Chapter 7 and 8.
[331] J. Savulescu & R.W. Momeyer, 'Should Informed Consent Be Based on Rational Beliefs?' (1997) 23(5) *J Med Ethics* 282-288; J. Coggon & J. Miola, 'Autonomy, Liberty, and Medical Decision-Making.' (2011) 70(3) *Camb L J* 523-547, 527-528
[332] A.R. Maclean, 'The Doctrine of Informed Consent: Does it exist and has it crossed the Atlantic?' (2004) 24(3) *Legal Studies* 386-413, 391-394
[333] R. R. Faden & T. L. Beauchamp, *A History and Theory of Informed Consent*. (Oxford University Press, 1986), 241-248
[334] I. Kennedy & A. Grubb, *Medical Law*. (Butterworths, 2000), 615
[335] J. Coggon & J. Miola, 'Autonomy, Liberty, and Medical Decision-Making.' (2013) 70(3) *Camb L J* 523-547. Also, M.A. Jones & K. Keywood, 'Assessing the Patient's Competence to Consent to Medical Treatment.' (1996) 2 *Med L Int* 107, 118: "There is clearly a strong temptation, however, to look for a higher level of understanding where the patient is declining treatment where that refusal could have serious implications. In these circumstances the assessment of the reasonableness of the decision itself may influence the judgement as to whether the patient was in fact competent to make the decision. There is, however, the danger of categorising patients as incompetent simply because they have not chosen the medical option that some other person (whether it be the doctor, a relative or the court) would have chosen in the circumstances and allowing that person to substitute their own paternalistic view of what is in the patient's best interests."
[336] *Re T (Adult: Refusal of Medical Treatment)* [1992] 2 All ER, per Lord Donaldson, at 652-653; *Re MB (An Adult: Medical Treatment)* [1997] 2 FLR 427; *Airedale NHS Trust v Bland* [1993] 1 All ER, per Lord Goff at 866 & per Lord Mustill at 889
[337] R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 241
[338] *Ibid*, 242

would have to know potential risks, and benefits, for them to have intentionally accepted the consequences of a given treatment, as, 'for an act to be intentional, it must correspond to the actor's conception – his or her plan – of the act in question.'[339]It is not enough that a patient chose a desired end, for example, that a fracture be repaired, as the patient would not have expressly agreed within the act of touching which required consent.[340]

(b) Objective understanding:

Understanding and intentionality are related because one is not able to do an intentional act without understanding the nature of that act, likewise, one is likely to always have intentionality if they complete an intentional plan with understanding.[341] Unlike a libertarian model of autonomous choice, the capacity to understand is not enough; patients need an *actual* understanding as the basis of an autonomous choice.[342] This threshold of understanding, however, goes further than intentionality. The patient must also have a reasonable, or objective, threshold of knowledge about the risks, benefits and options, of a proposed treatment, or investigation, to make a rational choice.[343] As the objective content is delineated by the doctor (based on medical values) and contains information that the doctor thinks the reasonable patient in the circumstances should know, it is *ideal* in nature. As this content of information is based on medical values, the subsequent interpretation, and thus understanding of information required by the patient can be considered *ideal* in nature. The content of understanding necessary to have a rational choice is therefore not value neutral.[344] O' Neil for example, argued that the principles or values used to delineate a content of understanding can be deontologically justified if they are categorical imperatives – and are thus universalisable.[345] Coggon adopts the same justification in his definition of ideal autonomy:

> […] it requires an agent's decision-making to accord with some objective set of ideals. […] This theory holds that whilst it is important that we be in control of our decision-making, we must not try to imagine ourselves in the untenable vacuum that is sometimes implied by individualism. Ideal desire autonomy requires agents to consider their reason for acting, and only to pursue a course of action if it could be made a universal law.[346]

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[339] *Ibid*
[340] *Ibid*, 242-243
[341] *Ibid*, 243-244
[342] *Re C* [1994] 1 All ER 819; *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 3 All ER 402, per Lord Scarman at 424; *Re E (A Minor) (Wardship: Medical Treatment)* [1993] 1 FLR 386; *Re S (A Minor) (Consent to Medical Treatment)* [1994] 2 FLR 1065 107-147, 115-117
[343] J. Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism?' (2007) 15 *Health Care Analysis* 235-255, 240-241
[344] T.L. Beauchamp & J.F. Childress, Principles of Biomedical Ethics. (Oxford University Press, 2019), 449-456
[345] O' Neil, *Autonomy and Trust in Bioethics.* (Cambridge University Press, 2002), Chapter 4
[346] J. Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism?' (2007) 15 *Health Care Analysis* 235-255, 240-241

However, the internal values that underpin the objective content of information could similarly be defined empirically.[347]

The content of information must ensure that the patient, too is able to use the content of that information to make a rational decision. This will vary depending on the complexity and nature of the information. For example, understanding the risks of an appendectomy is likely to be less complex than the implications of treatments for genetic disorders.[348]The content of the understanding necessary to have an autonomous choice occurs on a spectrum between enough information necessary to have an intentional choice, by understanding the nature of a decision, up to full understanding of that choice;[349] where the patient had all potential material information which could potentially occur as a result of a treatment. [350] This has the benefit of ensuring that a patient who can make an autonomous decision will have considered and rationally weighed all potentially material information before coming to a conclusion. However, it is uncertain whether an objective threshold of full understanding could be psychologically achieved by most patients due to the nature the patients' illness. Therefore, as Faden and Beauchamp argues, the level of understanding will likely be have to be set at a threshold which compromises the maximisation for rational choice and practical achievability.[351] Much of the medico-legal commentary debates the optimum threshold of understanding, albeit in the language of standards of care in negligence (necessary to maximise the autonomy of patient decisions).[352] Faden and Beauchamp argue, for example, that the problem of a definitive threshold can be overcome by adopting a more realistic watershed of 'substantially autonomous'[353] where, to be recognised as 'substantially autonomous' the patient's understanding has to be 'somewhere between midpoint and fully autonomous.'[354] This threshold, whilst narrowing down the range of optimum content suffers from the fallibility of uncertainty: how does one define a threshold of full understanding, and more importantly, a mid-point of understanding?[355] This may be essentially a psychological question, which would vary between both patient groups, and indeed individual patients, however, if this is the case the concept of understanding becomes useless as the conceptual basis for a normative system such as law. Indeed, requiring an objective standard of material information could have the effect of barring the patient from

[347] See, A. Maclean, 'Giving the Reasonable Patient a Voice: Information Disclosure and the Relevance of Empirical Evidence.' (2005) 7(1) *Med Law Int* 1-40
[348] See for example, V.M. Marsh, *et al*, 'Experiences with Community Engagement and Informed Consent in a Genetic Cohort Study of Severe Childhood Diseases in Kenya.' (201) 11(13) *BMC Medical Ethics* 2-11; C. Ayuso, 'Informed Consent for Whole-Genome Sequencing Studies in the Clinical Setting. Proposed Recommendations on Essential Content and Process.' (2013) 21 *European Journal of Human Genetics* 1054-1059
[349] R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 238-240
[350] *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 3 All ER 402 per Lord Scarman at 424
[351] A. Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge*. (Cambridge University Press, 2009), 80-81
[352] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of the Law?' (1987) 7(2) *Legal Studies* 169-193; A. Maclean, 'From Sidaway to Pearce and Beyond: Is the Legal Regulation of Consent Any Better Following a Quarter of a Century of Judicial Scrutiny?' (2012) 20(1) *Med L Rev* 108-129
[353] R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 239.
[354] *Ibid*, 241
[355] *Ibid*, 240

making a choice. However, if understanding was particular to the decision, then the law would have no proactive normativity, and standards would only be realised in hindsight.[356]

Once the doctor had defined the materiality of the content of information, delineated the information to a level where the patient could understand, he then needs to disclose the information to the patient. This would require an external duty to: (1) disclose information to an objective threshold necessary for a substantial understanding; (2) communicate so that the particular patient understands. As individuals learn differently, the standards of communication would have to be subjective to the needs of the actual patient; their learning style and circumstances.[357]

(c) Rationality:

To ensure a rational choice, the disclosure of information must be actually understood. Actual understanding requires a type of understanding where the values inherent within information are internalised. The patient must, in essence, believe the information in the way that the information is intended to be communicated. Faden and Beauchamp, for example, argue that there are three categories of understanding, which must be distinguished:[358]

(i) *Understanding how*: is the competence or ability to understand to do an activity, or to utilise a concept, so you have know-how to do something.

(ii) *Understanding what*: is appreciation of knowledge or concepts, so that the patient can be said to understand that the doctor is telling her of their professional perception of risk or benefits. However, the patient does not need to believe or adopt this interpretation of the risks and benefits. This can be seen as a formulistic type of understanding; where the patient appreciates the information but may also have pre-formed internal values which allow them to resist communications.[359] To provide consent with intentionality requires that the patient understands the propositional nature of what is being asked, but they do not have to internalise a value-content of information.[360]

(iii) *Understanding that*: is propositional knowledge, where the patient would have to internalise a substantive content of information, and accept it as true, before they could be said

[356] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law?' (2018) 7(2) *Legal Studies* 169-193, 189-199; J. Coggon & J. Miola, 'Autonomy, Liberty, and Medical Decision-Making.' (2011) 70(3) *Camb L J* 523-547, 528

[357] R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 314-316; A. Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge.* (Cambridge University Press, 2009), 81-82 & 243-244

[358] *Ibid*, 250-251

[359] H.G. Frankfurt, On *Bullshit.* (1986) 6(2) *Raritan Quarterly Review* 81-100; H.G. Frankfurt, *On Bullshit* (Princeton University Press, 2005)

[360] R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 251

to have understood it.[361] This content of understanding would include an appreciation of the values intrinsic to risks and benefits, which were attached to the information by the doctor according to the test of materiality. This value-content is essential because it allows the patient to adopt those values as a basis to make decisions on an objective rational basis.[362] To actually understand, then, the patient must internalise and believe the values of that information (as a second order desire).[363] For example, in cases which have related to those with eating disorders, especially anorexia nervosa, the inability of those patients to internalise values, and *understand that*, nutrition is essential to their welfare, means that they are not considered to have capacity.[364] Commentators have argued that failing to differentiate between formulistic and substantive understanding has acted as the foundation to arbitrarily refuse to recognise capacity, usually based on diagnosis.[365]

For a liberal model of autonomy, the patient must a have *understand that* level of understanding. Specifically, that the prima facie information, the reasons why the doctors consider that information material, and the doctor's hierarchy of benefit and seriousness. The patient must then use this to make a decision: weighing and balancing information so that they can make a rational choice.[366] If patients do not make rational decisions, on this basis, it defeats the ethical purpose of constructing objective duties of disclosure to ensure understanding.[367] However, requiring this highly content controlled type of decision-making has led commentators to argue that patients are not making a *free choice*.[368] Proponents for authenticity argue that decisions made on subjective, and thus, personal values are essential for the patient to make a true autonomous choice.[369] There is also the question of whether this type of substantive understanding is actually achievable; as it falls foul of the internally opaque nature

[361] *Ibid*, 251
[362] J. Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism?' (2007) 15 *Health Care Analysis* 235-255, 240; D.O. Brink, "Kantian Rationalism: Inescapability, Authority and Supremacy." In G. Cullity & B. Gaut (eds.), *Ethics and Practical Reason.* (Clarendon Press, 1997), 272; B. Gaunt, "The Structure of practical reason" In G, Cullity & B. Gaut (eds.), *Ethics and Practical Reason*. (Clarendon Press, 1997), 161-162
[363] G. Dworkin, *The Theory and Practice of Autonomy*. (Cambridge University Press, 1988), Chapter 1; H.G. Frankfurt, 'Freedom of Will and the Concept of Person.' (1971) 68(1) *Journal of Philosophy* 5-20
[364] *A Local Authority v E (by her Litigation Friend, the Official Solicitor) & Others* [2012] EWHC 1639 (COP); *The NHS Trust v L (by her Litigation Friend, the Official Solicitor & Others* [2012] EWHC 2741 (COP); *An NHS Foundation Trust v Ms X* [2014] EWCOP 35; *Betsi Cadwaladr University Local Health Board v Miss W (by her Litigation Friend, the Official Solicitor)* [2016] EWCOP 13; *Cheshire & Wirral Partnership NHS Foundation Trust v Z* [2016] EWCOP 56; *Northamptonshire Healthcare NHS Foundation Trust v AB* [2020] EWCOP 40
[365] E. Cave & J. Tan, Severe and Enduring Anorexia Nervosa in the Court of Protection in England and Wales. (2017) 23(17) *International Journal of Mental Health and Capacity Law* 4-24
[366] M. Somerville, 'Refusal of Medical Treatment in 'Captive' Circumstances.' (1985) 63 *Canadian Bar Review* 59, 65-68; R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 260-261; T. L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics.* (Oxford University Press, 2013), 131-134
[367] See, A. Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge*. (Cambridge University Press, 2009), 13: "The purpose of rationality is to provide sufficient consistency to justify reliance on the outcome of the reasoning process. As such, even where it is only relied on by the reasoner, there must be a certain objectivity or 'generality' to the reasoning."
[368] T. L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics.* (Oxford University Press, 2013), 138-150; R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), Chapter 10
[369] M.A. Jones & K. Keywood, 'Assessing the Patient's Competence to Consent to Medical Treatment.' (1996) 2 *Med L Int* 107-147, 135

of communication and decision-making,[370] or whether such a requirement could be constructed through normative rules.[371] Requiring a type of ideal decision-making could lead to denying patient choices respect because of external judgements of the construction and weighing of values.[372] Essentially, if the patient does not reach the same conclusion of the doctor, they could be found to lack capacity.

(d) Non-control:

The core of autonomy is understood as liberty from interference or 'self-determination.'[373] However, as already been explained, the substantive requirements of the liberal model of autonomy, flowing from the requirement of rationality, places quite significant restrictions on the content and method of patient decision-making. Theoretically, it is necessary for the patient to adopt medical values, and use them as the basis of their consent, for that decision to be respected. Despite this, Faden and Beauchamp, who are advocates for this liberal type of autonomy, argue that the patient should still be substantially non-controlled – in the sense that they have made a voluntary consent. They argue that control should be understood in terms of *influence* and *resistance*.[374] A fully non-controlled act (an act with full liberty) would theoretically have no external influence in the form of other people's values, or because an attempt of persuasion is defeated by a robust resolve, derived from the patient's own values.[375] If, on the other hand, the values of the persuader would be irresistible, or that the patient had no resistance (e.g. due to a lack of personal values, or because of their lack of resolve in the circumstance), then they would be controlled to a greater or less extent – along a spectrum of control.[376]

The requirement to be non-controlled can therefore be achieved from two angles. First, by helping the patient achieve resilience where they are substantially non-controlled, second, by controlling communication so that it is not irresistible to the reasonable patient. As resilience is individual to the patient, and is likely to change, dependant on the context (e.g. time or place) of disclosure, it is sensible that Faden and Beauchamp focus on ways to ensure non-control through substantially controlling (manipulation of choice, and coercion) and non-controlling (persuasion, and manipulation of options) communication.[377] For example, whilst the doctor could not threaten the patient, the doctor might rationally nudge the patient,[378] by providing advice, or information, about how they might structure

[370] O. O'Neil, *Autonomy and Trust in Bioethics.* (Cambridge University Press, 2002), 39
[371] T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics*. (Oxford University Press, 2013), 262-266
[372] This sort of backward-looking focus, and questioning of patient values, is rejected by the Libertarian approach to legal capacity adopted by the Mental Capacity Act s1(4). See, *Heart of England NHS Foundation Trust v JB* [2014] EWHC 342 (COP); *York City Council v C* [2014] 2 WLR 1. Also, *R v Cooper* [2009] 1 WLR 1786
[373] R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent.* (Oxford University Press, 1986), 256
[374] *Ibid*, 256
[375] *Ibid*, 258
[376] *Ibid*, 258
[377] *Ibid*, 337
[378] R.H. Thaler & S.C.R. Sunstein, *Nudge: Improving Decisions about Health, Wealth and Happiness.* (Yale University Press, 2008). Irrational nudging, however, would not be ethical communication: W. Simkulet, 'Nudging, Informed Consent and Bullshit.' (2017) *J Med Ethics* 1-7, 2-3

their decision to have a rational choice.[379] The doctor can also limit the 'choice architecture,' which in turn, would narrow the spectrum of choice, without being directly coercive.[380] These limitations of choice are seen as legitimate as they would not overwhelm the average patient's resistance.[381] Limitation of the content of choice is also legitimised because requiring an understanding for a rational choice, as Cohen argues, allows patients to act in their own best interests; bridging the gap between autonomy and beneficence.[382] The obvious problem with this approach is that communicative acts affect individuals in different ways, depending on their *particular* resilience. What may be seen as a gentle suggestion by one patient may cause another to hand complete control over to the doctor.[383] Requiring a content of information disclosure necessary for rationality could have the potential, for some patients, to defeat their ability to have an intentional choice.

2.3.4. Authenticity Model

Unlike the liberal model, which requires the patient to adopt a form of rationality based on an objective understanding, an authenticity model argues that the basis of patient decision-making should be grounded on the facilitation of their subjective values.[384] The authenticity model distinguishes between two types of values or 'desires':

> (1) First order desires are values which make you want to do an action in the immediate, based on a short-term value, such as an impulse.[385] Dworkin gives the example of a person who has a drug addiction, they may want to give up the drugs, but their first order desires, in the form an addiction would overpower their ability to resist.[386]
>
> (2) Second order desires are values which are integral to the individual and their character, which might have been formed or held over a long period of time.[387] If a patient acts in accordance with these more long held values they can be said to be acting authentically in their decision-making. [388]

[379] S. Cohen, 'Nudging and Informed Consent.' (2013) 13(6) *The American Journal of Bioethics* 3-11
[380] R.H. Thaler & S.C.R. Sunstein, *Nudge: Improving Decisions about Health, Wealth and Happiness.* (Yale University Press, 2008); A. Wertheimer, 'Should 'nudge be salvaged?' (2013) 39 *J Med Ethics* 498-499; Y. Saghai, 'The concept of nudge and its moral significance: a reply to Ashcroft, Bovens, Dworkin, Welch and Wertheimer.' (2013) 39(8) *J Med Ethics* 499
[381] S. Cohen, 'Nudging and Informed Consent.' (2013) 13(6) *The American Journal of Bioethics* 3-11,4-5
[382] *Ibid*
[383] F.J. Ingelfinger, 'Informed (But Uneducated) Consent.' (1972) 287 *New England Journal of Medicine* 466
[384] See, G. Dworkin, *The Theory and Practice of Autonomy.* (Cambridge University Press, 1988), Chapter 1. See also, H.G. Frankfurt, 'Freedom of Will and the Concept of Person.' (1971) 68 *J Philos* 5-20, 7; R. Macklin, *Man, Mind and Morality: The Ethics of Behaviour Control* (Prentice-Hall, 1982), 57
[385] G. Dworkin, *The Theory and Practice of Autonomy.* (Cambridge University Press, 1988), 15.
[386] *Ibid*, 16
[387] *Ibid*
[388] *Ibid*, 15

To have these second order desires, and thus to act with authenticity, requires capacity for the formation and decision-making based on these authentic values. *Authenticity* requires what Dworkin terms[389] the ability to undertake the act of *identification* – this means that the individual has the ability to reflect on their values, and select their preferred desires (and then act in line with those desires).[390] Dworkin argued, that ultimately, the inability to undertake this reflective process means that these people lack authenticity, and therefore the ability to make an autonomous decision.[391] Decision-making grounded on second order desires has been termed, by Coggon, a form of best desire autonomy. This form of autonomy differs from a liberal model; as individuals 'may be selfish, self-destructive, or subject to some other condition that would make them impossible to hold as a universal law,' however, decisions based on these values must be respected. [392] If the patient fails to make a decision based on their authentic values they have not made an autonomous choice.[393]

(i). Internal and external requirements

(a) Non-control

To ensure that the patient's decisions are authentic requires that the doctor to maintain the integrity of the patient's second order desires, and to assess whether the patient is using these values as the basis of their decision.[394] Dworkin argued that one can be self-determined if the values on which one is making a decision have been formed through a process of *procedural independence.* This type of independence is focused on how the second order desires have been realised.[395] Procedural control is conceptualised as an external liberty (and later a capacity)[396] to select one's desires so that they are not controlled by another.[397] Unlike Faden and Beauchamp's theory, a distinction is not made between the types of communication but on the impact of the communication by others on the formation of individual values.[398]

> Authenticity, while necessary for autonomy, is not sufficient. A person's motivational structure may be *his*, without being his *own*. This may occur in either of two ways. First, the identification with his motivations, or the choice of the type of person he wants to be, may have been produced

[389] *Ibid*
[390] G. Dworkin, "The Concept of Autonomy." In J. Christman, *The Inner Citadel: Essays on Individual Autonomy*. (Oxford University Press, 1989), 61: "A person is autonomous if he identifies with his desires, goals, and values, and such identification is not influenced in ways which make the process of identification in some way alien to the individual."; G. Dworkin, *The Theory and Practice of Autonomy.* (Cambridge University Press, 1988), 15
[391] G. Dworkin, *The Theory and Practice of Autonomy* (Cambridge University Press, 1988), 16.
[392] J. Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism?' (2007) 15 *Health Care Analysis* 235-255, 241
[393] F. Kraemer, 'Authenticity or Autonomy? When deep brain stimulation cases a dilemma.' (2013) 39 *J Med Ethics* 757-760
[394] J. Christman, 'Introduction' In J. Christman (ed.), *The Inner Citadel: Essays on Personal Autonomy*. (Oxford University 1989), 7
[395] G. Dworkin, 'Autonomy and Behaviour Control.' (1976) 6(1) *The Hastings Center* 23-28, 25-26
[396] G. Dworkin, *The Theory and Practice of Autonomy* (Cambridge University Press, 1988), 15; L. Haworth, 'Review: *The Theory and Practice of Autonomy* by Gerald Dworkin.' (1991) 102(1) *Ethics* 129-139, 132-133
[397] G. Dworkin, *The Theory and Practice of Autonomy.* (Cambridge University Press, 1988), 14 & 18
[398] G. Dworkin, 'Autonomy and Behaviour Control.' (1976) 6(1) *The Hastings Center* 23-28, 25-26

> by manipulation, deception, the withholding of relevant information, and so on. It may have been influence in decisive ways by others in such a fashion that we are not prepared to think of it as his own choice. I shall call this a lack of procedural independence.[399]

Dworkin recognised that it was enough that a person should have *procedural independence,*[400] rather than *substantial independence*: which requires independent creation, or sourcing of values. This is because values are inevitably formed, and influenced, by experience, or communication with others. The formation of values are, thus, never truly free of control. Indeed, if this was a requirement to be autonomous would be inconsistent with: 'loyalty, objectivity, commitment, benevolence, and love.'[401]For example, 'to be committed to a friend or cause is to accept the fact that one's actions and even desires, are to some extent determined by others.'[402] Second, values 'develop socially and psychologically in a given environment, with a given set of biological endowments. The content of the desires could, therefore, have been acquired by manipulation and coercion during childhood. [403] Value purity would require the doctor to embark upon an historical investigation as to how one's choice about values were reached.[404] This is realistically impractical as the basis for medical duties. Recognising the potential for influence also requires one to recognise a further higher-order set of desires that may have influenced the process of *identification* of second order desires. This invites the problem of an infinite regress of potential values[405] – to the extent that the doctor may not be able to practically identify if the decision has actually been sufficiently independent.[406]

(b) Subjective understanding

Putting the problem of independence to the side, for a moment, the doctor would be obliged to delineate a content of information to ensure the patient understood information in accordance with their authentic desires. Like a libertarian model, the patient would have freedom to choose the content of information, however, only if that content met the requirements of *authenticity.*[407] In normative terms, the doctor would be facilitating a subjective standard of understanding, through a particular patient standard of care. The standard would have to be subjective; as otherwise any information the doctor discloses may

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[399] *Ibid*, 25
[400] *Ibid*. See also, G. Dworkin, 'Acting Freely.' (1970) 4 *Nous* 4; H. Frankfort, 'Freedom of Will and the Concept of a Person.' (1971) 68(1) *J Philos* 5-20
[401] G. Dworkin, *The Theory and Practice of Autonomy* (Cambridge University Press, 1988), 21. For examples of theories of autonomy with substantive independence see: R.P. Wolff, 'In Defense of Anarchism.' (1971) 46 *Philosophy* 301; J. Rachels, 'God and Human Attitudes.' (1971) 7 *Religious Studies* 334; T. Scanlon, 'A Theory of Freedom of Expression.' (1972) *Philosophy and Public Affairs* 215
[402] *Ibid*, 23
[403] G. Dworkin, 'Autonomy and Behaviour Control.' (1976) 6(1) *The Hastings Center* 23-28, 24.
[404] G. Dworkin, *The Theory and Practice of Autonomy.* (Cambridge University Press, 1988), 18
[405] J. Anderson, 'Disputing Autonomy: Second-Order Desires and the Dynamic of Ascribing Autonomy.' (2008) 9(1) *Nordic Journal of Philosophy* 7-26, 9-11
[406] J. Ahlin, 'The impossibility of reliably determining the authenticity of desires: implications for informed consent.' (2018) 21(1) *Med Health Care Philos* 43-50
[407] G. Dworkin, *The Theory and Practice of Autonomy.* (Cambridge University Press, 1988), 15

alter the second order values of the individual, and thus the value-basis of the choice, making the decision non-autonomous.

A normative requirement to facilitate a subjective value-content of information is problematic: first, it relies on a communicative relationship where the patient is able to accurately describe her authentic-values.[408] This places a heavy responsibility on the patient, who may not be able to express their authentic selves because of relational barriers (such as family), or the circumstances of illness.[409] The experience of illness, and communicating with a doctor, may in itself be creating values which are more synchronically authentic, than long-held diachronic values; especially, if patients are making decisions in novel circumstances.[410] This places a conflict between immediate, but strongly held values, and long-held but potentially less relevant values, as a basis to facilitate understanding.[411] If the doctor is able to identify the patient's authentic values, this does not ensure that they are relevant or sufficient, for the disclosure of medical information. Indeed, if they are illogical. or irrational, they may not be applicable to any information, or they may require disclosing of information which is contradictory. This content of information will not provide the patient the ability to make a balanced decision, or lead to the provision of information which is actively misleading.[412] On this basis, disclosure under the authenticity model is potentially in opposition to the requirement for rationality, in the liberal model.

Once the doctor has decided on a material content of information there would need to be a further external duty to disclose that information in a way that the patient could understand. However, the doctor must take care to not alter the authentic values on which materiality was decided, through the process of actually communicating information. This is again problematic, as even with the most value-neutral communication, could potentially overwhelm the patients values, or augment their process of weighing and balancing risks; thus, making the decision non-autonomous.[413]

3.4. The Consumer Relationship and Informed Consent

> Consumerism is with us. The doctor has the choices only of accepting it willingly and co-operating, or of accepting it unwillingly.[414]

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[408] M. Brazier, 'Do No Harm – Do Patients Have Responsibilities Too?' (2006) 65(2) *Camb L J* 397-422
[409] I. Hyun, 'Waiver of Informed Consent, Cultural Sensitivity, and the Problem of Unjust Families and Tradition.' (2002) 32(5) *The Hastings Center Report* 14-22
[410] C. Mackenzie & W. Rogers, 'Autonomy, Vulnerability and Capacity: A Philosophical Appraisal of the Mental Capacity Act.' (2013) 9(1) *International Journal of Law in Context* 37-52, 44-45
[411] J. Ahlin, 'The Impossibility of Reliably Determining the Authenticity of Desires: Implications for Informed Consent.' (2017) 21 *Med Health Care and Philo* 43-50
[412] T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics*. (Oxford University Press, 2013), 150-153
[413] See Chapter 5, Section 3; Chapter 6, Section 3; A Bhangu *et al*, 'Informed Consent Effective in Trauma Patients?' (2008) 34 *J Med Ethics* 780-782; R.P. Dutton, 'Impediments to Obtaining Informed Consent for Clinical Research in Trauma Patients.' (2008) 64(4) *The Journal of Trauma and Acute Care Surgery* 1106-1112
[414] I. Kennedy, 'Consumerism in the Doctor-Patient Relationship.' (1980) Dec 11 *The Listener* 777-780, 778

The adoption of a consumer-type relationship was first suggested (within the UK) by Ian Kennedy – in an article published in *the Listener*,[415] and subsequently in an expanded lecture as part of his 1980 Reith lecture series.[416] Consumerism was seen as a form of social engineering. To ensure effective service provision, and financial efficacy, state agencies (including the courts) were justified in constructing, and promoting, the rights and interests of patients; who were reconceptualised as *consumers* of medicine. Consumers were expected to be self-determined, and to participate in responsible decision-making. This ensured that patients were protected from the therapeutic relationship which 'threatens to infantilise […] patient[s], to undermine his power of self-determination, to act in a paternalistic manner.'[417] This relationship chimed with the growth of the rights school of thought; where power was transferred from the expert doctor, to the patient. In the consumer relationship, power always existed with the service user. Patient rights became mechanisms by which consumer-patients could assert their power in a market of medicine. The provision of services, however, required regulation service-providers. This would be achieved through patient rights to standards of care, or information. Acceptable standards could be accomplished through internal rules; for example, Kennedy suggests peer review and audit (although, this was unlikely due to professional reluctance), or the creation of external standards, through regulatory agencies, ethical guidance, and law. Kennedy (initially) preferred externally defined consumer rights, which would manifest through litigation and result in limiting medical discretion.[418]

Teff, similarly, recognised the legal movement towards a model of the consumer-relationship, corresponded with value commitments to neo-liberal politics, and health policy.[419] For example, with the adoption of the language of commerce and the market place in the National Health Service and Community Care Act 1990.[420] Like Kennedy, Teff recognised the consumer relationship as one which refocused ethical and legal duties (and standards) towards the patient. This refocus on the patient required the stretching of existing causes of action to facilitate 'patient rights.' However, there was debate as to how this relationship would best be accommodated within existing legal frameworks.[421] Teff, suggested two methods: the 'trade model,' or 'therapeutic alliance.' The trade model would be

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[415] *Ibid*, 777
[416] I. Kennedy, *The Unmasking of Medicine*. (George Allen & Unwin, 1981), Chapter 6
[417] *Ibid*, 777
[418] *Ibid*, 777-778
[419] H. Teff, 'Medical Models and Legal Categories: An English Perspective.' (1993) *J Contemp Health L & Pol'y* 211, 215-216.
[420] Department of Health, *Working for Patients* (HMSO, 1980); Department of Health, *Working Paper 2: Funding and Contracts for Hospital Services; Self-Governing Hospitals: An Initial Guide; Contracts for Health Services: Operational Principles*. (HMSO, 1989).
[421] For example, the "Priestly" and "Engineering" Model (R.M. Veatch, 'Models for Ethical Medicine in a Revolutionary Age.' (1972) 2(3) *The Hasting Center Report* 5-7, the "Shared Decision-Making" model (C. Charles, *et al*, 'Decision Making in the Professional Patient Encounter: Revisiting the Shared Treatment Decision Making Model.' (1999) 49 *Soc Sci Med* 651-661; C. Charles, *et al*., 'What do we mean by Partnership in Making Decisions about Treatment?' (1999) 319 *BMJ* 780-782; G. Elwyn & C. Charles, "Shared Decision Making: the Principles and the Competences." In A. Edwards & G. Elwyn, *Evidence-Based Patient Choice?* (Oxford University Press, 2001), 120-121), the "Deliberative" "Informative" and "Interpretative" Model (E. Emanuel & L. Emanuel, 'Four Models of the Physician-Patient Relationship.' (1992) 267(16) *JAMA* 2221-2226).

based on a contractual, or fiduciary relationship, where the doctor was obliged to act in accordance with the patient's choices.[422] To operate effectively, the trade relationship required the NHS to be broken down into its' constituent parts, so services could compete for patients, and thus maximise competition and therefore efficiency. The successful services, would, theoretically, be those that best aligned with the needs of the patient. The therapeutic alliance, on the other hand, sought to bridge the gap between the expertise of the medical practitioner and the customer patient, with a collaborative approach; where the doctor and patient would co-create the aims of medicine. This approach sought to define outcomes in terms of preventative and holistic benefit to the patient, rather than technical success or cure.[423]

Despite differences in the theoretical construction of patient and medical roles, and within normative rules, in law, all models of the consumer relationship were (to a greater or lesser extent) orientated towards the teleological purpose of maximising choice.[424] One of the primary requirements for maximising choice under the model of consumerism was through the facilitation of patient autonomy.[425] As the previous section has demonstrated, ensuring an autonomous choice is not a singular requirement: it is predicated on a number of internal and external requirements, both for its phenomenological manifestation, and it's recognition by third parties.[426] These conditions, or requirements, placed responsibilities on both consumer patients and doctors. As Teff argued, doctors were required to facilitate contractual, or fiduciary, duties (i.e. doctors as state actors); to ensure conditions of: intentionality, understanding, non-control, capacity, rationality, and/or authenticity were met. As Faden and Beauchamp argued, informed consent remains a species of autonomous authorisation, or choice.[427] It is a descriptor for a number of duties operating together, within a single space and time, to ensure an ethical form of autonomous authorisation.[428] A model of autonomous choice, is then preferred by the law, as the basis of recognising the ability of the individual to enter a market of healthcare (or otherwise to waive the patient's right to bodily integrity).[429] In this sense, informed consent, is simply one part, or manifestation, of the greater whole of the consumer model of the medical relationship.

3.4.1. The Consumer and Therapeutic Relationship in Conflict

The previous section set out the three versions of autonomy that have been used as the basis for models of informed consent within the law. Requiring a substantive autonomous choice, as the basis of an

[422] H. Teff, 'Medical Models and Legal Categories: An English Perspective.' (1993) *J Contemp Health L & Pol'y* 211, 219 & 225-227
[423] *Ibid*, 221-224
[424] G. J. Annas, *Some Choice: Law, Medicine, and the Market*. (Oxford University Press, 1998), xi-xv, 11-15
[425] See for example, A. Mold, 'Patient Groups and the Construction of the Patient-Consumer in Britain: An Historical Overview.' (2010) 39(4) *J Soc Policy* 505-521; M.A. Kekewich, 'Market Liberalism in Health Care: A Dysfunctional View of Respecting "Consumer" Autonomy.' (2014) 11 *Journal of Bioethical Inquiry* 21-29
[426] Chapter 3, Section 3
[427] R.R. Faden & T.L. Beauchamp, *A History and Theory of Informed Consent*. (Oxford University Press, 1998), 274-297
[428] A.R. Maclean, 'The Doctrine of Informed Consent: Does it exist and has it Crossed the Atlantic?' (2018) 24(3) *Legal Studies* 386-413
[429] See, N.C. Manson & O. O'Neil, *Rethinking Informed Consent in Bioethics.* (Cambridge University Press, 2007)

informed consent, cannot be accommodated within the therapeutic model of the medical relationship; as the purpose of disclosure shifts from acting in the best interest of the patient, to achieving autonomy, (so that the patient can access treatment in a market of medicine).[430] As the model of the medical relationship shifts so too does the source of obligations between the doctor and the patient. The ethical model of the consumer relationship would therefore require the doctor to abandon the Hippocratic moral tradition, and instead, replace it with the consumer relationship where obligations flowed from the private contractual terms, or moral obligations of a state actor to citizen, in a fiduciary relationship.[431] Fundamentally, though, the ethical purposes (teleology) of both relationships are distinct; the therapeutic relationship is orientated around achieving the best interests of the patient[432] and the consumer relationship seeks to maximises choice, however, to do so required a mandatory autonomy, through an informed consent.[433] By maximising choice, the consumer approach also conceptualises medical functions (diagnosis, treatment, and advice) as delineable care packages.[434] As Montgomery argues, this division of functions/roles is justified on the basis of the jurisdiction argument i.e. that doctor's lack of expertise in the area of morality means that their authority should only be limited to technical service.[435] The irony is that markets within the consumer relationship (advocated for by Kennedy to ensure a wider conceptualisation of illness and care) encourage the adoption of scientific categories to plan and provide care.[436] Important for this thesis is the recognition that the two models of the medical relationship are teleologically incompatible. The purpose of disclosure, within these relationships, therefore, cannot be achieved through a single rule or cause of action.

3.4.2. Conflict in decision-making

Whilst the provision of information for the purpose of therapeutic disclosure, and informed consent, can both be described as 'information disclosure,' in reality, the form of medical decision-making, and communicative processes necessary to ensure understanding exist as two distinct phenomena. This is because disclosure under a therapeutic regime, as opposed to a consumer regime, have diametrically opposed purposes. As such, the deontic requirements for medical decisions to achieve those distinct

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[430] S. Little, 'Consumerism in the Doctor-Patient Relationship.' (1981) 7(4) *J Med Ethics* 187-190; I. Kennedy & A. Grubb, *Medical Law: Text and Materials*. (Butterworths, 1989), 229-230; H. Teff. 'Medical Models and Legal Categories: English Perspectives.' (1993) 9 *J Contemp Health L & Pol'y* 211, 219-220

[431] T.H. Boyd, 'Cost Containment and the Physician's Fiduciary Duty to the Patient.' (1989) 29(1) *DePaul Law Review* 131; E.C. Hui, 'Doctors as Fiduciaries: Do Medical Professionals have the Right not to Treat? (2005) 3 *Poesis & Praxis* 256-276

[432] J. Montgomery, 'Patient No Longer? What Next in Healthcare Law?' (2017) 70(1) *Current Legal Problems* 73-109, 80-84; T. *Parsons, The Social System.* (Routledge & Kegan Paul, 1951), 440-446; J. Montgomery, Medicine, Accountability and Professionalism.' (1989) 16 *Journal of Law and Society* 319-339

[433] C.E. Schneider, *The Practice of Autonomy: Patients, Doctors, and Medical Decisions*. (Oxford University Press, 1998), 10-32 & 137-179

[434] J. Montgomery, 'Patient No Longer? What Next in Healthcare Law?' (2017) 70(1) *Current Legal Problems* 73-109, 79

[435] *Ibid*, 88-93

[436] G. J. Annas, *Some Choice: Law, Medicine, and the Market*. (Oxford University Press, 1998), i-xi, 55-62; L. G. Reeder, 'The Patient-Client as Consumer: Some Observations on the Changing Professional-Client Relationship.' (1972) 13(4) *Journal of Health and Social Behaviour* 406-412; P. Bartlett, 'Doctors as Fiduciaries: Equitable Regulation of the Doctor-Patient Relationship.' (1997) 5(2) *Med L Rev* 193-224

ends is also different.[437] Information disclosure for informed consent is to achieve a standard of understanding, for a one-off act of autonomous patient decision-making. The patient is seen to have been 'consented.'[438] If one adopts a liberal model of autonomy, the doctor would have to provide an objective standard of information, necessary for the reasonable, prudent-patient, to make an informed choice. The materiality and threshold of information could be decided, for example, by experience, or empiricism. However, to achieve an objective level of understanding, the doctor would have to ignore the actual information needs of the patient, the values and interpretation of the patient to ensure rationality, and potential harm to the patient caused by anxiety and fear.[439] Autonomy would be mandatory, regardless of patient welfare, as to not ensure an autonomous choice would deny patients access to treatment according to the consumer model.[440] Patients would, similarly, not be entitled to any information beyond facilitating an objective understanding. To achieve the ends of a therapeutic disclosure, on the other hand, the doctor would have to utilise *circumstantial-moral* decision-making.[441] Information need would therefore be identified throughout the relationship, according to a patient's needs, and if the information would be of a therapeutic benefit. Whilst autonomy would be maximised, it would not be achieved at all costs; information that was significantly harmful to the patient would be limited; as it would not be in their best interests. The internal content of medical decisions emanating from the medical relationship is again, not compatible.[442]

3.4.3. Accommodating the Consumer Model in Law

Informed consent, as a rights construct, did not have direct effect through human rights treaties, therefore implementation required utilising conventional legal architecture at common law.[443] As Brazier and Cave argued, this could theoretically occur through the creation of a distinct set of legal duties, 'which are directly enforceable against public authorities' so that an individual who 'considers that her rights have been violated by a public authority can sue for damages.'[444] The problem with an actionable free-standing human right, as a cause if action, is that it required grounding on a legally recognisable fiduciary duty; as such, it would only apply to doctors who were performing functions of a public nature.[445] The cause of action could, therefore, not compel those in private practice to provide

[437] H. Teff, 'Medical Models and Legal Categories: An English Perspective,' (1993) 9 *J Contemp Health L & Pol'y* 211
[438] J.W. Berg, *et al*, *Informed Consent: Legal Theory and Clinical Practice.* (Oxford University Press, 2001), 167-173; M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law.' (1987) 7 *Legal Studies* 169, 176
[439] There is obviously a therapeutic privilege within the moral construction of the informed consent model. However, the content of the therapeutic privilege is ill-defined. See E. Cave, 'The Ill-Informed: Consent to Medical Treatment and the Therapeutic Exemption.' (2017) 46(2) *Common Law World Review* 140-168
[440] C.E. Schneider, *The Practice of Autonomy: Patients, Doctors, and Medical Decisions*. (Oxford University Press, 1998), 10-32, 137-179
[441] See Section 1.2
[442] This was similarly recognised in R.R. Faden & T.L. Beauchamp, *A History of Informed Consent*. (Oxford University Press, 1986), 59
[443] M. Brazier & M. Cave, *Medicine, Patients and the Law.* (Manchester University Press, 2016), 35-36
[444] *Ibid*, 37
[445] *Ibid*, 37-38

information beyond existing obligations in tort, or contract.[446] Commentators, such as Brazier and Cave, therefore argue that many of the rights which form the basis of the consumer relationship 'already exist in the law of torts'[447]therefore the model of the consumer relationship, and particularly informed consent, can be incorporated within existing common law.[448] However, this approach fails to recognise that existing causes of action already facilitate and regulate the therapeutic medical relationship, which has a distinct purpose, and therefore rules and norms, which are not automatically compatible with the ethical purpose and requirements of informed consent.[449] The law of consent in battery, for example, seeks to protect patient self-determination, or liberty.[450] Arguably, a liberal model of informed consent shares the ethical groundwork; as both require that the patient know the nature of a choice as a basis to consent.[451] Battery could therefore act as a conduit for normative rules.[452] However, if the model of autonomy adopted is too substantive, in terms of the standard of understanding, this could act to blur the requirements in battery with the tort in negligence. This would have the effect of preventing patient's from accepting treatment, unless they have reached a substantive standard of understanding, or rationality. Similarly, the requirement of understanding could be accommodated within the law of negligence; however, negligence has a distinct aim of setting standards for the therapeutic relationship. For law to guide medical decision-making, the purpose of information disclosure must be conceptually certain. The remainder of this section will set out the potential side-effects of inserting a model of informed consent within into the existing causes of action of Battery and Negligence.

(i) Battery

The purpose of the law of battery, conventionally understood, is grounded on ensuring that a patient can refuse touching from third parties, without a valid legal justification.[453] Defences to battery include: when a person lacks capacity,[454] the doctor is acting in an emergency (necessity),[455] the patient is being detained under mental health legislation,[456] and consent to treatment.[457] Consent is therefore a

[446] See, the public function test in: *London and Quadrant Housing Trust v R (on the application of Weaver) and Equality and Human Rights Commission)* [2009] EWCA Civ 587; *R (Heather) v Leonard Cheshire Foundation (Cheshire)* [2001] EWHC Admin 429; *YL v Birmingham City Council* [2007] UKHL 27.
[447] M. Brazier & M. Cave, *Medicine, Patients and the Law.* (Manchester University Press, 2016), 37
[448] J. Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas.' (2009) 17(1) *Med L Rev* 76-108
[449] C. Purshouse, 'Liability for Lost Autonomy in Negligence: Undermining the Coherence of Tort Law?' (2016) 22 *Tort Law Journal* 226-249
[450] *Re R (A Minor) (wardship: medical treatment)* [1991] 4 All ER 177, per Lord Donaldson MR, at 184; *Re W (A Minor) (Medical Treatment)* [1992] 4 All ER 627, per Lord Donaldson MR, at 635; Re *T (Adult: Refusal of Medical Treatment)* [1992] 4 All ER 649, per Lord Donaldson, at 661 & per Butler-Sloss LJ at 665
[451] T. Keng Feng, 'Failure of medical advice: trespass of negligence.' (1987) *Legal Studies* 149-168, 161
[452] *Ibid*, 167-168
[453] *Mohr v Williams* 104 NW 12 (Minn, 1905); *Murray v McMurchy* [1949] 2 DLR 442; *Hamilton v Birmingham RHA* [1969] 2 BMJ 456; *Abbass v Kenney* (1995) 31 BMLR 157. See also, J. Katz, *The Silent World of Doctor and Patient.* (The Johns Hopkins University Press, 1984), 68; H. Teff, 'Consent to Medical Procedures: Paternalism, Self-determination or Therapeutic Alliance.' (1985) 101 *L Q Rev* 432, 436
[454] Mental Capacity Act 2005; *Re C (Adult: Refusal of Medical Treatment)* [1994] 1 All ER 819
[455] For example, *Marshall v Curry* [1933] 3 DLR 260, per Chisholm CJ, at 265; *Murray v McMurchy* [1949] 2 DLR 442
[456] s.2, s.3, s.5(2) & s.5(4) and Part IV Mental Health Act 1983
[457] *Freeman v Home Office* [1984] 1 All ER 1036, per Sir John Donaldson MR, at 1044

mechanism for ensuring that the right to non-interference is not abused. The right to bodily integrity and dignity are negative rights (rather than a more substantive form of autonomous choice).

To ensure that consent is intentional the patient must know the broad nature and purpose of a touch; enough to have a *bare* understanding of the actions involved.[458] In *Chatterton v Gerson*, for example, Bristow J stated that the consent had to be *real* and was vitiated if the patient is 'not informed in broad terms of the nature of the procedure which is intended, and gives her consent, that consent is real, and the cause of action on which to base the claim for failure to go into risks and implications is negligence, not trespass.'[459] Tan Keng Feng argues, the defence of consent could therefore contain an extended concept of understanding as the basis of treatment[460] (and there is certainly common law precedent, from North America, for this conceptual extension).[461] However, in England and Wales, the requirement for an extended disclosure, to ensure a higher level of understanding, has had less judicial traction.[462] This was because of the unacceptableness of classifying doctors as having intentionally battered their patients.[463] For example, Lord Scarman, agreeing with Skinner J in *Hills v Potter*, stated: 'it would be deplorable to base the law in medical cases of this kind of the tort of assault and battery.'[464] This judgement conflated the tort of battery, which requires a bare intention to touch, with the criminal requirement of intentional harm (similar to malice aforethought),[465] criminal misrepresentation, or fraud.[466] As a doctor is usually acting with the intentionality, this could lead to regular accusations of battery. As McCoid argued, in jurisprudential terms, all that was required was an intention to touch. The nature of the touch, whether it be with criminal intent, because of a lack of consent, or therapeutically, is irrelevant.[467] However, as the doctor has the primary intention of acting in the patient's best interests, it was it was justificable to construct a presumption that he could never commit a battery. On this policy basis the judiciary have therefore barred battery as a cause of action through which informed consent could be accommodated.[468] This is problematic if the doctor has not acted

[458] *Chatterton v Gerson* [1981] QB 432, per Bristow J, at 265; *Hills v Potter* [1983] 3 All ER 716, per Hirst J, at 728
[459] *Ibid*
[460] T. Keng Feng, 'Failure of medical advice: trespass of negligence.' (1987) *Legal Studies* 149-168, 167-168. Also, MA. Somerville, 'Structuring the Issues in Informed Consent.' (1981) 25 *McGill Law Journal* 740. In I. Kennedy, (ed.), *Medical Law*. (Butterworths, 2000), 654-655
[461] *Mohr v Willaims*, 104 N W 12 (Minn, 1905); *Pratt v Davies*, 118 III App 161 (1905); *Salgo v Leland Stanford Jr University Health Board of Trustees*, 317 P. 2d 170 (Cal. Dis. Ct. App, 1957). See J. Katz, *The Silent World of Doctor and Patient.* (The Johns Hopkins University Press, 1984), 52-59.
[462] *Davis v Barking, Havering and Brentwood Health Authority* [1993] 4 Med L R 85; Appleton *v Garret* [1996] 5 PIQR PI
[463] J. Katz, *The Silent World of Doctor and Patient.* (The Johns Hopkins University Press, 1984), 67. Quoting from: *Natanson v Kline*, 350 P. 2d 1093 (Kan. 1960)
[464] *Sidaway v Governors of Bethlem Royal Hospital* [1985] 1 AC 871, per Lord Scarman at 883.
[465] Which seems to an adoption of a malice aforethought: s. 8 Criminal Justice Act 1967; *R v Belfon* (1976) 3 All ER 46; *R v Maloney* (1985) 1 All ER 1025; *R v Nedrick* (1986) 83 Cr App R 267; *R v Woolin* (1998) 4 ER 103 (HL). Which is beyond the conventional meaning of intentionality within tort: *Wilson v Pringle* [1996] 2 All ER 440
[466] *Sidaway v Governors of Bethlem Royal Hospital* [1984] 1 All ER 1018, per Lord Donaldson, at 1026 & per Dunn LJ at 1029
[467] A.H. McCoid, 'Reappraisal of Liability for Unauthorized Medical Treatment.' (1957) 41(4) *Minnesota Law Review* 381, 392; T. Keng Feng, 'Failure of medical advice: trespass of negligence.' (1987) *Legal Studies* 149-168.
[468] *Chatterton v Gerson* [1891] QB 432, per Bristow J, at 443; Hills v Potter [1981] 1 All ER 257, per Hirst J at 728

negligently, but without consent.[469] Informed consent has been forced to develop, instead, through the law of negligence.[470]

(ii) Negligence

The law of negligence is not a suitable conduit for the consumer relationship; as it has historically been used to regulate the therapeutic relationship.[471] Whilst both the therapeutic and consumer relationship share a duty to provide information, the teleological purpose of the disclosures do not point in the same direction, and are, therefore, 'sometimes conflicting' and 'sometimes unattainable.'[472]The purpose of disclosing information to achieve the patient's therapeutic best interests may, in certain circumstances be diametrically opposed to ensuring a type of substantive autonomous decision. For example, providing a content of information for an objective understanding may completely ignore areas of information need which the patient would prefer to focus. Providing information according to the therapeutic relationship also creates an ongoing duty, whilst the provision of information for the consumer relationship is to ensure a standalone consent. The facilitation of substantive models of informed consent, however, requires normative standards, which have the effect of ossifying *circumstantial-moral* decision-making.[473] If both medical relationships exist in one cause of action, or worse one standard, then the doctor has no clear conceptual basis on which to make decisions about the relevance, or materiality, of information. The remainder of this thesis develops these conceptual problems to explain the deviation between standards and practice within the UK. The integration of the opposing models of the medical relationship occur through three broad typologies within the law of negligence.[474]

(a) Integration:

Integration describes how a normative standard of material information, necessary for understanding (i.e. for an informed consent), can be accommodated, through distinct standards, or requirements, within

[469] This is admittedly going to be a startlingly slim range of circumstances. However, those who are in a persistent vegetative state, and can communicate through an MRI may be battered if consent is not sought. Indeed, it is not normal practice to ask their consent before turning off life-support: A.M. Owen, 'Detecting Awareness in the Vegetative State.' (2006) 313(5792) *Science* 1402; M.M. Monti, *et al*, 'Wilful Modulation of Brain Activity in Disorders of Consciousness.' (2010) 362(7) *The New England Journal of Medicine* 579; D. Cruse, *et al*, 'Bedside Detection of Awareness in the Vegetative State: A Cohort Study.' (2011) 378 (9809) *The Lancet* 2088-2094; L. Naco & A. M. Owens, 'Making Every Word Count for Nonresponsive Patients.' (2013) 70(10) *JAMA Neurol* 1235-1241. See, BMA & RCoP, *Clinically-Assisted Nutrition and Hydration (CANH) and Adults who lack the Capacity to Consent: Guidance for Decision-Making in England and Wales.* (BMA & RCoP, 2018)

[470] See Chapter 4, Section 1; Chapter 5, Section 1; Chapter 6, Section 1

[471] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 583

[472] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, per Lord Scarman at 903

[473] See Chapter 2, Section 4

[474] One may also add 'legislation' as a method for incorporating the relationships, for example, as done in New Zealand, however, this has so far not been adopted in the Law of England and Wales and will therefore not be examined here. See, P.D.G. Skegg, 'English Medical Law and 'Informed Consent': An Antipodean assessment and alternative.' (1999) 7 *Med L Rev* 135-165; J. Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas.' (2009) 17 *Med L Rev*, 76-198, 93-95; J. Manning, 'Informed Consent to Medical Treatment: The Common Law and New Zealand's Code of Patient's Rights.' (2004) 12(2) *Med L Rev* 181-216

the wider therapeutic discretion.[475] This internal rights position was taken by Lord Templeman, when he suggested that there should be disclosure of specific risks (beyond general risks) which the prudent patient would want to know, which would (albeit circumstantially) facilitate an informed consent.[476] The level of materiality could be set at a fixed percentage threshold of occurrence,[477] for example, the 10% chance of stroke.[478] This approach was adopted in *Reibl v Hughes*[479] where Laskin CJ, found that the surgeon had specific duties to provide information about the 10% risk of stroke during the operation on the plaintiffs brain.[480] Similarly, in *Canterbury v Spence*, Robinson J found that there was a general presumption that the very significant risk of death, or disability (1-3%), should be disclosed,[481] which was similar to the requirement to disclose the 1-2% chance of spinal cord damage in *Rogers v Whitaker*.[482] The problem with this judicial approach, however, is it provides no reflection on the significance or seriousness of a risk, either on biomedical terms, or based on the patients experience. This also works from the presumption that 'everyone is presumed to be familiar with the "reasonable man" standard, regardless of lack of experience.'[483] Indeed, as Maclean argued, this presents a problem because the threshold of materiality is artificially constructed by the decision-maker – this can either be the judge, who would be making a decision with hindsight, in which case the standard is unknowable for the doctor. Alternatively, the standard is decided by the doctor, and then endorsed by judges in law, which reintroduces the problem of deference.[484]

(b) Incorporation:

Incorporation utilises a dual standard of care; where the therapeutic relationship is housed in one limb of the negligence test, and the requirement of informed consent in another. For example, in *Rogers v Whitaker*, Mason CJ stated that: 'the paramount consideration that a person is entitled to make his own decision about his life.'[485] However 'the choice is, in reality, meaningless unless it is made on the basis of relevant information and advice' therefore the patient should have the standard of information that a prudent patient would need.[486] However, the need to have an informed consent should also be

[475] *Gold v Haringey Health Authority* [1988] QB 481 per Lord Justice Lloyd, at 489
[476] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, per Lord Templeman, at 903
[477] A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5 *Med L Int* 205, 214
[478] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, per Lord Templeman at 903
[479] *Reibl v Hughes* [1980] 2 SCR 880
[480] *Ibid*, 893
[481] *Canterbury v Spence* 464 F 2d 772 (1972), per Robinson J, at 788. Relying on 3% chance of death or paralysis in *Bowers v. Talmage*, 159 So.2d 888 (Fla.App. 1963), the 1% chance of loss of hearing in *Scott v. Wilson*, 396 S.W.2d 532 (Tex.Civ.App. 1965), aff'd, 412 S.W.2d 299 (Tex. 1967), and the 1.5% loss of an eye in *Stottlemire v. Cawood*, 213 F.Supp. 897, 898 (D.D.C.), new trial denied, 215 F.Supp. 266 (1963). Although, failure to disclosure between 1/250 and 1/500 chance of perforated oesophagus in*: Starnes v. Taylor*, 272 N.C. 386, 158 S.E.2d 339, 344 (1968), and 1/800'00 chance of aplastic anaemia was negligent in *Yeates v. Harms*, 193 Kan. 320, 393 P.2d 982, 991 (1964), on rehearing, 194 Kan. 675, 401 P.2d 659 (1965).
[482] *Rogers v Whitaker* (1992) 16 BMLR 148, 153. Also see *F v R* (1983) 33 SASR 189, 194
[483] J. R. Waltz & T.W. Scheuneman, 'Informed Consent to Therapy.' (1969) 64 *Nw U L Rev* 628, 639
[484] A.R. Maclean, 'The Doctrine of Informed Consent: Does it exist and has it Crossed the Atlantic?' (2004) 24(3) *Legal Studies* 386-413, 408
[485] *F v R* (1983) 33 SASR 189, 194
[486] *Rogers v Whitaker* (1992) 16 BMLR 148, 156

considered in conjunction with a duty to provide a wider therapeutic disclosure (found in *F v R*),[487] which would consider: 'the nature of the matter to be disclosed; the nature of the treatment; the desire of the patient for information; the temperament and health of the patient; and the general surrounding circumstances.'[488] Unlike the integration method, which used a single test to accommodate the dual relationship, Mason CJ instead adopted a dual test.[489] The objective limb of the test would accommodate the therapeutic relationship:

> The laws should recognise that a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it […].[490]

Informed consent was accommodated in a subjective test:

> […] if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk would be likely to attach significance to it.[491]

The particular patient test accommodated an authentic model of patient autonomy, as the basis of an informed consent; where the doctor disclosed information according to the patient's values. This test may have been chosen as it was the only way that Mason CJ could find liability. The patient was blind in one eye, and there was a 1 in 14'000 risk of sympathetic ophthalmia, which was not disclosed. This was a risk that the prudent patient would not have found material – however, '[i]t would be reasonable for a person with one good eye to be concerned about the possibility of injury from a procedure which was elective.'[492] The law was chosen as a mechanism to ensure liability. However, the policy implications of the judgement may not have been thought through. It is not clear how these two models should be ordered in decision-making in practice, for example, the doctor could interpret incessant questioning as indicative of the patient values, thus requiring a disclosure, or a patient in need of assurance under the therapeutic model. The subjective limb would also require a distinct process of decision-making which requires the doctor to reconstruct the values of the patient into some rational form for a decision about materiality. If the doctor cannot attain the values of the patient e.g. if the patient is unwilling to either ask or answer questions, they may be found liable as they were unable to

[487] *Ibid*, 157; *F v R* (1983) 189, per King CJ at 192-193.
[488] *F v R* (1983) 33 SASR 189, 194.
[489] *Rogers v Whitaker* 16 BMLR 148, 151. Quoting *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, per Lord Diplock, 893
[490] *Rogers v Whitaker* (1992) 16 BMLR 148, 157
[491] *Ibid*, 157
[492] *Ibid*, 158

ensure an authentic autonomous choice. It is also not clear how the doctor can provide material information if the values of the patient are completely irrational, either because of circumstances, or capacity. Providing confused, or irrational information, would undermine the therapeutic limb of the test; as the doctor would not be acting in the best interests of the patient. Providing information in the patients' best interest's, may also contain an objective content of information which risks corrupting or altering the values of the patient, and undermining their ability to make an authentic autonomous choice. As such, the correct methodology to ensure both an informed consent, in the patient's best interests, is unknowable.[493] Australian commentators have argued that this offers the litigious patient the opportunity to retroactively interpret conversations and place emphasis or words of actions that could have indicated their values.[494] The ability to reinterpret communications has led to the adoption of defensive practices.[495] Despite these problems this standard was adopted as the optimum ethical standard in the law of England and Wales.[496]

(c) Rejection:

This mechanism pays lip-service to the therapeutic relationship, but when the aims of the patient's best interests' or need to have an autonomous choice for an informed consent are placed into conflict the consumer model take priority. As Coggon and Miola have identified, this form of duty driven autonomy which ignores the patients' interests, also ignores patient liberty and the right to waive that information[497] - instead information can be forced on patients, so that they make at least a formulistic informed consent. This ethical orientation has rightly been described by Schneider as a form of mandatory autonomy and manifests throughout the ethical literature.[498] In *Canterbury v Spence,*[499] for example, Judge Robinson both recognised the fiduciary duty to ensure an autonomous choice[500] through informed consent, and thus 'to impart information which the patient has every right to expect,'[501]and recognised that the purpose of negligence was to regulate *circumstantial-moral* decision-making.[502]

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[493] I. Freckelton, '*Rogers v Whitaker* Reconsidered.' (2001) 9 *Journal of Law and Medicine* 5, 6. D. Newnes & G. Pynt, 'Failure of Surgeons to Advise Patient of Risk of Sympathetic Ophthalmia.' (1993) *Int. I. LR* 81-83; F.A. Trindade, 'Disclosure of Risks in Proposed Medical Treatment.' (1993) 109 *L Q Rev* 352. See, *Rosenberg v Percival* (2001) 205 C.L.R. 434, at 435; *Ardnt v Smith* [1997] 2 S.C.R. 539

[494] *Ibid*

[495] N. Olbourne, 'The Influence of *Rogers v Whitaker* on the Practice of Cosmetic Plastic Surgery.' (1998) 5 *Journal of Law and Medicine* 334, 343; R. Milstein, 'High Court Rules on Informed Consent.' (1992) 1(4) *Australian Health Law Bulletin* 37; P.D. Mahar & J.A. Burke, 'What is the Value of Professional Opinion? The Current Medicolegal Application of the "Peer Professional Practice Defence" in Australia.' (2011) 194(5) *MJA* 253-255

[496] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11

[497] J. Coggon & J. Miola, 'Autonomy, Liberty, and Medical Decision-Making.' (2011) 70(3) *Camb L J* 523-547

[498] C.E. Schneider, *The Practice of Autonomy.* (Oxford University Press, 1998), 10-17; D. Brock, *Informed Consent, in Life and Death: Philosophical Essays in Biomedical Ethics.* (Cambridge University Press, 1993), 33; E. Haavi Morreim, *Balancing Act: The New Medical Ethics of Medicine's New Economics.* (Georgetown University Press, 1995), 139; J. Katz, *The Silent World of Doctor and Patient.* (Free Press, 1984), 122; W.G. Bartholome, *A Revolution in Understanding: How Ethics Has Transformed Health Care Decision Making*. (1992) 18 *Quality Rev Bulletin* 6, 10; R. M. Veatch, 'Abandoning Informed Consent.' (1995) 25 *HCR* 5, 9

[499] *Canterbury v Spence* (1972) 464 F 2d 772

[500] *Ibid*, 782

[501] *ibid*

[502] *Ibid*, 783

However, Robinson J argued that as there was no collective normative standard internal to medical decision-making, [503] that the right of the patient should take precedence in setting the standard of materiality. He argued that the sociological test should therefore be rejected.[504] Instead, the content of the decision should maximise, rather than limit, patient autonomy: 'the patient's right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patients possess enough information to enable an intelligent choice.'[505] Autonomy was conceptualised as a liberal autonomous choice, which required a consent based on an objective content of understanding. Thus, Robinson J adopted the prudent patient test[506] set out by Scheuneman and Waltz.[507]

> A risk is thus material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to undergo the proposed therapy.[508]

This objective approach was used because a standard cannot be set by the judge 'with the benefit of hindsight. It must consider that the physician has to be the first decision-maker and that the correctness of his decision must be assessed on the basis of the data then available to him.'[509] Robinson J, similarly, found that the 'physician obviously cannot be required to know the inner workings of his patient's mind. He can however, employ his general experience with people.'[510] The content of the liberal standard, however, would include, as Scheuneman and Waltz argue, a therapeutic 'style' balancing of considerations, such as: the nature of the condition, the nature of therapy, for example, where the treatment was innovative,[511] and as Robinson J, argued: 'significance', 'the dangerousness of medical techniques', 'the incidence of injury' and 'degree of harm threatened'[512] and: 'inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the results likely if the patient remains untreated.'[513] Therapeutic considerations, then, were included in constructing a right to autonomy.

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[503] *Ibid*, 784: "We cannot floss over the inconsistency between reliance on a general practice respecting divulgence, and on the other hand realization that the myriad of variable among patients makes each case so different that its omission can rationally be justified only by the effect of its individual circumstances."
[504] *Ibid*, 782
[505] *Ibid*, 787
[506] *Ibid*, 786
[507] J. R. Waltz & T.W. Scheuneman, 'Informed Consent to Therapy.' (1969) 64 *Nw U L Rev* 628, 639
[508] *Canterbury v Spence* (1972) 464 F 2d 772, 787. Relying on J. R. Waltz & T.W. Scheuneman, 'Informed Consent to Therapy.' (1969) 64 *Nw U L Rev* 628, 640
[509] *Ibid*
[510] *Canterbury v Spence* (1972) 464 F 2d 772, 787, relying on J. R. Waltz & T.W. Scheuneman, 'Informed Consent to Therapy.' (1969) 64 *Nw U L Rev* 628, 639-640
[511] J. R. Waltz & T.W. Scheuneman, 'Informed Consent to Therapy.' (1969) 64 *Nw U L Rev* 628, 640; relying on R.E. Ritts, A Physician's View of Informed Consent in Human Experimentation. (1968) 36 *Ford L Rev* 631, 635; Note, Experimentation on Human Beings, (1967) 20 *Stan. L. Rev.* 99, 102-111.
[512] *Canterbury v Spence* (1972) 464 F 2d 772, 787-788
[513] *Ibid*, 784 & 787-788

3.5. The conceptualisation of the consumer patient: from rhetoric to reality

To properly facilitate the aim of ensuring a patient choice requires a reconceptualization of the patient as a consumer of medical services, within the law.[514] Reconceptualising the patient as atomistic, and independent, and therefore capacitous, justifies the adoption of substantive internal requirements to have an autonomous choice. [515] This re-definition of the patient has been justified by ethical arguments, but the practical impact on patients has seldom been analysed. Instead, commentators are reliant on rhetoric. Kennedy, for example, argued:

> The patient may no longer be given commands for his own good, but rather advice which he can take or leave […] the more widespread use of the language of human rights is important, bringing with it the idea that we have certain rights which apply to medical practice just as to other areas.[516]

This rhetoric was repeated more recently by Brazier and Cave, who argued:

> Patients are no longer content to be passive recipients even of 'good' care. They want a say in what 'good' care comprises. The pace of medical developments is such that, particularly in the context of reproductive medicine and genetics, new questions surface daily around the implication of certain kinds of treatment.[517]

The UK House of Lords Select Committee on ethics, in the 1990's, similarly argued:

> [m]ost individuals wish to take more responsibility for the course of their lives and this applies equally to decisions about medical treatment.[518]

McLean boasted:

[514] H. Teff, *Reasonable care: Legal Perspectives on the Doctor/Patient Relationship*. (Clarendon Press, 1994), 101-102; J. Montgomery, 'Patient No Longer? What Next in Healthcare Law?' (2017) 70(1) *Current Legal Problems* 73-109

[515]L.H. Roth & C.W. Lidz, 'Tests of Competency to Consent to Treatment.' (1977) 134 *Am J Psychiatry* 279; I. Kennedy & A. Grubb, *Medical Law: Text and Materials*. (Butterworths, 1989), 229; The President's Commission, *Making Health Care Decisions: The Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship*. (Government Printing Office, 1983), 31-35

[516] I. Kennedy, "Emergent Problems of Medicine, Technology, and the Law." In I. Kennedy (eds.), *Treat Me Right: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 9

[517] M. Brazier & E. Cave, *Medicine, Patients and the Law*. (Manchester University Press, 2016), 31. Relying on *Montgomery v Lanarkshire Health* Board [2015] UKSC 11, [75]: "[…] patients are now widely regarded as persons holding rights, rather than as the passive recipients of the care of the medical profession. They are also widely treated as consumers exercising choices: a viewpoint which has undermined some of the developments in the provision of healthcare services."

[518] House of Lords Select Committee on Medical Ethics, *Report of the Select Committee on Medical Ethics* (HL Paper, 21-1, 1994), 7[4]

> The dye is now cast: the rhetoric, if not the reality, of the relationship between physician and patient has been irrevocably changed by contemporary recognition of the importance of patient self-determination. Not only do patients increasingly view healthcare decisions as a matter of individual choice, medicine has had to respond to the changing climate. It is anticipated, then, that patients will be the primary decision-makers in the healthcare context, and there is considerably less significance attached to the importance of the physician as decision maker. This change is, according to some, a direct result of the failure of trust between patient and doctor. Perhaps because the historical inattention to their rights and an accompanying diminution of trust, many patients now demand that doctors respect them and their decisions.[519]

However, the substantive requirements to have a liberal, or authentic, autonomous choice, places a heavy burden of responsibility on the consumer patient; for example, a model of liberal autonomy would require the patient to understand an objective content of information, potentially up to a full understanding, and to have a rational choice on this basis. This ethical requirement places several implicit duties on patients, which require more substantive capacities than those currently recognised within the law of England and Wales.[520] Instead of aligning the capacities of the ethical model, of informed consent in information disclosure, with that of the psychological competences necessary to have legal capacities, the law adopts a rebuttable presumption of capacity regardless of the choice, or the potential consequences of a decision.[521] As Lord Donaldson in *Re T* stated, the patient 'has an absolute right to choose whether to consent to medical treatment, to refuse it or to choose one rather than another of the treatments being offered.'[522] This was reaffirmed by Bulter-Sloss LJ in *Re MB*:

> A mentally competent patient has an absolute right to refuse to consent to medical treatment for any reason, rational or irrational, or for no reason at all, even whether that decision may lead to his or her own death.[523]

And, Lord Goff in *Airedale NHS Trust v Bland*, similarly stated:

> […] the principle of self-determination requires that respect must be given to the wishes of the patient, so that if an adult of sound mind refuses, however unreasonably, to consent to treatment or care by which his life would or might be prolonged, the doctors responsible for his care must

[519] S.A.M. McLean, *Autonomy, Consent and the Law.* (Routledge, 2010), 31
[520] M. Brazier, 'Do No Harm – Do Patients Have Responsibilities Too?' (2006) 65(2) *CLJ* 397-422; J. Coggon, 'Would Responsible Medical Lawyers lose their Patients?' (2012) 20(1) *Med L Rev* 130-149.
[521] *Re C* [1994] 1 All ER 819; s. 1(1) Mental Capacity Act 2005
[522] *Re T (Adult: Refusal of Medical Treatment)* [1992] 2 All ER, 652-653
[523] *Re MB (An Adult: Medical Treatment)* [1997] 2 FLR 427. Also seen Sidaway *v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, per Lord Templeman at 904-905; *Re T (Adult: Refusal of Treatment)* (1993) Fam 95, 116-117

> give effect to his wishes, even though they do not consider it to be in his best interests to do so.[524]

The law of capacity bars the doctor from interfering with a decision unless they can show that there is a functional impairment of disturbance with the mind or brain, which means that an individual cannot: (a) understand, (b) retain information, (c) use or weigh that information, (d) communicate that decision.[525] This creates a capacity-gap between the autonomy model facilitated in the law of negligence, and the model of capacity necessary to consent in the law of battery. In practice, this will mean a proportion of patients will be making choices without having an informed consent. Rather than mitigate the potential harms, by reducing standards of understanding, and accommodating patient capacities, the consumer relationship strips the doctor of the ability to protect patients.[526]

If the right to self-determination is respected, and thus, the presumption of capacity is interpreted robustly, then several patients will be making decisions which are not liberally, or authentically, autonomous (which defeats the purpose of the requirement of informed consent). Alternatively, if the substantive requirements of the law of capacity are equivocal to more robust models of autonomy, many patients would lack capacity to make healthcare choices (defeating the utility of moving to a consumer model). Indeed, as Schneider argued, the doctor is obliged by the consumer relationship to disclosure an objective content of information to ensure a mandatory autonomy.[527] As Morreim argued:

> [I]n matters of health, and health care, it is time to expect competent patients to assume substantially greater responsibility. In the first place, they should generally make their own decisions. Not only is the patient entitled to decide these issues that affect his life so fundamentally; he has a presumptive obligation to do so.[528]

This lack of reflexivity, on the needs of the actual patient, imposes a form of tyranny on the individual;[529] as they are required to meet the demands of the hypothetical average autonomous person[530] and have no choice as to how this construct is conceptualised. Autonomy then, undermines the consumer patient's negative rights to liberty.[531]

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[524] In *Airedale NHS Trust v Bland* [1993] 1 All ER, per Lord Goff at 866 & per Lord Mustill at 889; B *v An NHS Trust* [2002] EWHC 429
[525] s.2(1) & s.3(1) Mental Capacity Act 2005
[526] J. Montgomery, 'Law and the Demoralisation of Medicine.' (2006) 26(2) *Legal Studies* 185-210, 187
[527] C.E. Schneider, *The Practice of Autonomy: Patients, Doctors, and Medical Decisions.* (Oxford University Press, 1998), 10-33
[528] E.H. Morreim, *Balancing Act: The New Medical Ethics of Medicine's New Economics.* (Georgetown University Press, 1995), 139
[529] C. Foster, *Choosing Life, Choosing Death: The Tyranny of Autonomy in Medical Ethics and Law.* (Hart Publishing, 2009), 3-15
[530] C.E. Schneider, *The Practice of Autonomy: Patients, Doctors, and Medical Decisions.* (Oxford University Press, 1998), 33
[531] J. Coggon and J. Miola, 'Autonomy, Liberty, and Medical Decision-Making.' (2011) 70(3) *Camb L J* 532-547, 545

Whilst one could, hypothetically, construct a waiver to the requirements within the conceptual model,[532] to do so would be to allow the patient to be harmed, as he would not be able to make a type of choice which would prevent exploitation of the commercially orientated doctor, and the market of healthcare. The teleology of the consumer relationship would also be defeated. Creating a waiver and at the same time removing the therapeutic medical relationship would also disproportionately affect those individuals who cannot reach the levels of competence to be a consumer patient; by the logic of the rights school, the most vulnerable in society would therefore become the most harmed.[533] This thesis argues that Law has failed to recognise the gap between the ethical model of the patient consumer, and its application in practice. This is only too evident in the rhetoric adopted by the Supreme Court in *Montgomery*:

> [P]atients are now widely regarded as persons holding rights, rather than as passive recipients of the care of the medical profession. They are also widely treated as consumers exercising choices: a viewpoint which has underpinned some of the developments in the provision of healthcare services.[534]

The continued use of the consumer model, remains justified on two assumptions: first, that the patient wants an informed consent, second, that the average patient has capacity to have an informed consent. The next section will argue that neither of these assumptions stands up to empirical scrutiny. [535]

3.5.1. Patients want an informed consent.

Much of the rights argument about the utility of the consumer relationship is predicated on two sociological claims about the average patient: [536] first, that patients wishes to depart from a therapeutic relationship and instead want information to make an independent and informed decision, second, that the average patient can reach the threshold of capacity necessary to provide an informed consent. [537] Neither of these claims is backed up by sound sociological evidence, indeed there is evidence to the contrary.

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[532] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law.' (1987) 7 *Legal Studies* 169, 177-178; D.W. Brock, *Life and Death: Philosophical Essays in Biomedical Ethics.* (Cambridge University Press, 1993)

[533] E.D. Pellegrino & D.C. Thomasma, *The Virtues in Medical Practice*. (Oxford University Press, 1993), 44-48; E.D. Pellegrino, 'The Medical Profession as a Moral Community.' (1990) 66(3) *Bull N Y Acad Med* 221-232, 229; E.D. Pellegrino, 'Patient and Physician Autonomy: Conflating Rights and Obligations in the Physician-Patient Relationship.' (1994) 10 *J Contemp Health Law Policy* 47-68.

[534] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [75]

[535] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law.' (1987) 7 *Legal Studies* 169, 176

[536] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treat Me Rights: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 187-188

[537] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law.' (1987) 7 *Legal Studies* 169, 176; H. Teff, 'Medical Models and Legal Categories: An English Perspective,' (1993) 9 *J. Contemp Health L & Pol'y* 211, 212 & 222

Much of the evidence relied upon to make sociological arguments for the adoption of informed consent, into UK law, has been reliant on empirical studies conducted in the US.[538] As Maclean rightly argues, relying on studies conducted outside of the UK are dubious because "culture and values may affect patients' information needs" as such

> these studies are of questionable relevance to determining a legal standard of disclosure. Even within the UK, there may be regional variations in demands for information and this is without considering the question of whether the law should be sensitive to different culturally driven demands that may co-exist within a jurisdiction.[539]

The libertarian trends in US society has historically underpinned by the United States Constitution, and other foundational texts, which enshrined rights-language in the public consciousness.[540] The British experience of healthcare is much more communitarian in nature, and flows from collective and beneficent values.[541] Patients do not see themselves as atomistic and making decisions divorced from their community; instead they would prefer to trust their doctor's decision-making,[542] and therefore often reject the additional responsibilities of the consumer patient.[543] The utility of conceptualising the function of medicine within society is lost if this is not mimicked by a willingness of patients to become empowered consumers, making individualised decisions. Meisel and Roth go further to attack the quality of the US studies themselves; they argue that the evidence utilised in support of the consumer relationship was of a poor methodological quality.[544]

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[538] H. Teff, 'Consent to Medical Procedures: Paternalism, Self-Determination or Therapeutic Alliance?' (1985) 101 *L Q Rev* 432; Office of Health Economics, W*hat Are My Chances Doctors? A Review of Clinical Risks.* (Office of Health Economics, 1986)

[539] A. Maclean, 'Giving the Reasonable Patient A Voice: Information disclosure and the Relevance of Empirical Evidence.' (2005) 7 *Medical Law International* 1-40, 15

[540] D.S. Brody, 'The Patient's Role in Clinical Decision-Making. (1980) 93(5) *Annals of Internal Medicine* 718-722; C.L. Kaufmann, 'Informed Consent and Patient Decision Making: Two Decades of Research.' (1983) 17(21) *Social, Science & Medicine* 1657-1664

[541] H. Teff, *Reasonable Care: Legal Perspectives on the Doctor-Patient Relationship*. (Clarendon Press, 1994), 69-93; J. Gubb, 'Have Targets Done More Harm than Good in the English NHS? Yes.' (2009) 338 *BMJ* 3130; K. Beaver, *et al*, 'Decision-Making Role and Preference and Information Needs: A Comparison of Colorectal and Breast Cancer.' (1999) 2 *Health Expectations* 266-276

[542] J. Miola, & R. Gilbar, 'One Size Fits All? On Patient Autonomy, Informed Consent and the Impact of Culture.' (2015_ 23(3) *Med L Rev* 375-399

[543] See Chapter 3, Section 5, Chapter 4, Section 3, Chapter 5, Section 3, and Chapter 6, Section 3

[544] A. Meisel & L.H. Roth, 'Towards an Informed Discussion of Informed Consent: A Review and Critique of the Empirical Studies.' (1983) 25 *Ariz L Review*, 265, 269: "To the casual observer, it would appear as though there is a vast amount of knowledge about the operation of informed consent. In a sense there is. But if we are to do more than take these findings at face value, we find that much of what purports to be fact is of dubious validity. The empirical investigations of informed consent are so riddled with conceptual, methodological, and ideological flaws that the sum and substance of the corpus of their findings are of questionable worth. Because of the manner in which many studies are designed, conducted, or reported, we believe that it is impossible for the discerning reader of these studies to make independent determinations of their validity. […] What began as an effort on our part to report on what we do and do not know about informed consent has been partially transformed into a pleas to current and potential investigators of informed consent not to repeat the conceptual, methodological and ideological errors of many of the existing studies. This requires not only a thorough knowledge of empirical methods, but also a far better understanding of the problem under investigation – informed consent – than many investigators seem to have. Because of the questionable validity of many of the findings of informed consent studies, lawmakers who seek to rely upon an empirically generated body of knowledge in making informed consent law must proceed cautiously and critically."

A full analysis of the literature supporting the assertions which have influenced the movement towards the consumer model in law; and thus, affected medical decision-making are beyond this thesis. Instead, this section selects a single example, from the seminal article by Brazier, to highlight and rebut the sociological claims of the rights school.[545]

To make the argument that patients want an informed consent, Brazier relies on the findings of the Alfadi[546] survey.[547] However, as Meisel and Roth[548] argued, the conclusions of the study were not supported by the statistical evidence.[549] For example, Alfadi found that 89% of patients, who were informed of the serious risks of angiography, 'appreciated' receiving the information[550] but were 'less comfortable' with this information.[551] In a later study where Alfadi designed the methodology so that doctors asked the patient whether they wanted more information, less than 1/3 of patients wanted to be told about risks.[552] Whilst other studies support Alfadi's initial conclusions about patient's information preferences,[553] other empirical work contradicted these finding.[554] For example, Meisel and Roth found exactly the opposite trend. In their study, patients wanted information for their own personal and therapeutic ends, but did not want the responsibility of making their own decisions.[555] This was because patient preference is personal and relative; decision-making preference varied dependent on the age of the patient, and the type of decisions that were being made. Indicating, personal and circumstantial factors affect patient information choices; rather than a value commitment to a type of (or preferred role within a) medical relationship.[556]

[545] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law.' (1987) 7 *Legal Studies* 169
[546] R. J. Alfidi, 'Informed consent: a study of patient reactions.' (1971) 216 *JAMA* 1325; R.J. Alfadi, 'Controversy, alternatives and decisions in complying with the legal doctrine of informed consent,' (1975) 114 *Radiology* 231
[547] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law.' (1987) 7 *Legal Studies* 169, 174-175
[548] A. Meisel & L.H. Roth, 'Towards an Informed Discussion of Informed Consent: A Review and Critique of the empirical studies.' (1983) 25(2) *Arizona Law Review* 265-346
[549] A. Meisel & L. Roth, 'What we do and do not know about Informed Consent.' (1981) 246 *JAMA* 2473-2477
[550] R.J. Alfadi, Informed Consent: A Study of Patient Reaction. (1971) 216 *JAMA* 1325, 1328
[551] *Ibid*, 1328
[552] R.J. Alfadi, 'Controversy, Alternatives and Decisions in Complying with the Legal Doctrine of Informed Consent.' (1975) 114 *Radiology* 231, 233
[553] R. J. Alfadi, 'Informed Consent and Special Procedures,' (1973) 40 *Clev Clinic Q* 21, 22
[554] For example, Lankton found that 25% (n=16) were frightened by disclosure of the risks of anaesthesia: J.W. Lankton, 'Emotional Responses to Detailed Risk Disclosure for Anaesthesia a Prospective Randomized Study.' (1977) 46 *Anaesthesiology* 294-245, 295; In Rolling *et al*, 34% of patients (n=100) undergoing peroral endoscopy felt that full disclosure increased their apprehension: G. T. Roling *et al*, 'An Appraisal of Patients' Reactions to "Informed Consent" for Peroral Endoscopy.' (1977) 24 *Gastrointestinal endoscopy* 69, 70. Taken from A. Meisel & L.H. Roth, 'Towards an Informed Discussion of Informed Consent: A Review and Critique of the empirical studies.' (1983) 25(2) *Arizona Law Review* 265, 346, 277-279.
[555] A. Meisel & L.H. Roth, 'Towards an Informed Discussion of Informed Consent: A Review and Critique of the Empirical Studies.' (1983) 25(2) *Arizona Law Review* 265, 346, 327. Relying on I.B. Vertinsky, *et al*, 'Measuring Consumer Desire for Participation in Clinical Decisionmaking.' (1974) 9 *Health Service Research* 121.
[556] I.B. Vertinsky, *et al*, 'Measuring Consumer Desire for Participation in Clinical Decisionmaking.' (1974) 9 *Health Service Research* 121, 131.

Even if Alfadi's findings are representative of patient populations, they were conducted in the US, in the 1970's; so are unlikely to be a reliable reflection of modern preferences within the UK. For example, the majority of studies identified in the review conducted for this thesis, found that whilst patient's wanted information to make practical decisions about managing their health, the majority did not want to take an active decision-making role.[557] For example, Dawes *et al* found that the majority of patients (n=135) 'will do as the doctor says – he knows best.'[558] Beaver *et al*, similarly found that the majority (52%) of women (n=150), newly diagnosed with breast cancer would prefer the doctor to make the decision about the best course of treatment.[559]

Brazier also references the O'Brein report as evidence that patients have a preference for an informed consent within England and Wales.[560] The report, from the Office of Health Economics analysed the sociological data about the efficacy of the informed consent model,[561] facilitated through patient package inserts ("PPI's"), for oral contraceptives.[562] The data was again, almost exclusively, drawn from US studies, so is of limited applicability. The studies also related to information needed for packaging, rather than information needed in face-to-face interactions. The data was also far from unanimous: Mazis *et al* found a preference for longer and more detailed PPI's,[563] while Joubert & Lasanga identified that most respondents (93%) wanted to know the reasons for the medicines that they were using, the common side effects (89%), the risk of under and over dosing (82%), and the probability of rare side effects (81%);[564] Keown *et al* found that patients preferred to know all side effects, regardless of their severity and probability.[565] However, Beecher, for example, argued that patients do not want to know about risks and side-effects, and are generally incapable of understanding a medical-

[557] J.J. Ashcroft, *et al*, 'Breast Cancer – Patient Choice of Treatment: Preliminary Communication.' (1985) 78 *J R Soc Med* 43-46; J. Morris & G.T. Royle, 'Offering Patients a Choice of Surgery for Early Breast Cancer: A Reduction in Anxiety and Depression in Patients and their Husbands.' (1988) 26(6) *Soc Sci Med 583*-585; S.J. Leinster, *et al*, 'Mastectomy Versus Conservative Surgery: Psychosocial Effects of the Patient's Choice of Treatment.' (1989) 7 *J. Psychosoc Oncol.* 189-192 S. Waterworth & K.A. Luker, 'Reluctant Collaborators: Do Patients Want to be involved in Decisions Concerning Care?' (1990) 15(8) *J Adv Nurs* 971-976; P.J.D. Dawes, *et al*, 'Informed Consent: Using a Structured Interview Changes Patients' Attitudes towards Informed Consent.' (1993) 107 *The Journal of Laryngology and Otology* 775-779, 776-777; K. Beaver, *et al*, 'Treatment Decision Making in Women Newly Diagnosed with Breast Cancer.' (1996) 19(1) *Cancer Nursing* 8-19, 16

[558] P.J.D. Dawes, *et al*, 'Informed Consent: Using a Structured Interview Changes Patients' Attitudes towards Informed Consent.' (1993) 107 *The Journal of Laryngology and Otology* 775-779, 777.

[559] K. Beaver, *et al*, 'Treatment Decision Making in Women Newly Diagnosed with Breast Cancer.' (1996) 19(1) *Cancer Nursing* 8-19, 16.

[560] B. O'Brien, *'What are my Chances Doctor?' A Review of Clinical Risks. (*Office of Health Economics, 1986)

[561] *Ibid*. Relying on C. Keown *et al*, 'Attitudes of Lay-people, Physicians and Pharmacists Towards Seriousness and Need for Disclosure for Prescription Drug Side Effects.' (1981) 3(1) *Health Psychology* 1-11. The motivating principle for inclusion of PPI's was that "patients have a right to know about the effects, positive and adverse, of prescription medicines, and that such information will promote the safe and effective use of such products."

[562] *Ibid*, 35

[563] M. Mazis *et al*, 'Patient Attitudes about Two Forms of Printed Oral Contraceptive Information.' (1978) 16 *Medical Care* 1045-1054.

[564] P. Jombert & L. Lasagna, 'Patient Package Inserts: Nature and Needs.' (1975) *Clinical Pharmacology & Therapeutics* 507-513

[565] C. Keown *et al*, 'Attitudes of Lay-people, Physicians and Pharmacists towards Seriousness and Need for Disclosure of Prescription Drug Side Effects.' (1984) 3(1) *Health Psychology*. 1-11

type disclosure of risks and benefits.[566] Similarly, the Gibbs *et al* study found that 69% of patients who had been provided written information, on a consent form, had not read it before signing.[567]

The latter findings coincided with studies conducted in the UK, which found that patients did not want exhaustive disclosure, and instead wanted information that was targeted to their particular needs and circumstances.[568] Hawkins, for example, found that patients (n=399) required practical rather than risk orientated information e.g. risk of delays, waiting and recovery. Bunker, similarly, found that patients wanted information about how the operation would affect their everyday lives, and practical implications of recovery. For example, (83%) wanted to know how long their stay in hospital would be, and the details about the operation (75%): whether they would be on a drip (50%), or have a catheter (73%).[569] Information, however, needed to be tailored to the preferences and needs of the actual patient. For example Lonsdale and Hutchinson found that a minority of patients did not want to know any information,[570] or wanted an exhaustive disclosure.[571] The majority of patients were in fact satisfied with the current content of disclosure. For example, Hawkins found that 74% of patients (n=295) were satisfied,[572] Hawkey & Hawkey found that 69% of patients were positive about information about their underlying illness, 70% about investigations, 67% about reasons for doing investigations and 71% about treatment.[573] Dawes *et al*, found that 88% of patients (n=50) felt that they had about the right amount of information. [574]

The O'Brien study[575] also found that despite policy intentions it was unlikely that patients could understand the content of a full disclosure. The US Federal Register found that providing a high level

[566] H.K. Beecher, 'Consent to Clinical Experimentation – Myth and Reality.' (1966) 195 *JAMA* 39; See, M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law.' (1987) 7 *Legal Studies* 169, 174

[567] M.A. Jones, `Informed Consent and Other Fairy Stories.' (1999) *Med L Rev* 103-134, 126-129; S. Gibbs *et al*, 'Communicating Information to Patients about Medicine.' (1990) 83 *J Roy Soc Med* 292. Also see, A.P. Armstrong, *et al*, 'Informed Consent: Are We Doing Enough?' (1997) 50(8) *Br J Plast. Surg* 637

[568] C. Meredith, *et al*, 'Information Needs of Cancer patients in West Scotland: Cross sectional Survey of Patient Views.' (1996) 313 *BMJ* 724-726, 725; M. Lonsdale & G.L. Hutchinson, 'Patients' Desire for Information about Anaesthesia: Scottish and Canadian Attitudes.' (1991) 46 *Anaesthesia* 410-412, 411.

[569] T.D. Bunker, *et al*, 'An Information Leaflet for Surgical Patients.' (1983) 65 *Annuls of the Royal of Surgeons of England* 242-243, 242

[570] M. Lonsdale & G.L. Hutchinson 'Patients' Desire for Information about Anaesthesia: Scottish and Canadian Attitudes." (1991) 46 *Anaesthesia* 410-412, 411; P.J.D. Dawes *et al*, 'Informed Consent: Using a Structured Interview Changes Patients' Attitudes towards Informed Consent.' (1993) 107 *The Journal of Laryngology and Otology* 775-779, 777; C. Meredith, *et al*, 'Information Needs of Cancer Patients in West Scotland: Cross Sectional Survey of Patient Views.' (1996) 313 *BMJ* 724-726, 725

[571] P.J.D. Dawes, *et al*, 'Informed Consent: The Assessment of Two Structured Interview Approaches Compared to the Current Approach.' (1992) 106 *The Journal of Laryngology and* Otology 420-424; C. Meredith, *et al*, 'Information Needs of Cancer Patients in West Scotland: Cross Sectional Survey of Patient Views.' (1996) 313 *BMJ* 724-726, 725; Royal Commission on the National Health Service, *Patients' Attitudes to the Hospital Service. Research Paper Number 5.* (Stationary Office, 1979), 104

[572] C. Hawkins, 'Patients' Reactions to their Investigations: A Study of 504 Patients.' (1979) 2 *BMJ* 638-640, 640

[573] G.M. Hawkey & C.J. Hawkey, 'Effect of Information Leaflets on Knowledge in Patients with Gastrointestinal Disease.' (1989) 30 *BMJ* 1641-1646, 1645. However, patients were less satisfied by information provided by a GP: 37% were positive about information relating to illness, 48% relating to investigations, 40% relating to reasons for investigations, 46% in information relating to treatment, 16% for side-effects, and 34% for desirable changes in lifestyle.

[574] *Ibid*, 1645

[575] B. O'Brien, *'What are my Chances Doctor?' A Review of Clinical Risks.* (Office of Health Economics, 1986), 35-37

of information led patients to misunderstand very small probabilities, and to conflate risks which were probable, and those that were possible. This was important, as it affected their compliance with treatment; possibly resulting in patients failing to take medications. On this basis the FDA decided to 'keep PPIs short and simple.'[576] O'Brian recognised that the data is not certain on whether the patient is able to comprehend information to a level necessary to have an informed consent (at least to a liberal standard of autonomy).[577] He warned that moving to informed consent would open the floodgates of litigation triggering the practice of defensive medicine.[578] Patients within the UK also shared the concern that the provision of an objective content of information was for the purpose of medico-legal protection, [579] rather than being orientated around their information need so that they could make an informed choice.[580]

2.5.2. Patients can understand informed consent

The rhetoric of the rights school assumes that the reasonable patient has the capacity to give an informed consent. However, even the most evangelical rights proponents admitted that the empirical evidence (of both the doctors communication, and patient capacity) demonstrated that the average person in the UK could not attain the level of understanding necessary to be recognised as a 'consumer of medicine' or give an 'informed consent.'[581] As Robertson argued:

> Given that empirical research has shown the inadequacies of doctor-patient communication to be such as to make the giving of truly "informed consent" almost a forlorn hope in practice, it is perhaps not surprising that American courts have tended to overlook the question of patient comprehension and to concentrate instead solely on the doctor's obligation to disclose the information.[582]

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[576] US Federal Register, *Prescription Drug Products: Patient Labelling Requirements.* (1979)
[577] B. O'Brien, '*What Are My Chances Doctor? A Review of Clinical Risks. (*Office of Health Economics, 1986), 37
[578] *Ibid*
[579] P.J.D. Dawes, *et al*, 'Informed Consent: Using a Structured Interview Changes Patients' Attitudes Towards Informed Consent.' (1993) 107 *The Journal of Laryngology and Otology* 775-779, 775-777; P.J.D. Dawes & P. Davison, 'Informed Consent: What Do Patients Want to Know?' (1994) 87 *J R Soc Med* 149, 150
[580] J.J. Ashcroft *et al* 'Breast Cancer-Patient Choice of Treatment: Preliminary Communication.' (1985) 78 *J R Soc Med* 43-46, 45. See also, K. Beaver, *et al*, 'Decision-Making Role Preferences and Information Needs: A Comparison of Colorectal and Breast Cancer.' (1999) 2 *Health Expectations* 266-276, 273
[581] P. Ley & M.S. Spelman, *Communicating with the Patient.* (Staples Press, 1967), 45-57; G. Stimson & B. Webb, *Going to See the Doctor: The Consultation Process in General Practice*. (Routledge & Kegan Paul, 1975), 80. Royal Commission on the National Health Service. *Patients' Attitudes to the Hospital Service. Research Paper Number 5.* (Stationary Office, 1979), 111; J.J. Ashcroft, *et al*, 'Breast Cancer-Patient Choice of Treatment: Preliminary Communication.' (1985) 78 *J R Soc Med* 43-46, 45; D.J. Byrne, *et al*, 'How Informed is Signed Consent?' (1988) 296 *BMJ* 839; A.P. Armstrong, *et al*, 'Informed Consent: Are We Doing Enough?' (1997) 50 *British Journal of Surgery* 637-640, 637-638; P.J.D. Dawes, *et al*, 'Informed Consent: The Assessment of Two Structured Interview Approaches Compared to the Current Approach.' (1992) 106 *The Journal of Laryngology and Otology* 420-424, 423
[582] G. Robertson, 'Informed Consent to Medical Treatment. (1981) 97 *L Q Rev* 102-126, 112. Relying on Cassileth, *et al*, 'Informed Consent – Why Are Its Goals Imperfectly Realized?' (1980) 302(16) *N Engl J Med* 896-900; S.H. Rosenberg, 'Informed Consent – A Reappraisal of Patients' Reactions.' (1978) 119(5) *Cal Med* 64-68; R.J. Alfadi, 'Informed Consent – A Study of Patients Reaction.' (1971) 216 *JAMA* 1325; C.M. Boyle, 'Difference Between Patients' and Doctors' Interpretation of Some Common Medical Terms.' (1970) 2 *BMJ* 286.

Both Brazier and Jones accept that there is robust empirical evidence to suggest that patients have poor recall of information.[583] For example, Jones accepted that the Byrne *et al* study found that after 2-5 days of an operation, 27% of patients had forgotten what organ had been operated on, and 44% were unaware of the basic facts of the operation i.e. that the gall bladder had been removed.[584] Byrne *et al* concluded:

> […] although signing the consent form before surgical treatment fulfils a legal requirement, it in no way guarantees that the patient is fully aware of the exact nature of the treatment. The problem seems to be particularly prevalent in the elderly although it is not confined to that age group.[585]

This was also reflected in the UK studies identified in this review: Ley and Spelman undertook a review of patient comprehension between 1949 and 1967, the studies found that whilst patients could understand physical ailments, they did not understand more complex information about the nature of their cancer diagnosis.[586] For example, 40% of patients thought that lung cancer and chronic bronchitis could be cured by treatment.[587] Similarly, the study by the Royal Commission found that 49% of patient's did not understand the content of a usual disclosure, and 36% of patients aged between 17-34, and 26% of patients between 25- 54, could not understand terminology.[588] The study also found that some patients (31-32%) worried if they could not understand.[589] The studies identified by this thesis, also found that patients struggled to retain information.[590]

Several UK studies identified poor patient recall. Dawes *et al* found that 1-2 hours after a disclosure 13% of patients could not recall the explanation of an operation, and 37% could not recall the name of the procedure.[591] Whilst there is some evidence that providing patients with written information may improve their recall, this trend was not reproduced in other studies.[592] Clark *et al*, for example, provided one group of patients with pre-printed anaesthesia consent forms, which set out risks, and another oral

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[583] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law.' (1987) 7 *Legal Studies* 169, 177. Relying on: A. Meisel & L. Roth, 'What We Do and Do Not Know About Informed Consent.' (1981) 246 *JAMA* 2473-2477; M.A. Jones, `Informed Consent and Other Fairy Stories.' (1999) *Med L Rev* 103-134, 126-129

[584] D.J. Byrne, *et al*, 'How Informed is Signed Consent? (1988) 296 BMJ 839. In M.A. Jones, `Informed Consent and Other Fairy Stories.' (1999) *Med L Rev* 103-134, 126.

[585] *Ibid*

[586] P. Ley & M.S. Spelman, *Communicating with the Patient.* (Staples Press, 1967), 45-46

[587] *Ibid*, 49-51

[588] Royal Commission on the National Health Service, *Patients' Attitudes to the Hospital Service. Research Paper Number 5.* (Stationary Office, 1979), 106. However, 10-20% could not understand because of capacity issues.

[589] *Ibid*, 111

[590] G. Stimson & B. Webb, *Going to See the Doctor: The Consultation Process in General Practice.* (Routledge & Kegan Paul, 1975), 80

[591] P.J.D. Dawes, *et al*, 'Informed Consent: The Assessment of Two Structured Interview Approaches Compared to the Current Approach.' (1992) 106 *The Journal of Laryngology and Otology* 420-424, 423

[592] See, S. Gibbs, *et al*, 'Communicating Information to Patients about Medicine.' (1990) 83 *J Roy Soc Med* 292; A.P. Armstrong, *et al*, 'Informed Consent: Are We Doing Enough.' (1997) 50 (8) *B r J Plast Surg* 637

information. The group that was provided the oral information could recall more about the risks of anaesthesia, post-operatively.[593] Jones, similarly, identified that the Australian study by Olver found that only 34 out of 100 patients understood the purpose of chemotherapy after being provided information on a written consent form, 75% could not name the relevant drug, and only 15 remembered the side-effects. The study concludes that these forms could not ensure an informed consent.[594] If patients recall information, they are more likely to recall benefits than risks of treatment,[595] which raises questions about whether the patient is able to make a rational decision based on an objective standard of understanding.

The studies identified also found that, if retained, patients struggled to conceptualise and weigh information appropriately; which may bar patients from making rational decisions necessary for a liberal model of autonomous choice.[596] In the Ashcroft study, patients were given a choice about treatment options for breast cancer. They were then asked to rate the potential risks of available treatments between 1-100. The study found that:

> […] some patients were confused and bewildered that they were given a choice of treatment. Giving these women information about their disease and about alternative treatments was often not enough to enable them to decide. Further discussion was necessary in order to establish the patient's personal needs and to consider how the alternative treatments might meet those needs.[597]

Stimson and Webb argued that this is because patients reappraise information in line with their own values, irrespective of what they have been told. [598] This means that requiring a mandatory autonomy will create a two tier-system between those patients who have the ability to understand, retain and utilise information to an autonomous standard[599] and those patients who seemingly have capacity but are not able to make an rational choice.[600] According to the logic of the external critique, these patients, who

[593] M.A. Jones, `Informed Consent and Other Fairy Stories.' (1999) *Med L Rev* 103-134, 126; S.K. Clark, *et al*, 'A Risk-Specific Anaesthesia Consent Form May Hinder the Informed Consent Process.' (1991) 3 *J Clin Anaesthesia* 11
[594] *Ibid* 127; I.N. Olver, *et al*, 'Impact of an Information and Consent Form on Patients Having Chemotherapy.' (1995) 162 *Med J Aust* 82. Also see, D. McCormack, *et al*, 'An Evaluation of Patients Comprehension of Orthopaedic Terminology: Implications for Informed Consent.' (1997) 42 *J R Coll Surg Edinb* 33; R.J. Simes, *et al*, 'Randomised Comparison of Procedures for Obtaining Informed Consent in Clinical Trials of Treatment for Cancer.' (1986) 293 *BMJ* 1065, 1067
[595] K. Chee Saw, *et al*, 'Informed Consent: An Evaluation of Patients' Understanding and Opinion.' (1994) 87 *J Roy Soc Med* 143; R.J. Hekkenberg, *et al*, 'Informed Consent in Head and Neck Surgery: How Much Do Patients Actually Remember?' (1997) 26 *J Otolaryngology* 155, 158. Although this may be because doctors frame information in a positive way: D.K. Smith, *et al*, 'Informed Consent to Undergo Serum Screening for Down's syndrome: The Gap Between Policy and Practice.' (1994) 309 *BMJ* 776
[596] J.J. Ashcroft, et al, 'Breast Cancer-Patient Choice of Treatment: Preliminary Communication.' (1985) 78 *J Roy Soc Med* 43-46, 45
[597] *Ibid*
[598] P. Ley & M.S. Spelman, *Communicating with the Patient.* (Staples Press, 1967), 86-87
[599] See, Section 4
[600] D.J. Byrne, *et al*, 'How Informed is Signed Consent?' (1988) 296 *BMJ* 839

cannot attain an informed consent, are at risk of exposure to paternalistic decisions. This is especially problematic, as Schwartz and Grubb recognised, because resources will be planned on these capacity assumptions, doctors in practice will therefore have little time to bridge this capacity gap.[601] The lack of robust empirical support for the requirement of informed consent exposes the political, rather than ethical, nature of many of the patient rights arguments.[602]

3.5.3. The benefit of a bad situation?

Upon recognising the flaws arising from the practical implementation of the rights model, commentators[603] such as Jones adopted a consequential approach, arguing that as informed consent increased the amount of disclosure it justified the potential harms.[604]

> The increase in malpractice litigation since the early 1980s may well have had some effect on the practice of doctors. There has undoubtedly been a change in the consent procedures for sterilisation: patients will now be told about the risks of the operation not producing complete sterility. One study concluded that in the four year period since an earlier study ENT surgeons were disclosing more about potential complications to patients: 'This either reflects the predicted and long expected increase in defensive medicine as a response to an increasing medical litigation or an increased awareness that patients want to know more about treatment.' […][605] In an unpublished survey conducted in 1994, 75 per cent of doctors said that they gave more information about the risks involved in a proposed procedures simply because the patient could bring a claim against them for negligence (total sample 1'462)[…] Moreover, as professional attitudes to the question of information change (whether through gentle persuasion or the threat of litigation) patients will become 'entitled' to more information under the *Bolam* standard (assuming, of course, that changes in practice will reflect the growing concern that consent should be 'informed').
>
> More generally, doctors are probably now more careful about obtaining consent. The consultant will usually get the registrar or SHO to consent the patient, rather than the nurse (or cleaning lady).[606]

[601] R. Schwartz & A. Grubb, 'Why Britain Can't Afford Informed Consent.' (2985) 15(4) *The Hastings Center Report* 19-25
[602] J. Montgomery, *et al,* 'Hidden Law-Making in the Province of Medical Jurisprudence.' (2014) 77(3) MLR 343-378, 375-378
[603] I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treatment Me Rights: Essays in Medical Law and Ethics.* (Clarendon Press, 1988), 189
[604] M.A. Jones, 'Informed Consent and Other Fairy Stories. (1999) 7 *Med L Rev* 103-134, 105. Relying on A.S. Kessel, 'On Failing to Understand Informed Consent.' (1994) 52 *Br J Hosp Med* 235, 237; D.D. Kerrigan, *et al,* 'Who's Afraid of Informed Consent? (1993) 306 BMJ 298; C. Lavelle-Jones, *et al,* 'Factors Affecting Quality of Informed Consent' (1993) 306 *BMJ* 885
[605] P.J. Dawes 'Informed Consent: Questionnaire Survey of British Otolaryngologists.' (1994) 19 *Clin Otolaryngol* 388, 392; A.G.D. Maran, 'Informed Consent in Head and Neck Surgery.' (1990) 15 *Clin Otolaryngol* 198
[606] M.A. Jones, 'Informed Consent and Other Fairy Stories. (1999) 7 *Med L Rev* 103-134, 124-125

The increase in disclosure, through defensive practice, was also identified by Robertson after *Reibl v Hughes,* which, as already argued, implemented a model of informed consent. Before the case 25% of doctors that were aware of the ethical requirement to provide informed consent had begun to change their practices.[607] However, studies conducted after 1990 identified a significant shift in medical practice towards incorporating the consumer relationship.[608] As Dickens suggests:

> […] physicians appear to have absorbed the message of the law, expressed in *Reibl v Hughes* that they must communicate more adequately with their patients. Spending more time in discussion does not ensure, of course, that the time is well spent; increased quantity of interactive time does not guarantee the quality of the discourse and critical information exchange. An increase in time spent may, however be positively related to, and may even be a precondition of, achievement of the required quality of human interaction. Accordingly, increased time spent in the physician-patient interaction may indicate that the value embodied in the judgement in *Reibl v Hughes* is being respected and perhaps achieved.[609]

Katz also argued that the effect of changes in law may be of more symbolic significance, but 'symbols can agg and prod and disturb and ultimately bring about some change.'[610] Whilst rights commentators may herald this a success, Jones rightly recognised that this change is brought about by fear of litigation rather than an attempt to ensure an autonomous choice.[611] Informed consent is seen as an event, often left to the junior staff members, which requires information to be dumped upon patients to ensure that the fiduciary duties of medical practice are met.[612] Disclosure was divorced from therapeutic considerations to become a formulaic process, which often means patients fail to understand.[613] Teff responded that the risk of defensive medicine is overstated because of the private system of healthcare in the US.[614] This may be true, but it does not extinguish the reality that informed consent was operating on doctors in the UK as a mechanism of fear, rather than a mechanism to ensure patient autonomy.

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[607] G. Robertson, 'Informed Consent in Canada: An Empirical Study.' (1984) 22(1) *Osgoode Hall Law* J 139-161
[608] G. Robertson, 'Informed Consent Ten Years Later: The Impact of *Reibl v Hughes*.' (1991) 70(3) *The Canadian Bar Review* 423-447
[609] B. M. Dickens, "The Effect of Legal Liability on Health Care Providers" In J.R.S. Pritchard, *Report of the Federal/Provincial/Territorial Review on Liability and Compensation Issues in Health Care*. (1990), 51; F. Sellers, "Report on the Survey of the Impact of Medical/Legal Liability on Patterns of Practice," In J.R.S. Pritchard, *Report of the Federal/Provincial/Territorial Review on Liability and Compensation Issues in Health Care*. (1990)
[610] J. Katz, *The Silent World of Doctor and Patient* (John Hopkins University Press, 1984), 60.
[611] A. Jones, 'Informed Consent and Other Fairy Stories.' (1999) 7 *Med L Rev* 103-134, 125; Relying on A. W. Morrison, 'Silence in Court: Twenty One Years of Otolaryngology Litigation.' (1990) 104 *J. Laryngol Otol.* 162. Also, see G. Robertson, 'Informed Consent Ten Years Later: The Impact of *Reibl v Hughes*.' (1991) 70(3) *The Canadian Bar Review* 423
[612] M.A. Jones, 'Informed Consent and Other Fairy Stories.' (1999) 7 *Med L Rev* 103-134,125
[613] *Ibid*, 126-129. Relying on I.C. Paterson, 'Consent to Treatment: Somebody's Moved the Goalposts.' (1994) 6 Clin Oncology 179; A.S. Kessel, 'On Failing to Understand Informed Consent.' (1994) 52 *Br J Hosp Med* 235
[614] H. Teff, 'Consent to Medical Procedures: Paternalism Self-Determination of Therapeutic Alliance.' (1985) 101 *L Q Rev* 432, 435

CHAPTER 4. *PEARCE* AND THE PRUDENT PATIENT 1998-2004

Chapter 3 illustrated how the jurisdiction school's argument for normativity led to a growth in collectivisation of medical practice, after the *Bolitho* judgement; to ensure that decisions could be characterised as being 'logical.'[1] Heywood, for example, argued that this led to an ossification of the presumptions within the internal morality,[2] which set the threshold of disclosure of risks at around 1-2%.[3] The collectivisation of these thresholds and presumptions were then explicated within (semi) formal medical ethics.[4] As Samanta *et al*, argued, these guidelines were used within litigation as both a sword and a shield.[5] This, again, encouraged adherence to mechanistic methods of decision-making. Indeed, Brazier and Miola argued that the logical requirement of *Bolitho*, offered an opportunity for judges to interrogate the decision-making about information disclosure.[6] As the methodology for decision-making became less dynamic, this offered more opportunity to attack it for arbitrariness and rigidity, particularly, (as chapter 3 argued) in line with the internal critique of Lord Scarman.[7] Indeed, this critique manifested within post-*Bolitho* case-law.[8] For example, in *Marriott v West Midlands HA*[9] the Court of Appeal found that the doctor had failed to properly weigh the test results against symptoms of drowsiness, headaches and lack of appetite, in reaching a diagnosis. In doing so, the judge was obliged, under the *Bolitho* test, to assess the logic of a decision independently from expert evidence. Similarly, in *Smith v Tunbridge Wells HA*, Morland J. found that the doctor had a duty to ensure that a patient was informed of potential risks of a rectal prolapse operation; even though other doctors may have done the same.[10] Lord Donaldson speaking extra judicially stated that: '[i]t seems clear that in England *Sidaway* will have to be read in light of *Bolitho*,' thus,

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[1] *Bolitho v City and Hackney Health Authority* (1997) 39 BMLR 1, 10

[2] R. Heywood, 'Excessive Risk Disclosure: The Effect of the Law on Medical Practice.' (2005) 7 *Med L Int* 93-112, 108; W. Hussain, *et al*, 'Consent and Invasive or Interventional Cardiology.' (2001) 7 *Clinical Risks* 127, 129: "Doctors are under a duty to ensure that their patients receive information they need to give an informed consent to surgical and other healthcare decisions. In particular, the physician must discuss with their patients the nature of their illness and of the recommended treatment, disclose the material risks involved in that course of action, and discuss any alternatives as well as the consequences of doing nothing. I suspect that this is what most responsible doctors have for generations been in the habit of doing."

[3] R. Heywood, 'Excessive Risk Disclosure: The Effects of the Law of Medical Practice.' (2005) 7 *Med L Int* 93-112, 95. In response to the claim that there was no inner morality in: I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treat Me Right: Essays in Medical Law and Ethics* (Clarendon Press, 1988), 189

[4] GMC, *Seeking Patients Consent: The Ethical Considerations* (GMC, 1998). See also, Department of Health Circular, *Good Practice in Consent Implementation Guide: Consent to Examination or Treatment.* (DoH, 2001)

[5] A. Samanta, *et al*, 'The Role of Clinical Guidelines in Medical Negligence Litigation: A Shift from the *Bolam* Standard?' (2006) 14(3) *Med L Rev* 321-366. Also see, A. Samanata, *et al*, 'Legal Considerations of Clinical Guidelines: Will NICE Make a Difference?' (2003) *J Roy Soc Med* 133-138

[6] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 103

[7] *Sidaway v Board of Governors and Bethlem Royal Hospital* [1985] AC 871, per Lord Scarman 887-890; M. Brazier & J. Miola, 'Bye-Bye *Bolam*: Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 113

[8] See for example, *McAllister v Lewisham and North Southwark Health Authority* [1994] 4 Med LR 343, per Rougier J; *Smith v Salford Health Authority* [1994] 5 Med LR 321 per Potter J; *Smith v Barking, Havering and Brentwood Health Authority* [1994] 5 Med LR 285; *Joyce v Merton, Sutton & Wandsworth HA* [1996] 7 Med L R 1; *Wisznieski v Central Manchester Health Authority* [1996] 7 Med LR 245

[9] *Marriott v West Midlands HA* [1999] Lloyds MR Med 23, per Bedlam LJ; per Pill LJ & Swinton Thomas LJ in agreement. See, M. Jones, 'The Illogical Expert.' (1999) 15 *Professional Negligence* 117, 120

[10] *Smith v Tunbridge Wells HA* [1994] 5 Med LR 334

> [a] doctor's decision not to disclose risks will now have to be subjected to logical analysis, and if he had withheld without a good reason information that should have been disclosed then he will be liable even though his decision will have been consonant with ordinary professional practice.[11]

This ability to critique the internal weighing of values and relevant factors within medical decision-making led to a slow creep towards replacing the methodology of the therapeutic relationship with the normative standards 'through the back door.'[12] As chapter 3 argued, the movement towards normativity was filled with the top-down ethical content of the rights school, which shifted the purpose of disclosure from facilitating the needs of the patient, to facilitating a model of autonomous choice, through an informed consent.

This chapter argues that *Pearce* was the first substantive step to incorporating a model of autonomy into the law by requiring the doctor to disclose risks which the reasonable patient would need to know.[13] However, Lord Woolf MR failed to extrapolate which model of autonomy the standard was facilitating, both commentators and subsequently judges in the lower courts were divided about whether the test was objective or subjective, and thus, whether a liberal or authentic model of autonomy was being facilitated. Section 2 argues that rather than attempt to rationalise the conceptual inconsistency within the standards, the formal sector straddled the binary, encouraging doctors to disclose both an objective and a subjective content of information in an exhaustive disclosure. However, as chapter 3 illustrated, a patient cannot have both a subjective and objective standard of understanding as the basis of an autonomous choice. The guidance also attempted to integrate a libertarian presumption of capacity, which prevented the doctor from: (1) ensuring that the patient had an *actual* understanding, for a rational choice, and (2) whether they had fallen between the capacity-consent gap. Section 3 argues that the conceptual conflation in the guidance caused a methodological divide in medical decision-making in practice. There was evidence that some doctor adopted a method of integration (which saw them provide an exclusive threshold of information), some adopted defensive practices (by formulaically providing exhaustive disclosure), and other doctors ignored the law and ethics completely and continued to make decision using *circumstantial-moral* decision-making. Despite normative rules not achieving the aim of ensuring a substantive autonomy, some commentators continued to advocate for further movements to a consumer styled relationship.

[11] Lord Woolf, 'Are the Courts Excessively Deferential to the Medical Profession?' (2001) 9(1) *Med L Rev* 1-16, 11
[12] R. Heywood, 'Informed Consent through the Back Door.' (2005) 56(2) *NIQR* 266-274
[13] *Pearce v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, 124.

4.1. The reasonable patient in law

The claimant in *Pearce* argued that the conservative option, of vaginal birth, provided by a consultant (Mr Riven) was negligent; as the defendant had failed to provide the claimant with the option of a caesarean section, which resulted in still birth.[14] The claimant argued that a proper interpretation of the *Bolam* standard allowed the judge to evaluate the moral presumptions on which a decision rested.[15] Thus, if a patient asked a question that it was in her best interest's interest to know. This that this could be extended by the courts to create a generalisable right to information which the average patient may want to know (if every reasonable patient would ask a similar question).[16] Lord Woolf MR, stated that Lord Bridge[17] and Diplock[18] provided the leading judgement in *Sidaway*. On this basis, he recognised that the doctor operated in the therapeutic relationship and therefore had to act in the patient's best medical interest's. However, in delineating what information the patient should know, the doctor had to consider all of the circumstances. [19] Additionally, he argued that Lord Templeman and Lord Scarman's approach correctly recognised a presumption that an autonomous choice would be in the reasonable patient's best interest's.[20]

> If the doctor making a balanced judgment advises the patient to submit to the operation, the patient is entitled to reject that advice for reasons which are rational or irrational or for no reason. The duty of the doctor in these circumstances, subject to his overriding duty to have regard to the best interests of the patient, is to provide the patient with information which will enable the patient to make a balanced judgement if the patient chooses to make a balanced judgment. A patient may make an unbalanced judgment because he is deprived of adequate information. A patient may also make an unbalanced judgment if he is provided with too much information and is made aware of possibilities which he is not capable of assessing because of his lack of medical training, his prejudices or his personality.[21]

As a result, Lord Woolf argued that this principle of autonomy was integrated within the therapeutic decision, but was ensured through a distinct content of information, required by the normative legal standard. Failure to incorporates this presumption requires a logical justification.[22] As such:

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[14] *Ibid*, 119-120

[15] *Ibid*: "(1) Is the advice rational having regard to the context and purpose for which it is required? (2) Is the advice responsible in that it alerts the patient to the particular risk of which the patient should know? (3) Is the advice responsive in that it deals with the questions and concerns of the particular patient?"

[16] *Ibid*, 120-121

[17] *Sidaway v Bethlem Royal Hospital Governors* (1985) 1 AC 871, per Lord Diplock at 895

[18] *Ibid*, per Lord Bridge at 900

[19] *Pearce and another v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, 123-125: "The doctor has to take into account all the relevant considerations when deciding how much to tell a patient, including the patient's physical and emotional state at the time, and his or her ability to comprehend information."

[20] *Ibid*, 122-123

[21] *Sidaway v Bethlem Royal Hospital Governors* (1985) 1 AC 871, per Lord Templeman at 904

[22] *Pearce and another v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, 124; Relying on *Bolitho v City and Hackney Health Authority* (1997) 3 WLR 1151, per Lord Browne-Wilkinson at 1160.

> In a case where it is being alleged that a plaintiff has been deprived of the opportunity to make a proper decision as to what course he or she should take in relation to treatment, it seems to me to be the law, as indicated in the cases to which I have just referred, that if there is a significant risk which would affect the judgment of a reasonable patient, then in the normal course it is the responsibility of a doctor to inform the patient of that *significant risk*, if the information is needed so that the patient can determine for him or herself as to what course he or she should adopt.[23]

Lord Woolf argued that the standard of significance should be set as a percentage threshold linked to the frequency of occurrence - he adopted the 10% threshold, in line with Lord Bridge's judgement, and the expert evidence.[24]On this basis Lord Woolf came to the conclusion that the statistical risk of stillbirth of between 0.1%- 0.2% was below what was material in the circumstances.[25] The *Pearce* judgement therefore advocates for a minimum content of disclosure, along the lines of the internal rights school critique.[26] However, the judgement fails to define what is meant by 'seriousness'; and thus: what model of autonomy the standard seeks to facilitate, or the methodology that should be used to identify material information.

(i) The prudent patient standard

Commentators were divided on what amounted to serious information. One approach was to adopt and objective interpretation, and in doing so adopt a liberal model of autonomy. This content could be defined by medical experts based on what the ordinary patient would wish to know. As Maclean argues, the use of the term 'in the ordinary event'[27] infers that the judge was attempting to define a content of information which the average person would inevitably find material due to the serious nature of the risk.[28] For example, by its' nature a caesarean section will have some significant risks, which mothers would inevitably wish to know irrespective of the particularities of their circumstances or values.[29] However, Maclean argues that the percentage threshold of serious risk will be defined by the doctor, and in certain circumstances, the requirement to disclose can be rebutted: '[t]here can often be situations where a course different from the normal has to be employed.'[30] The decision about ensuring an

[23] *Ibid*, 124
[24] *Ibid*, 124: "A. If she hadn't asked I wouldn't have mentioned the subject as she was already distressed and the risk is excessively small. I generally practice according to the belief that it is not the doctor's duty to warn of very small risks. If the risk, however, was of the order 10%, for instance, then of course it would be my duty to warn against such a level of risk."
[25] *Ibid*, 125
[26] Chapter 2, section 1
[27] *Pearce and another v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, 125.
[28] A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5 *Med L Int* 205-230, 213-214
[29] A. Maclean, 'The Doctrine of Informed Consent: Does it exist and has it Crossed the Atlantic?' (2004) 24 (3) *Legal Studies* 386-413, 409
[30] *Pearce and another v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, 125

autonomous choice is therefore incorporated into the wider therapeutic decision, and the doctor continues to act as a gatekeeper of information.[31] Maclean argues that the doctor would be obliged to provide this information if the patient has sufficient capacity.[32] This is convincing, as Kennedy and Grubb concede, as the model of patient autonomy operates within the context of the therapeutic relationship.[33] Certainly, the benefit of this approach is that information is not forced onto the patient, abstracted from their circumstances. It also means that the patient does not fall down the capacity gap.[34] In later publications, Maclean advocates for the definition of 'significance' to be defined by empiricism rather than the expertise.[35]

Heywood similarly argued that the judgement incorporated a prudent patient standard; however, he offers a slightly different interpretation than Maclean. He argues that Lord Woolf required that the actual patient was presumed as competent therefore a threshold of information should be provided regardless of the circumstances.[36] The baseline of disclosure would be set at 10%, after which information would be added to the disclosure, taking into account 'all the relevant considerations' at play for the purpose of achieving an autonomous choice.[37] The distinction is that Heywood does not see the purpose of the disclosure as integrated, and therefore the doctor would have no justification to limit the content of the disclosure in the patient's best interest. Heywood agreed with Maclean, that empiricism was necessary to define the threshold that the reasonable patient would want (albeit, as a baseline for an autonomous choice).[38]

(ii) The particular patient standard

However, Lord Woolf may not have required a fixed threshold, as Heywood postulated, but a threshold of significant information defined in the circumstances of the actual case. An immutable cut-off threshold, of 10% chance of a risk occurrence, whilst logical in some contexts, for example, the risk of bruising, in other contexts, such as a lower but serious risk of paralysis, becomes less coherent. As

[31] A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5 *Med L Int* 205-230, 214
[32] *Ibid*, 213
[33] I. Kennedy & A. Grubb, *Medical Law* (Butterworths, 2000), 709
[34] A. Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge.* (Cambridge University Press, 2009), 175: "Since the judgement of significance preceded the assessment of whether disclosure would have affected the reasonable patient's decision, it acts as a filtering device which, being placed in the medical profession's hands, undermines the apparent weight given to patient autonomy. Before the reasonable-patient test is engaged the medical expert acts as gatekeeper determining the significance of the risk and 'insignificant' risks are excluded from further considerations."
[35] A. Maclean, 'Giving the Reasonable Patient a Voice: Information Disclosure and the Relevance of Empirical Evidence.' (2005) 7 *Med L Int* 1-49
[36] R. Heywood, 'Re-Thinking the Decision in *Pearce*.' (2005) 7(3) *CIL* 264-280, 270-272
[37] R. Heywood, 'Re-Thinking the Decision in *Pearce*.' (2005) 7(3) *CIL* 264-280, 269-273. R. Heywood, 'Informed Consent in Hospital Practice: Health Professionals' Perspectives and Legal Reflections.' (2010) 18 *Med L Rev* 152-184, 174; Relying on I. Kennedy, "The Patient on The Clapham Omnibus Postscript: The House of Lords' Decision" In I. Kennedy (ed.), *Treat Me Right: Essays in Law and Medical Ethics* (Clarendon Press, 1988), 200
[38] R. Heywood, *The Law and Practice of Consent to Medical Intervention.* (PhD Thesis, Sheffield Hallam University, 2006); R. Heywood, 'Informed consent in hospital practice: Health Professionals' perspectives and legal reflections.' (2010) 18 *Med L Rev* 152-184

Maclean argues, '[a] frequency of 1:10 is such a high cut-off that, in the world of modern medicine, it will exclude perhaps most of the risks of serious permanent harm.'[39] It is unlikely that Lord Woolf intended a fixed threshold of disclosure, as he rejected the prudent patient standard in Lord Scarman's judgement and instead defined materiality, in 'all the relevant circumstances, which include the ability of the patient to comprehend what he has to say to him or her and the state of the patient at the particular time, both from the physical point of view and an emotional point of view.'[40] A threshold of significance must therefore include a conception of magnitude of harm, alongside frequency. The inclusion of a concept of magnitude invites moral interpretation about what the average patient would find significant. As Maclean recognised "[t]he inescapability of interpretation makes risks infinitely malleable and, as Beck insists: 'open to social definition and constructions'."[41] This could be defined objectively, for example through empiricism, or through the particular values at play in the case.

Lord Woolf seemed to suggest that the values should not be set normatively as: 'it would not be proper for the courts to interfere with the clinical opinion of the expert medical man responsible for treatment Mrs Pearce.'[42] Miola and Brazier therefore argued that as the relevant values were constructed in the circumstances, these would necessarily include the biopsychosocial values of the patient. Therefore, what the ordinary patient in the circumstances wanted to know amounted to the particular patient test.[43] This would invite the assumption that the standard of care is facilitating an authentic autonomous choice. They argued:

> Even the cynic must concede that, whatever the outcome on the facts, the 'reasonable doctor' tests received a body blow in *Pearce*. It survives only if the 'reasonable doctor' understands that he must offer the patient what the 'reasonable patient' would likely need to exercise his right to make informed decisions about his care.[44]

This position is jurisprudentially persuasive, because requiring a doctor to provide a fixed standard or threshold of information irrespective of the circumstances would mean that doctors were making illogical decision.[45] A fixed threshold would also ignore the overarching requirement to act in the best interest, in the particular circumstances - undermining the *Bolam* standard - as it would force doctors to

[39] A. Maclean, 'Beyond *Bolam* and Bolitho.' (2002) 5 *Med L Int* 205-230, 213
[40] *Pearce and another v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, 122
[41] A. Maclean, 'The Doctrine of Informed Consent: Does it exist and has it Crossed the Atlantic?' (2004) 24(3) *Legal Studies* 386-413, 409. Relying on B. Adam, U. Beck and J van Loon (eds.), *The Risk Society and Beyond: Critical Issues for Social Theory*. (Sage, 2000), 4
[42] *Pearce and another v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, 125
[43] M. Brazier & J. Miola, 'Bye-Bye Bolam: Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 109-110. Also see, A. Grubb, 'Negligence: Causation and *Bolam*.' (1998) 6 *Med L Rev* 378, 384
[44] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 110. Relying on A. Grubb, 'Medical negligence: duty to disclose after Bolitho.' (1999) 7 *Med L Rev* 61, 63
[45] *Bolitho v City and Hackney Health Authority* (1997) 39 BMLR 1, 10

make arbitrary decisions.[46] The way that Miola and Brazier present the interpretation of *Pearce*, is also in line with the way Mr Richardson (counsel for the claimant) presented the case – which was the line of thinking endorsed by the Court.

> Mr Richardson draws attention the fact that this is converse of the position which regularly comes before the courts, where the doctor has treated the patient because the doctor considers that treatment is appropriate, and the patient, when the treatment does not have the beneficial effect expected, complain that he or she was not informed of the risks which were inherent in the treatment. Mr Richardson submits that the issue which he identified involves the right of a patient to determine his or her own future, and the right of the patient to have a second opinion.[47]

Whilst this position is ideal it does not account for the actual decision of Lord Woolf, which analysed the reasonableness of the disclosure in terms of a statistical frequency; defined by the expert, and not patient, values. As Maclean argued:

> This approach turns the Brazier and Miola argument back on its head. The standard becomes: the doctor must disclose those risks that the reasonable doctor believes that the reasonable patient ought to find significant to a decision. This view may be cynical, but the judgement in *Pearce*, and the court's apparent reliance on percentages and expert assessment of significance, does nothing to dispel the cynicism.[48]

This conceptual quagmire within academic commentary was reproduced within subsequent case-law.

3.1.3. Post-*Pearce* case-law: the beginning of blinkered moralism

Uncertainty about the model of autonomy being facilitated within *Pearce* led to division in the first-tier courts. Some judges conceptualised significance as requiring the disclosure of a distinct content of objectively defined information, whist others saw that the circumstances required the content of information to be particularised to the circumstances.

In *Wyatt v Curtis*, for example, Sedley LJ stated that the doctor must disclose 'substantial risk of grave consequences'[49] as the basis of an objectively defined prudent patient standard. The threshold of *seriousness* was defined by the doctors; using the process of circumstantial decision-making, endorsed by *Sidaway*.[50] Mrs Curtis claimed that the doctor had failed to ensure her understanding of foetal

[46] M.A. Jones, 'Informed Consent and Other Fairy Stories.' (1999) 7 *Med L Rev* 103, 125
[47] *Pearce and another v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, 119-120
[48] A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5 *Med L Int* 205-230, 214
[49] *Wyatt v Curtis* [2003] EWCA Civ 1779, per Sedley J at [15]
[50] *Ibid*, [17] – [18]

abnormality resulting from chicken pox, in a subsequent consultation. The judge decided that the doctor had no distinct duty in negligence to ensure that the patient understood a prudent patient content of information. However, in identifying the statistical frequency of materiality, the patient's actual values would be included in the process of medical decision-making and therefore would be persuasive as to what a prudent patient might want to know.[51] On this basis Sedley J found that although the risk of foetal disability was below the 10% threshold, at 2%, the magnitude of risk was such, that an ordinary patient would want know because of the objectively serious nature of that risk.[52] However, the doctor was under no specific duty to ensure that the patient understood that information so that she could make a rational choice; only that she had been provided disclosure. The judge recognised that the definition of serious risk - this potentially opened the floodgates to the particular patient standard.[53] Thus, Kay LJ warned:

> The court should, I believe be very careful that decisions in cases of this kind do not drive doctors into a position where they feel reluctant to give proper consideration of the effect of the advice on the patient the weight that it merits.[54]

On the other hand, in *Deriche v Ealing Hospital NHS Trust*, Buckley J sitting at the High Court, took the opposite approach and endorsed the particular patient standard of care, based on a very similar factual matrix.[55] The claimant argued that the defendant had a duty to ensure that the patient understood the 2% risk of foetal abnormality, resulting from chicken pox, according to their own values.[56] The doctor had provided information and advice, in line with an objective view of risks, rather than provide information to endorse the patient's anxiety.

The judge found that the threshold of materiality was constructed from the circumstances of the actual patient. The risk of abnormality was at 2%, below the 10% threshold, however:

> As Mr Hare, in particular, pointed out; even a small risk of potentially devastating abnormalities is likely to be regarded as highly material to a pregnant woman. It also seems to me to be important because in such a case, views a doctor my hold on such a delicate matter, should not be allowed to affect the tenor of advice. I have in mind religious or other personal views on the question of abortion.[57]

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[51] *Ibid*, [16]
[52] *Ibid*, per Sedley J. at [18]-[21] and Kay LJ at [23]
[53] M. Brazier, 'Patient Autonomy and Consent to Treatment: The Role of Law.' (1987) 7 *Legal Studies* 169, 189-191
[54] *Wyatt v Curtis* [2003] EWCA Civ 1779, per Sedley J at [17] – [18], [22]
[55] *Deriche v Ealing Hospital NHS Trust* [2003] EWHC 3104 (QB)
[56] *Ibid*, [34] & [39]
[57] *Ibid*, [49]

The defendant disclosed the risk stating it was a 'very small risk' rather than giving the percentage.[58] However, the judge relied on expert evidence to argue that there was a distinct duty 'to ensure that Mrs Deriche fully understood the nature of risks.'[59] He therefore found that "[…] Mr Haeri's consultation with Mrs Deriche might be regarded as too reassuring particularly bearing in mind his comment that Mrs Deriche would not need a termination. Taken with the omission to ensure Mrs Deriche understood the nature of the risks, it evidenced a somewhat unbalanced consultation." [60] The judge therefore required that the patient to not just understand information, but to do so according to her own values (rather than the values of the doctor). The judge, rather unconvincingly, distinguished between *Wyatt* on a number of grounds:

> (1) The point of law was distinguished on the facts of the case (even though they were identical)[61]
> (2) That the duty to ensure a subjective understanding had emerged between 1991 and 1996[62]
> (3) That the patient had expressed a need for the defendant's advice, and raised questions with the doctor (although this point is not developed)[63]
> (4) That the submission that the doctor had a duty to ensure understanding had not been raised.[64]

This thesis would argue that this distinction is not made on substantive factual ground, but rests entirely on the 'blinkered moralism' of the individual judge.[65] Buckley J seems to have simply chosen an authentic model of autonomy, because it allowed him to vindicate some semblance of patient rights in the circumstances.[66] The problem with judges picking and choosing between the models of autonomy; as the basis for defining *significant* risks, is that the standard of materiality, and therefore the content of information that should be disclosed, becomes unknowable. This is worsened when one recognises that the doctor has a legal duty to integrate this content of information into a wider therapeutic decision. From the factors of these cases, it is unclear, for example, how the doctor should utilise evidence of the patient's anxiety and distress. For Sedley J, who emphasised a therapeutic approach, this would indicate potentially withholding information in the patient's best interest[67] (i.e., adopting the Maclean

[58] *Ibid*, [43]
[59] *Ibid*, [42]
[60] *Ibid*, [44]
[61] *Ibid*, [45]-[46]
[62] *Ibid*, [47]
[63] *Ibid*
[64] *Ibid*
[65] J. Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism?' (2007) 15 *Health Care Analysis* 235-255
[66] A similar approach as that taken by the High Court of Australia in *Rogers v Whitaker* (1992) 16 BMLR 148, 158
[67] *Wyatt v Curtis* [2003] EWCA Civ 1779, per Sedley J. at [17] – [18]

interpretation). For Buckley J, however, this anxiety would be interpreted as a requirement to disclose further specifics.[68] Only a very high threshold of harm would justify non-disclosure.

> Thus if a doctor forms the view that injury would follow from further discussion, of course, he would not proceed and the Court would support him. However, something more than temporary distress would be needed. That should surely be outweighed by the devastation a mother would suffer if the risk materialises and she feels she was not fully warned of it and thus deprived of her right to decide. This is an areas where the patient's right to know and be informed of up-to-date medical knowledge is clearly important, but no doctor who, on sensible medical grounds, withholds certain information need be concerned that a Court would not support that decision.[69]

If the proportionality of the harm of disclosing is to be weighed against the potential harm of the risk actually occurring, then this thesis cannot envisage a situation where the doctor should not disclose. In reality this requirement would make disclosure almost mandatory. The doctor is thus placed in the impossible position of choosing between models.

4.2. The ethical guidance: proliferating uncertainty

This section sets out the reaction of the formal ethical sector to the conceptual confusion created by the standard of care in *Pearce*.[70] It argues that the formal sector has attempted to straddle the binary of the liberal and authenticity model of autonomy, operating in the wider therapeutic medical relationship, whilst also accommodating the libertarian model in relation to the presumption of mental capacity. In an attempt ensure doctors avoid liability, the formal ethical sector has proliferated rather than rationalised the conceptual confusion in medical practice. The semi-formal sector was more successful in rationalising the conflicting standards by ordering the models of autonomy; for example, the BMA guidance[71] seemed to suggest that the particular patient model should be prioritised. This seems sensible, as it is aligned with the patient-focus of *circumstantial-moral* decision-making. The prudent patient standard would only be utilised if patient values were not identifiable.

4.2.1. The Formal Sector

Formal sector guidance, during this period, was comprised of: (1) the Department of Health *Reference Guide* to consent[72] (which sought to create a universal methodology of medical decision-making

[68] *Deriche v Ealing Hospital NHS Trust* [2003] EWHC 3104 (QB), [49]
[69] *Ibid*, [50]
[70] *Pearce and another v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, 124
[71] British Medical Association Ethics Department, *Medical Ethics Today: The BMA's Handbook of Ethics and Law 2nd Edition.* (BMJ Books, 2004),78
[72] Department of Health, *Reference Guide to Consent for Examination or Treatment*. (DoH, 2001). See also similar reference guidance published for devolved Wales and Northern Ireland: Welsh Assembly Government, *Reference Guide for Consent to*

through the introduction of consent forms and associated policies),[73] (2) the GMC's *Good Medical Practice* guidelines[74] (which were general guidelines and standards for decision-making), and the specific consent guidelines contained in *Seeking Patient's Consent*.[75] All of the guidance recognised that medical decision-making operated in the context of a trusting therapeutic relationship; with the aim of acting in the patients' best interest. For example, *Good Medical Practice* stated:

> Patients must be able to trust doctors with their lives and well-being. To justify that trust, we as a profession have a duty to maintain a good standard of practice and care and to show respect for human life.[76]

Seeking Patient Consent argued that 'Successful relationships between doctors and patients depend on trust'[77] and that the therapeutic obligations require a 'continuing dialogue' throughout the medical relationship.[78] The *Reference Guide* recognised the therapeutic nature of decision-making in information disclosure by endorsing the *Bolam* standard.

> […] the legal standard to be used when deciding whether adequate information had been given to a patient should be the same as that used when judging whether a doctor had been negligent in their treatment or care of a patient: a doctor would not be considered negligent if their practice conformed to that of a responsible body of medical opinion held by practitioners skilled in the field in question (known as the "Bolam test").[79]

All of the guidance seems to assume that facilitating a patient's autonomy, through normative standards, is compatible with acting in the patient's best interest.[80] For example, *Seeking Patients* argued:

Examination or Treatment. (WAG, 2002); Department of Health, Social Services and Public Health, *Reference guide to consent for examination, treatment or care*. (DHSSPS, 2003).

[73] The Department of Health recognised the need to create a universal standard and methodology for consent. This was achieved by requiring institutional change, requiring NHS Trusts throughout the NHS to adopt a model consent policy, consent forms and information leaflets from 1st April 2002. The Reference Guide to Consent for Examination and Treatment was produced and distributed in March 2001, to act as a universal guide for consent after these systemic changes. Department of Health and Social Care, *Reference Guide to Consent for Examination or Treatment* (DoH, 2001), (<http://psychrights.org/Countries/UK/DOHPolicyInfCons.pdf>)

[74] GMC, *Good Medical Practice.* (GMC, 2001)

[75] GMC, *Seeking Patient's Consent: The Ethical Considerations*. (GMC, 1998)

[76] GMC, *Good Medical Practice.* (GMC, 2001), *The Duties of a Doctor Registered with the General Medical Council*

[77] GMC, *Seeking Patient's Consent: The Ethical considerations*. (GMC, 1998), [1]

[78] *Ibid*, [13]

[79] Department of Health, *Reference Guide to Consent for Examination or Treatment*. (DoH, 2001), 6 [5.1]. Relying on *Chatterton v Gerson* [1981] 1 All ER 257; *Appleton v Garrett* (1995) 34 BMLR 23; *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871; *Smith v Tunbridge Wells HA* (1994) 5 Med LR 334; *Bolitho v City & Hackney HA* [1997] 4 All ER 771; *Pearce v United Bristol Healthcare NHS Trust* (1999) 48 BMLR 118

[80] *Ibid*, [1]

> To establish that trust you must respect patients' autonomy – their right to decide whether or not to undergo any medical intervention even where a refusal may result in harm to themselves or in their own death.[81]

Miola and Forvargue argued that the GMC, particularly *Seeking Patient Consent*[82] aimed to set ethically higher standard than in common law, which merely requires the doctor to list information.[83] For example, *Good Medical Practice* stated that:

> You must respect the right of patients to fully involved in decisions about their care. Whenever possible, you must be satisfied, before you provide treatment or investigate a patient's condition, that the patient has *understood* what is proposed and why, any *significant risk*s or side effects associated with it, and has given consent. You must follow the guidance in *Seeking Patients' Consent: The Ethical Considerations*.[84]

In *Seeking Patient Consent*, the GMC began to construct the external facilitative duties necessary for the patient to have an actual autonomous choice, for example, the doctor was required to provide 'effective communication' which was 'key to enabling patient's to make informed decision' the doctor must 'find out what patient's want to know and ought to know about their condition' and respond effectively to the needs of the patient.'[85] The doctor must also ensure that his patient 'is best able to understand and retain the information.'[86]However, there is an element of instrumentality to the guidance; as the GMC go on to say: 'patients who have been able to make properly informed decisions are more likely to co-operate fully with the agreed management of their conditions.'[87] The rhetoric of patient rights[88] is similarly mobilised in the *Reference Guide*,[89] however, the *Department of Health* was more forthright in expressing that the purpose of the guidance and explained the law so that the doctor can avoid liability.[90]

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[81] GMC, *Seeking Patient's Consent: Ethical Considerations*. (GMC, 1998), [1]
[82] *Ibid*, [2]
[83] S. Forvargue & J. Miola, 'One Step Forward, Two Steps Back? The GMC, The Common Law and 'Informed' Consent.' (2010) 36 *J Med Ethics* 494-497, 496: Department of Health, *Reference Guide to Consent for Examination or Treatment*. (DoH, 2001), [7]: "The standards expected of health professionals by their regulatory bodies may at times be higher than the minimum required by the law. Although this Guidance focuses primarily on the legal position, it will also indicate where regulatory bodies have set out more stringent requirements. It should be noted that the legal requirements in negligence cases (see chapter 1 paragraph 5) have historically been based on the standards set by the professions for their members, and hence where standards required by professional bodies are rising, it is likely that the legal standards will rise accordingly."
[84] GMC, *Good Medical Practice.* (GMC, 2001), [17]
[85] GMC, *Seeking Patient's Consent: Ethical Considerations*. (GMC, 1998), [2]
[86] *Ibid*, [13]
[87] *Ibid*, [3]
[88] Department of Health, *Reference Guide to Consent for Examination or Treatment*. (DoH, 2001), [5]
[89] *Ibid*, [1]: "It is a general legal and ethical principle that valid consent must be obtained before commencing examination, starting treatment or physical investigation, or providing personal care. This principle reflects the right of individuals to determine what happens to their own bodies, and is a fundamental part of good practice"
[90] Department of Health, *Reference Guide to Consent for Examination or Treatment*. (DoH, 2001), [3] & [7]

> Further, if health professionals fail to obtain proper consent and the patient subsequently suffers harm as a result of treatment, this may be a factor in a claim negligence against the health professional involved. Poor handling of the consent process may also result in complaints from patients through the NHS complaints procedure or to professional bodies.[91]

Whilst all of the guidance recognises a positive duty to provide a content of information to ensure an autonomous choice, post-*Pearce*,[92] none of the guidance is explicit about which model of autonomy is being utilised as the basis of rules. Indeed, within the GMC guidance the rules blur the conceptual line between providing an objective and/or subjective understanding as the basis of an informed consent.

(i) Liberal model

The *Reference Guidance* for example, recognises that a valid consent in the law of battery requires 'informing individuals of the nature and purpose of procedures' which 'enables valid consent as far as any claim of battery is concerned.'[93] However, it argues that since *Sidaway*, it has been 'open to the courts to decide that information about a particular risk was so obviously necessary that it would be negligent not to provide it'[94] and that 'courts are willing to be critical of a "responsible body" of medical opinion.'[95] On this basis the *Reference Guidance* suggests that it is:

> […] advisable to inform the person of any "material" or "significant" risks in the proposed treatment or care, any alternatives to it, and the risks incurred by doing nothing. A Court of Appeal judgement in a health care case stated that it will normally be the responsibility of the doctor to inform a patient of "a significant risk which would affect the judgement of a reasonable patient.[96]

One could assume that a reasonable patient is subjectively defined by the medical profession as the guidance stated that the GMC (as opposed to the DoH) have 'gone further, stating that doctors should do their best to find out about patients' individual needs and priorities when providing information about treatment options.'[97] However, this characterisation of the GMC guidance is an oversimplification. The GMC in *Seeking Patient Consent*, endorsed, within some rules, an objective content of information, and in others, a particularised disclosure. For example, the guidance requires

[91] *Ibid*, [3]
[92] *Ibid*, [5.2]; GMC, *Seeking Patient's Consent: Ethical Considerations*. (GMC, 1998), [4]
[93] *Ibid*, [4.3]
[94] *Ibid*, [5.1]
[95] *Ibid*, [5.2]
[96] *Ibid*, [4.3]
[97] *Ibid*, [5.4]. Referring to GMC, *Seeking Patient's Consent: Ethical Considerations*. (GMC, 1998)

that the doctor to consider disclosing an extensive content of information, irrespective of the patient's values, for example:

> (1) 'details of the diagnosis, and prognosis and the likely prognosis if the condition is left untreated',
> (2) 'options for treatment […]'
> (3) 'the purpose of the proposed investigation; details of the procedures or the therapies involved, including subsidiary treatment such as methods of pain relief; how the patient should prepare for the procedure; and details of what the patient might experience during or after the procedure including common and serious side effects'; and
> (4) 'the probabilities of success or the risk of failure of, or harm associated with options for treatment, using accurate data.'[98]

This content of information was to be understood on an objective-value basis, requiring the doctor to 'give a balanced view of the options' to ensure that the decision was both voluntary and made with a rational understanding.[99] *Good Medical Practice*, similarly argues that disclosure is to ensure that the 'patient has understood what is proposed and why, and significant risks or side effects associated with it.'[100] This requirement of understanding required the external duty of communication.[101] To meet the requisite standard to ensure understanding, *Seeking Patient Consent* recommended a suite of methods to ensure a tailored communication strategy.[102] These communication requirements would not be necessary unless the doctor was required to ensure a particular type of understanding necessary for a rational choice. For example, the guidance suggests to:

- Use up-to-date written material, visual and other aids to explain complex aspects of the investigation, diagnosis or treatment where appropriate and/or practicable;
- Make arrangements, wherever possible, to meet particular language and communication needs, for example through translations, independent interpreters, signers, or the patient's representative.
- Where appropriate, discuss with patients the possibility of bringing a relative or friend, or making a tape recording of the consultation.[103]

[98] GMC, *Seeking Patient's Consent: Ethical Considerations*. (GMC, 1998), [5]
[99] *Ibid*, [5]
[100] GMC, *Good Medical Practice.* (GMC, 2001), [17]
[101] *Ibid*, [21]
[102] Although these suggestions are not supported with any clear empirical data about the efficacy of these methodologies, which is concerning.
[103] GMC, *Seeking Patient's Consent: Ethical Considerations*. (GMC, 1998), [13]

Adopting this substantive model of autonomy also placed the inchoate burdens of mandatory autonomy on the patient. Even if the patient was overwhelmed with the standards of understanding required for an autonomous choice, the guidance recommends extending the period of disclosure, so information can be given in 'manageable amounts, with appropriate written or other back-up material, over a period of time, or to repeat it.'[104] The patient would also have to understand information that was distressing, which may imply that receiving that information might not be in their best interests.

> […] information which patients may find distressing is given to them in a considerate way. Provide patients with information about counselling services and patient supports groups, where appropriate.[105]

The only limit would be if the information would cause the patient serious harm i.e., beyond being 'upset'; to the extent that this distress would cause them to irrationally refuse treatment.[106] The patient cannot even waive information:

> If patients ask you to withhold information and make decisions on their behalf, or nominate a relative or third party to make decisions for them, you should explain the importance of them knowing the options open to them, and what the treatment they may receive will involve. If they insist they do not want to now the detail about their condition and its treatment, you should still provide basic information about the treatment.[107]

The liberal model of autonomy adopted within the guidance also adopts the presumptions of the consumer patient posited by the rights school.[108] The requirement of a mandatory 'informed' consent i.e. that the patient must receive at least some information, mean the ethical rules within *Seeking Patient Consent*, are potentially at odds with the moral obligations to act in the actual patient's best interest; to either limit information to avoid harm, or to respect the patient's liberty-rights to choose the content of, and how they wish, to make their decision.

(ii) Authentic Model

Rather than choosing to endorse a single model of substantive autonomy, the GMC attempted to straddle the binary of the autonomy models within the *Pearce* judgement. This meant that the rules contained within *Good Medical Practice* and *Seeking Patient's Consent*, also facilitated the external requirements of an authenticity model of autonomy, and therefore required a particular patient standard of disclosure.

[104] *Ibid*, [13]
[105] *Ibid*, [13]
[106] *Ibid*, [10]
[107] *Ibid*, [11]
[108] Chapter 2, Section 5

For example, the general principles of Good *Medical Practice* required that the doctor listen to patients and respect their views, [109] and have consent where they are 'fully involved in decisions about their care.'[110] *Seeking Patient Consent* is more specific about the practical requirements needed to facilitate this model, for example, the doctor was obliged to particularise disclosure according to the patient's needs and wishes.[111]

> For example, patients may need more information to make an informed decision about a procedure which carries a high risk of failure of adverse side effects; or about an investigation for a condition which, if present, could have serious implications for the patient's employment, social or personal life.[112]

The guidance then required that doctors 'must' use patient values as the basis of their determinations about materiality to ensure a subjective understanding as the basis of a patient decision.

> When providing information you must do your best to find out about patients' individual needs and priorities. For example, patients' beliefs, culture, occupation or other factors may have a bearing on the information they need in order to reach a decision. You should not make assumptions about patients' views, but discuss these matters with them, and ask them whether they have any concerns about the treatment or the risks it may involve. You should provide patients with appropriate information, which should include an explanation of any risks to which they may attach particular significance. Ask patients whether they have understood the information and whether they would like more before making a decision.[113]

The Department of Health, similarly, recognised that the ethical requirements of the GMC went beyond that required by the law; requiring doctors disclose information about 'individual needs and priorities' and to answer, 'specific questions about procedure and associated risk.' [114]

Facilitating an authentic model of information required additional external duties within the doctor-patient relationship, for example through a facilitative standard of communication:

> You must take appropriate steps to find out what patients want to know and ought to know about their condition and its treatment. Open, helpful dialogue of this kind with patients leads

[109] GMC, *Good Medical Practice.* (GMC, 2001), The duties of a doctor registered with the General Medical Council.
[110] GMC, *Good Medical Practice.* (GMC, 2001),[17]
[111] GMC, *Seeking patient's consent: ethical considerations.* (GMC, 1998), [4]
[112] *Ibid*, [4]
[113] *Ibid*, [6]
[114] Department of Health, *Reference Guide to Consent for Examination or Treatment.* (DoH, 2001), [5.4]

> to clarity of objectives and understanding, and strengthens the quality of the doctor/patient relationship. It provides an agreed framework within which the doctor can respond effectively to the individual needs of the patient.[115]

Seeking Patient Consent also creates a positive duty for the doctor to respond to questions:

> You must respond honestly to any question the patient raises and, as far as possible, answer as fully as the patient wishes.[…][116]

The GMC guidance actively encouraged that patients understand information, according to their own values, as the basis of an informed consent to treatment; by protecting those values from the medical perception of the patients' best interests.[117]

> It is for the patient, not the doctor, to determine what is in the patient's own best interests. […] you must not put pressure on patients to accept your advice.[118]

The doctor also had duties to protect patients from third party interference; thus ensuring an adequate level of non-control so that the patient can make an authentic decision.[119] The rules relating to a patient standard of information, and requirement of non-control, are obviously at odds with the requirements for disclosure of an objective content of biomedical information (relating to the patient's medical condition), and the requirement that the patient have a balanced and thus rational choice.[120] Similarly, the patient cannot choose the information that they wish to receive, if they cannot waive their right to do so.[121] Achieving an autonomous choice, as the basis of an informed consent, may be unachievable, as the conceptual confusion in the rules undermine both models of autonomy. One way out of this circularity, however, is to create a conceptual hierarchy. Forvargue and Miola identify, the use of the imperative 'must' indicates that the authentic model of autonomy is the model preferred.[122] However, this conceptual hierarchy is not made explicit by the guidance, which is problematic if the doctors were forced to rely on their formulation as a basis to prove the logic of their decision in law.[123]

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[115] GMC, *Seeking patient's consent: ethical considerations*. (GMC, 1998), [3]
[116] *Ibid*, [9]
[117] *Ibid*, [15]. This goes beyond the requirements of preventing coercion in Department of Health, *Reference Guide to Consent for Examination or Treatment*. (DoH, 2001), [3.1] & [4.1]
[118] GMC, *Seeking patient's consent: ethical considerations*. (GMC, 1998), [15].
[119] *Ibid*, [16]
[120] *Ibid*, [5]
[121] *Ibid*, [11]
[122] S. Forvargue & J. Miola, 'One Step Forward, Two Steps Back? The GMC, the Common Law and 'Informed' Consent.' (2010) 36 *J Med Ethics* 494-497, 494-495
[123] *Deriche v Ealing Hospital NHS Trust* [2003] EWHC 3104 (QB), [49]

(iii) The capacity-consent gap

All of the formal sector guidance requires that the patient achieve either an objective, or subjective, standard of understanding.[124] To achieve a rational choice, as the basis of a liberal model, would necessarily require that the doctor test both the content and value-basis of an understanding. This would require the doctor asking the patient's questions, testing their knowledge and recall, and perhaps assisting them with the formulation of their decision. Similarly, a subjective standard of understanding would require the doctor to ask about the values which the patient will use to make a decision to ensure that it is authentic.[125] Both models in a sense require lifting the veil on the patient's decision-making. However, common law created a presumption of capacity,[126] which manifest within the ethical guidance as a prohibition on evaluating the rationality of the patient's decision.[127] For example, the *Reference Guide* stated:

> The patient is entitled to make a decision which is based on their own religious belief or value system, even if it is perceived to be irrational, as long as the patient understands what is entailed in their decision.[128]

Irrationality had a high threshold and was defined as a decision which was 'so outrageous in its defiance of logic or of accepted moral standards that no sensible person who had applied his or her mind to the question could have arrived at it.' There had to be some inability to perceive reality for a patient's capacity to be challenged, rather than just an irrational value-system.[129] The GMC provided stronger safeguards, for example, *Seeking Patient's Consent* recognised a right to self-determination[130] this meant that a patient's choice should be respected, even if their decision was irrational:

> If a patient's choice appears irrational, or does not accord with your view of what is in the patient's best interest, that is not evidence in itself that the patient lacks competence. In such circumstances it may be appropriate to review with the patient whether all reasonable steps have been taken to identify and meet their information need […].[131]

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[124] GMC, *Good Medical Practice.* (GMC, 2001), The duties of a doctor registered with the General Medical Council, [17] & [21]
[125] Chapter 2, section 3
[126] *Re C (Adult: Refusal of Treatment)* [1994] 1 All ER 819.
[127] GMC, *Seeking patient's consent: ethical considerations*. (GMC, 1998), [19]
[128] Department of Health, *Reference Guide to Consent for Examination or Treatment*. (DoH, 2001), [2.3]
[129] *Ibid*, [2.5]: "[…] if the decision which appears irrational is based on a misperception of reality, as opposed to an unusual value system – for example an individual who, despite the obvious evidence, denies that his foot is gangrenous, or an individual with anorexia nervosa who is unable to comprehend her failing physical condition – then the individual may not be able to comprehend and make use of the relevant information and hence may lack capacity to make the decision in question."
[130] GMC, *Seeking patient's consent: ethical considerations*. (GMC, 1998), [1]. The guidance refers the doctor to *St George's Healthcare NHS Trust v S* [1998] Fam Law 526, 662; *Re MB (An Adult: Medical Treatment)* [1997] 2 FCR 541
[131] *Ibid*, [19]

The GMC guidance would therefore bar the doctor from ensuring that the patient's value-system is rational, on this basis a liberal model of autonomous choice could not be achieved. The doctor was also barred from interrogating the basis of the decision, to ensure authenticity, as a decision must be respected, 'even where a refusal may result in harm to themselves or in their own death.'[132] This places patient liberty in direct conflict with the ethical duties within the guidance to ensure an actual autonomous choice. This means that the most vulnerable patients, would be allowed to make an irrational or arbitrary decision as basis of their consent, and thus suffer resultant harm, without intentionally accepted that harm.

Rather than rationalise the conceptual conflict between a libertarian approach to capacity, and the actual levels of capacity needed for choices utilising substantive models of autonomy (as the basis for ethical duties), the guidance refers doctors to the law,[133] or to seek clarification from the semi-formal sector[134] to ensure that a legal, if not ethical, decision is made.

> Advice can be obtained from medical defence bodies such as the Medical Defence Union, Medical Protection Society, the Medical and Dental Defence Union of Scotland, or professional associations such as the BMA, or your employing organisation.[135]

It is therefore necessary to examine how the semi-formal sector dealt with this conceptual quagmire.

4.2.2. The Semi-Formal Sector

Like the formal sector, the amount of guidance produced by the semi-formal sector increased substantially after the *Bolitho* judgement.[136] The most influential of these guides was the second edition of *Medical Ethics Today* ("The Blue Book") which substantially increased the content of ethical guidance provided to doctors.[137] Whilst much of the content remained discursive, rather than directive,[138] the guidance reflected ethical debate in medical practice following the legal requirement of normative rules and scientifically supported practices.[139] The debate not only centred on the correct standard of materiality, but also whether a therapeutic or consumer relationship served the needs of the

[132] *Ibid*, [1], [18] & [22]
[133] Department of Health, *Reference Guide to Consent for Examination or Treatment*. (DoH, 2001), Chapter 2 [4]; GMC, *Seeking patient's consent: ethical considerations*. (GMC, 1998), [26]
[134] *Ibid*, Chapter 1 [2.1]; GMC, *Seeking Patient's Consent: Ethical Considerations*. (GMC, 1998), [19] Footnote 6: BMA & Law Society, *Assessment of Mental Capacity: Guidance for Doctors and Lawyers*. (BMA, 2004)
[135] GMC, *Seeking Patient's Consent: Ethical Considerations*. (GMC, 1998), Footnote 2
[136] For example, British Society of Gastroenterologists, *Guidelines for Informed Consent for Endoscopic Procedures*. (BSoG, 1999); Federation of Royal Colleges of Physicians, *Good Medical Practice for the Physician*. (RCP, 2001); *Medical Protection Society, Consent to Treatment.* (MPS, 2002); Medical Defence Union, *Consent to Treatment* (MDU, 2004).
[137] British Medical Association Ethics Department, *Medical Ethics Today: The BMA's Handbook of Ethics and Law 2nd Edition.* (BMJ Books, 2004)
[138] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship.* (Hart Publishing, 2007), 51
[139] British Medical Association Ethics Department, *Medical Ethics Today: The BMA's Handbook of Ethics and Law 2nd Edition.* (BMJ Books, 2004),13

modern day patient.[140] As Miola argued, this lack of direction created more uncertainty for doctors who were forced to rely on the semi-formal sector to rationalise the confusion within the normative rules of the formal sector and law.[141]

(i) The standard of care for information disclosure

The BMA guidance, like the formal sector, repeated the autonomy binary within the Law. The Blue Book stated that: '[d]octors should presume that patients want to be well informed and should volunteer information of the type that is necessary for patients to make informed choice.' This would indicate a preference for a prudent patient standard. However, in the next sentence the BMA require: 'doctors should always be prepared to answer patients' questions truthfully, and to refer them to other sources of specialist advice if necessary.' [142] They endorse the GMC requirements the doctor provide an almost exhaustive list of information to ensure that the patient is informed. But go on to argue:

> Factors such as the nature of the condition, the complexity of the treatment, the risks associated with the treatment or procedure, and the patient's own wishes all affect how much information should be given. Doctors must take steps to find out what patients want to know about their condition and its treatment.[143]

This ethical confusion is similarly reflected in their analysis of the law. Rather than situate this debate in the case of *Pearce*, directly, the BMA analyse the judgements of *Sidaway*.[144] They argued that Lord Scarman's judgement is the true ethical position and is currently the endorsed as the leading judgement by the Court of Appeal in *Pearce*:[145]

> Ideally, the court should ask itself whether in the particular circumstances the risk was such that this particular patient would think it significant if he was told it existed. I would think that, as a matter of ethics, this is the test of the doctor's duty. The law, however, operates not in Utopia bit in the world as it is: and such an inquiry would prove in practice to be frustrated by the subjectivity of its aim and purpose. The law can, however, do the next best thing, and require the court to answer the question, what should a reasonably prudent patient think significant if in the situation of this patient. The "prudent patient" cannot, however, always provide the

[140] *Ibid*, 18
[141] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship.* (Hart Publishing, 2007), 43, 51-52
[142] British Medical Association Ethics Department, *Medical Ethics Today: The BMA's Handbook of Ethics and Law 2nd Edition.* (BMJ Books, 2004),78
[143] *Ibid*
[144] *Ibid*, 78-79
[145] Chapter 2, Section 1

> answer for the obvious reason that he is a norm (like the man on the Clapham omnibus), not a real person: and certainly not the patient himself.[146]

However, rather than recognising that the doctors should therefore be utilising the prudent patient standard; and thus, endorsing a liberal model of autonomy, the BMA argue that *Pearce* requires a particular patient standard of disclosure.[147]

The BMA were, however, more helpful (than the formal sector) in their guidance as they recognised a need to prefer one model over the other. Therefore, they advised at first instance, that the doctor provide a tailored disclosure, so that the patient can receive a particular patient standard of disclosure – for an authentic autonomy. However, if this was not practically achievable, or the patient had no values which corresponded with the context of the medical decision, the doctor should instead provide the patient with the information that the 'average' patient would want to know.[148] The BMA argued against a purist view of autonomy[149] and that both models are ethically sufficient depending on the context.

> Doctors' actions will meet the ethical and legal requirements if they inform patients about the general risks inherent in the treatment, and also any risks that may be particularly important to the individual.[150]

Whilst this thesis agrees ethical puritanism is often unnecessary in practice, the external duties constructed in law, are grounded on these distinct ethical approaches. The duty to ensure a rational, or authentic, decision is ethically predicated on providing disclosures which are substantially distinctive, both in terms of methodology, content and values. Emphasising the importance of patient values/choice about the content of information at the outset of a disclosure process is counter-intuitive if the patient waives a disclosure, or indeed, has values which are irrelevant, or so irrational, that any disclosure would mislead the patient.[151] It is also debatable whether accommodating the uncertainty of the law, by attempting to combine the two conceptual models of autonomy, is proportionate in terms of the global aim of the medical relationship – to act in the patient's best interest, in terms of information disclosure.

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[146] British Medical Association Ethics Department, *Medical Ethics Today: The BMA's Handbook of Ethics and Law 2nd Edition.* (BMJ Books, 2004),79. Quoting from *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, 888-889
[147] *Ibid*, 78-79
[148] *Ibid* ,78
[149] *Ibid*, 78
[150] *Ibid*, 79
[151] GMC, *Seeking Patient's Consent: Ethical Considerations*. (GMC, 1998), [5]

4.2.3. The problem for medical decision-making

(i) The impossibility of shared decision-making

The multiple model approach found within the ethical guidance has been rhetorically framed as a process of shared decision-making.[152] Emphasis on normative ethical rules to ensure a standard of autonomy conceptualised the patient and doctor as equal partners in decision-making. This conceptualisation purposefully attempted to redistribute power within the medical relationship.[153] Whilst this model is certainly an ideal outcome within practice, it cannot be mandated within the structure of normative legal rules for two reasons: (1) for the law to act as a retributive mechanism, to provide compensation, one must be able to identify a clear locus of responsibility, from which legal duties emanate. If a model of shared decision-making is constructed in law, with duties and corresponding counter-duties, the patient would be hard pressed, unless they were themselves faultless, to prove that a chain of causation had not been broken within this web of responsibility.[154] (2) It would be manifestly unfair to create normative rules which require a model of shared decision-making when doing so would be equally reliant on the willingness and ability of the patient, to contribute to conversation, identify pertinent values, understand and perhaps make a rational choice.[155]

(ii) The normative vacuum

If there is no certainty about the model of autonomy being utilised in law, doctors are forced to look to ethical guidance for clarity; this is both a practical choice, and a legal necessity as *Bolitho* required decision-making to be evidence-based. Indeed, the ethical guidance recognised that the law now looked to the ethical sector to rationalise the reasonable standard.[156] However, rather than take the initiative and delineate a coherent practical-ethics, the ethical sectors simple referred the doctor back to law i.e. to seek legal advice or a high court application.[157]

> Case law on consent has evolved significantly over the last decade. Further legal developments may occur after this guidance has been issued, and health and social care professionals must remember their duty to keep themselves informed of legal developments which may have a

[152] E. Emanuel & L. Emanuel, 'Four Models of the Physician-Patient Relationship.' (1992) 267(16) *JAMA* 2221-2226, 2224; C. Charles, *et al*, 'What do we Mean by Partnership in Making Decisions about Treatment?' (1999) 319 *BMJ* 780-782, 781; G. Elwyn & C. Charles, "Shared Decision Making: The Principles and the Competences." In A. Edwards & G. Elwyn, *Evidence-Based Patient Choice?* (Oxford University Press, 2001), 120-121; A. Edwards & G. Elwyn, *Evidence-Based Patient Choice: Inevitable or Impossible?* (Oxford University Press, 2001), 122

[153] See for example, H. Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship.* (Clarendon Press, 1994), 197-239; H. Teff, 'Medical Models and Legal Categories: An English Perspective (1993) 9 *J Contemp Health L & Pol'y* 211, 221-224

[154] G. Williams, 'The Aims of the Law of Tort.' (1951) 4(1) *Current Legal Problems* 137-176, 137-138

[155] M. Brazier, 'Do No Harm – Do Patients Have Responsibilities Too? (2006) 65 *Camb L J* 397-422, 406-413

[156] *Bolitho v City and Hackney Health Authority* (1997) 39 BMLR 1, 10

[157] Department of Health, *Reference Guide to Consent for Examination or Treatment*. (DoH, 2001), Chapter 2 [4]; GMC, *Seeking Patient's Consent: Ethical Considerations*. (GMC, 1998), [26]

bearing on their practice. Legal advice should always be sought if there is any doubt about the legal validity of a proposed intervention.[158]

The failure of the formal sector to structure normative rules which prefer one model of autonomy meant that the standard of care for materiality continued to be unknowable in practice. This unknowability of normative rules meant that law and ethics could not be used as a proactive form of guidance to orientate decision-making.[159] This thesis would posit that the ethical sector were reluctant to take the reins because of practical limitations i.e. that the regulators recognised that guidelines lacked the final authority of law, and the GMC lacked the range of coercive powers afforded to the judiciary. Similarly, judges had made clear that they were the ones who should set the standards.[160] This rhetoric, however, created a regulatory vacuum, where law and ethics effectively cancelled each other out.[161] Doctors were obliged to fill in the ethical gaps and this happened in a disjointed way, because the conceptual confusion remained in the law.[162] The doctor was left with three options:

(1) To abandon the model of autonomy within the normative rules and simply undertake a process of circumstantial-moral decision-making;
(2) To arbitrarily select a model of autonomy as a basis to provide information; or
(3) To provide an exhaustive disclosure, that attempts to straddle the autonomy-binary.

4.3. *Pearce* in practice

Many of the studies conducted during this period attempted to define the threshold of 'significant' information through empirical study of patient information need dependent on given biomedical circumstances. This content of information could then form the basis of a logical medical decision.[163] This preponderance on patient information; as a way to formalistically avoid liability, meant that processes of medical decision-making which integrated this content of information into a wider therapeutic decision about materiality were seldom studied during this period. As a result, the studies

[158] Department of Health, *Reference Guide to Consent for Examination or Treatment*. (DoH, 2001), [4]
[159] M. Jones, 'Informed Consent and other Fairy Stories' [1999] 7 *Med L Rev* 103, 106
[160] J. Miola, "Moralising medicine and decision-making." In S. Forvargue & A. Mullock, *The Legitimacy of Medical Treatment.* (Routledge, 2017), 77; Relying on J. Miola, 'Medical Law and Medical Ethics: Complementary or Corrosive?' (2004) 6 *Med L Int* 251
[161] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship.* (Hart Publishing, 2007), 18
[162] R. Heywood, 'Re-Thinking the Decision in *Pearce*.' (2005) 7(3) *CIL* 264-280, 279: As Heywood recognised: […] from a purely legalistic viewpoint, it is a somewhat worrying proposition that the standard required by the profession is demanding much more than the law itself seeks to enforce. It is becoming increasingly apparent that the practical application of the law in this field is falling behind modern developments within the profession itself. Thus, to paint a clearer picture one needs to consider informed consent beyond the courts.[83] In doing so it will soon become visible that the only people that can improve the consent process are the medical profession and the patients themselves, certainly not the lawyers!"
[163] K. Haddow, 'Consent – Who, What Where, When?' (2000) 59(3) *Health Bulletin* 218, 219. Relying on A.G.D. Morrison, ''Silence in Court" Twenty-One Years of Otolaryngology Litigation.' (1990) *104 The Journal of Laryngology and Otology* 162-165; A. Brooks, *et al*, 'Information Required to Provide Informed Consent for Endoscopy: and Observational Study of Patients' Expectations.' (2005) 37 *Endoscopy* 1136-1139, 1136

indicate that the requirements of achieving an autonomous choice dominated medical considerations about what was in the patient's best interest.

Doctors, chose option 1 as the primary methodology for delineating a material content of information. If the *Pearce* requirement was accommodated, doctors took a very literal approach to the legal requirement; based on disclosure of information above certain percentage thresholds. However, this did not ensure that patients received a form of liberal autonomous choice, as: doctors seldom achieved the external standards of communication, or interpersonal skills, necessary to ensure that patients could understand information to come to a balanced judgement. Studies also identified that patients did not interpret information of significant risk in an objective way; which barred them from achieving a rational choice. To avoid liability doctors also ignored the needs and circumstances of the actual patient, and adopted formulistic process of decision-making and disclosure, which potentially caused patient's harm. This was problematic as studies indicated that there was a wide variation in the information preferences and needs of patients. Many patients wanted a more tailored disclosure, which would facilitate an authentic choice. However, there were practical barriers which led doctors to prefer the former option. First, evidence of risks was based on population data which required interpretation. Second, there were practical barriers in terms of time and capacity. Third, interpreting statistics placed the doctor at risk of liability as interpretation necessarily introduced a discretionary and therefore moral element into medical decision-making. This meant that some doctors adopted defensive practices to actively avoid facing patient's questions about their particular circumstances.

Due to the practical problems with accommodating either a liberal or authentic model of autonomy, some doctors therefore rejected a model of shared decision-making. Despite these problems, many of the studies continued to interpret data through the interpretative lens of the rights school and recommend the adoption of a consumer patient relationship as a panacea.

4.3.1. The prudent patient standard in practice

Doctors continued to make decisions about treatment option based on the patient's best interest (75% of the time); indicating that the medical relationship was still therapeutic in nature.[164] Doctors disclosed information about the nature of their condition (100%) enough for a bare legal consent,[165] however, beyond this content of information doctors only disclosed information which was objectively significant. For example, doctors disclosed specific significant risks about surgery (92%) rather than more commonly occurring less serious risks (25%).[166] This shift in emphasis occurred both orally and

[164] Ellamushi, *et al*, 'Consent to Surgery in a High Risk Speciality: A Prospective Audit.' (2000) 82 *Ann R Coll Surg Engl 213*-216, 214-215
[165] *Ibid*, 213
[166] *Ibid*, 213-215

though information leaflets. For example, in the Garrund *et al* study, information leaflets were updated in an attempt to improve patient understanding of laparoscopic procedures. The old leaflet provided minimal information about the procedure, anaesthesia and normal side-effect.[167] The new leaflet provided detailed statistics about significant risks and complications.[168] The authors argued that the drivers for this change 'have been more stringent consent requirements' and the 'promotion of shared decision making' propagated in ethical guidelines.[169] Elwyn *et al*, similarly, found that the amount of statistical information about risks, and general statements relating to risks increased from 40% to 65% during this period. The focus on risk in information disclosure (rather than a more balanced content of information) increased from 15% to 65% and numeral disclosure increased from 4% to 78%.[170] Doctors, focused on significant risks, and failed to consider other biopsychosocial and circumstantial factors, which were necessary to provide information to accommodate the patient's *actual* information need.[171] For example, Elwyn *et al*, in a later study, found that clinicians did not regularly ask patient's about their preferences for information, or treatment options (69.9%).[172] This thesis would argue that the exclusionary focus on the disclosure of particularly significant risks is a result of a literal interpretation of the legal requirement in the *Pearce* judgement, along the lines predicated by Maclean.[173] The problem with this approach is that the therapeutic purpose of disclosure became ignored. The reliance on percentages and statistics led to the ossification of disclosure practices: where doctors simply read from a checklist of information.[174]

(i) Achieving a liberal autonomous choice?

Whilst the intention of the prudent patient approach was to achieve a form of rational autonomous choice, doctors failed to facilitate the external duties necessary to ensure that patients made an informed

[167] P. Garrud, *et al*, 'Impact of Risk Information in a Patient Education Leaflet.' (2000) 43 *Patient Education and Counseling* 301-304, 302
[168] *Ibid*, 303
[169] *Ibid*, 301
[170] G. Elwyn, *et al*, 'Achieving Involvement: Process Outcomes from a Cluster Randomized Trial of Shared Decision Making Skill Development and use of Risk communication.' (2004) 21(4) *Family Practice* 337-346. 344.
[171] G. Elwyn *et al*, 'Shared Decision Making: Developing the OPTION Scale for Measuring Patient Involvement.' (2003) 12 *Qual Saf Health Care* 93-99, 93; C. Charles, *et al*, 'Shared Decision-Making in the Medical Encounter: What does it Mean? (Or it takes at Least Two to Tango).' (1997) 44 *Soc Sci Med* 681-692; C. Charles, *et al*, 'Doing Nothing is No Choice: Lay Constructions of Treatment Decision-Making Among women with early-stage breast cancer.' (1998) 20 *Sociology of Health and Illness* 71-95; C. Charles, *et al*, 'Decision Making in the Physician-Patient Encounter: Revisiting the Shared Treatment Decision-Making Model.' (1999) 49 *Soc Sci Med* 651-66; G. Elwyn, *et al*, 'Shared Decision Making: The Neglected Second Half of the Consultation.' (1999) 49 *Br J Gen Pract* 477-482; G. Elwyn, *et al*, 'Towards a Feasible Model for Shared Decision-Making: A Focus Group Study with General Practice Registrars.' (1999) 319 *BMJ* 753-757; G. Elwyn, *et al*, 'Is a 'Shared Decision' Feasible in a Consultation for a Viral Upper Respiratory Tract Infection: Assessing the Influence of Patient Expectations for Antibiotics Using Discourse Analysis.' (1999) 2 *Health Expect* 105-117; G. Elwyn, *et al*, 'Shared Decision Making and the Concept of Equipoise Defining the Competences in Involving Patients in Healthcare Choices.' (2000) 50 *Br J Gen Pract* 892-899; G. Elwyn, *et al*, 'Shared Decision-Making Observed: Visual Displays of Communication Sequence and Patterns.' (2001) 7 *J Eval Clin Pract* 211-221
[172] G. Elwyn, *et al*, 'Shared Decision Making: Developing the OPTION Scale for Measuring Patient Involvement.' (2003) 12 *Qual Saf Health Care* 93-99, 93
[173] A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5 *Med L Int* 205-230; A. Maclean, 'The Doctrine of Informed Consent: Does it exist and has it Crossed the Atlantic?' (2004) 24 (3) *Legal Studies* 386-413, 408-409
[174] D. Black, "Foreword." In B. Hurwitz (ed.), *Clinical Guidelines and the Law: Negligence, Discretion and Judgement.* (Radcliffe Medical Press, 1998)

consent.[175] Studies continued to find that patients did not understand the statistical information that they had received. For example, in the Akkad *et al* study, one third (29%) of the patients undergoing elective surgery, and over half of patients undergoing emergency surgery (51%) (n=1006), did not understand the information they received on printed leaflets.[176] A minority of patients of (21% emergency and 11% elective) stated that they did not understand that what they were signing was a consent form. [177]

Some patients found it difficult to conceptualise and understand statistical information.[178] Even when an objective content of statistical information was retained, this did not ensure that the patient accepted the value-basis on which that information should be appreciated; which of course meant that patients could not make a rational choice, according to the liberal model. For example, Misselbrooke and Armstrong found that doctors understood risks as a hypothetical reduction from the status quo. Patients, on the other hand, interpreted risks on a very personal level - applying the risks to their situation.[179] Patients struggled to understand the weight that was attached to population-based risks, as they could not interpret them in a value-neutral way. Thus, the authors argued:

> General practitioners have been urged to use […] statistics as the basis for treatment decisions, and to use it to convey benefits and risks to the patients. If patients were given this information then a sizeable proportion may choose not to take treatment for their mild hypertension. On the other hand, it might be argued that patient should be encouraged to use the personal probability of benefit statistics as their task is to consider their own wellbeing alone. This would imply an even larger group of current hypertension patients declining medication. This raises the possibility that patients would also decline treatment for many other conditions where they considered the probability of benefit was not sufficiently persuasive.[180]

[175] See Chapter 2 Section 3
[176] A. Akkad, *et al*, 'Informed Consent for Elective and Emergency Surgery: Questionnaire Study.' (2004) 111 *BJOG* 1133-1138, 1135
[177] *Ibid*, 1136
[178] A.E. Rogers, *et al*, 'Knowledge and Communication Difficulties for Patients with Chronic Heart Failure.' (2000) 321 *BMJ* 605-607; N. Beresford, *et al*, 'Risks of Elective Cardiac Surgery: What Do Patients Want to Know? (2001) 86 *Heart* 626-631; A. Agard, *et al*, 'Patients' Experience of Interventional Trials of Acute Myocardial Infarction: is it Time to Adjust Informed Consent Procedures to the Patient's Capacity? (2001) 86 *Heart* 632-637; A. Lloyd, 'The Extent of Patients' Understanding of Risk?' (1999) 10(1) *Quality of Health Care* 14-18; A.J. Lloyd, *et al*, 'Patients' Ability to Recall Risk Associated with Treatment Options.' (1999) 353 *Lancet* 645; D.A. Grimes, & G.R. Snively, 'Patients' Understanding of Medical Risks: Implications for Genetic Counselling and Research.' (1999) 93 *Obstet Gynecol* 910-14
[179] D. Misselbrook & D. Armstrong, 'Patients' Responses to Risk Information about Benefits of Treating Hypertension.' (2001) 51 *Br J Gen Prac* 276-279
[180] *Ibid*, 278. Relying on, T. Fahey & J. Newton, 'Conveying the Benefits and Risks of Treatment.' (1995) 45 *Br J Gen Prac* 339-341

Walter & Britten [181] found a similar dissociation between the medical conceptualisation of risk and the patient's interpretation of risk through their own values.[182] For example, the worse symptoms that the patient suffered the less risky a potential treatment was perceived if the treatment had the potential to reduce the patient's suffering.[183] Benson and Britten, similarly, found that irrespective of the objectivity of the disclosure, patients do not internalise medical values. Instead, they interpret information, and the magnitude of risk, according to their own values. Negative views about drug treatments were made based on feelings. This was demonstrated through patients commenting they were 'not for them', 'unsafe' or 'unnatural'; rather than basing their decisions on objective understanding (n=28/38).[184]

Whilst the law focused medical minds on achieving an appropriate content of disclosure, the same emphasis was not placed on achieving the facilitative duties to ensure an understanding. As Davies *et al*[185] found, doctors focused on disclosing a high threshold of objective information; using numerical figures and graphs, which were not necessarily tailored to ensure patient understanding.[186] Caress *et al* also identified that patient's thought doctors' inter-personal and communication skills were poor - this acted as a barrier to their understanding and involvement.[187] One patient stated that:

> We changed doctors to this one 'cos the other one, he was always – he never made us feel as though he wanted us there. And you have to feel as though you can discuss something with your doctor, and if he doesn't want you there he's like trying to get you out of there so he can see somebody else. And he didn't seem to put all the effort into it or prescribe you such and such a thing. And his attitude in general – the whole family thought "get lost"[188]

Elwyn *et al*, in their study of patient attitudes to information disclosure, similarly, found that the control group for information disclosure did not tailor communication so that patients could understand (98.4%). When asked whether doctors had provided information in a way that ensured understanding

[181] F.M. Walter & N. Britten, 'Patients' Understanding of Risk: A Qualitative Study of Decision-Making about the Menopause and Hormone Replacement Therapy in General Practice.' (2002) 19(6) *Family Practice* 579-586
[182] Ibid, 582: "Personal interpretation of the meaning of a risk involved in using their knowledge, the presentation and context of that risk, together with their unique belief system particular relating to representation of womanhood, lay beliefs and fatalism, control and choice. Experience, age and emotions often modified the meaning of a risk, and participants then use this meaning to weigh up the risks and benefits of a particular threat."
[183] *Ibid*, 582: "It's got to be how you're suffering. Say with HRT, if you have certain symptoms that you actually cannot cope with, when somebody says you've got an x chance of getting whatever [side-effect], you would actually think 'I'm prepared to take that risk because if that's the only way I can get rid of these feelings, I'm willing to take the risk." (Patient) Also see, J. Benson & N. Britten, 'Patients' Decisions about Whether or Not to take Antihypertensive Drugs: Qualitative Study.' (2002) 325(873) *BMJ* 1-5, 4
[184] J. Benson & N. Britten, 'Patients' Decisions about Whether or Not to Take Antihypertensive Drugs: Qualitative Study.' (2002) 325(873) *BMJ* 1-5, 2
[185] R.E. Davies, 'Exploring Doctor and Patient Views about Risk Communication and Shared Decision-Making in the Consultation.' (2003) 6 *Health Expectations* 198-207, 203
[186] *Ibid*, 206
[187] A. Carress, *et al*, 'A Qualitative Exploration of Treatment Decision Role Preference in Adult Asthma Patients.' (2002) 5 *Health Expectations* 223-235, 229-230
[188] *Ibid*, 229-230

26.9% of patient disagreed and 34.9% patients strongly disagreed.[189] Ultimately, if the external requirements for an autonomous choice are not met, then the purpose of the legal standard (to ensure an informed consent) is defeated.

(ii) Patient preferences and the therapeutic disclosure

The focus on disclosing an statistical content of significant information also meant that doctors were failing to properly weigh the information preference and values of the actual patient and therefore particularise the information to the patient's circumstances. Akkad *et al*, for example, argued that:

> […] current official guidance may be inadequate, particularly because it had made the information more complex, has standardised the process regardless of the underlying clinical situation and does not provide appropriate guidance on other aspects of the process that are important to patients. Clearly, what is required is a new approach which takes into account the preferences of patients themselves, and recognises the differing needs of elective and emergency patients.[190]

The studies identified a wider range of information preference, which were not accommodated by a disclosure based on a rigid threshold of materiality. For example Brooks *et al* found that 19% of gastroscopy patients, and 14% of colonoscopy patients wanted an exhaustive disclosure, a larger proportion (51%) only to know only about less commonly occurring serious risks, for example, 51% of gastroscopy patients did not want to know about the risk of a sore thought (10% chance of occurring) and instead (39%) wanted to know about the risk of perforation of haemorrhage (0.1% chance of occurring) or death (0.01% chance of occurring).[191] However, as chapter 2 illustrated, a significant minority of patients continued to not want any information about risks. For example, 33% of gastroscopy patients did not want to know even minor risks.[192] The Akkad *et al* study found that over half (56%) of emergency patients and a quarter of elective patients (25%) did not read the pre-printed information sheets as the basis of an informed consent. The main being that they preferred to rely on 'verbal explanation' (44% of elective and 50% emergency) and 'trust in the doctor' (32% elective and 31% emergency). [193]

[189] G. Elwyn, *et al*, 'Shared Decision Making: Developing the OPTION Scale for Measuring Patient Involvement.' (2003) 12 *Qual Saf Health Care* 93-99, 96
[190] A. Akkad, *et al*, 'Informed Consent for Elective and Emergency Surgery: Questionnaire Study.' (2004) 111 *BJOG* 1133-1138, 138
[191] A. Brooks, *et al*, 'Information Required to Provide Informed Consent for Endoscopy: and Observational Study of Patients' Expectations.' (2005) 37 *Endoscopy* 1136-1139, 1138
[192] *Ibid*, 1136
[193] A. Akkad, *et al*, 'Informed Consent for Elective and Emergency Surgery: Questionnaire Study.' (2004) 111 *BJOG* 1133-1138,1135

> […] items held important by health care providers, such as being consented by the operating surgeon, or receiving detailed information about complications, did not significantly contribute to satisfaction in this model. The variables which best explained satisfaction were those relating to communication. Patients were more likely to be satisfied if they were informed in detail about what was going to happen to them- preferably by a familiar health care professional – and if they read the consent form and in detail […]. This is not surprising, as it appears that satisfaction was linked to factors that helped patients feel more in control […].[194]

Edwards *et al*, surveyed doctors' experiences of the consent process, and found that they continued to identify patients who found disclosure confusing and would prefer the doctor to make decisions about the materiality of information and treatment choices. One doctor said, about asking patients questions:

> Sometimes it meets with a really flat response because it's something that they have never really encountered before. Sometimes you will be surprised and they turn around and say "well yeah, of course I want to be involved". But sometimes people turn around and say "tell me what to do doc."[195]

Jenkins *et al* similarly found that a significant minority of patients (13.2%) stated that they preferred the standard of disclosure to be decided by the doctor in their best interest.[196] The Leyden *et al* studies[197] of oncology patients (n=17) experience of information disclosure, found that patients (n=11/17) only wanted basic information, such as their diagnosis,[198] they preferred to have faith in the expertise of the doctor, rather than have the responsibility to define the information agenda, or seek further information.[199] If patients did want a high standard of information, this was sometimes related to therapeutic interests such as developing a collaborative approach, as the foundation of trust, rather than seeking to ensure an informed consent.

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[194] *Ibid*, 1135

[195] A. Edwards, *et al*, 'Shared Decision Making and Risk Communication in Practice: A Qualitative Study of GP's Experiences.' (2005) 55(510) *Br J Gen Prac* 6-13, 9

[196] V. Jenkins, *et. al*, 'Information Needs of Patients with Cancer: Results from a Large Study in UK Cancer centres.' (2001) 84(1) *British Journal of Cancer* 48-51, 49. Also, F.M. Walter, *et al*, 'Women's Views of Optimal Risk Communication and Decision Making in General Practice Consultations about the Menopause and Hormone Replacement Therapy.' (2004) 53 *Patient Education and Counselling* 121-128, 127; A. Edwards, *et al*, 'Patient-Based Outcomes Results from a Cluster Randomized Trial of Shared Decision Making Skill Development and Use of Risk Communication Aids in General Practice.' (2004) 21(4) *Family Practice* 347-354, 352-353. Supported by: S. Campbell, *et al*, 'Identifying Predictors of High Quality Care in English General Practice: Observational Study.' (2001) 323 *BMJ* 990-882; G. Freemen, *et al*, 'Evolving General Practice Consultation in Britain: Issues of Length and Context.' (2002) 324 *BMJ* 880-882

[197] G. Leydon, *et al*, 'Faith, Hope, and Charity: An In-Depth Interview Study of Cancer Patients' Information Needs and Information-Seeking Behaviour.' (2000) 320 *BMJ* 909-913; G. M. Leydon, *et al*, 'Cancer Patients' Information Needs and Information Seeking Behaviour: In Depth Interview Study.' (2000) 320 *BMJ* 909-913.

[198] *Ibid*, 909-910

[199] *Ibid*

> I'm no expert on the condition of asthma, but it looks to me like, I mean, I read it (the sort card) like he says "he seriously considers my opinion." Erm, so that's like, it's obvious to me that if I had a doctor like that then he would be sitting with me and listening to what I've got to say. You know? As well as him telling me what he's got to say. So I have to listen to his point of view, and he's basically told me what he thinks would be best for me which, erm, suits me right down to the ground, you know? So if he's convinced me that after listening to what I have to say this is what treatment he thinks would be good for me then I would be quite happy to go away you know with knowing that. (Most preferred role – Semi-passive).[200]

Some patients felt that medical knowledge was too complex, uncertain, and difficult to understand. This attitude was particularly found amongst older patients.

> I didn't know what to expect with the treatment, I was optimistic. I couldn't even think about how I could do chemotherapy. I prepared my mind for whatever it takes, [to] follow the rules of the experts: they have said that this is what I've go[t] to do to get better, and I've got to – whatever way, shape, or form – get better.[201]

> To be honest, when they said to me it's cancer. I thought I'll put it in their hands now because sometimes it can be a dangerous thing when you start listening and looking. We only have a certain amount of intellect, and we only have a certain amount of education. There is nothing like an ignorant man trying to learn and know every little thing about it. With regards to medicine and the like, the less you know, the better.[202]

Both Jenkins *et al*[203] and Elwyn *et al*, found that an increase in the patient age led to a reduction in preference for involvement.[204] Jenkins *et al* found that some patients with poor diagnoses wanted to retain hope and felt that information beyond this standard was 'unsafe' – with some actively resisting disclosure.[205] Akkad *et al*, for example, found that some patients avoid information by not reading information sheets.[206]

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[200] A. Carress, et al, 'A Qualitative Exploration of Treatment Decision Role Preference in Adult Asthma Patients.' (2002) 5 *Health Expectations* 223-235, 226-227, 228

[201] G. Leydon, *et al*, 'Faith, Hope, and Charity: An In-Depth Interview Study of Cancer Patients' Information Needs and Information-Seeking Behaviour.' (2000) 320 *BMJ* 909-913, 910-911

[202] *Ibid*, 910- 911.

[203] V. Jenkins, *et al*, 'Information Needs of Patients with Cancer: Results from a Large Study in UK Cancer Centres.' (2001) 84(1) *British Journal of Cancer* 48-51, 49

[204] G. Elwyn, *et al*, 'Shared Decision Making: Developing the OPTION Scale for Measuring Patient Involvement.' (2003) 12 *Qual Saf Health Care* 93-99, 95

[205] G. Leydon, 'Faith, Hope, and Charity: An In-Depth Interview Study of Cancer Patients' Information Needs and Information-Seeking Behaviour.' (2000) 320 *BMJ* 909-913, 909 & 911

[206] A. Akkad, *et al*., 'Informed Consent for Elective and Emergency Surgery: Questionnaire Study.' (2004) 111 *BJOG* 1133-1138, 1136

There was also variation in the decision-making role that patients wished to take when making a decision between competing options. Caress *et al*, for example, undertook in-depth interviews of asthma patients (n=32) about relationship preference found the majority of patients preferred a passive therapeutic relationship (active (n=7), collaborative (n=11) and passive (n=14)).[207] The more severe the patient's condition the more they placed trust in the doctor and adopted a more passive position in the doctor-patient relationship.[208] Some patients would lack the intelligence to understand the complexity of the medical decisions and thus would not be able to contribute effectively to the decision:

> But I think it's going to vary very much from patient to patient, except for reasonably intelligent people that can manage it themselves; where perhaps like some less fortunate people would probably have to be told what to do.[209]

Walter *et al*, similarly, found that patients felt uncomfortable with the responsibility of being a decision-maker, and doctors to 'decide what was in their best interest.'[210]

> Every time I go to the doctors they say "Well it's up to you if you feel you'd like to take it" And I think 'I come for you to tell me what to do [about HRT], because I wouldn't have bothered to come if I really felt I knew.' I do feel that doctors don't adamantly say to you now "You must do this, or you must do that!" unless there's something acute of course.[211]

(iii) Defensive disclosure

The practical barriers for implementing a liberal model of informed consent were compounded by the conceptual confusion, particularly, within the GMC's ethical guidance.[212] As Hurwitz argued, the ethical guidance failed to create 'a clear semantic boundary between guidelines, guidance and recommendations.'[213] Indeed, as the *Reference Guide* warned, all the GMC guidance could potentially be used as evidence of the reasonable standard of information disclosure. Brook *et al* agreed, arguing

[207] A. Carress, *et al*, 'A Qualitative Exploration of Treatment Decision Role Preference in Adult asthma patients.' (2002) 5(3) *Health Expectations* 223-235, 226-227.
[208] *Ibid*, 229
[209] *Ibid*, 229
[210] F.M. Walter, *et al*, 'Women's Views of Optimal Risk Communication and Decision Making in General Practice Consultations about the Menopause and Hormone Replacement Therapy.' (2004)53 *Patient Education and Counselling* 121-128, 124
[211] *Ibid*, 124
[212] See for example, Ellamushi, *et al*, 'Consent to Surgery in a High Risk Speciality: a Prospective Audit.' (2000) 82 *Ann R Coll Surg Engl.* 213-216, 214. Referring to: The Medical Defence Union, *Consent to Treatment*. (Medical Defence union, 1997); The Senate of Surgery of Great Britain and Ireland, *The Surgeons Duty of Care*. (The Senate of Surgery of Great Britain and Ireland, 1997); General Medical Council, *Seeking Patients' Consent.* (General Medical Council, 1998)
[213] B. Hurwitz, *Clinical Guidelines and the Law: Negligence, Discretion and Judgement.* (Radcliffe Medical Press, 1998), 8

that the introduction of the DoH guidance also encouraged a formulistic process of medical decision-making which orientated around the completion of a uniform pan-NHS consent form.[214]

Heywood suggested, that consent forms caused some doctors to provide an excessive amount of risk disclosure, which ignored the therapeutic interests of the patient.[215] For example, Elwyn *et al* found that when doctors (n=182) had access to statistical information, within communication aids, general statements about risk increased from 40% to 65% and numerical disclosures increased from 4% to 78%, however individualised information only increased from 0 to 4%.[216] Akkad *et al*, illustrated that this defensive practice was harmful to patients because it failed to acknowledge their particular method of understanding.[217]

Other patients felt that the provision of an objective standard of information was indicative of the doctor failing to take account of their unique medical position, values and medical needs.[218] For example, women in the Walter *et al* study were facing the choice of whether or not to take HRT felt that disclosure failed to take account of their distinct physiological needs.[219] One patient stated:

> I would consider information that's more tailored to the individual instead of being given books that say "The risk is this, the risk is that." It's too general. Why isn't it tailored for the person who's there? Instead it's a blunderbuss approach really, it's just kind of so wide. […]
> I've never actually had this feeling that the HRT is really based on what one's own individual body needs. It's a blanket therapy. If there were tests that could identify what amount of medication you need to take, so that it was all pretty much clear cut and you're not taking too little, and you're not taking too much.[…][220]

Many of the emergency patients in the study reported that they were unwell, tired, exhausted, drugged, or in pain when signing the consent form (69%). Both elective (33%) and emergency patients (55%) felt that they were scared and frightened when signing the consent form. Over a third of emergency

[214] A. Brooks, *et al*, 'Information Required to Provide Informed Consent for Endoscopy: and Observational Study of Patients' Expectations.' (2005) 37 *Endoscopy* 1136-1139, 1139
[215] R. Heywood, 'Excessive Risk Disclosure: The Effects of the Law on Practice.' (2005) 7(2) *Med L Int* 93-112, 96-97
[216] G. Elwyn, *et al*, 'Achieving Involvement: Process Outcomes from a Cluster Randomized Trial of Shared Decision Making Skill Development and Use of Risk Communication.' (2004) 21(4) *Family Practice* 337-346
[217] A. Akkad, *et al*, 'Informed Consent for Elective and Emergency Surgery: Questionnaire Study.' (2004) 111 *BJOG* 1133-1138
[218] F.M. Walter, *et al*, 'Women's Views of Optimal Risk Communication and Decision Making in General Practice Consultations about the Menopause and Hormone Replacement Therapy.' (2004)53 *Patient Education and Counselling* 121-128, 125
[219] *Ibid*, 125
[220] F.M. Walter, *et al*, 'Women's Views of Optimal Risk Communication and Decision Making in General Practice Consultations about the Menopause and Hormone Replacement Therapy.' (2004)53 *Patient Education and Counselling* 121-128, 124.

patients (37%) agreed strongly that they had no choice but to sign the consent form [221] and would have signed the consent form whatever was written on it. Akkad *et al* argued that:

> […] A substantial proportion of emergencies felt they had no choice about signing the form, and many would have signed it regardless of its content. Many did not read or understand the consent form, or did not feel that they had an opportunity to ask questions. These findings suggest important problems for emergency patients, and indicate that different types of patients may have different requirements, which is in direct contrast to the current approach of standardising the consent process […].[222]

These findings would suggest that attempting to facilitate a model of autonomous choice through normative rules, undermined the circumstantial consideration of both biomedical and patient factors, when identifying the content, when, and how, information should be disclosed. The result was that the doctor both failed to act in the patient's best interests, or ensure that they received an informed consent.

4.3.2.The (Im)possibility of a particular patient standard?

A number of studies argued, that a particular patient approach to information disclosure should be adopted.[223] Walter & Britten,[224] for example, argued:

> Practitioners should ask patients about personal risk experiences and their beliefs as well as current symptoms. Risk communication may become more effective when it acknowledges the patient's perspective on 'language', framing and personalized approach, as well as the effects of severity, lay beliefs and emotions caused by the risk under discussion.[225]

[221] A. Akkad, *et al*, 'Informed Consent for Elective and Emergency Surgery: Questionnaire Study.' (2004) 111 *BJOG* 1133-1138, 1136
[222] *Ibid*, 1137
[223] F.M. Walter, *et al*, 'Women's Views of Optimal Risk Communication and Decision Making in General Practice Consultations about the Menopause and Hormone Replacement Therapy.' (2004)53 *Patient Education and Counselling* 121-128, 126: "In this study, participants rejected general population risks to inform their decisions about HRT and wanted more personalised risk information. The majority mentioned the need for accurate, truthful and individualised risk information, supporting the view that choice, consent and trust are key issues in the communication of risk: such views reflect the trend in modern society towards consumerism and unlimited access to information. Although risk communication in one-to-one health encounters is more effective when individually calculated risk estimates are used there appeared to be little appreciation of the tension created when using population-based data to present apparently individualised risk information."
[224] F.M. Walter & N. Britten, 'Patients' Understanding of Risk: a Qualitative Study of Decision-Making about the Menopause and Hormone Replacement Therapy in General Practice.' (2002) 19(6) *Family Practice* 579-586, 584: "I would consider [information] that's more tailored to the individual, instead of given books that say "The risk is this, the risk is that." It's too general. Why isn't it tailored for the person who's there? Instead it's a blunderbuss approach really, it's just kind of so wide."
[225] *Ibid*, 585

Akkad *et al* similarly argued that the *Reference Guide* required the adoption of a particular patient disclosure process[226] which could be evaluated through patient experience and satisfaction.[227] However, the particular patient standard never actualised as the basis of a disclosure because of practical barriers to its implementation.

First, the studies indicated that doctors found that patients did not have strong values as the basis for a subjective, or particularised, standard of disclosure.[228] The Misselbrook and Armstrong study, for example, found that the framing of disclosure statistics had the potential to augment patient decision-making and persuade them to adopt the doctors understanding of information.[229] Davies *et al*, similarly found that that after information disclosure 14 out of 24 patients simply agreed with the doctor priorities.[230] Edwards *et al*, in their interviews with practitioners, found that patients do not have strong values in relation to decision-making about risks and benefits of treatment;[231] it was therefore difficult for doctors to ascertain patient preferences as a basis to define a content of material information.[232] As one doctor said:

> I think we overestimate our abilities to do that. And, er, I think to use the shared decision-making model, there is a point in the model which I find most alien to natural practice, is where you are actually meant to ask the patient how they wish to proceed. You might say "do you want to decide, do you want me to decide, or should we decide together?" And I find this impossible to get across to patients […] and through chance the first two were on my tape, if had asked me beforehand, before I got to that stage in the consultation, I would have predicted that the first patient would have said "you decide" and the second one would have wanted to decide from the way they took the information and what I knew about them already, and the way I looked at them and decided what sort of person they were. And I would have been completely the wrong way round.[233]

The inability for patients to rationally reflect on their core values means that shared decision-making processes become counterintuitive to the facilitation of an authentic autonomous choice. Davies *et al*,

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[226] A. Akkad, *et al*, 'Informed consent for Elective and emergency surgery: questionnaire study.' (2004) 111 *BJOG* 1133-1138, 1133-1134
[227] *Ibid*, 1134
[228] Chapter 3, Section 3
[229] D. Misselbrook & D. Armstrong, 'Patients' Responses to Risk Information about Benefits of Treating Hypertension.' (2001) 51 *Br J Gen Prac* 276-279, 278. Relying on: T. Fahey & J. Newton, 'Conveying the Benefits and Risks of Treatment.' (1995) 45 *Br J Gen Prac* 339-341
[230] R.E. Davies, 'Exploring Doctor and Patient Views about Risk Communication and Shared Decision-Making in the Consultation.' (2003) 6 *Health Expectations* 198-207, 204
[231] A. Edwards, *et al*, 'Patient-Based Outcomes Results from a Cluster Randomized Trial of Shared Decision Making Skill Development and use of Risk Communication Aids in General Practice.' (2004) 21(4) *Family Practice* 347-354, 353
[232] *Ibid*, 9
[233] *Ibid*, 9

found that patients were more likely to take an active role in decision-making when doctors had been trained to give objective disclosure, rather than facilitate shared decision-making.[234] The more the patient objectively understood information, the more active role they were able to take.[235] The Elwyn *et al* study similarly found that implementing a model of shared decision-making without educating patient, and thus affording them the ability to forge their own views and values, reduced communication, which increased paternalistic decisions: as doctors were not obliged to act in the patients' best interests[236] Davies *et al* also found that using a model of shared decision-making as the basis of disclosure was confusing as the patient and the doctor could not identify who made the final decisions (i.e. if there was a clash between patient and medical values). [237]

Second, even if patient values could be identified doctor struggled to find relevant evidence, or information, (which was required by the *Bolitho* judgement)[238] as the basis of a disclosure. Scientific data relating to risks was based on population statistics; which were not tailored to the particular circumstances, or values, of actual patients.[239] As the scientific evidence was focus on disease and procedure, rather than patient needs, the risks were conceptualised through a biomedical lens which ignored the values of the actual patient.[240] One doctor in the Edwards *et al*'s study argued the information that patients particularly wanted did not exist: '[…] I was talking about choices, and people were asking me questions and I didn't have the knowledge to back up what the choices were.'[241] Independently reinterpreting population statistics for the individual patient also risked the doctor being criticised for introducing external values; rather than providing a logical (and thus objective) content of information.[242]

Third, doctors also did not have the time, or capacity, to undertake the extended research,[243] interpretation, and communication of complex information, in a way necessary to provide a suitable

[234] R.E. Davies, *et al*, 'Exploring Doctor and Patient Views about Risk Communication and Shared Decision-Making in the Consultation.' (2003) 6 *Health Expectations* 198-207, 202
[235] A. Carress, *et al*, 'A Qualitative Exploration of Treatment Decision Role Preference in Adult Asthma Patients.' (2002) 5 *Health Expectations* 223-235, 226-227 & 228
[236] G. Elwyn, *et al*, 'Achieving Involvement: Process Outcomes from a Cluster Randomized Trial of Shared Decision Making Skill Development and use of Risk Communication.' (2004) 21(4) *Family Practice* 337-346, 344
[237] R.E. Davies, 'Exploring doctor and patient views about risk communication and shared decision-making in the consultation.' (2003) 6 *Health Expectations* 198-207, 206
[238] A. Samanta, *et al*, 'The Role of Clinical Guidelines in Medical Negligence Litigation: A Shift from the *Bolam* Standard?' (2006) 14 *Med L Rev* 321-366
[239] F.M. Walter, *et al*, 'Women's View of Optimal Risk Communication and Decision Making in General Practice Consultations about the Menopause and Hormone Replacement Therapy.' (2004) 53 *Patient Education and Counselling* 121-128, 126
[240] *Ibid*, 126
[241] A. Edwards, *et al*, 'Shared Decision Making and Risk Communication in Practice: A Qualitative Study of GP's Experiences.' (2005) 55(510) *BJOG* 6-13, 7-8
[242] *Ibid*, 10 & 12
[243] *Ibid*, 10

understanding.[244] For example, one doctor in the Edwards *et al* study stated that: '[s]even-and-a-half minutes to do something like this is impossible.'[245] Another stated that the:

> The fear is that if I introduce this concept now, or if I introduce it with everybody, in 3 years' time I will be wading through extremely long consultations discussing all the ins and outs. And so I would suspect we would end up rationing that as a well the way we do other things.[246]

Elwyn *et al* found that only 4% of information disclosure was therefore tailored to the circumstances of the actual patient.[247] Even when doctors were given training, Edwards *et al* found that lack of time during consultation acted as a significant barrier to ensuring patient understanding and participation during the disclosure process.[248] Without more time communication scores after training were lower (n=1284).[249]

(i) Avoiding authenticity

The practical problems with accommodating patient values in decisions about materiality encouraged some doctors to resort to defensive practice. The studies identified that some doctors attempted to avoid the risks of particularising information by reducing the time for conversation and patient questions. Elwyn *et al* found that at baseline clinician's (n=21) often did not provide a suitable opportunity for the patient to ask questions (17.2% of patients disagree and 36% strongly disagree there was enough time). [250] Patients involvement was limited (84.9%), resulting in patients deferring their decision-making role (83.3%).[251] Akkad *et al* found that a minority of patients (n=1006) were not given the opportunity to clarify their understanding by asking questions (29% emergency and 11% elective) even though a vast majority felt that this was important (93% and 98%).[252] Only in a minority of cases (31% and 40%) did

[244] F.M. Walter, *et al*, 'Women's Views of Optimal Risk Communication and Decision Making in General Practice Consultations about the Menopause and Hormone Replacement Therapy.' (2004)53 *Patient Education and Counselling* 121-128, 125 & 126. Relying on: M. Marshall & M. Roland, 'The New Contract: Renaissance or Requiem for General Practice?' (2002) 52 *Br J Gen Prac* 531-532; A. Edward, *et al*, 'Shared Decision Making and Risk Communication in Practice: A Qualitative Study of GP's Experiences.' (2005) 55(510) *Br J Gen Prac* 6-13, 6; M. Holmes-Rovner, et.al., 'Implementing Shared Decision-Making in Routine Practice: Barriers and Opportunities.' (2000) 3 *Health Expectations* 182-191; M. Holmes-Rovner, *et al*, "Moving to the Mainstream." In A. Edwards & G. Elwyn, *Evidence-Based Patient Choice*. (Oxford University Press, 2000)

[245] *Ibid*, 10

[246] *Ibid*, 11

[247] G. Elwyn, *et al*, 'Achieving Involvement: Process Outcomes from a Cluster Randomized Trial of Shared Decision Making Skill Development and Use of Risk Communication.' (2004) 21(4) *Family Practice* 337-346, 344.

[248] A. Edwards & G. Elwyn, 'Involving Patients in Decision Making and Communicating Risk: A Longitudinal Evaluation of Doctors' Attitudes and Confidence during a Randomized Trial.' (2004) 10(3) *Journal of Clinical Practice* 431-437, 434

[249] A. Edwards, *et al*, 'Patient-Based Outcomes Results from a Cluster Randomized Trial of Shared Decision Making Skill Development and Use of Risk Communication Aids in General Practice.' (2004) 21(4) *Family Practice* 347-354, 352

[250] G. Elwyn, *et al*, 'Shared Decision Making: Developing the OPTION Scale for Measuring Patient Involvement.' (2003) 12 *Qual Saf Health Care* 93-99, 96

[251] *Ibid*, 96

[252] A. Akkad, *et al*, 'Informed Consent for Elective and Emergency Surgery: Questionnaire Study.' (2004) 111 *BJOG* 1133-1138, 1136

doctors check understanding, despite patients feeling it was important (86% and 88% respectively).[253] The Davies *et al* found that in general doctors did not seek or discuss the patient's priorities for treatment (n=3/11).[254] Instead, doctors adopted defensive practices of 'dumping information on patient's' which undermined their ability to make autonomous choices.[255] They therefore concluded:

> […] results from the study confirm that the practice of GPs, as represented by this sample (who are "above average" sample in terms of MRCGP membership and willingness to participate in this type of research), lies far away from espoused models in books and communication skills courses.[256]

4.3.3. Rejecting informed consent

Some doctors rejected the normative requirement to disclose a content of information entirely, and instead continued to adopt a *circumstantial-moral* process of decision-making, which balanced the benefits of patient autonomy within the context of the actual patient. For example, when doctors were trained in using decision-aids, which contained an objective content of statistical information, (in the Davis *et al* study) these aids were only used selectively.[257] In Edwards *et al* study, GP's were trained in information disclosure and in shared decision-making processes, however, in the exit interviews GP's (n=20) stated that they were unwilling[258] to adopt these practices if they were appropriate and feasible in the circumstances.[259] Whilst doctors were enthusiastic about implementation of shared decision-making practices they were only utilised where the patient was able to take on the additional responsibilities of the relationship. [260] Edwards *et al* found that patient's characteristics, such as age, educational level, and clinical problems influenced what information patients were provided and the extent to which the doctors invited discussion about treatment options.[261] This thesis would argue that this illustrates a proportion of doctors retained a moral commitment to the therapeutic aims of the medical relationship, rather than ensuring a (formulistic) disclosure at all costs.

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[253] *Ibid*, 1136
[254] R.E. Davies, 'Exploring Doctor and Patient Views about Risk Communication and Shared Decision-Making in the Consultation.' (2003) 6 *Health Expectations* 198-207, 204
[255] G. Elwyn, *et al*, 'Shared Decision Making: Developing the OPTION Scale for Measuring Patient Involvement.' (2003) 12 *Qual Saf Health Care* 93-99, 97
[256] *Ibid*, 98. In support, P. Little, *et al*, 'Preferences of Patients for Patient Centered Approach to Consultation in Primary Care: An Observations Study.' (2001) 322 *BMJ* 468-472
[257] R.E. Davies, 'Exploring Doctor and Patient Views about Risk Communication and Shared Decision-Making in the Consultation.' (2003) 6 *Health Expectations* 198-207, 206. Also see, M. Holmes-Rovner, *et al*, 'Implementing Shared Decision-Making in Routine Practice: Barriers and Opportunities." (2000) 3 *Health Expectations* 182-191
[258] A. Edwards, *et al*, 'Shared Decision Making and Risk Communication in Practice: A Qualitative Study of GP's Experiences.' (2005) 55(510) *Br J Gen Prac* 6-13, 7
[259] *Ibid*, 6
[260] *Ibid*, 7
[261] *Ibid*, 11

(i) The resilient rights rhetoric

Despite the practical problems identified by the studies, and the resilience of the therapeutic model of decision-making, the narrative of patient rights remained the dominant lens of analysis within the identified studies. There was, however, some strong empirical support for increased emphasis to be placed on prioritising patient values, when deciding on information need, for example Jenkins *et al* found that 87% of patient (n=233) wanted all possible information (good and bad news) about their cancer, and 98% wanted to know their diagnosis. [262] Jenkins *et al* argued, for example:

> We know that clinicians tend to underestimate the amount of information that patients require[263] [….] and while fewer these days are reluctant to use the word cancer, many still believe that disclosure should only be made to those patients who actively seek it. Unfortunately, unless invited to ask directly, patients assume that the doctor would have told them everything relevant, other worry that they will appear foolish if they reveal their ignorance by asking questions, and some feel that they have already taken up too much time.[264]

However, Charles *et al* found the key distinction between the older and younger generations is a choice to trust medical decision-making (rather than fear).[265] Younger people more readily adopted the role of consumer patient, whilst older people preferred to choose the relationship of trust. Despite not wanting to make decisions older people wanted a high standard of information: 89.2% of them absolutely needed, or would like, all the possible information about treatments, 95.5% would wish to have all the possible information about side-effect, and 84.5% would want to know how treatment works.[266] Jenkins *et al* similarly identified:

> The notion that the older patient prefers the doctor to determine how much information to provide is only weakly upheld by the study. Although significantly more of the older (i.e., those over 70 years) patients indicated a preference to leave details up to the doctor, most (98%) still wanted specific information about treatment and side effects, especially whether they or not they had cancer. Negative stereotypes of the elderly are common among health care professionals […]. If clinicians assume that there is increased passivity and helplessness in the

[262] V. Jenkins, *et al*, 'Information Needs of Patients with Cancer: Results from a Large Study in UK Cancer Centres.' (2001) 84(1) *British Journal of Cancer* 48-51, 48

[263] L. Fallowfield, *et al*, 'No News is Not Good News: Information Preferences of Patients with Cancer.' (1994) 4 *Psycho-oncology* 197-202; L.F. Degner, *et al*, 'Information Needs and Decisional Preferences in Women with Breast Cancer.' (1997) 277(18) *JAMA* 1485-1492

[264] V, Jenkins, *et al*, 'Information Needs of Patients with Cancer: Results from a Large Study in UK Cancer Centres.' (2001) 84(1) *British Journal of Cancer* 48-51, 48. Relying on L. Fallowfield & V. Jenkins, 'Effective Communication Skills are the Key to Good Cancer Care.' (1999) 35(11) *Eur J Can* 1592-1597

[265] C. Charles, *et al*, 'Nothing is No Choice: Lay Construction of Treatment Decision Making Among Women with Breast Cancer.' (1998) 20 *Socio Health and Illness* 71-95. Also see, V, Jenkins, *et al*, 'Information Needs of Patients with Cancer: Results from a Large Study in UK Cancer Centres.' (2001) 84(1) *British Journal of Cancer* 48-51, 51

[266] *Ibid*

> elderly patient, then it is more likely that these negative aspects will prevail in consultations. This leads to doctor-centred rather than patient-centered interaction, with the doctor in control of information giving.[267]

The problem with the rhetoric, however, was that the authors were less concerned about the conceptual difference between a consumer relationship (or a shared decision-making), which required a high standard of information to achieve an autonomous consent, and the requirements of providing information according to the therapeutic relationship; which was to act in the best interests of the patient according to their actual needs and values.[268] Preference for having a high standard of information, particularly among older people, was conflated as support for a model of informed consent. This position could only be reached by ignoring reasons for information preference i.e., for practical purposes, and as a way to develop a relationship of trust.[269] Even when evidence did not support the adoption of models of shared decision-making, commentators such as Edwards *et al* argued: 'as there was no evidence of major adverse effects on patients; one can advocate SDM from values and ethical principles.' [270] As chapter 5 will argue, the rhetoric of the rights school allowed the authors to abandon the precautionary principle,[271] and ignore the potential negative effect of the consumer model.[272]

[267] See, V. Jenkins, *et al*, 'Information Needs of Patients with Cancer: Results from a Large Study in UK Cancer Centres.' (2001) 84(1) *British Journal of Cancer* 48-51, 50

[268] F.M. Walter, *et al*, 'Women's Views of Optimal Risk Communication and Decision Making in General Practice Consultations about the Menopause and Hormone Replacement Therapy.' (2004)53 *Patient Education and Counselling* 121-128, 127: "Many authors have expressed the view that shared decision making is the goal of the consultation, particularly in areas of clinical uncertainty, but the extent to which patients and their GP's support this remains unclear. Many patients in this study talked about shared decision making and informed choice in an interchangeable way, although informed consent is really a predicted outcome of the shared decision making process. The concept of shared decision making is characterised by both patient and doctor sharing information to inform the process of treatment decision making agreed by both. […]."

[269] A. Carress, *et al*, 'A Qualitative Exploration of Treatment Decision Role Preference in Adult Asthma Patients.' (2002) 5 *Health Expectations* 223-235, 226-227, 228

[270] A. Edwards, *et al*, 'Patient-Based Outcomes Results from a Cluster Randomized Trial of Shared Decision Making Skill Development and use of Risk Communication Aids in General Practice.' (2004) 21(4) *Family Practice* 347-354, 353

[271] D.B. Resnick, 'The Precautionary Principles and Medical Decision Making.' (2004) 29(3) *J Med Philos* 281-299

[272] F.M. Walter, *et al*, 'Women's Views of Optimal Risk Communication and Decision Making in General Practice Consultations about the Menopause and Hormone Replacement Therapy.' (2004)53 *Patient Education and Counselling* 121-128, 127. Relying on L. Trevena & A. Barratt, 'Integrated Decision Making Definitions for a New Discipline.' (2000) 50 *Patient Educ Couns* 265-268

CHAPTER 5: *CHESTER* AND THE CONSUMER RELATIONSHIP: 2005-2014

This chapter argues that the case of *Chester*[273] failed to rationalise the model of autonomy that was being used as the basis of the standard of care in *Pearce*.[274] Instead, *Chester* attempted to bypass the conceptual and practical problems of accommodating a model of informed consent (within the therapeutic relationship), by adopting a distinct consumer relationship model as the basis of medical decision-making about information disclosure. This moved the purpose of information disclosure from facilitating patient information need, to providing information exclusively for the purpose of an autonomous choice. A failure to ensure an autonomous choice could therefore automatically be indicative of negligent decision-making about the materiality of information necessary to ensure an appropriate understanding.[275] This movement, however, marked a paradigm shift in the law of negligence, away from regulating the moral aims of medical decision-making in practice, to mandating the purpose and process of decision-making. This created fundamental problems for the lower courts as the House of Lords, in Chester, failed to prescribe the model of autonomy that was being facilitated, the particular standard of materiality, or the facilitative duties necessary to ensure an autonomous choice. On this basis, the Court of Appeal sensibly distinguished the judgement in *R (on the application of Burke)*[276] which was later ratified by the judgement in *Aintree v James*,[277] clarifying that of medical decisions (about the treatment options, and vicariously information disclosure about options) were grounded on the therapeutic relationship (and thus, were to be made on beneficent medical principles).

However, *Chester* had a lasting jurisprudential legacy, in allowing a significant body of conflicting case-law to develop which required the doctors to ensure a model of autonomous choice[278] - problematically, models of authentic and liberal autonomy continued to be used interchangeably as the basis of an informed consent, so that the standard of care in information disclosure remained unknowable. This has created a conflicting body of law which requires doctors to facilitate both a therapeutic and a consumer relationship as the basis of their decision-making.

The second section of this chapter will argue that the reaction by the formal medical ethics sector, particularly the GMC, was again to simply proliferate, rather than rationalise the conceptual

[273] *Chester v Afshar* [2004] UKHL 41
[274] *Pearce v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118
[275] For example, *Cooper v Royal United Hospital Bath NHS Trust* [2004] EWHC 3381; *Jones v North West Strategic Health Authority* [2010] EWHC 178 (QB); *Webb v Norfolk & University Hospital NHS* Trust [2011] EWHC 3769; *Border v Lewisham and Greenwich NHS Trust* [2015] EWCA Civ 8; *Al Hamwi v Johnston and Another* [2005] All ER (D) 278; *N M v Lanarkshire Health Board* [2013] CSIH 3
[276] *Burke v GMC* [2005] EWCA Civ 1003
[277] *Aintree University Hospitals NHS Foundation Trust v James* [2013] UKSC 67
[278] *Cooper v Royal United Hospital Bath NHS Trust* [2004] EWHC 3381 (QB); *Birch v United College London Hospital NHS Foundation* Trust [2008] EWHC 2237 (QB); *Jones v North West Strategic Health Authority* [2010] EWHC 178 (QB); *Webb v Norfolk & University Hospital NHS* Trust [2011] EWHC 3769; *Border v Lewisham and Greenwich NHS Trust* [2015] EWCA Civ 8

incompatibility in *Chester*, by creating rules which attempted to straddle the divide between the consumer and therapeutic relationship. However, the GMC did prefer the use of the authentic model of autonomy as the basis of an informed consent. This meant, albeit superficially, that the rules relating to the therapeutic interests of the patient, and ensuring an autonomous choice, were both directed at identifying and facilitating the information needs of the *actual* patient. However, the long list of potentially material information (contained within various guidance) also encouraged the adoption of defensive practices (by doctor's providing exhaustive disclosures which could evidence consideration of both patient information need, and a content of information necessary for an informed choice), thus, mitigating the risk of liability.

The lack of certainty about the correct legal model of the medical relationship meant that the deontic methods of identifying material information were incompatible. The combined effect of *Pearce* and *Chester* was to fracture medical decision-making in practice, both horizontally (along the relationship axis) and vertically (along the methodology axis). Doctors could not be sure what method they should be utilising to facilitate the medical relationship:

> (1) a *circumstantial-moral* decision-making process which facilitated the therapeutic relationship,
> (2) providing an objective content of disclosure for a rational autonomous choice,
> (3) a subjective content of information as the basis of an authentic choice.

To avoid this uncertainty a large proportion of doctor simply adopted exhaustive disclosure practices as a way to mitigate the risk of inevitable liability. This thesis will argue that this had detrimental effects of patients, by acting as a barrier to understanding, ignoring their information choices, and failing to achieve the ends of either model of the medical relationship. On this basis, it is understandable why some patients, and doctors, continued to reject the consumer model and prefer information disclosure based on the medical conceptualisation of the patient's best interests.

5.1. Moving to a consumer relationship in *Chester*

The previous Chapter argued that *Pearce* catalysed a normative shift; where judges began specifying the content of information material to the reasonable patient (in their therapeutic interests). For a doctor to achieve the standard of a *responsible* medical body, and for their decision to be *logical* (under the joint *Bolam/Bolitho* standard), required them to disclose information so that the patient could have an autonomous choice, as the basis of consent to treatment. This disclosure needed to contain information that was *significant* in the circumstances. What was *significant* could be conceptualised as an objective threshold (serving a liberal model of autonomy) or as a subjective or particularised content of

information (servicing an authentic model). In practice, doctors formulaically provided a statistically significant objective standard of disclosure, utilising population statistics. However, a large proportion of patients struggled to understand this information and apply it to their position. This failure to ensure that patients understood information meant that the purpose of a liberal model of autonomous choice was defeated. This led some commentators to argue that the therapeutic relationship should be abandoned and instead replaced by a consumer model which created conceptual clarity about the method and purpose of disclosure i.e., to ensure an informed consent. [279]

This section will illustrate how the judgement of the House of Lords in *Chester* utilised the rules of causation to implicitly adopt the consumer model of the medical relationship into the law of negligence. They argued that this was necessary as otherwise doctors would avoid liability if they had been negligent, but the circumstances of their choice to accept treatment broke the chain of causation. The law of causation failed to recognise the dignitary harm to the patient's autonomy caused by the negligent act. This was because the patient had not intentionally accepted the potential risks associated with a treatment. However, by abandoning a strict interpretation of causation, whilst perhaps ethically justified, had the effect of requiring the doctor to ensure autonomy as the basis of information disclosure. Failing to provide information and thus cause an injury to the patient's autonomy had the effect of reorienting the purpose of disclosure to achieve a mandatory informed consent.

5.1.1. The *Chester* judgement

The claimant suffered repeated episodes of lower back pain, due to marked protrusion of discs in the spinal cord. Her condition deteriorated over a number of years, and she was eventually referred to the defendant (Mr Fari Afshar), a consultant neurosurgeon, who recommended surgery. Unfortunately, the claimant developed cauda equina syndrome and argued the defendant was negligent in failing to warn about the small 1-2%[280] risk that she may develop this as a result of the operation.[281] The judge at first instance decided that the Defendant had breached his duty of care to the claimant.[282] However, the case fell down on the issue of causation as the judge found that Miss Chester would have gone through the procedure three days after her consultation regardless. There was no harm on which to pin the injury to the claimant's autonomy. The Court of Appeal (Hale LJ, Sir Christopher Slade and Sir Denis Henry) upheld the judgement.[283] The House of Lords was divided. Lord Bingham and Lord Hoffmann

[279] See for example: P. Cane, 'A Warning about Causation.' (1999) 115 *L Q Rev* 21; T, Honore, 'Medical Non-Disclosure, Causation and Risk: *Chappel v Hart*.' (1999) 7 *Torts L J* 1; M. Staunch, 'Taking the Consequences for Failure to Warn of Medical Risks.' (2000) 63(2) *MLR* 261; A. Grubb, Clinical Negligence: Informed Consent and Causation.' (2002) 10 *Med L Rev* 322; M. Jones, "But for' Causation in Action for Non-Disclosure of Risk.' (2002) 18 *Professional Negligence* 192; J. Stapleton, 'Cause-in-Fact and the Scope of Liability for Consequences.' (2003) 119 *L Q Rev* 388
[280] *Chester v Afshar* [2004] UKHL 41, [48]
[281] *Ibid*, [5]
[282] *Chester v Afshar* [2003] QB 368.
[283] *Chester v Afshar* [2002] EWCA Civ 724

(dissenting) argued that whilst the doctor was negligent, in failing to disclose the risks of surgery, the test to be applied in the causation was the 'but for' test,[284] thus, as the claimant consented to surgery, and no negligent cause, he could not be found negligent (even though the patient had not given an informed consent).[285] Lord Hoffman, in agreement, argued that ensuring that the patient was informed of the risk was irrelevant, as the patient neither considered it necessary to make a decision based on that information (according to their own information need), nor did knowledge of that risk actually change the chances of that risk occurring on the actual, or another, occasion:

> In my opinion this argument is about as logical as saying that if one has been told, on entering a casino, that the odds on No 7 coming up at roulette were only 1 in 37, one would have gone away and come back next week or gone to a different casino. The question is whether one would have taken the opportunity to avoid or reduce the risk, not whether one would have changed the scenario in some irrelevant detail. The judge found as a fact that the risk would have been precisely the same whether it was done then or later or by that competent surgeon or by another.[286]

The majority of the House of Lords (Lord Steyn, Lord Hope[287] & Lord Walker),[288] however, took the opposite view and argued that law of causation failed to recognise and defend the purpose of the standard of care in negligence: that the patient had a 'right to be appropriately warned.'[289] The Lords took a purposive interpretation of *Pearce*, to argue that the assumption that an autonomous choice was in the patient's best interests created an ostensible and thus actionable right that the patient should have an autonomous choice. This extended the internal rights argument outwards, as a hook to hang liability within negligence.[290]

This conceptual extension of the law was ethically justified by adopting the conventional approach of the rights school.[291] It is helpful, then, to deconstruct the steps that the majority used to find liability, and in so doing, to point out the conceptual conflations which have subsequently led to confusion in medical decision-making.

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[284] *Chester v Afshar* [2004] UKHL 41, per Lord Bingham [9]. Relying on *Chappel v Hart* (1998) 195 CLR 232.
[285] See this line of precedent in: *Smith v Barking, Havering and Brentwood Health Authority* [1994] 5 Med L R 285, per Hutchinson J.; *Smith v Salford Health Authority* [1994] 5 Med L.R. 321, per Potter J.; *McAllister v Lewisham and North Southwark Health Authority* [1994] 5 Med L.R. 343; *Smith v Tunbridge Wells Health Authority* [1994] 5 Med L.R. 335.
[286] *Chester v Afshar* [2004] UKHL 41, per Lord Hoffmann, at [31]. See also, Lord Bingham, at [9], relying on the reasoning in the dissenting judgement in *Chapel v Hart* (1998) 195 CLR 232.
[287] *Ibid*, per Lord Hoffmann, at [87] – [88].
[288] *Ibid*, per Lord Hoffmann, at [90]
[289] *Chester v Afshar* [2004] UKHL 41, per Lord Bingham, at [9].
[290] See Chapter 3, Section 2
[291] *Ibid*

(i) The patient had a right to make an autonomous decision (whether to consent, not consent, or consent later).

Lord Steyn, for example, began by arguing that the law recognised a (negative liberty) right to self-determination: '[t]he starting point is that every individual of adult years and sound mind has a right to decide what may or may not be done with his or her body.' [292] From this position he extended the concept outwards by arguing that without information, and thus a substantive understanding, the patient is barred from making 'important medical decisions affecting their lives for themselves.' [293] Lord Steyn grounded this conceptual extension on Dworkin's *Life's Dominion* to argue that self-determination was not possible without autonomy.[294] Lord Hope, similarly, argued that the principle of autonomy flows from the right to liberty.[295] A right of freedom from interference and thus to refuse or reject a treatment, was conflated with a right to choose based on a substantive understanding.

> Individuals have a right to make importance decisions affecting their lives for themselves […] Surgery performed without the informed consent of the patient is unlawful.[296]

(ii) The purpose of the duty to disclose information, established in the law of negligence, was to facilitate a patient's autonomous choice.

Lord Steyn adopted a sociological approach to justifying a duty to provide information for an informed consent. He argued that as the presumption of an autonomous choice was in the patient's best therapeutic interest, the sociological standard also recognised this presumption in law. As the presumption was a legal standard, this has had the effect of creating a freestanding right to an informed consent in practice.[297] The judiciary could therefore legitimately recognise the legal requirement of an informed consent.[298]

> A surgeon owes a legal duty to a patient to warn him or her in general terms of possible serious risks involved in the procedure. The only qualification is that there may be wholly exceptional

[292] *Ibid*, per Lord Steyn, at [14]
[293] *Ibid*, per Lord Steyn, at [18]
[294] R. Dworkin, *Life's Dominion: An Argument about Abortion and Euthanasia, and Individual Freedom.* (1993), 224: "The most plausible [account] emphasizes the integrity rather than the welfare of the choosing agent; the value of autonomy, on this view, derives from the capacity it protects: the capacity to express one's own character – values, commitments, convictions, and critical as well as experiential interests – in the life one leads. Recognizing an individual right of autonomy makes self-creation possible. It allows each of us to be responsible for shaping our lives according to our own coherent or incoherent – but, in any case, distinctive – personality. It allows us to lead our lives rather than be led along them, so that each of us can be, to the extent a scheme of rights can make this possible, what we have made of ourselves. We allow someone to choose death over radical amputation or a blood transfusion, if that is his informed wish, because we acknowledge his right to a life structured by his own values."
[295] *Chester v Afshar* [2004] UKHL 41, per Lord Hope, at [54]
[296] *Ibid*, per Lord Steyn, at [14]
[297] *Ibid*, per Lord Steyn, at [15]. Relying on B*olitho v City Hackney Health Authority* [1998] AC 232, 259
[298] *Ibid*, per Lord Steyn, at [16]

> cases where objectively in the best interests of the patient the surgeon may be excused from giving a warning. This is, however, irrelevant in the present case.[299]

However, if the *Bolam* standard requires that the doctors act in the actual patient's best interest, then, even though an autonomous choice may be required in the circumstances, it cannot be incorporated as a rule or right. Doing so would replace the focus on decision-making from the patient onto achieving that right. Arguing that the effect of *Pearce* has caused doctors to regularly provide a content of information purposefully conflates the ethical purpose of that information with the consequential effect of a rule. It is an improper way of thinking as it proceeds backwards from an outcome, and constructs rules by justification, rather than application to a decision.[300] In adopting this argument positive autonomy rights of individuals are preferred above their negative liberty rights to consent, or refuse.[301] As such, the patient and doctor enter a consumer relationship, where the purposes of duties are not to ensure understanding, but to maximise choices.

Lord Hope similarly adopted informed consent as a right, but justified it ethically rather than sociologically.[302] He argued that whilst the court in *Sidaway* rejected a normative legal standard of information disclosure, they did recognise that an ethical consent required an autonomous choice.[303] Lord Hope argued that the law should be ethical, and should therefore recognise that the purpose of information disclosure was to redress the balance of power between a doctor and patient, caused by the inequity of knowledge. Doctors therefore had to ensure a standard of understanding as the basis of an informed consent. [304] This, of course, completely rejected the therapeutic purpose of negligence;[305] and replaced it with the consumer relationship.[306]

> (iii) The doctor is facilitating an informed consent, thus failure to ensure an adequate understanding meant that the patient did not have an autonomous choice

By incorporating a freestanding right to an informed consent, the consumer relationship implicitly created a duty to ensure the patient understood the risks. Part of this understanding included that the patient appreciate, and intentionally choose, the circumstances of the risk i.e. when and where they

[299] *Ibid*, per Lord Steyn, at [16]
[300] *Ibid*, per Lord Steyn, at [17]
[301] See Chapter 3, Section 2, 4 & 5
[302] *Chester v Afshar* [2004] UKHL 41, per Lord Hope, at [53]
[303] *Ibid*, per Lord Hope, at [54]
[304] *Ibid*, per Lord Hope, at [54]-[55]: "Thus, the right to make a final decision and the duty of the doctor to inform the patient if the treatment may have special disadvantages or dangers go hand in hand. In this case there is no dispute that Mr Afshar owed a duty to Miss Chester to inform her of the risks that were inherent in the proposed surgery, including the risk of paralysis. The duty was owed to her so that she could make her own decision as to whether or not she should undergo the particular course of surgery which he was proposing to carry out. That was the scope of the duty, the existence of which gave effect to her right to be informed before she consented to it. It was unaffected in its scope by the response to which Miss Chester would have given had she been told of these risks."
[305] See Chapter 3, Section 4
[306] *Chester v Afshar* [2004] UKHL 41, per Lord Hope, at [58].

would accept the risk of surgery.[307] Lord Steyn relied on *Chappel v Hart* to jurisprudentially ground this claim, arguing, that if the patient did not intentionally choose the nature and circumstances of a risk then they were not morally responsible for that risk occurring.[308]

> (iv) In failing to have an autonomous choice, the patient missed the opportunity to delay the operation [loss of opportunity]; or

It was here that Lord Steyn and Lord Hope departed ways. Lord Steyn argued that the causal link required was not between the injury and the failure to disclose, but between the failure to disclose which denied Mrs Chester the ability to intentionally choose to take on that risk, and thus have an autonomous choice.[309] Recognising the scant judicial authority for this proposition,[310] Lord Steyn looked to academic commentary (with its continued hegemony of rights orientated commentators) to support his assertion that the patient has a right to an autonomous choice.[311] Lord Steyn, particularly, relied on Honore who argued that the:

> duty of a surgeon to warn of the dangers inherent in an operation […] is also intended to enable then patient to make an informed choice whether to undergo the treatment recommended and, if so, at whose hands and when.[312]

The judge argued that *Fairchild v Glenhaven Funeral Services Ltd*,[313] afforded him the discretion to expand the rules of causation to ensure the integrity of the right to informed consent: otherwise, the rules in negligence would be undermined.[314] Lord Steyn's judgement allowed a patient to argue they have been morally harmed any time circumstances change between disclosure and the anticipated performance of the treatment. The result is a law of causation which would penalise the doctors, not for the harm that actually occurred, but for the chaos of reality coupled with the changeability of the patient's mind. Clark and Nolan rightly recognise the artificial distinction made between cases of 'no-difference'; where the patient would have had the operation if they were told all the risks, and 'delayed operation' where the patient would not have consented immediately.[315] Hogg argued this approach fails to recognise that the negligence has not fundamentally changed the nature of the decision. The danger is intrinsic to the nature of the choice, irrespective of the context, and therefore cannot be avoided. This

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[307] See Chapter 3, Section 3
[308] *Chester v Afshar* [2004] UKHL 41, per Lord Steyn, at [21]; *Chappel v Hart* (1998) 195 CLR 232.
[309] *Ibid*, per Lord Steyn, at [22]
[310] *Ibid*, per Lord Steyn, at [23]
[311] *Ibid*, per Lord Steyn, at [22]. Relying on P. Cane, 'A Warning about Causation (1999) 115 *L Q R*ev 21; A. Grubb, 'Clinical Negligence: Informed Consent and Causation.' (2002) 10 *Med L Rev* 322; T. Honore, 'Medical Non-Disclosure: Causation and Risk: *Chappel v Hart*.' (1999) 7 *Torts L.J* 1; M. Jones, '" But-For" Causation in Actions for Non-Disclosure of Risk.' (2002) 18 *PN* 192; J. Stapleton, 'Cause-in-Fact and Scope of Liability for Consequences.' (2003) 119 *L Q R*ev 388
[312] T. Honore, 'Medical Non-Disclosure: Causation and Risk: *Chappel v Hart*.' (1999) 7 *Torts L.J* 1, 8
[313] *Fairchild v Glenhaven Funeral Services Ltd* [2002] UKHL 22
[314] *Chester v Afshar* [2004] UKHL 41, per Lord Steyn, at [22]
[315] See this distinction also made in the Australian context: *Wallace v Kam* [2013] HCA 19, (2013) 87 ALJR 648.

approach, then, does not so much alter the rules of causation as abandon them.[316] Concerningly, the law may penalise doctors who justifiably deviated in the carrying out of a treatment which would to benefit or potentially save a patient's life.[317] This conceptualisation of the rules of causation also encouraged doctors to provide an exhaustive disclosure to cover all potential deviations from a procedure, all potential benefits, harms, risks and options, to avoid liability; irrespective of whether the risks may be relevant to the actual circumstances, the patients information needs, or capacity to understand. The decision the patient is making may itself become uncertain.

(v) The failure to ensure an autonomous choice caused distinct moral harm [strict liability].

Lord Hope, instead, argued that the failure to ensure an informed consent was a distinct actionable harm.[318] The judge relied on the persuasive judgement of Gaudron J; who was in the majority in *Chappel v Hart*, to argue that failure to provide information to ensure an understanding should be seen as a matter of 'common sense' i.e. as a strict liability offence, if the risk that the doctor failed to disclosure in fact manifest.[319] Otherwise, this would undermine the purpose of the duty to provide information disclosure.[320] Lord Hope seemed to have been similarly persuaded by academic commentators (particularly Cane, Stauch, and Honore[321]), who argued that causation was only to act as a mechanism for attributing legal responsibility, rather than locating and connecting an actual cause or type of harm to the negligence.[322] All that was needed to attribute legal causality, rather than actual causality, was foreseeability of harm i.e. that it was foreseeable that the patient would suffer by the omission of information. If any harm was foreseeable, by an act or omission, this would have the effect of reversing the burden of proof to require the doctor to prove that there was a good reason that the type

[316] M. Hogg, 'Duties of Care, Causation, and the Implication of *Chester v Afshar*.' (2005) 11(9) *Edinburgh Law Review* 156-167, 162. T. Clarke & D. Nolan, 'A Critique of *Chester v Afshar*.' (2014) 34 *Ox J Legal Studies* 659-692, 665

[317] T. Clarke & D. Nolan, 'A Critique of *Chester v Afshar*.' (2014) 34 *Ox J Legal Studies* 659-692,664-665

[318] *Chester v Afshar* [2004] UKHL 41, per Lord Hope, at [62]. Miola also took the view that Lord Hope argued that failure to ensure a right to autonomy is an actionable harm: J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship*. (Hart Publishing, 2007), 77

[319] *Chester v Afshar* [2004] UKHL 41, per Lord Hope, at [74]: "[…] The questions of causation are not answered in a legal vacuum. Rather they are answered in the legal framework in which they arise and for present purposes that framework was the law of negligence […]. It was not disputed that the defendant was under a duty to inform his patient of the risk. The duty was called into existence because of the foreseeability of that risk, it was not performed and the risk eventuated. That was often the beginning and the end of the inquiry whether breach of duty materially caused or contributed to the harm suffered […]. She accepted that where there is a duty to inform it is necessary for the plaintiff to give evidence as to what would or would not have happened if the information had been provided. But it is to apply sophistry rather than common sense to say that, although the risk of physical injury but simply resulted in the loss of an opportunity to pursue a different course of action […]. The physical injury having occurred, breach of the duty was treated as materially causing or contributing to that injury unless there was sufficient reason to the contrary."

[320] *Chester v Afshar* [2004] UKHL 41, per Lord Hope, at [77]

[321] P. Cane, 'A Warning about Causation." (1999) 115 *L Q Rev* 21; argued taking a strict view of causation would weaken the duty to provide information; T. Honore, 'Medical Non-disclosure, Causation and Risk: *Chappel v Hart*.' (1999) 7 *Torts LJ* 1 argued the paramount importance of the principle of autonomy means recovery should be allowed; M. Stauch, 'Taking the Consequences for Failure to Warn of Medical Risks.' (2000) 63 *MLR* 261; argued that the doctor-patient relationship required to doctor to promote patient autonomy; failure to do so, meant that the doctor assumed the risk of harm; A. Grubb, 'Clinical Negligence: Informed Consent and Causation.' (2002) 10 *Med L Rev* 322, 324

[322] *Chester v Afshar* [2004] UKHL 41, per Lord Hope, at [77] – [79]

of injury that occurred would have happened irrespective of their negligence.[323] This created a strict liability requirement to ensure an informed decision.

The logic of the liability-at-all costs approach was not only legally and logically dubious, but dangerously uncertain. The model of autonomy that the doctor was required to facilitate was undefined in the substantive judgement. As the model relied on the standard of materiality that was established in the *Pearce* judgement, it operated on two incompatible models of autonomy.[324] This meant that the information that the patient would need would be unknowable and thus potentially negligent. This negligence, in and of itself, would be potentially foreseeable, and any risks that flowed from an operation which could manifest may be potentially foreseeable. If there was no need for an actual link between the negligence and the type of harm; failing to provide either a rational choice, or an authentic choice could, forms a type dignitary harm that could be actionable under Lord Hope's legal interpretation. The irony of this position is that in attempting to protect the patient's autonomous choice in the law relating to the duty of care, Lord Hope in fact undermined respect for patient's autonomy in the law of causation; by failing to give due respect for the agency of the patient to identify whether an aspect of the disclosure would in fact have changed their mind.

Whilst *Chester*'s approach to causation has generally been interpreted as an exceptional departure from normal principles, it is concerning that more recent cases have left the door open in circumstances where the patient asserts that they would have delayed their operations.[325]

5.1.2. Post-*Chester*

This section will argue that the impact of *Chester* should not be underplayed, it marked a paradigm shift in the purpose of the law of medical negligence, which was recognised and adopted by judges in the High Court and Court of Appeal as a basis to extend patient rights to not just disclosure, but the provision of diagnostic and treatment options.[326] In reaction, other judges distinguished the case and reasserted the therapeutic relationship as the basis of the law of negligence. This conceptual divide as to the appropriate medical relationship divided both the judiciary, academic commentary, and

[323] *Ibid*, per Lord Hope, at [75]. Referring to the decision in *Chappel v Hart*, Lord Hope argues that: "In [Mason CJ's] opinion it was for Dr Chappel to demonstrate some good reason for denying to Mrs Hart recovery in respect of injury which she would not have suffered at his hands but for his failure to advise her, and he had failed to do so […]. To make good her case and obtain damages, Mrs Hart was not required to negative the proposition that any later treatment would have been attended with same or a greater degree of risk."

[324] See Chapter 3 Section 1

[325] Although *Chester* was distinguished, it is still being used by Counsel as a persuasive judgement to expand concepts of consumer patient: *Correia v University Hospital of North Staffordshire NHS Trust* [2017] EWCA 356, per Lord Justice Simon at [2], [12]-[13], [22]-[28]; *Duce v Worcestershire Acute Hospitals NHS* Trust [2018] EWCA Civ 1307, per Lord Justice Hamblen, at [50]-[71], & per Lord Justice Leggatt, at [81]-[92]

[326] Pursehouse for example, questions whether the requirement for autonomous choice amounted to a distinct actionable harm: C. Pursehouse, 'Liability for Lost Autonomy in Negligence: Undermining the Coherence of Torts Law? (2015) 22(3) *Torts L J* 226-249

subsequently the law.[327] Thus, the medical profession was obliged to apply laws which emphasised the need to both ensure the patient had information in their best interests (according to the circumstances) and an informed consent.

(i) Autonomy rules, OK?[328]

For example, in *Cooper v Royal United Hospital Bath NHS Trust,*[329] the defendant doctors failed to explain the risks and benefits of a repeat biopsy; after identifying calcification in the claimants breast tissue. Instead of giving the patient the option of a repeat biopsy, and a histology analysis, the doctors chose a treatment plan where the patient would, instead, receive a repeat mammogram after 12 months. The patient developed terminal breast cancer and died before the judgement was given. Butterfield J found the doctors negligent; as they had failed to ensure that the patient had a balanced and rational understanding of the treatment options (adopting a model of liberal autonomy) and allowed 'Mrs Cooper to believe that either method was of equal value.'[330] The judge concluded that a reasonable doctor would have explained to the patient the benefits of having a biopsy and the risks of avoiding one.[331] Similarly, in *Birch v University College London Hospital NHS Trust,* a diabetic patient presented with pupil sparing right third nerve palsy. The consultant neuroradiologist and consultant neurosurgeon thought that the cause might be a life-threatening aneurysm, which could not wait for an MRI scan. They performed a catheter angiogram, which resulted in stroke.[332] The claimant argued that the doctors should have presented her with other options. Cranston J found that the 1% risk of stroke was an 'objectively significant risk.'[333] Thus, he found that *Chester* placed a gloss on the *Pearce* test to ensure that the patient could decide between treatments.

> Lord Steyn added, in his own words, that generally speaking, in modern law medical paternalism no longer rules and 'a patient has a *prima facie* right to be informed by a surgeon of a small, but well established, risk of serious injury as a result of surgery.' The obvious rationale is patient autonomy and respect for the reality that it is the patient who must bear any consequences if a risk transforms itself into reality.[334]

[327] J. Miola, 'Autonomy Rued, OK?' (2006) 14 *Med L Rev* 108-114
[328] S. Devaney, 'Autonomy Rules OK.' (2005) 12 *Med L Rev* 102
[329] *Cooper v Royal United Hospital Bath NHS Trust* [2004] EWHC 3381 (QB) written judgement published on 6 October 2004. It is unclear whether the hearing for this case was before the written judgement of the House of Lords in *Chester v Afshar* [2004] UKHL on 14 October 2004, but certainly after the Court of Appeal judgement of 27 May 2002 (*Chester v Afshar* [2002] 3 WLR 1195).
[330] *Ibid*, per Butterfield J, at [39] and [57]
[331] *Ibid*, per Butterfield J, at [53]. This caused doctors to alter their practice to clarify their practice: G. Ralleigh, 'Image-Guided Breast Biopsy,' (2005) 35 J R *Coll Physician Edinb* 219-220
[332] *Birch v United College London Hospital NHS Foundation* Trust [2008] EWHC 2237 (QB), per Cranston J, at [17]
[333] *Ibid*, per Cranston J, at [74]
[334] *Ibid*, per Cranston J, at [72]

This required that the doctor disclose the 'comparative risks associated with the alternative procedures.'[335]As the defendants had failed to do this (albeit, that this was an emergency situation) they were negligent. [336]

Following on from *Birch* a number of High Court judgements began relying on *Chester* to require doctors to provide additional options to the patient, as well as the risks and benefits of those options. For example, in *Jones v North West Strategic Health Board*[337] the claimant suffered cerebral palsy and severe development disabilities due to should dystocia occurring at birth. The claimant mother argued that the doctors should have advised her of the risk of should dystocia, and therefore also provided the option of having a caesarean section.[338] Nicol J found that, the leading case of *Chester* approved the dicta of Lord Woolf in *Pearce*, thus the doctor should have disclosed all significant risks.[339] If shoulder dystocia was a significant risk, then the next question would be what advice should have been given, and particularly whether the doctor should have offered a caesarean section.[340] The Defence argued that, based on contemporary guidance and research, the risk of should dystocia occurring was less than 10%, and the risk of serious harm was less the 1-2%; which was below the threshold of medical significance. However, Nicol J found that shoulder dystocia was intrinsically a serious outcome associated with vaginal birth, which 'itself is likely to engender an atmosphere of crisis', therefore the patient must be told.[341] Endorsing a right to information, the judge argued that disclosure should occur irrespective of common practice and a caesarean section should offered even if another method of delivery (i.e. vaginal delivery) was the best or correct medical course.[342]

Similarly, in *Webb v Norwich University Hospital NHS Trust,*[343] Hampton J found that disclosure of options should be provided to patients irrespective of their likelihood of success. The patient had a mastectomy and reconstruction of her right breast after a cancer diagnosis. She was not happy with the size of the implant, so had an enlargement, which led to complications in the healing process, meaning that the right implant was exposed. It was a medical necessity that the implant was removed. The claimant argued that she should have been given information and the option of salvaging the implant

[335] *Ibid*, per Cranston J, at [71] and [79]: "I am convinced that in Mrs Birch's case no reasonable, prudent medical practitioner would have failed to discuss the respective modalities and the risks with her along the lines outlined. In their absence she was denies the opportunity to make an informed choice. Even if I am wrong on this, the failure to discuss with Mrs Birch these matters could not be described in law as reasonable, responsible or logical."
[336] *Ibid*, per Cranston J, at [74]
[337] *Jones v North West Strategic Health Authority* [2010] EWHC 178 (QB).
[338] *Ibid*, [3]
[339] *Ibid*, [23]-[24]
[340] *Ibid*, [25]-[27]
[341] *Ibid*, [50]-[51]
[342] *Ibid*, [52]. This directive counselling was important as the mother was a Jehovah's Witness, the judge found that the mother would not have gone against the direct advice of the doctor and opted for a caesarean section due to the increase risk of bleeding (at [71])
[343] *Webb v Norfolk & University Hospital NHS* Trust [2011] EWHC 3769

and breast reconstruction.[344] Following the same line as reasoning as *Chester*, the judge found the claimant was entitled to be informed about all medical options. Particular emphasis was placed on the characteristics of the patient i.e. that she was concerned about her aesthetic and had previous surgeries. The Court Appeal also adopted a similar line of judicial reasoning. In *Border v Lewisham and Greenwich NHS Trust*[345] the Appeal court found that the right to choose between options trumped medical necessity. The Court of Appeal found Dr Prenter, was negligent for failing to attain an informed consent before inserting a cannula into the patient's left arm. The patient who had a left mammectomy and auxiliary node clearance, specifically stated that she did not want a cannula in her arm, due to the risk of further infection.[346]After searching for a suitable vein, the defendant followed normal practice and cannulated the left arm, thus avoiding the risk of sudden and serious deterioration and collapse of the claimant's condition.[347] Unfortunately, this resulted in later oedema and the claimant argued that as she did not consent to cannulisation. As such, the decision-making approach that the doctor took was irrelevant: '[i]t was for the patient, not the doctor, to make the choice between the alternatives of immediate insertion and "wait and see".'[348] The Court of Appeal agreed with the first instance judge that the failure disclose information to the patient was negligent, and his failure to wait for her consent was caused by a misapprehension that this was an emergency situation.[349]

This line of case-law established the requirement that there was no medical discretion for the doctor to decide between treatment options, or investigations towards a potential diagnosis. The patient was to be provided all of the potentially relevant information and required to make a decision about the best medical course to proceed. The technical as well as the moral element of decision was to be decided by the patient. Munby J, in *Burke v General Medical Council* gave a blockbuster judgement declaring that there now amounted to an actionable right to treatment.[350] Whilst this was later appealed, this placed the doctor between a conceptual rock and a hard place. The requirement to offer the patient all potential options and information would potentially mean that the doctor would not be acting reasonably according to a medical standard per *Bolam/Bolitho*.[351]

[344] *Ibid*, per Hampton J, at [22]
[345] *Border v Lewisham and Greenwich NHS Trust* [2015] EWCA Civ 8
[346] *Ibid*, per Lord Justice Richards, at [2]
[347] *Ibid*, per Lord Justice Richards, at [9]
[348] *Ibid*, per Lord Justice Richards, at [13]
[349] *Ibid*, per Lord Justice Richards, at [19]
[350] *Burke v General Medical Council (Official Solicitor intervening)* [2004] EWHC 1879 (Admin)
[351] *Wyatt v Curtis* [2003] EWCA Civ 1779, per Lord Justice Kay, at [21]. As Lord Justice Kay argues, this conceptualisation of a right to a level of understanding potentially forces the doctor to harm the patient, therefore "any doctor considering what was necessary in such circumstances would be bound to place in the balance the potential emotional distress that might be caused to the patient by reopening a question over which it was likely that she would have agonised in making her difficult decision following initial advice."

(ii) Autonomy Rued, OK?[352]

In stark contrast to the judgement of the House of Lords in *Chester* there were a number of cases within the lower courts, which ignored the paradigm shift to a patient-orientated medical relationship, and instead reasserted the values of the therapeutic relationship.[353] For example in *N M v Lanarkshire Health Board*, the prelude to the seminal case of *Montgomery v Lanarkshire Health Board*,[354] the Court of Sessions rejected that the doctor was required to ensure a patient knew all potential options necessary for an informed consent.[355] The judges found that a general warning about the significant risk of shoulder dystocia (10%) was sufficient. It was not necessary to delineate the minutiae of potential serious outcomes.[356] Second, the doctor was not obliged to provide all potentially relevant information, if the patient made a general enquiry. The extent of the duty to disclose information related to the specificity of the request. A general anxiety therefore did not create a duty to disclose 'every possible risk or complication which might attend surgical or other procedures which are in prospect.'; This was information need also had to be seen in the light of the corresponding duty of non-maleficence i.e. to not cause 'alarm' and thus harm the patient.[357]

Similarly, in *Al Hamwi v Johnston*, the High Court found that the doctor did not owe a duty to the patient to ensure an understanding for the purpose of consent. The claimant had a family history of down-syndrome and extensive mental and physical impairments.[358] The claimant sought genetic testing and was offered amniocentesis by the consultant obstetrician. The defendant informed the claimant that there was a 1 in 100 chance (1%) of miscarriage.[359] The patient declined the test believing instead that there was a 75% chance of miscarriage.[360] Unfortunately, her child (Ahmad) was born with disabilities. The case centred around three allegations: first, that the defendant hospital failed to provide adequate information and counselling about the risks of the amniocentesis; second, that the information was given in an unbalanced way by either significantly exaggerating the risk of miscarriage[361] (which, it was argued were indicated by the doctors personal Christian beliefs).[362] third, it should have been apparent that the patient misunderstood the risks of testing, as if she understood the risks she would have opted

[352] J. Miola, 'Autonomy Rued, OK?' (2006) 14 *Med L Rev* 108-114
[353] For example, see *Mrs Enid Smith v Lothian University Hospitals NHS Trust* [2007] CSOH 08, per Lady Clark of Calton, at [26]-[27]; *Meiklejohn v St George's Healthcare NHS Trust and Another* [2014] EWCA Civ 12, [64]– [66], [93]
[354] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11
[355] *N M v Lanarkshire Health Board* [2013] CSIH 3
[356] *Ibid*, per Lord Eassie, Lord Hardie and Lord Emslie at [29]
[357] *Ibid*, at [41]
[358] *Al Hamwi v Johnston and Another* [2005] All ER (D) 278, per Simon J., at [5] – [12] and [77] – [80]
[359] *Ibid*, per Simon J, at [25]. Although the Claimant claimed that "At no stage was she given an assessment of the risks of Amniocentesis in percentage terms. She was not told that the risk of miscarriage was 1%. She was left with the firm impression that the chance of miscarriage was extremely high, certainly more likely than not. In her own mind she thought the risk was in the region of 75%. She was not given the Leaflet. However, the judge relied on the policy form (or checklist) for information disclosure and the contemporaneous note proved by Miss Kerslake stating "1 in 100" and that "Amniocentesis leaflet given." (at [29] & [35])
[360] *Ibid*, per Simon J, at [15] & [18]
[361] *Ibid*, at [27]
[362] *Ibid*, at [47] – [52]

for the test (and a subsequently an abortion). [363] The claimant asserted that the doctor has a duty to ensure her understanding. The Judge recognised the doctor owed a duty to give a 'warning which is adequate in scope, content and presentation, and take steps to see that warning is understood.'[364] Relying on *Seeking Patients Consent*, the judge interpreted the ethical guidance as requiring that the doctor to tailor information to the needs of the individual patient; thus adopting a model of authentic autonomy.[365] Requiring an objective understanding would be in antithesis to the purpose of the particular patient standard. The judge recognised that ensuring an *actual* understanding as a distinct facilitative duty was, however, practically unachievable. [366]

> In my view that is to place too onerous an obligation on the clinician. It is difficult to see what steps could be devised to ensure that a patient has understood, short of a vigorous and inappropriate cross-examination. A patient may say she understands although she has not in fact done so, or has understand part of what has been said, or has a clear understanding of something other than what has been imparted. It is common experience that misunderstanding can arise despite reasonable steps to avoid them. Clinicians should take reasonable and appropriate steps to satisfy themselves that the patient has understood the information which has been provided; but the obligation does not extend to ensuring that the patient has understood. [367]

Simon J found that the content of the disclosure was not negligent as the doctor had attributed weight to all relevant considerations in the circumstances.[368] Her disclosure, or emphasis, was not based on her personal values.[369] The judge rightly declined to apply the rules of causation in *Chester v Afshar* i.e. that the patient lost the chance to avoid harm[370] as the doctor, rather than the patient, had power in medical decision-making.[371]

The right to treatment, as the basis of a consumer relationship,[372] was similarly rejected by the Court of Appeal in the withering judgement of *Burke*.[373] The case related to the patient (Oliver Leslie Burke) who suffered from cerebellar ataxia - a worsening condition. The patient would eventually require

[363] *Ibid*, at [3]
[364] *Ibid*, at [43]. Relying on *Lybert v Warrington Health Authority* [1996] 7 Med L R 334
[365] *Ibid*, at [45]
[366] *Ibid*, at [69]
[367] *Ibid*, at [69]
[368] *Ibid*, at [57]-[60]
[369] *Ibid*, at [63] – [67]
[370] *Chester v Afshar* (2005) UKHL 41. See, also: *Gregg v Scott* [2004] 3 WLR 927
[371] Although this was met with condemnation by the rights school: J. Miola, 'Autonomy Rued, OK?' (2006) 14 *Med L Rev* 108-114,113; J. Coggon & J. Miola 'Autonomy, Liberty, and Medical Decision-Making.' (2011) 70(3) *Camb L J* 523-547, 539; A. Maclean, *Autonomy, Informed Consent and Medical Law*. (Cambridge University Press, 2009), 221
[372] R (on the application of Burke) v GMC [2004] EWHC 1879
[373] *Burke* v *GMC* [2005] EWCA Civ 1003

significant care, and lose the ability to swallow, however, he would retain cognitive facilities. When the time came, he wished to be treated with Artificial, Nutrition and Hydration (ANH) until he died of natural causes. However, he was concerned that the doctors would not continue to treat him. Particularly, he argued that the current medical guidance issued by the GMC in relation to best interest's decision-making (para 81, in particular)[374] ignored his human right to have his autonomous wishes respected.[375] The Court of Appeal rejected that an advanced directive could compel a doctor to provide treatment. Instead, it would be taken into account as a relevant consideration within a wider circumstantial decision about the patients best interest's. The Appeal judges particularly criticised the judgement of Munby J's. Particularly, his attempt to extended human rights concepts, using the nudge-tactics of the rights commentators, to establish a right to preferred treatment.[376]

> The court should not be used as a general advice centre. The danger is that the court will enunciate propositions of principle without full appreciation of the implications that these will have in practice, throwing into confusion those who feel obliged to attempt to apply those principles in practice. This danger is particularly acute where the issues raised involve ethical questions that any court should be reluctant to address, unless driven to do so by the need to resolve a practical problem that requires the court's intervention.[377]

Lord Phillips argued that it was not the role of a judge to legislate or set out prospective principles. Instead, the judgement should be confined to the issues.[378]

> The judge himself observed that it was not the task of a judge when sitting judicially – even in the Administrative Court – to set out to write a text book or practice manual. Yet the judge appears to have done just that.[379]

This approach to discretion around treatment options was followed in *Aintree v James*, where the Supreme Court, agreeing with the Court of Appeal, stated that whilst the patient's values should be a central medical consideration, the overriding aim of the treatment must be to act globally act in the

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[374] *Ibid*, [16]: "However, where a patient wishes to have a treatment that – in the doctor's considered view – is not clinically indicated, there is no ethical or legal obligation on the doctor to provide it." See, *Burke v General Medical Council (Official Solicitor intervening)* [2004] EWHC 1879 (Admin), per Munby J, at [15]. Relying on GMC, *Withholding and Withdrawing Life-prolonging Treatments: Good Practice in Decision-making.* (GMC, 2000)
[375] *Burke v General Medical Council (Official Solicitor intervening)* [2004] EWHC 1879 (Admin), per Munby J, at [24]
[376] *Burke v GMC [*2005] EWCA Civ 1003, per Lord Phillips MR at [56]-[63]
[377] *Ibid*, per Lord Phillips MR at [19]
[378] See a similar argument made by, J. Montgomery, C. Jones & H. Biggs, 'Hidden Law-Making in the Province of Medical Jurisprudence.' (2014) 77(3) *Modern Law Review* 343-378; H. Biggs, 'Taking Account of the Views of the Patient', but only if the Clinician (and the Court) Agrees – *R (Burke) v General Medical Council*.' (2007) 19(2) *Children and Family Law Quarterly* 225-238
[379] *Burke v GMC [*2005] EWCA Civ 1003, per Lord Phillips MR at [19]

patient's best interest.[380] Medical discretion was therefore essential to this decision. As treatment options were limited so too was the content of information disclosure.

5.1.3 Legal uncertainty

(i) The purpose of information disclosure

The fundamental change arising from the House of Lord's judgement was the eradication of the therapeutic medical relationship from the negligence cause of action.[381] Inserting the legal requirement of informed consent in the law of negligence went beyond 'a powerful symbolic and galvanising role'[382] to alter the purpose of the disclosure process to ensure that the patient is informed so that they can have an autonomous choice. This seemed like the intention of Lord Hope when he states: 'informed consent could provide a stimulus to broader debate around the nature of the doctor-patient relationship.'[383] Devaney argued that the approach of the court was justified to ensure the principle of autonomy was properly protected.[384] This meant that doctor, was at least conceptually, obliged to ignore whether information benefited or harmed the patient and service the end goal of the medical relationship: an autonomous choice. It is doubtful whether patients could even legally waive disclosure as the basis for consent, as the Lord remained silent on a therapeutic privilege.[385] This actively encouraged defensive disclosures to ensure full understanding, which ignored patient liberty to choose the form of the relationship which they entered. As Coggon and Miola argued, autonomy and liberty 'can combine to cancel each other out, particularly if they are used in an unsophisticated form and without any key to autonomous decision-making.'[386] Informed consent is a normative construct that requires that the doctor to ignore the actual information choices of the patient. Whilst some case-law pushed back against the potential harms of the consumer relationship[387] this simply increased confusion for the ethical sector, which was obliged to provide guidance to practitioners. The ethical sector had the problem of either specifying the external facilitative duties for models of autonomy (as the basis of the consumer relationship), or the considerations necessary for *circumstantial-moral* decision-making (as the basis of the therapeutic relationship).

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[380] *Aintree University Hospitals NHS Foundation Trust v James* [2013] EWCA Civ 65, [18]-[19]
[381] *Chester v Afshar* [2004] UKHL 41, per Lord Bingham, at [14]
[382] *Ibid*, [58]
[383] *Ibid*, [58]. Responding to M.A. Jones, 'Informed Consent and Other Fairy Stories.' (1999) 7 *Med L Rev* 103, 129
[384] S. Devaney, 'Autonomy Rules OK.' (2005) 12 *Med L Rev* 102
[385] As Cave recognises, a model of the therapeutic privilege has failed to properly emerge in common law: E. Cave, 'The Ill-Informed: Consent to medical Treatment and the Therapeutic Exception.' (2017) 46(2) *Common Law World Review* 140-168, 144
[386] J. Coggon & J. Miola, 'Autonomy, Liberty, and Medical Decision-Making' (2011) 70(3) *Camb L J* 523-547, 532 & 537
[387] *Al Hamwi v Johnston and Another* [2005] All ER (D) 278

(ii) The standard of information disclosure

Whilst commentators hailed the *Chester* judgement as a shift to *informed consent* and thus, a victory for patient autonomy, they failed to recognise the uncertainty that it created; both within the law of negligence, and thus, for medical professionals interpreting the law as a basis for decision-making guidance. [388] As Chapter 3 illustrated, inserting a distinct right to an informed consent into an existing cause of action fundamentally alters the philosophical basis of that standard of care. This requirement supersedes the law in *Pearce*, as the purpose of the disclosure is no longer contained in the therapeutic relationship. The *Bolam* and *Bolitho* standard is abandoned and *Chester*, for this period at least, became the leading judgement in the standard of care for information disclosure. However, the judgement gives no specific indication as to what model of autonomy should be used as the basis of the duty to inform the patient's understanding i.e. an objective understanding (a liberal autonomy model), or a subjective understanding (an authentic autonomy model).[389] Nor, did the judgement specify which methodology to use to ensure that the patient attained the correct standard of information to consent to a treatment. This gave the doctor no guidance about how to make decisions which were in line with the spirit as well as the rule of law. Whilst this thesis would postulate that Lord Hope, at least, intended to adopt an objective model of disclosure (where serious risks up to 1-2% were disclosed),[390]as Coggon and Miola argued, more information does not ensure that the patient can understand.[391] The patient could also assert that they need a specific piece of information (however objectively immaterial or unlikely), for example, the 0.9 – 2% chance of causa equina syndrome,[392] to make an authentic autonomous choice. It is understandable why a doctor may be tempted to adopt a process of formulistic exhaustive disclosure to avoid liability. The obvious effect is that this methodology may defeat the purpose of disclosure.

5.2. Medical Ethics: competing for the medical relationship

This section will argue that *Chester* prompted the formal and semi-formal sector to take the driving seat in defining not just the standard of care in information disclosure, both optimum form of the doctor-patient relationship.[393] Lord Steyn's reliance on the guidance by the Royal College of Surgeons,[394] for example, demonstrated that the ethical sector had an increasingly important role in rationalising the ideal model of the decision-making in combination with their statutory and fiduciary duties to create practical guidance.[395] Lord Walker was more explicit in asserting that ethics, rather than law, should

[388] For example, E. Jackson, *Medical Law: Texts, Cases and Materials.* (Oxford University Press, 2009), 202-203; S. Devaney, 'Autonomy Rules OK.' (2005) 12 *Med L Rev* 102
[389] Chapter 2 Section 3
[390] *Chester v Afshar* [2004] UKHL 41, per Lord Hope [48]
[391] J. Coggon & J. Miola, 'Autonomy, Liberty, and Medical Decision-Making' (2011) 70(3) *Camb L J* 523-547, 532-535. Relying on A. Maclean, 'Autonomy, Consent and Persuasion.' (2006) 13 *European Journal of Health Law* 321
[392] *Chester v Afshar* [2004] UKHL 41, per Lord Hope [48]
[393] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship.* (Hart Publishing, 2007), 79
[394] This thesis would argue that the guidance itself actually provides little support for the adoption of the consumer patient relationship; Royal College of Surgeons, *Good Surgical Practice.* (Royal College of Surgeons, 2002), Chapter 4
[395] *Chester v Afshar* [2004] UKHL 41, per Lord Walker [58]. Although, Miola rightly argues that the Law Lords were not explicit about a hierarchy: J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship.* (Hart Publishing, 2007), 79

lead the way in delineating the ethical optimum.[396] The recognition of the symbiotic nature of law and ethics; where ethical guidance set gold standard of medical practice, allowed the ethical sector (during this period) to begin directing than proliferating the inconsistency within the law.[397] This section will argue, however, that the various ethical organisations reacted in different ways to their ethical responsibility. The GMC,[398]in *Consent: Patient and Doctors Making Decisions Together* ("*Making Decisions Together*"), departed from *Chester*, and attempted to adopt a the binary model of the medical relationship. To mitigate the risk of liability, the GMC created rules which implied that the doctor should disclose information to both facilitate the best interests of the patient and ensure an informed consent. Whilst a process of *circumstantial-moral* decision-making and authentic autonomy both identified patient values as relevant factors, the identification and weight applied to these factors because of the distinct telos, was not equivocal. To ensure the GMC did not fall foul of either side of the relationship binary, the *Making Decisions Together* suggested an exhaustive disclosure; without any guidance as to what content of information was essential,[399] and was even less prescriptive about the external duties necessary to ensure autonomous choices.[400] The Department of Health ("DoH") updated their *Reference Guidance,* in line with the GMC guidance, which recognised that the *Bolam/Bolitho* standard could now require an exhaustive disclosure.[401]

The semi-formal sector, remained divided about the purpose of information disclosure along the same lines as the judiciary.[402] The Royal College of Surgeon ("RCoS") guidance followed the lead of Lord Walker and Steyn in facilitating the consumer relationship, by creating specific external duties to ensure an informed consent.[403] The BMA, on the other hand, seemed to reverse it's previous ethical perspective, and defended the axiomatic principle of trust, beneficence, and non-maleficence. This approach seems to support a therapeutic type of medical decision-making; one which saw the duty of disclosure as an ongoing event.[404] As the next section will argue, the conflict about the potential material

[396] *Ibid*, per Lord Walker [58]: "[…] the law cannot play a direct role in setting out detailed rules by way of guidance to doctors, but that it can have a powerful symbolic and galvanising role and that this is its major strength. The message that he was seeking to convey was that, while the case law provided little guidance to doctors and even less comfort to patients, litigation on informed consent could provide a stimulus to the broader debate about the nature of the doctor-patient relationship. The "happy ending" of his title would be found if the iterative process between case law and professional guidance were to lead to the creation of a more substantive "right" to truly informed consent for patients."
[397] C. Foster & J. Miola, 'Who's in Charge? The Relationship between Medical Law, Medical Ethics, and Medical Morality?' (2015) 23(4) Med L Rev 505-530, 514-515
[398] GMC, *Consent: patients and doctors making decisions together*. (GMC, 2008)
[399] S. Forvargue & J. Miola, 'One Step Forwards, Two Steps Back? The GMC, The Common Law and 'Informed' Consent.' (2010) 36 *J Med Ethics* 494-497, 496-497
[400] *Ibid*, 496
[401] Department of Health, *Reference Guide to Consent for Examination or Treatment, Second Edition*. (DoH, 2009), [12]
[402] Chapter 4, Section 1
[403] Royal College of Surgeons, *Good Surgical Practice: The Royal College of Surgeons of England.* (RCoS, 2014).
[404] British Medical Association Ethics Department, *Medical Ethics Today.* (BMJI Books, 2012) see for example: 2, 5-7, 21, 25, 61.

content of disclosure created a climate of uncertainty and fear which encouraged the adoption of exhaustive disclosure practices.[405]

5.2.1. The Formal Sector

(i) The therapeutic relationship

The GMC attempted to straddle the two strands of judicial thinking about the appropriate model the medical relationship. The 2006 version of *Good Medical Practice* continued to suggest that the overriding principle of the guidance was that 'the care of the patients' should be the doctors 'first concern.'[406] This required doctors to create and maintain a relationship of trust: where doctors would act with the teleological goal of making decisions in the patients' best interests.[407] To make best interests decisions the doctors needed to take account of biomedical, as well as biopsychosocial patient values, including 'the patient's conditions, taking account of the history (including the symptoms, and psychological and social factors), the patient's views and where necessary examining the patient.'[408] The requirement to straddle the relationship divide was made more obvious in the 2013 guidance, which conceptualised the guidance as being based on two distinct principles:[409] the first principle required that 'doctors make the care of their patients their first concern' by establishing and maintaining 'good relationships with patients' grounded on trust;[410] the second principle, however, emphasised the need to facilitate patient values, it stated that: 'Good doctors work in partnership with patients and respect their rights to privacy and dignity. They treat each patient as an individual.'[411]

To facilitate the therapeutic relationship element, the guidance required the doctor to adopt a two stage test for decision-making[412] (which drew on paradigmatic experience of patient need, i.e. to 'apply knowledge and experience to practice').[413] This first required doctors to act on their biomedical and biopsychosocial knowledge of the circumstances of the actual patient.[414] Second, when making decisions about what treatment options the 2006 guidance required that the assessment be a 'clinical judgement about the likely effectiveness of treatment options.'[415] Whilst patient needs and priorities were taken into account they were not necessarily the determining factor.[416] The 2013 guidance,

[405] See, Chief Medical Officer, *Making Amends: A Consultation Paper Setting out Proposals for Reforming the Approach to Clinical Negligence in the NHS*. (Chief Medical Officer, 2003), 7. See also, A. Towse, *et al*, *Reducing Harm to Patients in the National Health Service. Will the Government's Compensation Proposals Help*? (Office of Health Economics, 2003); P. Fenn, *et al*, 'Making Amends for Negligence: Current System Operates Well, but Reforms are still Needed.' (2004) 328(7437) *BMJ* 417-418; J.B. Capstick, 'Making Amends- The Future for Clinical Negligence Litigation.' (2004) 328 *BMJ* 457-460
[406] GMC, *Good Medical Practice* (GMC, 2006), [1]
[407] *Ibid*, [20]-[21]
[408] *Ibid*, [2(a)]
[409] *Ibid*, [1]-[4]
[410] *Ibid*, [1]
[411] *Ibid*, [2]
[412] Chapter 1 Section 2
[413] GMC, *Good Medical Practice* (GMC, 2013), 7
[414] *Ibid*, [15]
[415] GMC, *Good Medical Practice* (GMC, 2006), [7] and [10]
[416] *Ibid*, [7] and [10]

similarly, required that the medical treatments options must remain a clinical decision grounded on *circumstantial-moral* decision-making.[417]

In an attempt to straddle the relationship divide the 2013 guidance provided a much less explicit requirement for the type of consent to treatment than previous iteration (which required an informed consent). The 2001 general guidance, for example, required:

> You must respect the right of the patients to be fully involved in decisions about their care. Wherever possible, you must be satisfied, before you provide treatment or investigate a patient's condition, that the patient has understood what is proposed and why, any significant risks or side effects associated with it, and has given consent.[418]

The 2006 guidance only required:

> You must be satisfied that you have consent or other valid authority before you undertake any examination or investigation, provide treatment or involve patients in teaching or research. Usually, this will involve providing information to patients in a way they can understand, before asking their consent.[419]

Whereas the former specified that the patient *must* have a high (substantive) level of understanding, as the basis of their consent, the newer guidance required only that the doctor try to ensure an understanding. This did not ensure an autonomous consent.[420] The 2013 requirement was reduced further and stated:

> You must be satisfied that you have consent or other valid authority before you carry out any examination or investigation, provide treatment or involve patients or volunteers or research.[421]

The guidance, again, did not mention a right to information, nor even require a content of information as the basis of consent. Instead, the content disclosure was focused on patient's practical needs (which were aimed at ensuring a relationship grounded on trust).[422] For example, the doctor was advised to disclose:

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[417] GMC, *Good Medical Practice* (GMC, 2013), [57]: "The investigations or treatment you provide or arrange must be based on the assessment you and your patient make of their needs and priorities, and on your clinical judgement about their likely effectiveness of the treatment option."
[418] GMC, *Good Medical Practice*. (GMC, 2001), [17]
[419] GMC, *Good Medical Practice* (GMC, 2006), [36]
[420] *Ibid*, [22]
[421] GMC, *Good Medical Practice* (GMC, 2013), [17]
[422] Chapter 2 Section 5

a. their condition, its likely prognosis and the option for treatment, including associated risks and uncertainties

b. the progress of their care, and your role and responsibilities in the team

c. who is responsible for each aspect of care and how information is shared within teams and among those who will be providing their care.[423]

This was a purposive movement away from exclusively facilitating consent as an autonomous choice, towards recognising the wider therapeutic benefits of information to patients. One can, however, clearly see a division between the approach taken between the general and specific guidance

(ii) The consumer relationship: straddling the divide

In 2008 the GMC published new guidance, which updated *Seeking Patient's Consent*[424] in line with the developments of *Chester*.[425] *Making Decisions Together* adopted the rhetoric of patient rights and the consumer relationship;[426] however, this was not borne out in the rules that were actually included within the guidance. A deductive approach to analysing the guidance illustrated that the ethical basis of the rules were often facilitating a mishmash of elements from a therapeutic and consumer relationship; [427] which had the effect of confusing the aim of disclosure.[428] Forvargue and Miola, characterised this approach as the GMC having taken a 'step backwards' in their guidance on consent.[429] This thesis argues that the regulator's approach was necessitated to ensure that the ethical guidance was compatible with the dual-model of the medical relationship which had begun emerged within the common law. In essence, the GMC could see the tide was turning. The overarching principles contained within *Making Decision Together* required that the doctor *must* facilitate a primarily authentic model of autonomy:

[…] you must work in partnership with your patient to ensure good care. In doing so you must:

a. listen to patients and respect their views about their health […]

c. share with patients the information they want or need in order to make decisions […]

e. respect patients' decisions.[430]

[423] GMC, *Good Medical Practice* (GMC, 2013), [49]
[424] GMC, *Seeking Patient's Consent: Ethical Considerations*. (GMC, 1998)
[425] GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008), 34; *Chester v Afshar* [2004] UKHL 41, per Lord Bingham at [16]
[426] *Ibid*
[427] GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008), [3]
[428] *Ibid*, see: The duties of a doctor registered with the General Medical Council
[429] S. Fovargue & J. Miola, 'One Step Forward, Two Steps Back? The GMC, the Common Law and 'Informed' Consent.' (2010) 36 *J Med Ethics* 494-497, 494
[430] GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008), [2] & [10]

In identifying the information that patient's wanted, the guidance stated that:

> You should do your best to understand the patient's views about preferences about any proposed investigation or treatment, and the adverse outcomes they are most concerned about. […][431]

This approach explicitly prefers patient values as the basis of determinations about materiality. The guidance is explicit that the doctor should make no assumptions about the information that patients may want to know – the decisions about what information they should find significant is a matter for the actual patient. [432] Indeed, the guidance required that the doctor does not provide information in a way that would influence the values or interpretation of the patient.[433] This preservation of values is conceptually necessary so that not to disturb the authenticity of a choice.[434]

> You must give information about risk in a balanced way. You should avoid bias; and you should explain the expected benefits as well as the potential burdens and risks of any proposed investigation or treatment.[435]

The guidance required a facilitative (external) standard of communication where the doctor *must* provide information in a neutral way to facilitate a subjective standard of understanding.[436] The doctor was required to not make assumptions about the patient's understanding; based on the values they used to interpret 'the importance that they attach to different outcomes.'[437] The doctor is obliged to appreciate that the patient 'may understand information about risk differently from you.'[438] The doctor was also required to accept a decision if it was based on an irrational, or potentially incorrect, understanding of information i.e. according to the patient's own values.[439] Indeed, the guidance also required that the doctor defend the authentic values of the patient from external influences of third patients (i.e. to ensure that the decision-making paradigm of the patient is authentic).[440]

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[431] *Ibid*, [31]
[432] *Ibid*, [10]-[11]
[433] For example, see Deriche *v Ealing Hospital NHS Trust* [2003] EWHC 3104 (QB)
[434] Chapter 2.3
[435] GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008), [33], also see [19] and [41]
[436] *Ibid*, [19] and [34]: "You must use clear, simple and consistent language when discussing risks with patients. You should be aware that patients may understand information about risks differently from you. You should check that the patient understand the terms you use, particularly when describing the seriousness, frequency and likelihood of an adverse outcome. You should use simple and accurate written information or other aids to explain risk, if they will help the patient to understand."
[437] *Ibid*, [31]
[438] *Ibid*, [34]
[439] *Ibid*, [43]
[440] *Ibid*, [33]; *Re T (Adult)* [1992] 4 All ER 649. Although, one would question the purpose of this requirement if second order desires are to act as the basis of decisions about materiality, as long-held desires would inevitably be impacted by third parties. Indeed, the GMC indicate that asking family and friends about the patient's values would assist in decisions about materiality, and help the patient understand, per [22].

However, this is not purely facilitating an authentic model of materiality as the basis of a therapeutic disclosure, as the guidance conceptualised the patient as holding decision-making power. The doctor was required to consider potential options suggested by the patient. Whilst the doctor could refuse to provide a treatment, they were obliged to offer the patient a second opinion.[441] Requiring that patient be offered a range of reasonable options is indicative of the market; thus, a consumer-type medical relationship. The guidance conceptualised the patient as taking on the responsibility of making both moral, and to some extent technical choices, from the various diagnostic and treatment options.

> The patient weighs up the potential benefits, risks and burdens of the various options as well as any non-clinical issues that are relevant to them. The patient decides whether to accept any of the options and, if so, which one. They also have the right to accept or refuse an option for a reason that may seem irrational to the doctor or for no reason at all.[442]

However, in other parts of the substantive rules disclosure operated in antithesis to this principle of autonomy.[443] As such, the orientating purpose of the guidance was fundamentally confused. For example, the doctor was required to make decisions about materiality not exclusively on the '(a) needs, wishes and priorities'[444] of the patient but also biomedical considerations such as '(c) the nature of the condition, (d) the complexity of the treatment, and (e) the nature and level of risk associated with the investigation of treatment.'[445] The guidance required that the doctor integrate objective biomedical values about need and subjective biopsychosocial values of the patient i.e. about what they want to know when making judgements about treatment and materiality.[446] In doing so, the guidance seemed to facilitate a dual-relationship without recognising that these relationships had distinct purposes and aims.[447] For example, the guidance stated:

> The doctor uses specialist knowledge and experience and clinical judgement, and the patient's views and understanding of their condition, to identify which investigations or treatments are likely to result in overall benefit for the patient. The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each options, including the

[441] *Ibid*, [5d]: "If the patient asks for a treatment that doctor considers would not be of overall benefit to them, the doctor should discuss the issues with the patient and explore the reasons for their request. If, after discussion, the doctor still considers that the treatment would not be of overall benefit to the patient, they do not have to provide the treatment. But they should explain their reasons to the patient and explain any other options that are available, including the option to seek a second opinion."
[442] *Ibid*, [5c]
[443] *Ibid*, [5] and [7]
[444] *Ibid*, [7]
[445] *Ibid*, [7]
[446] *Ibid*, [8]-[9], [30]
[447] *Ibid* [30]

> option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept their advice.[448]

The inclusions of biomedical elements was indicative of facilitating a therapeutic relationship, as these required the use of objective medical values, in antithesis to an authentic patient values. Disclosure of this information could (conceptually) pollute patient values. Indeed, this may have been inevitable; as the guidance required the disclosure of a mandatory list of objectively relevant information. Beyond this, the large content of information disclosure could have overwhelmed even the most resilient and capacitous patient.[449] The guidance went on to suggest that the doctor was responsible for constructing a plan of proposed treatments.[450] Again, this was in antithesis to the aims of the consumer relationship; which sought to establish the patient as having decision-making authority.[451]

Worse still, elements of the guidance sought to facilitate the therapeutic ends of the medical relationship, conceptualised in liberal, rather than authentic terms. As Chapter 3 argued, a liberal model of autonomy required a content and value-objective understanding as the basis of a rational decision, rather than one grounded on subjective personal information need and values. For example, the guidance required that the doctor '*must* tell patient's if an investigation might result in serious adverse outcome, even if the likelihood is very small.'[452] Whilst the guidance stated that the patient 'may understand risks differently', it went on to require that the patient understood the 'terms that you use, particularly when describing the seriousness, frequency and likelihood of an adverse outcome.' If the patient was to understand these terms, one could argue that they must also have understand the value-basis on which the terms are used; so to properly conceptualise and appreciate the level of risk. This required the patient to understand the information from the doctor's point of view.[453] Indeed, the doctor was required to check the level of patient understanding; which infers that there was an appropriate objective basis on

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[448] *Ibid*, [5b]
[449] *Ibid*, [9]: "(a) the diagnosis
(b) any uncertainties about the diagnosis or prognosis, including options for further investigations
(c) options for treatment or managing the condition, including the option not to treat
(d) the purpose of any proposed investigation or treatment and what it will involve
(e) the potential benefits, risks and burdens, and the likelihood of success, for each options; this should include information, if available, about whether the benefits or risks are affected by which organisation or doctor is chosen to provide care.
(f) whether a proposed investigation or treatment is part of a research programme or is an innovative treatment designed specifically for their benefit
(g) the people who will be mainly responsible for any involved in their case, what their roles are, and to what extent students may be involved;
(h) their right to refuse to take part in teaching or research
(i) their right to seek a second opinion
(j) any bills they will have to pay
(k) any conflicts of interest that you, or your organisation, may have
(l) any treatments that you believe have greater potential benefit for the patient than those you or your organisation can offer."
[450] *Ibid*, [38]
[451] *Ibid*, [5c]
[452] *Ibid*, [32] & [29]
[453] *Ibid*, [34]

which the patient should understand.[454] This was problematic as it not only undermined an authentic consent but also the legal presumption that a decision of a patient should be respected, regardless of the basis on which the decision was made.[455] This confabulation of elements of the consumer and therapeutic model placed some of the rules in direct conflict with the therapeutic model adopted in the 2006 and 2013 *Good Medical Practice*, and with the judicial line of case-law which retained medical discretion; as the basis of the law of negligence. The effect of this conflation is that the purpose of disclosure becomes unknowable, for both the method of delineating treatment options and material information.[456]

(iii) Slipping through the cracks

In attempting to combine the therapeutic and consumer type relationships, the GMC guidance, required the doctor to disclose information that the patient would both want (according to their subjective values) and need (according to their medical circumstances). This created an exhaustive list of mandatory information that the doctor was required to disclose, and the patient was required to understand, as the basis of an autonomous consent.[457] This included information both about the potential treatment or diagnostic options, and the 'potential outcome of taking no action' including: the '(a) side effects, (b) complications, (c) failure of an intervention to achieve the desired aim.'[458] As this thesis has so far demonstrated, a significant minority of patients did not want significant information, and the majority of patients did not want to undertake the role of decision-maker (in regard to materiality or treatment options).[459] Patients were generally restricted in their capacity for understanding and recalling information.[460] Despite the empirical realities of patient capacities, the guidance enforced the role of consumer patients upon the individuals. For example, by assuming that every patient could construct and disclose relevant preferences for treatment, and values for information disclosure. Further, the guidance assumed patients could communicate these to the doctor, be proactive in seeking information, understand an exhaustive disclosure of potential diagnostic and treatment options, benefits and risks, and make a choice independent of the doctor (which would be respected even if it was not rationally made).[461] The guidance, respected the (potential) irrationality of consent, yet denied patients the liberty to make a rational decisions in refusing to accepted these responsibilities:

[454] *Ibid*, [44]: "Before accepting a patient's consent, you must consider whether they have been given the information they want or need, and how well they understand the details and implications of what is proposed. This is more important than how their consent is expressed or recorded."
[455] See Chapter 3, Section 3-4
[456] *Ibid*, [9] (b)-(d)
[457] *Ibid*, [9]
[458] *Ibid*, [29]
[459] See Chapter 2, Section 5, and Chapter 3, Section 3
[460] *Ibid*
[461] GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008), [5c]

> If a patient asks you to make decisions on their behalf or want to leave decisions on their behalf of wants to leave decisions to a relative, partner, friend, carer or another person close to them, you should explain that it is still important that they understand the options open to them, and what the treatment will involve. If they do not want this information, you should try to find out why.[462]

The guidance also restricts the patient's choice about what information they must have to consent to treatment – disclosure is therefore mandatory:

> If, after discussion, a patient still does not want to know in detail about their condition or the treatment, you should respect their wishes, as far as possible. But you must still give them the information they need in order to give their consent to a proposed investigation or treatment. This is likely to include what the investigation or treatment aims to achieve and what it will involve, for example: whether the procedure is invasive; what level of pain or discomfort they might experience, and what can be done to minimise it; anything they should do to prepare for the investigation or treatment; and if it involves any serious risks.[463]

If the patient insists, the doctor must still berate them with information:

> If a patient insists that they do not want even this basic information, you must explain the potential consequences of them not having it, particularly if it might mean that their consent is not valid. You must record the fact that the patient has declined this information. You must also make it clear that they can change their mind and have more information at any time.[464]

This requirement is counter-intuitive to the settled law that a capacitous patient should be free from interference and that their decisions be respected, regardless on the basis that it was made.[465] The guidance therefore acts against the legal rules by making respect for patient choices a qualified right. The patient can only access treatment if they are seen to have jumped through the ethical hoops necessary for their decision to be classed as an informed consent i.e., so that their decision is awarded a status worthy of respect. This thesis would argue that this should be considered a type of dignitary harm equivocal to failing to ensure an autonomous choice. As earlier chapters, and other commentators

[462] *Ibid*, [13]
[463] *Ibid*, [14]
[464] *Ibid*, [15]
[465] *Ibid*, [43], [64]-[65], See for example: *Re C (Adult: Refusal of Medical Treatment)* [1994] 1 All ER 819; *Re MB* [1997] EWCA Civ 309; *St George's Healthcare NHS Trust v S; R v Collins and Others, ex parte S* [1998] 3 All 678; *Re B (Adult: Refusal of Medical Treatment)* [2002] 2 All ER 449

have illustrated, forcing information on patients also has the potential to cause psychological injury.[466] Whilst the guidelines appreciated the risk of psychological harm and thus recognised a therapeutic exemption, the threshold of this exemption was both vague and set at an exceptionally high standard:

> You should not withhold information necessary for making decisions for any other reason, including when a relative, partner, friend or carer asks you to, unless you believe that giving it would cause the patient serious harm. In this context 'serious harm' means more than that the patient might become upset or decide to refuse treatment.[467]

A significant minority of patients have the potential to slip through the cracks, either by not being able to understand an exhaustive disclosure, and therefore not having an informed consent, or by refusing information and having their request ignored (potentially leading to harm). In both cases, neither the aims of the therapeutic, nor the consumer, relationship are fulfilled.

(iv) *Reference Guide*: enshrining an exhaustive disclosure

The DoH published a second edition of its set of guidance on the consent in 2009. The guidance is a summary of the law written by the Consent Advisory Group,[468] which recognised that *Chester* marked a paradigm shift to the facilitation of the consumer relationship.[469] The purpose of information disclosure, within the guidance, was therefore altered to ensure an informed consent:

> In considering what information to provide, the health practitioner should try to ensure that the person is able to make an informed judgement on whether to give or withhold consent.[470]

The guidance advised:

> [f]ollowing *Chester v Afshar*, it is advisable that healthcare professionals give information about *all significant possible adverse outcomes* and make a record of the information given.[471]

[466] See Chapter 3, Section 5 & Chapter 4, Section 3. See for example, C.N. O'Brien, *et al*, 'Consent for Plastic Surgical Procedures.' (2006) 59 *Journal of Plastic, Reconstructive & Aesthetic Surgery* 983-989; H. Ellis & A. Crowe, 'Medico-Legal Consequences of Post-Operative Intra-Abdominal Adhesions.' (2009) 7 *International Journal of Surgery* 187-191; O.A. Anderson & M.J. Wearne, 'Informed Consent for Elective Surgery – What is Best Practice?' (2007) 100(2) *J R Soc Med* 87-100

[467] GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008), [16] - [17]

[468] Department of Health, *Reference Guide to Consent for Examination or Treatment, Second Edition*. (DoH, 2009), 3-4 & 5

[469] *Ibid*, 8, 12-13 [17]-[18]

[470] *Ibid*, [18]

[471] *Ibid*, [18]

The DoH recognised that the GMC had gone further than the law to substantiate the model of the consumer patient.[472] The DoH argued that *Making Decisions Together* would have the effect of raising the standard of disclosure in law, through the combined requirements of *Bolam* and *Bolitho*[473] as:

> legal requirements in negligence cases have historically been based on the standards set by the professions for their members; therefore where the standards required by professionals bodies are rising, it is likely that the legal standards will rise accordingly.[474]

Thus, to avoid liability, doctors were encouraged, as a matter of form, to provide an exhaustive disclosure to meet the prospective legal standard.[475]

By adopting the full content of the GMC's recommendations[476] the DoH failed to recognise that this would create a sub-class of patients who were willing to have an autonomous choice, but simply would not have the capacity to have a full understanding. This would mean that they would not be having an informed consent, nor would they be protected by the doctor acting in their therapeutic best interests. Instead, the doctor would be making decisions to maximise choice, rather than benefit the actual patient. [477] If the doctor was placed in a position where they were compelled to harm the patient, then the *Reference* adopted the guidance issued by the GMC, that 'if in doubt about the amount of information to give a patient, doctors 'should contact their hospital lawyers or their medical defence organisation'.'[478] The ethical circularity continued.[479]

5.2.2. The Semi-Formal Sector

Unlike, the Royal College of Surgeons (RCoS), which supported the consumer patient relationship,[480] and endorsed an exhaustive disclosure in line with the GMC guidance,[481] the BMA recognised that law and ethics had gone too far in the specification of content of medical decision-making. In doing so the formal sector had limited the medical discretion to meet the information needs of the *actual* patient. [482]

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[472] *Ibid*, 13[19]
[473] See Chapter 2, Section 4
[474] Department of Health, *Reference Guide to Consent for Examination or Treatment, Second Edition*. (DoH, 2009), 8[12]
[475] *Ibid*, 11[13]-13[19]
[476] GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008), [9]
[477] Department of Health, *Reference Guide to Consent for Examination or Treatment, Second Edition*. (DoH, 2009), 13[19]-[20]
[478] *Ibid*, 13[20]. Relying on BMA, *Medical Ethics Today: The BMA's Handbook on Ethics and Law* (BMA, 2004), Chapter 2
[479] See Chapter 3, Section 2. J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship*. (Hart Publishing, 2007), 212-213
[480] Royal College of Surgeons, *Good Surgical Practice: The Royal College of Surgeons of England*. (RCoS, 2014), 41 [*3.5]*
[481] *Ibid*, 41 [*3.5.1]*. Although it is important to note that the same mandatory emphasis was not placed on the content of disclosure
[482] British Medical Association Ethics Department, *Medical Ethics Today – 3rd Edition*. (BMJI Books, 2012)., Preface & 1

> Doctors now have to prove their competence in medicine and decision making through revalidation at more stages of their careers. They are exhorted to combine traditional professional values with an ability to meet expanding patient expectations. In the past, doctors based their decisions on conscience, intuition, received wisdom and codes of practice. Now they need to use reason, analysis and knowledge of the law.[483]

The BMA recognised that increasing normativity fatally undermined the methodology of identifying material information.[484] Doctors were forced to follow procedures and process which, whilst evidence-based, were tailored to meet the needs of a hypothetical reasonable patient.[485] Whilst the characteristics of the reasonable patient may maximise outcomes, it is in reality a form of decision-making by consequentialism – those who are medically outside the expected norms are unlikely to have their particular needs sufficiently met.[486]

By attempting to construct protections to ensure the patient had the liberty (to attain the information they both needed and wanted), the law had created normative rules which operated to burden patients with all the information that they could have.[487] In achieving the aims of the law, the law had undermined the purpose of medicine; by placing unwilling patients in the decision-maker role's without the expertise of the medical profession. [488] Whilst this was framed in ethical codes as a relationship of rights and partnership, in practice, this operated to place moral responsibility overwhelmingly on the patient. The BMA categorically rejected this model, as well as decision-making by ethical formulism:[489]

> In the MEC's view, the primary focus of all professional groups should be a sense of special commitment rather than just working to a contract.[490]

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[483] *Ibid*, Preface & 1

[484] *Ibid*, Preface & 2: "Traditionally, professional ethics was what doctors defined for themselves, from their own perspective. Their duty was to work to the standards established by their peers and avoid any action that would bring the profession into disrepute. Ethics, in this sense, has always been a central concern of medicine. Doctors were expected to observe the duty to provide 'benefit' to the sick, respect confidentiality and demonstrate integrity. Such values, often labelled 'Hippocratic', are echoed in the writings of philosopher-physicians in all cultures. Through history, professional codes called on doctors to adhere to such virtues which, by constant repetition, because seen as part of what it is to be a doctor. Such traditional concepts remain relevant because doctors generally want solutions that not only make logical legal sense, but also do not contravene their intuitions about the core purpose of medicine."

[485] Even the methodology to analyse a potentially difficult situation must follow a given process. *Ibid*, 13-18.

[486] Processes grounded on value-assumptions about patient need risk excluding individuals because of their race, sexuality, gender and (dis)ability – as they do not fit within either societal or medical norms. See, R. Gilbar & J. Miola, 'One Size Fits All? On Patient Autonomy, Medical Decision-Making, and the Impact of Culture.' (2015) 23(3) *Med L Rev* 275-399

[487] British Medical Association Ethics Department, *Medical Ethics Today – 3rd Edition*. (BMJI Books, 2012), 2

[488] *Ibid*, 3

[489] The BMA argued that one way back was through the development of a theory of professionalism, which would reintegrate the therapeutic and moral virtues necessary for the caring relationship to operate: *Ibid*, 2-5. Also see, Kings Fund Report, *On Being a Doctor: Redefining Medical Professionalism for Better Patient Care.* (The King's Fund, 2001); Working Party of the Royal College of Physicians of London, *Doctors in Society: Medical Professionalism in a Changing World*. (Royal College of Physicians, 2005)

[490] *Ibid*, 5-6

This was reflected in their advice to doctors about information disclosure.

(i) The BMA pushing back against normativity

The BMA argued that:

> The effect of the *Chester* case is that doctors who fail to warn patients about material risks associated with treatment may be open to negligence claims should those risks materialise, despite the exercise of all proper care and skill in carrying out the operation, and despite the fact that the patient admits that they would have been prepared to run the risk on a future occasion.[491]

The BMA criticised the GMC for facilitating the a binary relationship which encouraged defensive practices. Instead, the BMA encouraged doctors to focus on the therapeutic needs of the particular patients.[492] Rather than disclosing an exhaustive list of relevant factors, which had the potential to abandon patients to their decision-making, doctors should instead provide targeted advice to patients.

> It is not sufficient for doctors simply to provide patients with a list of alternatives from which to select their preferred option. In seeking treatment, patients are generally looking for their doctor's advice about which procedure is likely to be the most effective or appropriate for them from a clinical perspective. Failing to give this advice can be as unhelpful as failing to offer any information about possible alternatives to the treatment proposed.[493]

The BMA endorsed the re-adoption of an ongoing medical duty to provide targeted clinical advice.[494]

> Doctors should presume that patients want to be well informed and should volunteer information of the type that is necessary for patients to make informed choices.[495]

They argued that in reality, for the majority of patients, disclosure will likely require the doctor to: (1) inform the patient about significant risks inherent in the treatment, (2) inform the patient about risks that may be particularly important to the individual, (3) inform the patient of the risks and benefits of alternatives and of non-treatment.[496] Understanding information was for a global therapeutic benefit,

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[491] *Ibid*, 66
[492] *Ibid*, 61
[493] *Ibid*, 66
[494] *Ibid*. See Chapter 2, Section 2. *Ibid*, 69. Relying on: J.K. Mason & G.T. Laurie, *Mason and McCall Smith's Law and Medical Ethics*, (Oxford University Press, 2011), 108
[495] *Ibid*, 66. Referencing, *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871; *Pearce v United Bristol Healthcare NHS Trust* (1999) 48 BMLR 118
[496] *Ibid*, 69

rather than for the exclusive need to ensure a formulistic informed consent.[497] It was therefore more important to ensure an actual understanding, rather than disclosure an exhaustive content of information. However, this content of information could be rebutted according to the needs or preferences of the actual patient. In endorsing the therapeutic telos of disclosure, and the sociological process of decision-making the BMA implicitly endorsed the movement back to a *Bolam*-like standard.[498] Perhaps, recognising that this went against the legal and ethical zeitgeist, the BMA warned about the importance of meticulous recording of the logic of their decision.[499] Despite the BMA's push-back, the next section will argue that adoption of the rhetoric of consumerism became the dominant reaction to the *Chester* judgement in practice.

5.3. Medical decision-making in practice

This section will argue that the confusion about the appropriate medical relationship, within the legal and ethical rules, manifested as defensive decision-making in practice.[500] It will argue that poor facilitation of individual models, and the incompatibility between models, of autonomy (primarily a liberal and authentic model), within normative rules, led to confusion about the purpose and therefore the method to identify material information. However, unlike the previous period, where information was limited to providing a content of additional 'significant risks,' doctors were now regularly providing an exhaustive disclosure of any relevant information about diagnostic tests and treatments.[501]

This section will go on to argue that formulaic and exhaustive disclosures resulted in patients perceiving consent as a bureaucratic process, and as a means to an end, rather than facilitating an autonomous choice.[502] Exhaustive disclosures made understanding, to a sufficient standard for an autonomous choice, unachievable for a significant proportion of patients. Those who could understand the minutiae of risks were sometimes unable to marshal this information to make balanced choices; thus, preventing them from making rational decisions. This disclosure process also failed to meet the information needs of individual patients; undermining their ability to make authentic decisions. Those patients who subsequently made the choice to waive information were ignored and had information forced upon them by doctors as a way to avoid potential liability. The studies identified that the majority of patients did

[497] *Ibid*, 61 & 64-65
[498] *Ibid*, 65: "Clinicians should be aware that they may be potentially negligent in law if they only provide information patients, for the purposes of gaining consent, immediately before a surgical or day procedure, as this is likely to deprive patients of the opportunity to fully absorb the information, understand the nature and purpose of the procedure, and ask questions. Consent obtained in such circumstances may not, therefore, be adequately informed and, as a consequence, may be invalid."
[499] *Ibid*, 71-72
[500] R. Heywood, 'Excessive Risk Disclosure: The Effects of the Law on Medical Decision-Making,' (2005) 7 *Med L Int* 93-112.
[501] See Chapter 4, Section 3
[502] For example, A. Akkad, *et al*, 'Patients' Perceptions of Written Consent: Questionnaire Study.' (2006) 333(7567) *BMJ* 528, 529

not want the responsibilities of the consumer-patient in a shared decision-making process.[503] These findings add weight to the global argument of this thesis: that normative rules in the law of negligence encouraged a formulism which failed to ensure a model of informed consent in practice and undermined patient liberty.

The harms created by normative rules resulted in a small proportion of practitioners, again, rejecting the consumer relationship and continuing to provide information to meet the therapeutic needs of the actual patient. The chapter concludes by arguing that confusion about the ethical basis of disclosure (within normative rules) fractured medical decision-making both horizontally: in relation to the factors which are relevant to achieve autonomous choice, and vertically: as to the purpose of disclosure.

5.3.1. Normative rules: encouraging defensive practice

The studies identified illustrated that the majority of doctors had implicitly recognised that the consumer relationship had been adopted into law;[504] as such, the patient controlled the values which dictated the materiality of information and doctors were obliged to ensure an informed consent.[505] For example, Jamjoon *et al* identified, 79% of doctors (n=148) thought that the purpose of consent was to respect patient autonomy.[506] The studies utilised the concept of SDM to describe the process of identifying material information, however, the models afforded patients the power to make the final decision on materiality.[507] Montgomery *et al* argued that:

> The shared model of medical decision-making, in which clinicians and patient exchange information reveal preferences for treatment, and jointly come to a decision, is now promoted in preference to other models.[508]

Bugge *et al* also stated:

[503] Perhaps following the model propounded by the GMC (GMC, *Consent: patients and doctors making decisions together*. (GMC, 2008)), which drew it's conceptualisation of the optimum relationship from C. Charles, *et al*, 'Shared Decision Making in the Medical Encounter: What does it mean? (Or it takes at least Two to Tango).' (1997) 44 *Soc Sci Med* 681-692; C. Charles, *et al*, 'Decision-Making in the Physician-Patient Encounter: Revisiting the Shared Treatment Decision-Making Model.' (1999) 49 *Soc Sci Med* 681-692

[504] R. Heywood, *et al*, 'Informed consent in Hospital Practice: Health Professionals' perspectives and legal reflections.' (2010) 18(2) *Med L Rev* 152-184, 153 & 156

[505] See Appendix 3

[506] A. A. B. Jamjoom, *et al*, 'Anaesthetists' and Surgeons' Attitudes towards Informed Consent in the UK: An Observational Study.' (2010) 11(2) *BMC Medical Ethics* 1-7, 2-3

[507] See for example, A. Edwards, *et al*, 'Shared Decision Making and Risk Communication.' (2005) 55 (510) *Br J Gen Prac* 6-13; A. Edwards & G. Elwyn, 'Inside the Black Box of Shared Decision Making: Distinguishing between the Process of Involvement and who makes the Decision.' (2006) 9 *Health Expectations* 307-320; M.C. Weiss & T.J. Peters, 'Measuring Shared Decision Making in the Consultation: A Comparison of the OPTION and Informed Decision Making Instruments.' (2008) 70 *Patient Education and Counseling* 79-86; D. Burton, *et al*, 'Shared Decision-Making in Cardiology: Do Patients want it and do Doctors provide it?' (2010) 80 *Patient Education and Counselling* 173-179

[508] A.A. Montgomery, *et al*, 'Two Decision Aids for Mode of Delivery among Women with Previous Caesarean Section: Randomised Controlled Trial.' (2007) 334(7607) *BMJ* 1305, 1305

> Perhaps the most widely advocated model of patient participation in decision-making is shared decision-making model described by Charles *et al*. […]. [T]here is a reasonable consensus that, broadly speaking, decision makers should consider all the relevant treatment options and their associated outcomes in light of each individual patient's values, where patients' values comprise their "informed and considered attitudes towards health states that might be affected by the decision; attitudes towards the risks associated with the relevant options; willingness to make trade-offs over time; and position in relation to other value-relevant issues involved in the decision.[509]

Heywood *et al*, too identified that patients felt that power in the medical relationship had shifted so doctors were providing information to facilitate their understanding.[510] This was demonstrated in patient's feeling empowered to ask questions and seek further information.[511]

It is debateable, however, whether this normative influence flowed directly from law, or vicariously through ethical guidance. There is a plethora of evidence that the majority of doctors adopted the binary position within the GMC guidance, due to the particular pattern of confusion about the theoretical basis of their medical decision-making.[512] Heywood *et al*, for example, implicitly exposed the origin of the model of decision-making, in his study on final year medical students (n=162). The study found that the most important normative source for decision-making was 'ethical obligations' (with 81.5% of the students rating it very important, and 17.9% rating it as important).[513] Law was seen as relatively less important (with 62.3% rating it very important and 37.7% rating it as important). Perhaps because of

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[509] C. Bugge, *et al*, 'The Significance for Decision-Making of Information that is not exchanged by Patients and Health Professionals during Consultations.' (2006) 63 *Soc Sci Med* 2065-2078, 2066. See also, C. Charles, *et al*, 'Shared Decision Making in the Medical Encounter: What does it mean? (Or it takes at least Two to Tango).' (1997) 44 *Soc Sci Med* 681-692; C. Charles, *et al*, 'Decision-Making in the Physician-Patient Encounter: Revisiting the Shared Treatment Decision-Making Model.' (1999) 49 *Soc Sci Med* 681-692

[510] R. Heywood, *et al*, 'Patient Perceptions of the Consent Process: Qualitative Inquiry and Legal Reflection.' (2008) 2 *Professional Negligence* 104-121, 112

[511] *Ibid*, 112: "Patient No 8: You see the consultants these days are very different to what they used to be, they talk to you and Mr X is especially good. When you are talking to Y she treats you like a friend. She is also very good indeed […]."

[512] See for example, A. Edwards, et. al. 'Shared decision making and risk communication.' (2005) 55 (510) *Br J Gen Prac* 6-13; C. Chew-Graham, *et al*, 'Informed Consent? How do Primary Care Professionals Prepare Women for Cervical Smears: A Qualitative Study.' (2005) 61 *Patient Education and Counseling* 381-388; C. Bugge, *et al*, 'The Significance for Decision-Making of Information that is not Exchanged by Patients and Health Professionals during Consultations.' (2006) 63 *Soc Sci Med* 2065-2078; B. Parsons, *et al*, 'A Review of Recorded Information given to Patients starting to take Clozapine, a Key Component of Information Consent.' (2007) 33 *J Med Ethics* 564-567; R. Heywood, *et al*, 'Medical Students' Perceptions of Informed Consent: Qualitative Inquiry and Legal Reflections on Clinical Education.' (2007) 23(3) *Professional Negligence* 151-164; M.C. Weiss & T.J. Peters, 'Measuring Shared Decision Making in the Consultation: A Comparison of the OPTION and Informed Decision Making Instruments.' (2008) 70 *Patient Education and Counseling* 79-86; J. Kai, *et al*, 'Challenges of Mediated Communication, Disclosure and Patient Autonomy in Cross-Cultural Cancer Care.' (2011) 105 *British Journal of Cancer* 918-924; E.J. Robinson, *et al*, 'Do the Public Share Practitioners' View about the Best Evidence?' (2012) 88 *Patient Education and Counseling* 325-329

[513] R. Heywood, *et al*, 'Medical Student's Perception of Informed Consent: Legal Reflections on Clinical Education.' (2007) 23(3) *Professional Negligence* 1-22, 8: (<http://shura.shu.ac.uk/5764/1/Macaskill_Medical_Students%27_Perceptions_of_Informed_Consent.pdf>)

the conceptual uncertainty present within the law at the time, which meant it could not be readily understood, or relied upon, to avoid liability.[514] The qualitative element of the survey identified what students (n=162) thought was ethically necessary for an informed consent, this included: risks (n=113), understanding, (n=82), Patients Agreement (n=73), Benefits (n=60), Alternatives (n=22).[515] The focus on ensuring the facilitative requirement of understanding, rather than a content of information, is indicative of reliance on regulatory, rather than legal requirements – as there was no specific legal duty to ensure understanding at the time.[516] Whilst doctors seemed to be following the formal sectors guidance[517] (along the lines anticipated by the House of Lords)[518] the rules in the guidance were seen as confusing by doctors.[519] For example, Heywood *et al* undertook 20 interviews with medical practitioners (8 consultants, 3 registrars, 6 senior house officers and 6 nurses) who undertook information disclosure,[520] to identify how they made decisions about materiality.[521] As Heywood *et al* identified, doctors found that medical guidance was over-complex, required an impractical model of consent, and eroded the scope for medical discretion.[522] In relation to consent forms, one practitioner stated:

> You have to pay attention to them but the trouble is sometimes they are not totally practical […] the danger is that people are overwhelmed with paper and don't read them anyway. They do it to cover themselves so that if anything goes wrong it is the doctors' fault that they didn't follow the guidelines so to speak. That doesn't help at the end of the day what it comes back to is does the patient understand what is being done to them.[523]

The threat of legal liability should not be underestimated as a coercive force on doctor's medical discretion.[524] Heywood *et al* identified that doctors felt 'that the law forces their hand to disclose.'[525] This fear of litigation caused doctors to adopt defensive approaches to disclosure.[526] Types of

[514] *Ibid*, 15
[515] *Ibid*, 15-16
[516] *Al Hamwi v Johnston and Another* [2005] All ER (D) 278; *Ibid*, 15-17
[517] *Ibid*, 8
[518] For example, *Chester v Afshar* [2004] UKHL 41, per Lord Walker, at [58]
[519] R. Heywood, *et al*, 'Informed Consent in Hospitals Practice: Health Professions' Perspectives and Legal Reflections.' (2010) 18 *Med L Rev* 152-184, 158
[520] *Ibid*, 153-155
[521] Whilst this is a relatively small study the detailed nature of the qualitative interviews provides insight into the influence of normative rules on decision-making – thus heavy reliance can be placed on the data. *Ibid*, 156
[522] *Ibid*, 170
[523] *Ibid*, 170
[524] *Ibid*, 167
[525] *Ibid*, 167-168: "[…] defensive medicine is defined as exposing the patient to excessive information about risks and alternatives that may be unnecessary in the circumstances and refusing to acknowledge the patient is entitled to waive their right to certain information, practices that are justified on the grounds of the need to avoid legal liability."
[526] O. Ortashi, *et al*, 'The Practice of Defensive Medicine among Hospital Doctors in the United Kingdom.' (2013) 14(42) *BMC Med Ethics* 1-6. Also see, A. O'Dowd, 'Doctors Increasingly Practice "Defensive" Medicine for Fear of Litigation, says Regulator.' (2015) 350 *BMJ* 87; N. Summerton, 'Trends in Negative Defensive Medicine within General Practice.' (2000) 50(456) *Br J Gen Pract* 565-566; N. Summerton, 'Positive and Negative Factors in Defensive Medicine: A Questionnaire

formulistic decision-making were also encouraged by the introduction of pro forma consent forms (e.g. by the DoH) which encouraged listing information:

> Now I object in many ways to the standard consent form that this hospital has ... the consent form is a generic consent form, which is actually misleading ... but the Trust, as advised by the lawyers, have said that we have to use this ridiculous form. In a sense the consenting is a number of events ... but because of the form I think it is nothing to do with consent. Now that signing of the consent form might be me saying to patient "sign this consent form." The radiographers will be entirely happy if there is a signature on the form even if I haven't gone through the proper process of consenting.[527]

Ortashi *et al* identified that 78% of respondents (n=204) reported practicing at least one form of defensive medicine.[528] Some doctors (9%) said that they would refuse to treat high risk patients. This follows the trend of litigation in the US, (following the adoption of the consumer model) where 96% of doctor's practiced defensive medicine.[529] In the UK, 90.6% thought that legal claims against doctors were increasing, and 14.2% had direct experience of being sued.[530] This was reflected in Heywood et al's qualitative work, where one practitioner stated:

> […] I think that there is argument that we feel obliged to tell patients everything because you are worried that if you don't say it, and then god forbid the 1:1000000 risk happens, that they are going to say to you "well you never said that." So I suppose there is a bit of defensive medicine going on there.[531]

What is clear is the reasoning within *Chester (*and the subsequent line of cases) and the formal sector had rhetorically shifted attitudes and asserted a preference for facilitating the consumer relationship. However, the normative guidance had failed to clarify the standard of materiality for information disclosure to ensure an informed consent.[532] Instead, the adoption of SDM (as a euphemism of the

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Study of General Practitioners. (1995) 310(6971) *BMJ* 27-29; C. Vincent, 'The Impact of Litigation on Obstetricians and Gynaecologists.' (1994) 14(6) *Journal of Obstetrics and Gynaecology* 381-387

[527] R. Heywood, *et al*, 'Informed Consent in Hospitals Practice: Health Professions' Perspectives and Legal Reflections.' (2010) 18 *Med L Rev* 152-184, 158-159

[528] *Ibid*, 3-4

[529] M.K Sethi, *et al*, 'Incidence and Costs of Defensive Medicine among Orthopaedic Surgeons in the United States: A National Survey Study.' (2012) 41(2) *Am J Orthop* 69-73

[530] O. Ortashi, *et al*, 'The Practice of Defensive Medicine among Hospital Doctors in the United Kingdom.' (2013) 14(42) *BMC Med Ethics* 1-6, 3-4

[531] R. Heywood, *et al*, 'Informed Consent in Hospitals Practice: Health Professions' Perspectives and Legal Reflections.' (2010) 18 *Med L Rev* 152-184, 168

[532] *Ibid*, 172: "The findings here reflect the view that doctors are also unsure about what to disclose in practice, although whether or not this confusion is caused by the law remains uncertain. For clinicians to be influenced by the law's uncertainty it would have to be proved that they know something about it and the indications are that the medical practitioners in the study only have a vague understanding of what the law says. Thus, it is possible that their confusion about what to disclose comes from elsewhere, perhaps stemming from uncorroborated collegial anecdotes about disclosure."

consumer relationship) acted as a mechanism to cloud the model of autonomy information disclosure was actually facilitating and thus the methodology that should be adopted in practice.[533] As El Wakeel *et al* argued, '[t]he legal requirement is vague and provides little help in predicting when consent is satisfactory.'[534] Jones, for example, had argued:

> Doctors are familiar with the principle of informed consent as an ethical requirement of practice, though they are less familiar with the legal ramifications. The underlying ethical principle of informed consent is that one should respect the patient's autonomy.[535]

Some studies identified that the ideal type of disclosure would provide information to a subjective standard to ensure and authentic understanding, perhaps in line with the preference for this model in the GMC guidance, however, this ethical model was seldom realised in practice.[536] The data showed little change in the types of biomedical information that was being disclosed compared to the previous period (which required a prudent patient standard of disclosure).[537] Doctors failed to delineate between disclosing information according to objective need (for a liberal autonomous choice)[538] and information that patient's wanted (for an authentic choice) and instead simply disclosed all potentially relevant information in an exhaustive disclosure process.[539] Consent in practice became bureaucratic, where doctors would run through a long list of information necessary to achieve, what the doctor perceived as, a legally valid consent: [540] As Heywood *et al* argued:

> The medical practitioners in this study do not perceive consent as being just a 'medico-legal requirement.' They demonstrate a commitment towards keeping the patient informed and look positively on the concept of shared-decision making. However, the language used by the participants reflects a view that the detailed nature of the consent form stifles some of the professional discretion that is needed in order to render consent a process in which the patient is truly involved. The medical practitioners perceived the over-complex nature of the standard

[533] For example, see A. Edwards, 'Inside the Black Box of Shared Decision Making: Distinguishing between the Process of Involvement and who makes the Decision.' (2006) 9 *Health Expectations* 307-320, 307; R. Heywood, *et al*, 'Informed Consent in Hospitals Practice: Health Professionals' Perspectives and Legal Reflections.' (2010) 18 *Med L Rev* 152-184, 156; D. Feldman-Stewart, *et al*, 'Practical Issues in Shared Decision Making.' (2000) 3 *Health Expectations* 46

[534] H. El Wakeel, *et al*, 'What do Patients Really Want to Know in an Informed Consent Procedure? A Questionnaire-Based Survey of Patients in the Bath Areas, UK.' (2006) 32 J *Med Ethics* 612-616, 612

[535] M. Jones, 'Informed Consent and Other Fairy Stories.' (1999) 7 *Med L Rev* 123, 123

[536] C. Bugge, *et al*, 'The Significance for Decision-Making of Information that is not exchanged by Patients and Health Professionals during Consultations.' (2006) 63 *Soc Sci Med* 2065-2078, 2066

[537] Chapter 4, Section 3

[538] See Chapter 3, Section 3: An objective standard of disclosure would be used to facilitate a liberal autonomous choice in the patient's best therapeutic interests.

[539] R. Heywood, *et al*, 'Informed Consent in hospital practice: health professionals' perspectives and legal reflections.' (2010) 18(2) *Med L Rev* 152, 170-171. A similar warning was given some years earlier by M. Jones, 'Informed Consent and Other Fairy Stories.' (1999) 7 *Med L Rev* 103, 125

[540] O. Ortashi, *et al*, 'The Practice of Defensive Medicine among Hospital Doctors in the United Kingdom.' (2013) 14(42) *BMC Med Ethics* 1-6, 3-4.

> NHS form as being driven by the law and believe this has turned consent into a regimented and bureaucratic procedure.[541]

For example, in relation to decisions about material risks Heywood *et al* found that doctors continued to disclose using percentage threshold, albeit risks were considered material if they manifest at 1% or lower; this information was provided to the patient irrespective of what the patient wanted to know.[542] The authors argued that the proliferation of a 1% threshold in medical journals resulted from the emphasis of the 1-2% risk of cauda equina syndrome in *Chester*.[543] Jamjoon *et al*, similarly, identified that 75% of respondents agreed with the statement that the threshold of disclosure was at 1%,[544] whilst 55% of respondents agreed it was 1 in 1000 and 45% of respondents agreed it was 1 in 10'000.[545] These authors argued that this attitude correlates with the exhaustive requirements in the GMC guidance which stated: 'you must tell patients if an investigation or treatment might result in a serious adverse outcome, even if the likelihood is very small.'[546]

In relation to the types of information that are considered material Jamjoon *et al* found that the majority of surgeons and anaesthetists surveyed agreed with statements that required an exhaustive content of information to be disclosed to patients. For example, doctors would always disclose: (1) what the procedure entails (95% and 83% respectively); (2) what the procedure aims to achieve (97% and 75%); (3) additional procedures that are likely to be necessary (95% and 83%); (4) a realistic outcome/results for the procedure (95% and 83%); (4) alternative forms of treatment (75% and 85%), the possibility of death (83% and 65%); the possibility of significant disability (86% and 70%).[547]
This defensive disclosure was seen as ethically justified as patients were perceived as a consumer of information, who would inevitably want an exhaustive disclosure, which included all the potential risks, benefits and outcomes. [548] For example, one doctor in the Heywood *et al* study stated:

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[541] R. Heywood, *et al*, 'Informed Consent in Hospital Practice: Health Professionals' Perspectives and Legal Reflections.' (2010) 18(2) *Med L Rev* 152, 170-171
[542] *Ibid*, 175
[543] *Ibid*, 160: "Consultant No 2: Yes, I mean let us say for example the consent for a hernia operation […] the threshold in percentage terms for informed consent is something like […] 2% OK. But then if you get a significant complication that is a lot rarer but is well recognised then you have to tell them that as well. Moving away from hernias for the moment […] I think the best example might by bowel surgery where you have got the risk of patient nerve damage which might be perceived to be less than 1% for example. I can't remember off the top of my head […] but there are certain operations that are well known to cause a very severe problem but only very rarely and you need to spell those out."
[544] A. A. B. Jamjoom, *et al*, 'Anaesthetists' and Surgeons' Attitudes towards Informed Consent in the UK: An Observational Study.' (2010) 11(2) *BMC Medical Ethics* 1-7, 5. In support A.P. Armstrong, *et al*, 'Informed Consent: Are We Doing Enough?' (1997) 50 *Br J Plas Surg* 637-640; K.C. Calman, 'Communication of Risk: Choice, and Trust.' (2002) 360 *Lancet* 166-168.
[545] *Ibid*, 5. Relying on GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008). Also see, The Association of Anaesthetists of Great Britain and Ireland, *Consent for Anaesthesia*. (AAGBI, 2006)
[546] *Ibid*, 5. Relying on GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008)
[547] *Ibid*, 4
[548] R. Heywood, *et al*, 'Medical Student's Perception of Informed Consent: Legal Reflections on Clinical Education.' (2007) 23(3) *Professional Negligence* 1-22, 15-16: (<http://shura.shu.ac.uk/5764/1/Macaskill_Medical_Students%27_Perceptions_of_Informed_Consent.pdf>)

> […] informed consent I think it is absolutely vital, it is one of the things that as a nurse practitioner I try to think of as sort of one of my babies really. I try to make sure that when I am taking consent from a patient that I think about all the things that I would want to know myself if that was me sat there. I think it is absolutely vital really and not just to protect us really but more so for the patient ... that they are making an informed choice about what they are agreeing to be involved in. Because I know that *I would want to receive all the relevant information*.[549] [Author's emphasis]

Another practitioner stated:

> […]. The process of informed consent is integral to our practice […] you need to tell them about the risk of perforation, the risk of death, the risk of a bleed and other associated problem as well, such as a stroke, myocardial infarction, post endoscopic complications such as pain. *The whole range must be explained.*[550] [Author's emphasis]

Instead, the consent process was a tick-boxing exercise, where equal weight was applied to all potentially material options and factors.[551] Abandoning of the values of the actual patient (for either an authentic or therapeutic disclosure) and the adoption of the hypothetical patient construct, was similarly illustrated by the Jamjoon *et al* study; where the majority of doctors (n=148) disagreed with the statement that information disclosure was sometimes unnecessary.[552] Despite the wealth of evidence[553] some doctors adopted the consumer rhetoric and thought patients always understood (46% and 38%) and always remembered (27% and 26%) information disclosure.[554] Disclosure to secure consent was seen as an event being done to patients.[555] Even when patients waived their right to information their choices were potentially ignored.

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[549] R. Heywood, *et al*, 'Informed Consent in Hospital Practice: Health Professionals' Perspectives and Legal Reflections.' (2010) 18 *Med L Rev* 152-184, 156

[550] *Ibid*, 159

[551] This is a similar argument made in relation to the approach to the balance sheet in best interest's decision-making i.e., where all values become morally equitable in weight when utilised in a formulaic way. See, C. Kong, J. Coggon, M. Dunn, A. Ruck-Keene, 'An Aide Memoire for Balancing Act? Critiquing the 'Balance Sheet' Approach to Best Interest Decision-Making.' (2020) 28(4) *Med L Rev* 753-780. See also, C. Kong, 'Beyond the Balancing Scales: The Importance of Prejudice and Dialogue In *A Local Authority v E & Ors.*' (2014) 26 *Child & Fam* LQ 216. For a philosophical critique of commensurability see: J. Waldron, 'Fake Incommensurability: A Response to Professor Schauer' (1994) 45 *Hastings LJ* 813

[552] Doctors said that they would never withhold information due to patient circumstances (88%), they did not think that informing patients about harmful risks may be harmful or worrying (66% and 52%) and did not think that patients may be confused by too many options (66% and 42%): A. A. B. Jamjoom, *et al*, 'Anaesthetists' and Surgeons' Attitudes towards Informed Consent in the UK: An Observational Study.' (2010) 11(2) *BMC Medical Ethics* 1-7, 4

[553] See Chapter 3, Section 5, Chapter 4, Section 3

[554] A. A. B. Jamjoom, *et al*, 'Anaesthetists' and Surgeons' Attitudes towards Informed Consent in the UK: An Observational Study.' (2010) 11(2) *BMC Medical Ethics* 1-7, 4

[555] R. Heywood, et al, 'Informed Consent in Hospitals Practice: Health Professions' Perspectives and Legal Reflections.' (2010) 18 *Med L Rev* 152-184, 181-182; K Williams, 'Comprehending Disclosure: Must Patients Understand the Risks They Run?' (2000) 4 *Med L Int* 97, 101

> Consultant No 3: I don't like the concept of withholding information because I think that that necessarily is not totally helpful. There maybe situations where the patients' intelligence or insight or illness doesn't allow them to fully understand it and you have to talk to the relatives more about it but I don't commonly and regularly withhold information.[556]

The failure to respect patient refusal is a prime example of the requirement of a substantive autonomy as the basis of respect to treatment. Again, this ethical positionality undermined the negative liberty rights of the patient.[557] For example, one doctor stated:

> Consultant No 8: No in fact there are times when the patient says "I don't want to know that." And I say, "I am sorry I am going to tell you."[558]

The focus on achieving a disclosure meant that other facilitative duties, such as ensuring a standard of understanding, or tailoring communication were at times, however, overlooked.[559] For example, Langseth *et al*, identified that doctors (10%) rarely checked understanding during consultations (n=49).[560] This could indicate that the legal focus on a standard or content of information did have at least some impact on the mind of doctor's. Albeit focus on the specifics, rather than the ethics undermining the law, acted counter-initiatively to undermine a patient's ability to make informed choices. As Heywood *et al* argued: '[h]ealth care professionals may well view consent as a mutual process, but these findings only portray the views of one party within this transaction.'[561]

5.3.2. The effect of defensive disclosure on patients

This sub-section will argue, first, that exhaustive disclosure practices manifested as a form of defensive medical practice. In antithesis to the purpose of the normative rules, these practices undermined the ability of the average patient to have an authentic autonomous choice; as the excessive content of disclosure overloaded patients and caused them to misunderstand.[562] This resulted in patients believing that the primary function of consent processes was to allow doctors to assume control of the medical

[556] *Ibid*, 160
[557] See Chapter 3, Section 2
[558] R. Heywood, *et al*, 'Informed Consent in Hospitals Practice: Health Professions' Perspectives and Legal Reflections.' (2010) 18 *Med L Rev* 152-184, 167
[559] Academic commentators over the Atlantic warned of this development: C. Jones, 'Autonomy and Informed Consent in Medical Decision-making: Towards a New Self-fulfilling Prophecy (1990) 47 *Wash & Lee L Rev* 379, 381
[560] M.S. Langseth, *et al*, 'Quality of Decision Making is related to Decision Outcome for Patients with Cardiac Arrhythmia.' 92012) 87 *Patient Education and Counselling* 49-53, 51-52
[561] R. Heywood, *et al*, 'Informed Consent in Hospitals Practice: Health Professionals' Perspectives and Legal Reflections.' (2010) 18 *Med L Rev* 152-184, 157
[562] A.A. Montgomery, *et al*, 'Two Decision Aids for Mode of Delivery among Women with Previous Caesarean Section: Randomised Controlled Trial.' (2007) 334(7607) *BMJ* 1305

relationship (65-71%) and protect hospitals (48%).[563] Second, some patients who had capacity to understanding the content of information were unable to employ this understanding as the basis of making an independent and/or balanced choice.[564] For example, one third of patients who received a full disclosure deferred the decision-making role to their doctor.[565] If patients refused information, their waiver was often ignored.[566] Third, from close reading of the data, there exists correlation between medical confusion, defensive practices, and the failure of the law and ethics,, to appropriately define both the limits of autonomy and/or a complementary model of the therapeutic privilege.[567] Fourth, a significant minority of patients rejected the role of the consumer patient, in making decisions, and would rather have information in their best therapeutic interests.[568] This section argues that the normative construction of the 'consumer patient' model of care, failed to respect the patients' autonomous wishes, about either the content of information they received, or the basis of their consent. Normativity within the law, has acted to undermine the principle of respecting patient autonomy in practice – this leads the author to suggest rules relating to autonomy may encourage a formulism which is self-defeating.

(i) Understanding an exhaustive disclosure

There is evidence to show that whilst patients had legal capacity they could not understand the full content of technical information necessary to have a full understanding of an exhaustive disclosure. For example, El Wakeel *et al* (2006) utilised a questionnaire on a large (n=732) number of women in an obstetrics and gynaecology teaching hospital.[569] After receiving information one in ten patients reported that they did not know what they agreed to when they signed (74/732) a consent form.[570] A larger proportion (40%) of patients signed the consent form so could have the operation (with 12% viewing the form as just another piece of paper), which implied that disclosure had some level of coercive

[563] A. Akkad, *et al*, 'Patients' Perceptions of Written Consent: Questionnaire Study.' (2006) 333 (7567) *BMJ* 528, 528-529. Also, R. Heywood, *et al*, 'Patient Perceptions of the Consent Process: Qualitative Inquiry and Legal Reflection. (2008) 2 *Professional Negligence* 104-121, 111-112

[564] *Ibid*

[565] C.M. Gaston, 'Information Giving and Decision-Making in Patients with Advanced Cancer: A Systematic Review.' (2005) 61 *Soc Sci Med* 2252-2264, 2252. Although, this thesis would disagree with the authors conclusion that 'almost all patients expressed a desire for full information.'

[566] R. Heywood, *et al*, 'Informed Consent in Hospitals Practice: Health Professionals' Perspectives and Legal Reflections.' (2010) 18 *Med L Rev* 152-184, 167

[567] R. Heywood, *et al*, 'Patient Perceptions of the Consent Process: Qualitative Inquiry and Legal Reflection.' (2008) 2 *Professional Negligence* 104-121, 113-114. Also see, R. Heywood, 'Excessive Risk Disclosure: The Effect of Law on Medical Practice.' (2005) 7 *Med L Int* 93-112, 104; R. Mulheron, 'The Defence of Therapeutic Privilege in Australia' (2003) 11 *JLM* 201, 211

[568] For example, some patient preferred to delegate decisions: K. Beaver & K. Booth, 'Information Needs and Decision-Making Preferences: Comparing Findings for Gynaecological, Breast and Colorectal Cancer.' (2007) 11 *European Journal of Oncology Nursing* 409-416; some patients would rather avoid information after a cancer diagnosis: L. Furber, *et al*, 'Patients Experiences of an Initial Consultation in Oncology.' (2015) 20(2) *British Journal of Health Psychology* 261-273

[569] H. El Wakeel, *et al*, 'What do Patients Really Want to Know in an Informed Consent Procedure? A Questionnaire-Based Survey of Patients in the Bath Areas, UK.' (2006) 32 J *Med Ethics* 612-616, 612: "A truly informed consent requires full disclosure of all relevant information by the doctor, competence of the patient to appreciate what the information signifies, understanding of the facts and issues by the patient and a voluntary non-coerced choice by the patient leading to an autonomous authorisation for treatment. Each of these conditions is hard to fulfil making a fully informed consent seldom, if ever possible."

[570] This is especially concerning as it raises questions about whether the women actually understood the nature of the decision that they were making enough to give the medical professionals a defence for the crime of battery. *Collins v Wilcock* [1984] 3 All ER 374

influence, and 46% believed that the main function of signing the consent form was to protect hospitals. Indeed, two-thirds (68%) of patients thought the process of consent gave doctors control over what happened.[571] All these women would have capacity to consent, but would perhaps not be providing an informed consent to treatment.[572] Gunfeld *et al*, similarly, found that of the women undergoing advanced breast cancer treatment (n=107): 14% could not recall discussions about management of their cancer, and levels of recall about treatment and adverse side effects to treatment were generally poor.[573] Only around half of patients could recall: what chemotherapy they were receiving (59%), the purpose of management (50%), and only 37% remembered any other options for treatment. In relation to side effects, only 56% of patients recalled hair-loss, 40% nauseas, 21% fatigue. Patients also retained information in line with their own values, rather than attaining an objective appreciation of material information. For example, patients receiving second line chemotherapy placed much more emphasis on hope (43%) and placed significantly less emphasis on side effects.[574]

Heywood *et al*, qualitative study also identified that patients struggled to appreciate and rationally understand information.[575] The majority of the patients surveyed (n=8) were unable to comprehend information at the time it was disclosed to them. One reason identified was because of their psychological inability to understand, which patients perceived as not being intelligent enough.[576] Other patients could not understand information because of circumstantial factors, for example, they became 'frightened and preoccupied with their own thoughts that they often just 'shut off' from what is being said.' Patients reported that once cancer was mentioned they would stop listening.[577]

Heywood, in earlier work, (adopted Miller's typology of patient coping mechanisms, which)[578] described patients as 'blunters' who avoid information or 'monitors' who seek out information.[579] What these groups indicate is that patients need tailored information according to their predilection, to avoid harm. Based on this data one could suggest that it is impossible for all patients to understand the exhaustive disclosures being regularly provided by doctors. If so, patients seldom have an informed consent, and more worryingly may even be confused about the nature of the treatment which they are

[571] A. Akkad, *et al*, 'Patients' Perceptions of Written Consent: Questionnaire Study.' (2006) 333(7567) *BMJ* 528, 529
[572] At least according to the liberal and authentic models of autonomy. See Chapter 3, Section 3
[573] E.A. Grunfeld, 'Advanced Breast Cancer Patients' Perceptions of Decision for Palliative Chemotherapy.' (2006) 24(7) *Journal of Clinical Oncology* 1090, 1092
[574] *Ibid*, 1092
[575] R. Heywood, *et al*, 'Patient Perceptions of the Consent Process: Qualitative Inquiry and Legal Reflection.' (2008) 2 *Professional Negligence* 104-121, 110
[576] *Ibid*, 108: "Patient No 7: […] it sounds awful doesn't it, but not everybody is intelligent. I mean if some elderly person goes in, as I have observed from some of my clients, and they explain it to them, they haven't clue have they […] It depends on the situation really, the level of intelligence, the age […] it could be anything really."
[577] *Ibid*, 109: "Patient No 2: […] you see when they tell you have got to have this big operation, like a heart bypass or bowel cancer, your mind goes blank. I believe now that I don't really know what they told me because it goes in one ear and out of the other."
[578] S.M. Miller, 'Coping with Impending Stress: Psychophysiological and Cognitive Correlates of Choice.' (1979) 16 *Psychophysiology* 572
[579] R. Heywood, 'Excessive Risk Disclosure: The Effects of the Law on Medical Practice.' (2005) 7 *Med L Int* 93-112, 95

being provided – which could place doctors at risk of civil, or criminal liability. Heywood suggests one way to improve understanding is through more focus on achieving standards of communication.[580] However, students (47.5%) felt that they had not been trained in methods to delineate materiality of communicate (73.5%) or to correct misunderstanding (64.8%); as a result the majority of students lacked confidence dealing with informed consent in practice (58%).[581] The current requirements to achieve an informed consent were seen as problematic and the majority of students thought that the ethical requirement to ensure that patients understood for an informed consent was difficult (50%).[582]

(ii) Inability to make balanced decisions

Even if patients could attain a full understanding necessary for an informed consent this did not ensure that they would be supported, or be able to independently utilise that understanding to make a form of autonomous choice. Dixon Wood *et al*, for example, identified that some women who consented to obstetric and gynaecological surgery (n=25) felt circumstantially overwhelmed, unable to make a balanced decision, or that they did not have the information they needed to support and justify their choices.[583] Montgomery *et al* found that detailed knowledge about all potential risks may cause patients anxiety which overwhelm their ability to make a balanced judgement necessary for a type of liberal autonomous choice.[584] For example, women during this period (n=742), who presumably would have received a detailed disclosure (in line with the ethical guidance) chose to have caesarean sections more often, perhaps indicating that this caused them to place more emphasis on risks of a natural delivery due to the type or content of communications.[585] Indeed, Montgomery et al argued that that patient decision-making reflected 'medico-legal concerns about vaginal birth after previous caesarean sections, vaginal breech delivery, and foetal distress in labour.'[586] Langseth *et al*, similarly found that those patients who supposedly had the best quality SDM process i.e. one that emphasised facilitating an

[580] R. Heywood, *et al*, 'Patient Perceptions of the Consent Process: Qualitative Inquiry and Legal Reflection.' (2008) 2 *PN* 104-121, 118-119

[581] R. Heywood, *et al*, 'Medical Students Perception of Informed Consent: Legal Reflections on Clinical Education.' (2007) 23(3) *Professional Negligence* 1-22, 8: (http://shura.shu.ac.uk/5764/1/Macaskill_Medical_Students%27_Perceptions_of_Informed_Consent.pdf)

[582] *Ibid*, 8

[583] M. Dixon-Woods, *et al*, 'Why do Women Consent to Surgery, even when they do not want to? An Interactionist and Bourdieusian Analysis.' (2006) 62 *Soc Sci Med* 2742-2753, 2749: "Even in that situation I think I probably could of said no but I didn't have nothing to justify why I was saying no […]. I didn't have anything to come back with to support my decision with why I was saying no and I felt by saying, if I would have said no, then they would have frowned on me and said how can you make that decision and I hadn't got any information at all to support my decision would have been no."

[584] Chapter 3, Section 3

[585] *Ibid*

[586] A.A. Montgomery, *et al*, 'Two Decision Aids for Mode of Delivery Among Women with Previous Caesarean Section: Randomised Controlled Trial.' (2007) 334(7607) *BMJ* 1305, 1305. Relying on W. Fraser, *et al*, 'Randomized Controlled Trial on Prenatal Vaginal Birth after Caesarean Section Education and Support Programme.' (1997) 176 *Am J Obstet Gynecol* 419-425

autonomous choice, chose less invasive options.[587] Heywood *et al* too, identified consultants who struggled to ensure that patients balanced information appropriately.[588]

> Consultant No 8: I will try and put it is terms that a patient can understand. I will say "there is 1:100 chance of death from this procedure" and they will say "that is not a very big risk is it?" I will say "well I wonder […] if you were travelling on an aeroplane to America, and on the side of the aeroplane it said 'we fall out of the sky 1:100 times' would you get on the aeroplane? The answer is no, of course they wouldn't. But if they were in some war torn state of Africa and they were about to be shot and there was one plane leaving that had the same message on it, would you get on the plane? Of course you would.[589]

The inability to make balanced decisions was also identified by doctors in the Jamjoon *et al* study:

> Several anaesthetists believed that the consent process was inappropriate as information disclosed may be confusing to patients or may dissuade them from undergoing the procedure. This goes against the current guidelines and legal position that the patient should be told 'what a reasonable patient in the patient's position would want to know.'[590] There may be some evidence to support such views as a study showed that up to 40% of patients feel more anxious after being informed of the risks of their procedure and there are reports that conveying rare complications will lead to an information overload of which there is no guarantee that the patient will retain or correctly understand the risk information.[591]

As patient decision-making often occurs in novel contexts, which patients are unlikely to have experienced, they are unlikely to have available pre-existing applicable or rational hierarchy of values as a basis of decision-making, or the ability to create them in the immediate circumstances. Without this value prism on which to interpret information[592] patients may not be able to either appreciate or rank those risks to be able to make a type of authentic decision.[593]. This is exacerbated if patients are

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[587] M.S. Langseth, *et al*, 'Quality of Decision Making is related to Decision Outcome for Patients with Cardiac Arrhythmia.' (2012) 87 *Patient Education and Counselling* 49-53, 49, 51-52

[588] R. Heywood, *et al*, 'Informed Consent in Hospitals Practice: Health Professions' Perspectives and Legal Reflections.' (2010) 18 *Med L Rev* 152-184, 164-167

[589] *Ibid*, 166

[590] *Pearce v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118 (CA)

[591] A. A. B. Jamjoom, *et al*, 'Anaesthetists' and Surgeons' Attitudes towards Informed Consent in the UK: An Observational Study.' (2010) 11(2) *BMC Medical Ethics* 1-7, 4

[592] A. Miles, *et al*, 'The Effect of Information about False Negative and False Positive Rates on People's Attitudes towards Colorectal Cancer Screening Using Faecal Occult Blood Testing (FOBt).' (2013) 93 *Patient Education and Counseling* 342-349

[593] For example, patients do not share practitioner's views about the importance of evidence: E.J. Robinson, *et al*, 'Do the Public Share Practitioners' views about the Best Evidence?' (2012) 88 *Patient Education and Counselling* 88 325-329. Patients did not appreciate the comparative survival gains for palliative chemotherapy: S. Audrey, *et al*, 'What Oncologists Tell Patients about Survival Benefits of Palliative Chemotherapy and Implications for Informed Consent: Qualitative Study.' (2008) 337(752) *BMJ* 1-7, 1

receiving disclosure as a value-neutral list of information i.e. which seems to be resulted from the recommendations of the GMC.[594] As Gunfeld *et al* argued, patients:

> […] pursue chemotherapy without a clear understanding of prognosis and management options, including supportive alternatives. In particular, there is concern that patients' understanding of the outcome of chemotherapy may be overly simplistic. They may be willing to accept anticancer treatment even if it provides a small chance and short duration of benefit.[595]

The combination of patients who could not attain a full understanding, chose to ignore, or misapprehended risks, form a significant minority of patients who would have capacity to consent, yet were not able to have an informed consent. This group of patients would therefore not be able to safeguard themselves against potential harms of medical treatment – as they would neither have the understanding to make a liberal autonomous choice; nor would they have had the information they needed according to their authentic values. As the therapeutic elements of the medical relationship are removed, the doctor would have no discretion to lower the threshold of information, nor would be inclined to do so because of the threat of liability. These patients have metaphorically slipped through the cracks.[596]

(iii) Patient information preference

The studies, identified for this phase, continued to recognise that patient information need was diverse.[597] Whilst patients generally wanted to know information about severe risks, other patients wanted to know all potential risks or no information at all.[598] Ultimately, patients continued to want information which was tailored to their particular practical circumstances. This often meant practical outcomes rather than statistical risks. For example, Beaver and Booth found that women (n=53), with gynaecological cancers, wanted to know about the effects of treatment, and information about when they could return to work, rather than the risks. They wanted to know stories about other patients, rather

[594] GMC, *Consent: Patients and Doctors Making decisions Together*. (GMC, 2008), [33], also [19] and [41]
[595] E.A. Grunfeld, *et al*, 'Advanced Breast Cancer Patients' Perceptions of Decision Making for Palliative Chemotherapy.' (2006) 24(7) *J Clin Oncol*. 1090-1098, 1090-1091. Relying on R.D. Rubens, *et al*, 'Appropriate Chemotherapy for Palliating Advanced Cancer.' (1992) 304(35) *BMJ* 41; E.A. Grunfeld, *et al*, 'Chemotherapy for Advanced Breast Cancer: What Influences Oncologists' Decision Making? (2001) 84 *Br J Cancer* 1172-1178; J.C. Weeks, *et al*, 'Relationship between Cancer Patients' Predications of Prognosis and their Treatment Preferences.' (1998) 279 *JAMA* 1709-1714; M. Gattellari, *et al*, 'When the Treatment Goal is not the Cure: Are Cancer Patients Equipped to Make Informed Decisions?' (2002) 20 *J Clin Oncol* 503-513; C.E. Balmer, *et al*., 'Who wants Second-Line Palliative Chemotherapy?' (2001) 10 *Psychoonocology* 410-418
[596] A concept of vulnerability might be able to bridge this gap, but as Dunn *et al*. warns the normativity of rules themselves may act to disempower individuals: M.C. Dunn, *et al*, 'To Empower or to Protect? Constructing the 'Vulnerable Adult' in English Law and Public Policy.' (2008) 28(2) *Legal Studies* 234-253
[597] See for example A.J. Brooks, *et al*, 'Information Required to Provide Informed Consent for Endoscopy: An Observational Study of Patients' Expectations.' (2005) 37(11) *Endoscopy* 1136-1139; R. Heywood, *et al*, 'Patient Perceptions of the Consent Process: Qualitative Inquiry and Legal Reflection. (2008) 2 *Professional Negligence* 104-121,107-108
[598] *Ibid*

than have statistical information which they struggled to relate to their everyday lives.[599] El Wakeel *et al*, similarly, identified that patient (n=77), continued to want to know about: major risks (95%), however, they were more concerned about the effect of treatment on their quality of life, for example, the effect that treatment might have on their ability to work, or do house work (88.1%), leisure activities, sports (77.1%), and personal and sexual relationships (mean: 83.3). Patients also found that being provided with alternatives to treatment were relatively unimportant (mean = 75.5) (in antithesis to the emphasis played on providing patients a suite of treatment choices per the consumer model).[600] Patients were seldom concerned with the technical details of the procedure, or the minor complications or risks.[601] Heywood *et al* also found that patients wanted to know information beyond what an objective reasonable patient (constructed by the doctor) may want to know, for example, about recovery time, and the effects of the operation (aftercare), the potential level of pain and suffering and the practical decisions that have to be made in event of death.[602]

The blanket adoption of an exhaustive disclosure, based on the ethically, rather than empirically, defined hypothetical patient's information need, potentially led to the misalignment between actual information that the patient would want to know (and the actual patient's preferred method of communication i.e. by anecdote) and the utopian disclosure.[603] On this basis, patients were unlikely to receive information for either an authentic autonomous choice (which was the proposed purpose of the ethical rules)[604] or information their best interests (which would have afforded due weight to patient choice). As Heywood *et al* argued, this defensive attitude 'is at odds with the underlying justification for consent and the legal rules which give teeth to the rights it protects, self-determination.'[605]

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[599] K. Beaver & K. Booth, 'Information Needs and Decision-Making Preferences: Comparing Findings for Gynaecological, Breast and Colorectal Cancers.' (2007) *11 European Journal of Oncology Nursing* 409-416, 413-412; V.A. Entwistle, *et al*, 'How Information about other People's Personal Experiences Can Help with Healthcare Decision-Making: A Qualitative Study.' (2011) 85 *Patient Education and Counseling* 291-298

[600] For example, this is in comparison to the number of patients who would want to know the qualifications of their doctor (80.2%). H. El Wakeel, *et al*, 'What Do Patients Really Want to Know in an Informed Consent Procedure? A Questionnaire-Based Survey of Patients in the Bath Areas, UK.' (2006) 32 J *Med Ethics* 612-616, 612, 613

[601] *Ibid*, 615

[602] R. Heywood, *et al*, 'Patient perceptions of the consent process: qualitative inquiry and legal reflection.' 92008) 2 *Professional Negligence* 104-121, 113: "Patient No 4: […] I think everybody would like to know […] I don't know percentage wise but I do know it is much better […] I mean they could make arrangements at home and one thing and another […] After the operation I knew to take my time and was sensible, I have cut my drinking out and I go walking […] I do still have a drink because I used to be a very heavy drinker, but I am just sensible now."

[603] The need to be able to relate information to the patient is especially important in relation to those from culturally diverse background. For example, J. Kai, *et al*, 'Challenges of Mediated Communication, Disclosure and Patient Autonomy in Cross-Cultural Cancer Care,' (2011) 105(7) *Br J Cancer* 918-924; R. Gilbar & J. Miola, 'One Size Fits All? On Patient Autonomy, Medical Decision-Making, and the Impact of Culture.' (2014) 23(3) *Med L Rev* 375-399

[604] See Chapter 5, Section 2

[605] R. Heywood, *et al*, 'Patient Perceptions of the Consent Process: Qualitative Inquiry and Legal Reflection.' (2008) 2 *Professional Negligence* 104-121, 115

(iv) Refusing patient waiver

Heywood *et al*, identified a proportion of patients actively avoided information; as a way of coping with their disease,[606] which they termed blunters.[607] The consumer conceptualisation of the patient failed to construct positive rules which sought to accommodate these individuals. Furber *et al*, for example, found that some participants avoided information about cancer diagnosis if they wished to protect themselves and/or their family from distress.[608] One doctor in the Heywood *et al*'s study stated that up to 30% of patients wanted to waive disclosure.[609] As these patients preferred not to listen to information, or waive their authority to make decisions, their choices were ignored. One doctor stated:

> Consultant No 8: No in fact there are times when the patient says "I don't want to know that." And I say, "I am sorry I am going to tell you."[610]

In seeking to ensure a right to autonomy, the GMC, as a conduit for the rights school of thought, have encouraged doctors in practice to undermine patient liberty and create a mandatory and exclusionary autonomy, warned about by Schneider, in the American context.[611] As Heywood acknowledged:

> [...] if the medical profession perceive the law as placing an obligation on them to bombard patients with risk information and they do so, this can surely be described as defensive practice, particularly if risks are slight. Demanding disclosure of these may unnecessarily deter the patient from undergoing relatively safe and necessary procedures, and perhaps more importantly, if may become clear the patient does not want to hear the risk. This being the case, if the doctor then feels compelled to inform them anyway, it could be classified as 'over-cautious' defensive medicine that is ultimately injurious to the patient.[612]

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[606] S.M. Miller, 'Coping with Impending Stress: Psychophysiological and Cognitive Correlates of Choice.' (1979) 16 *Psychophysiology* 572

[607] R. Heywood, *et al*, 'Patient Perceptions of the Consent Process: Qualitative Inquiry and Legal Reflection.' (2008) 2 *Professional Negligence* 104-121

[608] L. Furber, *et al*, 'Patients' Experience of an Initial Consultation in Oncology: Knowing and Not Knowing.' (2015) 20 *British Journal of Health Psychology* 261-273, 265-268

[609] R. Heywood, *et al*, 'Informed Consent in Hospital Practice: Health Professionals' Perspectives and Legal Reflections.' (2010) 18(2) *Med L Rev* 152-184, 164: "Consultant No 4: Yes I mean a lot of what I personally do is based on a basic psychological appraisal. Patients in information gathering fall into 2 groups. There are around 30% of the patient population who don't want to know anything and they are difficult because all they want to do is sign the consent form. They don't want any risk given they would rather walk away from it and you have to make a decision as to what length you will push them to listen. Most normal people are absolutely fine with it and they will keep on requesting further information. I would then go beyond my normal level in order to make sure that they are informed of every single risk. So you are making a basic and fairly primitive psychological assessment as to whether you should force the information on a patient or whether you would be overlooking the patient with too much information."

[610] *Ibid*, 167

[611] See Chapter 3, Section 2; C.E. Schneider, *The Practice of Autonomy: Patients, Doctors, and Medical Decisions.* (Oxford University Press, 1998), 8-11

[612] R. Heywood, 'Excessive Risk Disclosure: The Effects of the Law on Medical Practice.' (2005) 7 *Med L Int* 93-122, 96

This not only shows that the key element of patient autonomy was being undermined (i.e., self-determination), but that uncertain normative rules, polluted the moral pool, causing doctors to abandon the internal moral axioms of medical decision-making, and instead adopt formulism as the *modus operandi* for medical decision-making. To some extent, ethical rules, were themselves causative of the type of amoral decision-making which led to the types of patient harms complained of by Kennedy.[613]

5.3.3. Rejecting the consumer relationship

(i) Patients

Patient information preference and the role the they wished to take in making decisions about both materiality and treatment was mutually exclusive. Beaver and Booth found a small majority of patients wanted a high standard of information, whilst at the same time the majority of patients also wanted to play a passive role in decision-making. Information was required for therapeutic purposes rather than to make an autonomous decisions.[614] The study found that whilst patients wanted a shared role in the medical relationship (32.1%), only a minority of patients wanted to adopt an active role (20.8%).[615] Whilst the effect of the rights arguments, since the 1990's had encouraged more patients to adopt a SDM model, the majority wanted a more passive (47.2%) and thus therapeutic relationship.[616] Entwistle *et al* found, from semi-structured interviews, that diabetic patients (n=18), wanted a good relationship with their doctors, to discuss their thoughts their and values, have continuity of care, and wanted their views taken into account.[617] However, a high-quality therapeutic relationship was preferred.

> All participants respected and wanted to avail themselves of practitioners' expertise in relation to the management of their diabetes. They were generally inclined to accept treatment recommendations, although we heard several examples of patients having negotiated for something other than what their doctors first suggested. The few (including a nurse) who talked in terms of making 'informed choices' for themselves also noted that they valued a 'steer' from health professionals. […] [618]

[613] See, Introduction
[614] K. Beaver & K. Booth, 'Information Needs and Decision-Making Preferences: Comparing Findings for Gynaecological Breast and Colorectal Cancer.' (2007) 11 *European Journal of Oncology Nursing* 409-416, 412
[615] *Ibid*, 414.
[616] K. Beaver, *et al*, 'Treatment Decision-Making in Women Newly Diagnosed with Breast Cancer.' (1996) 19 *Cancer Nursing* 8-19; K. Beaver, *et al*, 'Decision-Making Preferences and Information Needs: A Comparison of Colorectal and Breast Cancer.' (1999) 2 *Health Expectations* 266-276. Also see, L. Fallowfield, 'Offering Choice of Surgical Treatment to Women with Breast Cancer.' (1997) 30 *Patient Education and Counselling* 209-214
[617] V. Entwistle, *et al*, 'Involvement in Treatment Decision-Making: Its Meaning to People with Diabetes and Implications for Conceptualisation.' (2008) 66 *Soc Sci Med* 362-375, 367
[618] *Ibid*, 369

Patients wanted information for therapeutic purposes, and wanted to know the rationale of medical decision-making, rather than independently making decisions. Whilst patients wanted the doctor to have the final decision, they wanted to be informed. [619] One patient stated:

> I like to be involved. I like to know why I have to take something and what it does to me. When they moved me onto Glimepride, it was explained what they did, and I was quite happy to take them. And I was on Glimepride for a while […] but the diabetes was getting worse and I needed something more, so they put me on to Rosiglitazone and explained what the Rosiglitazone did […] I did and was quite happy because I understand what she was saying. She was telling me what each of the tablets were doing.[620]

As the authors argued, these findings went against the 'dominant policy/professional discourse about patient involvement, which emphasises the content of information exchanged about treatment options and patients' preferences relating to these options.'[621] They argued that '[…] patients do not always expect or want to be given information about a menu of treatment options and responsibility for making choice between these."[622] If this data is accurate, then, the construction of the consumer patient in law was in antithesis to the average patients' preference.

(ii) Doctors

The studies during this period identified that a significant minority of doctors rejected the autonomy-at-all-costs approach of the consumer relationship and continued to make decisions utilising *circumstantial-moral* decision-making. [623] As Edward and Elwyn (proponents of SDM) argued, whilst practitioners involved patients within their decision-making, they retained ultimate decision-making power about the therapeutic optimum treatment and materiality. [624] For example, in Heywood *et al's* study, there were 31 occurrences where interviewee stated that they should make the decision about materiality in the best interests of the patient.[625]

[619] *Ibid*, 370
[620] V. Entwistle, *et al*, 'Involvement in Treatment Decision-Making: Its Meaning to People with Diabetes and Implications for Conceptualisation.' (2008) 66 *Soc Sci Med* 362-375, 370
[621] *Ibid*, 373
[622] *Ibid*, 363
[623] A. Edwards & G. Elwyn, 'Inside the Black Box of Shared Decision making: Distinguishing Between the Process of Involvement and Who Makes the Decision.' (2006) 9 *Health Expectations* 307-320, 307
[624] *Ibid*, 307
[625] R. Heywood, *et al*, 'Informed consent in hospital practice: health professionals' perspectives and legal reflections.' (2010) 18(2) *Med L Rev* 152-184, 163: "There were a total of 31 occurrences across the interviews: 21 occurrences in the consultants/registrars' interviews, 1 in the SHO/house officers' interviews and 7 in the nurses' interviews."

> Nurse Practitioner 5: When I am taking consent what is foremost in my mind is the patient, that I want them to be able to decide that what I am offering them and what I am proposing to do to them is in their best interests.[626]

Beaver and Booth found that a significant proportion of patients (n=53, 56.9%) wanted a passive role in decision-making (30.2%), where the doctor controlled all the decisions (28.3%), in antithesis to the active consumer-patient role expected by the ethical guidance.[627] This is a similar finding from Bugge *et al*, who examined deviation from a model of SDM within the doctor-patient relationship. [628] In their analysis (of 20 patients and doctors) they found 18 instances where treatment options, and material information, were not disclosed; this included: (a) details about the possible causes of symptoms, and differential diagnosis (b) information about poor prognosis and (c) information about the reasons for , and likely value of, tests. [629] Doctors explained that there were both practical reasons (such as time pressure) and principled reasons for not providing information. The doctors stated that the 'judged that information was not needed, wanted or appropriate – either for a group of patients in general or for a particular patient.' For example, a doctor make choose not to disclose information if it is:

> […] their belief that the patient did not want this information, and their concern that disclosing the information could have consequence they wished to avoid (for example, information about a poor prognosis and/or limited effectiveness of treatment might deter patients from accepting treatment or reduce their hope. [630]

Whilst one could reasonably term this resilient paternalism,[631] some patients agreed with this approach; trusting doctors as experts to act in the best interests.[632] A similar trend of taking clinically lead treatment decisions was identified by Audrey *et al*, in relation to 37 oncology consultations.[633] The study found that doctors mentioned, but did not endorse, the use of palliative chemotherapy if the patient was too unwell.[634] Decisions about whether treatment and information was made varied, as decisions

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[626] *Ibid*
[627] K. Beaver & K. Booth, 'Information Needs and Decision-Making Preferences: Comparing Findings for Gynaecological, Breast and Colorectal Cancer.' (2007) 11 *European Journal of Nursing* 409-416, 413-414
[628] C. Bugge, *et al*, 'The Significance for Decision-Making of Information that is not Exchanged by Patients and Health Professionals During Consultations.' (2006) 63 *Soc Sci Med* 2065-2078, 2075.
[629] *Ibid*, 2069
[630] *Ibid*, 2073: "For example, Mr G said in an interview that he had not wanted to know what his blood pressure reading was, and Ms. Q pointed out that the eye problems that were not discussed in her index consultation had been adequately discussed on a previous occasion."
[631] H. Teff, *Reasonable Care: Legal Perspectives on the Doctor-Patient Relationship*. (Clarendon Press, 1994), Chapter 2
[632] C. Bugge, *et al*, 'The Significance for Decision-Making of Information that is not Exchanged by Patients and Health Professionals during Consultations.' (2006) 63 *Soc Sci Med* 2065-2078, 2073
[633] S. Audrey, *et al*, 'What Oncologists Tell Patients About Survival Benefits of Palliative Chemotherapy and Implications for Informed Consent: Qualitative Study.' (2008) 227 *BMJ* a752, 5-9: (<https://www.bmj.com/content/337/bmj.a752>)
[634] *Ibid*, 5: "Oncologist 103: I don't think your general condition now would tolerate chemotherapy quite honestly.
Patient 334: Well no, I thought it might buy me some time, but I mean […]
Oncologist 103: And I think the problem is that because you've become so weak with it and lost so much weight […]

were made on an individual basis, and communicated so that patients could actually understand.[635] Audrey *et al*, rightly argue that whilst achieving and informed consent is an ideal, that doctors should take a *circumstantial* approach: 'it is not the job of the oncologist to deny hope, and few would want to do so.'[636] The problem, however, is that whilst the doctor may be morally correct in withholding information in a specific context, the normative effect of law means that their actions would be considered ethically and indeed potentially legally wrong. During this period the doctor was doomed to choose between ethics and morals as the basis of their decision-making.

Patient 334: And you don't want to eat.
Oncologist 103: Absolutely, and that's one of the commonest symptoms that the get-up-and-go gets up and goes, and one just doesn't want to.
Patient 334: Yes, and my get-up-and-go's gone.
Oncologist 103: Have you tried steroids or anything like that?
Patient 334: No, I, no.
Oncologist 103: Right. Well I think that will be a worthwhile thing to do, is for you to have some steroids and something to stop them upsetting your stomach."

[635] *Ibid*, 5: "Although there was no consistency in informing patients that a cure was not being sought, the amount of information given about survival benefit varied considerably […]. This ranged from giving numerical data, such as "about four weeks"; through an idea of timescales, such as "a few months extra"; to vague references, including "buy you some time"; to not being mentioned at all. During the recorded consultations, only six of the 37 patients were given numerical data about the survival benefit of treatment."

[636] *Ibid*, 8

CHAPTER 6: *MONTGOMERY* AND BEYOND: 2015+

Chapter 5 argued that *Chester* (and the subsequent case-law) attempted to displace the therapeutic doctor-patient relationship and instead give patients power to control the values that made up medical decisions about information disclosure.[1] An equally strong line of case-law argued that *Bolam/Bolitho* in combination with *Sidaway* and *Pearce* remained the leading judgements in information disclosure; and reasserted the need for medical discretion in practice.[2] The medical ethical sector, and particularly the GMC, attempted to straddle the two relationships,[3] by recommending a checklist of factors that the doctor must disclose to avoid liability. This manifested in practice by doctors undertaking formulaic disclosure processes and providing an exhaustive disclosure, which was tailored neither to achieving a liberal, or authentic, autonomous choice. In providing the necessary level of understanding, expressions by patients to waive or refuse their right to information were often ignored. Forcing the responsibilities of the consumer relationship on to patients, however, had the potential to cause psychological harm; as well as undermine their ability to make balanced decisions. Importantly, the introduction of the consumer relationship, through normative rules, caused some doctors to abandon the axiomatic moral foundation on which medical decision-making was based. This fractured the underlying medical morality, which regulated medical decision-making, allowing doctors to harm patients by not acting in their best interests. This fracture manifested both horizontally and vertically, between the values that were being adopted as purpose of the medical relationship, and subsequently the specific models of autonomy being facilitated in practice.

This Chapter will argue that the Supreme Court, in *Montgomery*, attempted to abandon the *Bolam* standard, and particularly the process of *circumstantial-moral* decision-making as a legitimate basis for medical decision-making.[4] In doing so the Supreme Court adopted the critique of the jurisdiction and rights school and reconceptualised the patient as a consumer.[5] However, the Supreme Court failed to learn of the follies of the House of Lords, first, by reintroducing a confused standard of care which explicitly placed both the requirement for a rational and authentic autonomous choice, as the basis of an informed consent, into law. Second, by incorrectly grounding this approach as equivocal to the GMC guidance, and then asserting the guidance was reflective of empirical reality, the Supreme Court adopting the confused model of the medical relationship into law.[6]

[1] *Chester v Afshar* [2004] UKHL 41.
[2] *Al Hamwi v Johnston and Another* [2005] All ER (D) 278; *Meiklejohn v St George's Healthcare NHS Trust and Another* [2014] EWCA Civ 1; *N M v Lanarkshire Health Board* [2013] CSIH 3; *Burke GMC* [2005] EWCA Civ 1003
[3] GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008); Department of Health, *Reference Guide to Consent for Examination or Treatment, Second Edition.* (DoH, 2009)
[4] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11
[5] See, Chapter 2, Section 1 and Chapter 3, Section 1,2 and 4.
[6] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [77]-[79]

This has subsequently divided the judiciary in its conceptualisation of the purpose and method by which doctors should be making decisions about material information.[7] Some judges adopted a *Bolam*-plus approach to the judgement: facilitating the therapeutic ends of the medical relationship, by placing emphasis on the objective limb of the test (with the subjective limb requiring consideration of patient values as part of a therapeutic disclosure).[8] Another group of judges took a the view of the House of Lords in *Chester*[9] i.e. that the purpose of disclosure was to ensure an informed consent; however the model of autonomy used as the basis of the legal standard was inconsistent.[10]

The second section argues that the Supreme Courts reliance on ethical guidance, raised the GMC's guidance to a level of quasi-law. This had the effect of stifling the formal sector's reaction to the change in the standard of care. This was problematic, as Miola argued, as the formal sector have previously been required to rationalise (and substantiate) the confused ethical basis of the law.[11] Instead, the semi-formal sector had to step into the breach. However, the guidance produced has since proliferated the intractable problems of facilitating distinct models of the medical relationship.

The third section argues that the conceptual problems contained in the law and ethics continued to confuse doctors as to the purpose and method of disclosing material information.[12] The studies identified that doctors were divided as to the correct model of the medical relationship. Some doctors adopted a process of particularised disclosure to facilitate a consumer relationship. However, barriers to ensuring an authentic autonomous choice led some doctors to adopt defensive practices. Other doctors rejected the consumer relationship and retained (or (re)adopted) therapeutic disclosure (utilising a process of *circumstantial-moral* decision-making); as a way to facilitate actual patient need.

6.1. *Montgomery*: Abandoning *Bolam*?

This section will argue that the intention of the Supreme Court was to abandon the *Bolam* standard and incorporate a model of the consumer relationship into the law. However, the lack of conceptual consistency about the model of informed consent has resulted in standard of care which straddles both a liberal and authentic model of substantive autonomy.

[7] A similar diagnosis is made by S. Devaney, *et al*, 'The Far Reaching Implications of *Montgomery* for Risk Disclosure in Practice.' (2018) 24(1) *Journal of Patient Safety and Risk Management* 25-29

[8] See Chapter 3, Section 1. This is a similar approach taken by Lord Scarman: *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, per Lord Scarman at 886-888.

[9] See Chapter 4, Section 1; *Chester v Afshar* [2004] UKHL 41, per Lord Steyn, at [16]

[10] See Chapter 2, Section 2: J. Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism?' (2007) 15(3) *Health Care Analysis* 235-255

[11] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship* (Hart Publishing, 2007), 217-219; C. Foster & J. Miola, 'Who's in Charge of the Relationship between Medical Law, Medical Ethics, and Medical Morality?' (2015) 23(4) *Med L Rev* 505-530, 514-515

[12] See Chapter 5, Section 3

Montgomery v Lanarkshire Health Board[13] was the first Supreme Court case to explicitly consider the standard of care for the materiality of information since *Sidaway*.[14] The case revolved around the failure of Dr Dina McLellan, a consultant obstetrician and gynaecologist, to disclose the risk of shoulder dystocia, and offer the option of caesarean section. During delivery Mrs Montgomery suffered shoulder dystocia and her son was asphyxiated developing cerebral palsy. At first instance, the judge rejected the argument that Mrs Montgomery should have been supplied information of the risks of shoulder dystocia. The claimant appealed on two grounds: i) that there was a right to information about serious risks, ii) that the doctor had a duty to answer the patients' question.[15] The Court failed to look at the logic of a medical decision and *Bolitho* was interpreted narrowly. Misdirecting himself on the law, the judge said that disclosure was only required when information was 'so obviously substantial that the court could say that no practitioner could reasonably omit to warn the patient.'[16] Lord Bannatyne, also made a finding of fact that the patient had not repeatedly questioned Dr McLellan,[17] and would need to ask about specific risks; as a basis to activate a therapeutic duty to disclose, in the circumstances.[18] At appeal, Lord Eassie adopted a similarly strict approach to answering questions[19] and rejected the argument that *Pearce* created a prima facie requirement that the doctor provide patients with a threshold of significant risks.[20]

Rather than adopt the correct course of criticising the judges analysis, utilising the *Bolam/Bolitho* test, the claimant sought to attack the law as it stood (using the arguments propounded by the rights school).[21] At the Supreme Court, counsel for the claimant argued that patients should have a right to information and thus should expect an informed consent.[22] Indeed, in speeches previous to the appeal Badenoch Q.C. (senior counsel for the claimant) indicated that this rights based argument was a tactical choice, as

[13] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.
[14] See Chapter 2, Section 3 and Chapter 3, Section 1
[15] *Nadine Montgomery v Lanarkshire Health Board* [2010] CSOH 104, per Lord Bannatyne at [227]- [263]
[16] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 [31]
[17] *Nadine Montgomery v Lanarkshire Health Board* [2010] CSOH 104, per Lord Bannatyne at [258]
[18] Also see, *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [3] & [26]-[28]; *N M v Lanarkshire Health Board* [2013] CSIH 3, [33]-[36] referring to *Nadine Montgomery v Lanarkshire Health Board* [2010] CSOH 104, [238]-[263], [240]-[251] & [255]-[263]. This thesis would argue that the lower court erred in their judgement by failing to recognise that general queries would engage the requirement to give information in the patients' best interests. Failing to provide this information would therefore fall below a reasonable standard in the circumstance (sociologically defined). For example, Lord Diplock stated 'No doubt if the patient in fact manifested this attitude by means of direct questioning, the doctor would tell him whatever it was the patient wanted to know.' Similarly, Lord Templeman indicated that questioning created a greater duty of disclosure, and Lord Bridge's similarly indicated that information disclosure would likely be in the patients' best interests. Certainly, after *Blyth v Bloomsbury HA* there was a duty to answer general questions as being indicative of information need, based on the *Bolam* principles. See, *Sidaway v Governors of Bethlem Royal Hospital* [1985] 1 AC 871, per Lord Scarman at 888, per Lord Diplock at 895, per Lord Templeman at 890, per Lord Bridge at 898; *Blyth v Bloomsbury Health Authority* [1993] 4 Med LR 151, per Neill LJ. Also see *Gold v Haringey Health Authority* [1998] 1 QB 481. See also, *Rogers v Whitaker* [1992] HCA 58; [1992] 175 CLR 479, at 491.
[19] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [29]
[20] *Ibid*, [31]
[21] *Ibid*, [30]
[22] *Ibid*, [30]

these arguments were in vogue with members of the Scottish judiciary[23] and the Appeal Courts, [24] and could therefore provide a conduit by which the claimants arguments might win the day.[25] Counsel therefore relied on *Chester v Afshar* to argue that the purpose of disclosure was to ensure an autonomous choice, and that this created a legal right to the provision of information the patient wanted and disclosure of additional treatment options – irrespective of whether she would have taken up the doctor's advice.[26]

(i) The Supreme Court judgement

Lord Kerr and Lord Reed giving the majority judgement, at the Supreme Court, in *Montgomery*, adopted the jurisdiction school of thought, relying particularly on the dicta of *Rogers v Whitaker*, to argue that decision-making around medical disclosure 'is not a question the answer to which depends upon medical standards of practices.'[27] The value basis of decision-making was therefore not medical. This was in antithesis to the majority in *Sidaway*, where Lord Diplock had argued that medical decision-making was 'not subject to dissection into a number of component parts to which different criteria of what satisfy the duty of care apply, such as diagnosis, treatment and advice.'[28] The Supreme Court, rejected this position, and instead argued that the 'overriding objective' or moral underpinnings of 'the patient's health,' as the basis of clinical judgement about information disclosure, should be

[23] Lord Hodge, *The Scope of Judicial Law-Making in the Common Law Tradition.* (Max Planck Institute of Comparative and International Private Law Hamburg, Germany, 28 October 2019): (<https://www.supremecourt.uk/docs/speech-191028.pdf>), [10]

[24] For example: *Border v Lewisham & Greenwich NHS Trust* [2015] EWCA Civ 8. Also, see contemporary decisions upholding patient rights: *Greater Glasgow Health Board v Doogan & Anor (Scotland)* [2014] UKSC 68 (which set aside the Inner House declaration that s.4(1) of the Abortion Act allowed religious midwives to refuse to delegate, supervise of support staff carrying out terminations); *(1) P v Cheshire West & Chester Council & Another; (2) P & Q v Surrey County Council* [2014] UKSC 19 (Recognised the need for Deprivation of Liberty Safeguards to ensure that HR of those without Capacity are equally protected); *R(On The Application of A and B) v Secretary of State for Health* [2017] UKSC 41 (The SC found this it was unlawful for the Secretary of State for Health not to make provisions for safe abortion in Northern Ireland); *Darnley v Croydon Health Services NHS Trust* [2018] UKSC 50 (that the medical receptionist owed a duty of care to a patient). For more general INISGHT into contemporary judicial activism see: B. Dickson, 'Activism and Restrain within the UK Supreme Court.' (2015) 21(1) *EJoCLI*. Although, Lord Hodge argued that there were more conservative judgements: *Ibid*, Lord Hodge, [30]. For example, in *AN NHS Trust & Others v Y & Anor* [2018] UKSC 46, Lady Justice Black, giving the majority judgement, found that when removing ANH, if there was family agreement then it was in P's best interest and did not have to be referred to the Court of Protection.

[25] J. Badenock, *Bolam-Let's Kill it Off: A Heretic's View* (2013), [21] (<http://connect-avma.public-i.tv/document/The_Continum_Relevance_of_the_Bolam_Test.pdf>). Indeed, in his speech, he recognised that *Bolam* test already invited the type of internal and external critique of decision-making complained about within the Appeal: "[The conventional *Bolam* standard] has been gradually undermined and may now be fatally weakened by appropriate use of the *Bolitho* principle in the Courts of England and Wales, by a decline in excessive judicial deference to the medical profession, and by the inexorable march of evidence based medicine. But there are other more deliberate effects at work. Take the so called "informed consent" cases, and the treatment risk which is statistically very small but extremely serious if it materialises. To this day there is a large, albeit diminishing, body of doctors who would choose not to warn of such remote risks as part of a paternalistic approach to patient care. Wide (and even general) medical approval of such concealment ought to provide a complete *Bolam* defence. Yet the growing emphasis on individual autonomy ("it's my body and I should decide what risks matter to me") makes for a judicial tendency to by-pass *Bolam* in these instances and find the failure to warn negligent. A detectable move towards the American principle that a patient must be informed of all and any treatment risks which a reasonable patient would consider relevant, however small, is another nail in the *Bolam* coffin is."

[26] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [4]. This argument was also popular in the academic literature during the period, for example: N. Priaulx, 'Joy to the World! A (Healthy) Child is Born! Reconceptualising Harm in Wrongful Conception.' (2004) 13 *Social and Legal Studies* 5; S. Devaney, 'Autonomy Rules OK.' (2005) 12 *Med L Rev* 102, 107

[27] *Ibid*, [71]; *Rogers v Whitaker* (1992) 175 CLR 479, per Mason CJ, Brennan, Dawson, Toohley, McHugh JJ at 489-490.

[28] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, 993

abandoned.[29] The doctor had to treat the patient as a consumer, and provide them with all reasonable variant treatments.[30] They also have the facilitative duty of making reasonable attempts to ensure understanding – as an additional facilitate duty of autonomy.[31]The seminal jurisdiction and rights school critiques were employed as a basis to demolish the legitimacy of medical-moral decision-making.[32] For example, the Supreme Court suggested that:

(1). Doctors lacked expertise in making these types of ethical decisions as they engaged complex societal and institutional questions of healthcare provision, management and justice, rather than dealing exclusively with ethical considerations within the doctor-patient relationship.[33] No empirical evidence is used to support this assertion about the usual content of decision-making, albeit the reliance on a rights schools rhetoric that the optimum relationship is one where the patient is a consumer. As the patient is a consumer, and the doctor a market provider, the doctor is obliged to engage with ethical questions about utility and distributive justice beyond purely biomedical considerations. It is no small irony, as will be illustrated later, that the Supreme Court critique led doctors to readopt rigid biomedical approaches to define the reasonable patient. [34]

(2). The Supreme Court suggested that to reflect the change in the type of relationship (and particularly that patients be viewed as consumers) required the recognition of free-standing patient rights.[35] Three justifications were made for this shift in the medical relationship:

> (i) that doctors and patients both have ready access to a marketplace of information, through the internet and media;[36]

[29] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [74]-[75]
[30] *Ibid*, [87]
[31] *Ibid*, [90]
[32] See Chapter 2, Section 2. As such the rights school especially has heralded Montgomery as a triumph. See for example: C. Edozien, 'UK Law on Consent Finally Embraces the Prudent Patient Standard.' (2015) 350 *BMJ* H2877
[33] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 [75]: "The treatment which they offer is now understood to depend not only upon their clinical judgement, but upon bureaucratic decisions as to such matters as resource allocation, cost-containment and hospital administration: decisions which are taken by non-medical professionals. Such decisions are generally understood within a framework of institutional rather than personal responsibilities, and are in principle susceptible to challenge under public law rather than, or in addition to, the law of delict or tort."
[34] *Ibid*, [74]
[35] *Ibid*, [75]: "Since *Sidaway*, however, it has become increasingly clear that the paradigm of the doctor-patient relationship implicit in the speeches in that case has ceased to reflect the reality and complexity of the way in which healthcare services are provided, or the way in which the providers and recipients of such services view their relationship. One development which is particularly significant in the present context is that patients are now widely regarded as persons holding rights, rather than as the passive recipients of the care of the medical profession. They are also widely treated as consumers exercising choices: a viewpoint which has underpinned some of the developments in the provision of healthcare services."
[36] *Ibid*, [76]: "[…] it has become far easier and far more common, for members of the public to obtain information about symptoms, investigations, treatment options, risks and side-effects via such media as the internet (where, although the information available is of variable quality, reliable sources of information can readily be found), patient support groups, and leaflets issued by healthcare institutions."

(ii) on this basis, the Supreme Court made the empirical claim that the ordinary patient is able and willing to make decisions about information preference and therefore treatment.[37] Although, the Court provides no empirical data on which to ground this claim.[38]

(iii) The Supreme Court argued that the medical guidance, particularly *Making Decisions Together*, is representative of current medical practice.[39] This position is, however, in antithesis the findings of the previous Chapter, as well as the empirical study produced by the GMC; which found that many doctors did not follow or ignored the guidance.[40] Further, the GMC guidance continued to endorse the therapeutic relationship and the importance of medical values within decision-making. [41]

Rather than relying on *Bolam* to reflect these changes sociologically, the Supreme court insisted on creating a normative standard.[42] It is unclear why the Supreme Court relies on sociological claims to justify this movement, and then opts to create a normative standards (particularly the definition of human rights).[43] By defining the content of rights and therefore the facilitative duties placed on the doctor, the Supreme Court specified the ethical considerations of disclosure decisions. The role of the doctor is thereby reduced to 'considering possible investigatory or treatment options' and her duty requires 'discussing with the patient any recommended treatment and possible alternatives, and the risk of injury that may be involved.'[44] In utilising a normative rule to set standards, the court eradicated the ability of the doctor to take into account of medical morality, circumstantial values, or ordering and weighing this content in context. As Montgomery has argued, the normative content of the law, and particularly the substantive ethical content of patient rights, prevents the doctor acting in line with his medical moral obligations. This *demoralises* decision-making,[45] but also *decontextualises* decisions, so the particularity of the values and concerns of the patient are potentially ignored. [46]

[37] As I argued in Chapter 1, the position of Lord Diplock, like Lord Bridge and Templeman was to recognise that the information disclosed to the patient was based on their individual need and ability to use that information to make an autonomous choice, rather than a normative assumption about the general trends of patient information need. *Ibid*, [76]: "[t]he idea that patients were medically uninformed and incapable of understanding medical matters was always a questionable generalisation, as Lord Diplock implicitly acknowledged by making an exception for highly educated men of experience. To make it the default assumption on which the law is to be based in now manifestly untenable."

[38] As Chapter 4, Section 3 identified some patients neither want a high level of technical information, nor wish to take an active role in the medical relationship; instead, they have been forced into this role by normative rules. Also see, GMC, *Attitudes Towards Consent and Decision-Making: Prepared for the General Medical Council by Ipsos MORI* (GMC, 2018), 2

[39] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [77]. Relying on GMC, *Good Medical Practice*. (GMC, 2013),[78]; GMC, *Consent: Patients and Doctor making decisions together*. (GMC, 2008). [5]

[40] GMC, *Doctors' Attitudes to Consent and Shared Decision Making: Full Research Report for the GMC*. (GMC, 2017).

[41] See Chapter 4, Section 2: GMC, *Consent: patients and doctor making decisions together*. (GMC, 2008), [3], [5], especially [5](d) and [6], [37]-[38]

[42] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [83]

[43] *Ibid*, [83]

[44] *Ibid*, [82]

[45] J. Montgomery, Law and the demoralisation of medicine.' (2006)26(2) *Legal Studies* 185-210.

[46] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [75] & [83]

The problem with this approach, however, is that if decision-making is demoralised, doctors have no moral obligation to act in the patient's to provide the patient information other than to avoid liability i.e. the moral foundation on which the duty of disclose rests is lost.[47] As the moral connection between the doctor and patient is lost, the law would have to rely on societal and fiduciary principles as a basis to construct rights and duties.[48] Indeed, this seems to be the intention of the Supreme Court when they suggest decisions are now made on public law, rather than tort law principles.[49] This becomes more than an academic problem, however, if the law fails to prescribe how and when rights are activated and how doctor's should make decisions. If the law fails to do so, the doctor has no moral requirement to act in the patient's best interests or even not to harm the patient beyond criminal law principles.[50] In novel circumstances, or when utilising new medical technology, the medical profession would not have developed the type of paradigmatic moral behaviour, on which to ground their decision-making.[51]

(3). Rather than acting to simply protect the right to patient choice (and to have decisions related to bodily integrity respected) the Supreme Court adopted the rights school position; that an informed consent was an ethically preferrable basis on which to ground legal respect for a decision.[52] Accordingly, the doctor now has a duty to ensure that the patient is 'aware of material risks' or indeed, understands those risks as the basis of their decisions.[53] The position in *Chester v Afshar* is therefore ratified, to redefine the purpose of information disclosure (rather than being therapeutic) to ensure that a patient has a substantive autonomous choice.[54]

6.1.2. The standard of materiality

This sub-section sets out the model(s) of disclosure adopted into law and highlights the conceptual inconsistency created by the models of autonomy utilised as the basis of standards of care. The Supreme Court argued that both the prudent patient standard in *Pearce* and the particular patient standard in *Roger*'s both ensure an informed consent. Failing to recognise the distinct ethical content the two

[47] *Ibid*, [82]
[48] The same type of argument is employed by Ost, to establish a wider duty of abuse of trust i.e., that doctors have a societal duty, linked to their functional role which creates additional expectations and requirements: S. Ost, 'Breaching the Sexual Boundaries in the Doctor-Patient Relationship: Should English Law Recognise Fiduciary Duties?' (2016) 24(2) *Med L Rev* 206-233. Also see, T.A. Faunce & S.N. Bolsin, 'Fiduciary Disclosure of Medical Mistakes: The Duty to Promptly Notify Patients of Adverse Health Care Events.' (2005) 12(4) *Journal of Law and Medicine* 478-482
[49] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [75]
[50] See for example, *Crossman v St George's Healthcare NHS Trust* [2016] EWHC 2872 (QB). See this argument in: C.A. Erin & S. Ost, *Criminal Justice System & Health Care*. (Oxford University Press, 2007). For more examples see: M. Kazarian, 'Defective Medical Devices: Analysing the Role of the Criminal Law in the PIP Breast Implants Scandal.' (2016) 13(4) *Contemporary Issues in Law* 1-18.
[51] See Chapter 1, Section 2 and Chapter 2, Section 2: it is ironic that the external critique used to justify the adoption of a rights-based system of regulation may have the effect of actually manifesting the harm that it intended to prevent.
[52] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 [80]. Relying on *S (An Infant) v S* [1972] AC 24, per Lord Reid at 43; *McColl v Strathclyde Regional Council* (1983) SC 225, 241; *Airedale NHS Trust v Bland* [1993] AC 789, per Lord Goff at 864. Also, Art 8 in *Glass v United Kingdom* (2004) ECHR 341; *Tysiac v Poland* (2007) 45 ECHR 947.
[53] *Ibid*,[82]
[54] *Ibid*, [82]

standards were facilitating (namely a liberal and an authentic model of autonomy) the Supreme Court simply adopted the binary test for materiality into the Law:

> The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatments. The test of materiality is whether, in the *circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk*, or the doctor is or should *reasonably be aware that the particular patient would be likely to attach significance to it*.[55](author's emphasis)

Heywood and Miola argued that the adoption of this test for materiality was simply a 'natural and predicated evolution of the law.'[56] This is true, in the sense that the judiciary have a long history of conflating the two models,[57] however, as the previous chapters show, this movement has occurred because of the adoption and propagation of a school of thought that favours patient's rights as a mechanism for regulation. Nor has this road been smooth; there has and remains problems of judicial interpretation, continued ethical confusion and unknowable application. *Montgomery* is not the heralded panacea because the consumer within the medical relationship must now be defined both in the abstract (as an objective legal construct) and in the particular (embodying the needs, values and circumstances of the actual patient), as the same time. Seldom will the actual patient be equivocal to the average patient.

(i) The objective test

Under the objective test it is unclear what model of the reasonable or prudent patient test is being adopted into the law. If it is the prudent patient in the *circumstances*, one must ask to what extent the *circumstances* of the patient are to be invoked to delineate what the objective patient would want.[58] Further, are the relevant circumstances themselves to be objectively defined, or are the circumstances that are considered themselves circumstantial, and thus variable? The Supreme Court have reduced certainty about this definition by rejecting percentages as a way of identifying serious information that the average patient may need.[59]

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[55] *Ibid*, [87]

[56] R. Heywood & J. Miola, 'The Changing Face of Pre-Operative Medical Disclosure: Placing the Patient at the Heart of the Matter.' (2017) 133 *Law Q Rev* 296-321, 300. Indeed, the position advocated by Miola in J. Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas.' (2009) 17 *Med L Rev* 76, was almost wholly adopted (albeit implicitly) by the Supreme Court.

[57] *Ibid*. They seem to argue that the Law has simply moved seamlessly from a reasonable doctor standard to a prudent patient test and then a particular patient standard i.e., a march on the road to patient rights.

[58] See Chapter 3, Section 1; M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 110; A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5 *Med L Int* 205-230, 214

[59] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [89]: "[…] the assessment of whether a risk is material cannot be reduced to percentages. The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for example, the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the

The benefit of using the objective statistical criteria of universal information need either across treatments, or for particular treatments, is that it creates a basic threshold at which a patient could be assured that they would receive information. By removing this baseline the courts risk either: (1) reintroducing the paternalism complained about (as the doctor has discretion to define seriousness of risk according his values), (2) creates a test which pays so much attention to individual circumstances that it misses information that a hypothetical reasonable patient may want to know.[60] This would undermine the conceptual difference between the liberal and authenticity model of the autonomy, operating as the basis of an informed consent.[61]

Commentators have primarily suggested two ways to define the objective test: (1) Miola and Heywood argue that the judge intended a strict binary in terms of the value-content which the tests deal with; the objective test relates to biomedical, or physical, factors, and the subjective test relates to biopsychosocial factors for delineating the significance of material information.[62] (2) Dunn *et al*, instead, argue that the requirement of reasonableness deflates the autonomy in *Montgomery;* the entirety of the legal test therefore facilitates the therapeutic, rather than the consumer relationship.[63] This is an attractive approach as it would mean the legal standard is not attempting to service, and thus conflate, two distinct models of autonomy. However, this approach runs counter to the thrust of the judgement: that the purpose of disclosure is to facilitate an informed consent.

If Miola and Heywood are correct, the objective test would relate solely to the physical symptoms/condition which the actual patient shared with the hypothetical reasonable patient. Whilst this would approach has the benefit of allowing doctors to identify material information directly from medical/sociological literature (which uses population based statistics),[64] as Austin rightly argues; Miola and Heywood's approach may unintentionally point back towards the *Bolam* standard: 'how will the courts know whether a treatment was fringe, alternative, or mainstream but inappropriate without recourse to expect medical evidence?'[65] Dingemans J in *A v East Kent University NHS Foundation Trust* [66] seems to exemplify Austin's worry. As Devaney *et al* argued, the judge simply agreed with the

patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient."
Rejecting, *Pearce and another v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, 124

[60] *Ibid*, [89]

[61] See M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 110; A. Grubb, 'Medical Negligence: Duty to disclose after *Bolitho*.' (1999) 7 *Med L Rev* 61, 63

[62] R. Heywood & J. Miola, 'The Changing Face of Pre-Operative Medical Disclosure: Placing the Patient at the Heart of the Matter.' (2017) 133 *Law Q Rev* 296-321, 304-305

[63] M. Dunn, *et al*, 'Between the Reasonable and the Particular: Deflating Autonomy in the Legal Regulation of Informed Consent to Medical Treatment.' (2019) 27 *Health Care Analysis* 110-127, 110

[64] See for example, A. Maclean, 'Giving the Reasonable Patient a Voice: Information Disclosure and the Relevance of Empirical Evidence' (2005) 7(1) *Med Law Int* 1-40

[65] L.V. Austin, '*Hii Chii Kok v (1) Ooi Peng Jin London Lucien; (2) National Cancer Centre*: Modifying *Montgomery*.' (2019) 27(2) *Med L Rev* 339-351, 347

[66] *A v East Kent Hospitals University NHS Foundation Trust* [2015] EWHC 1038, at [84]

doctor that a 1 in 1753 chance of a risk occurring was theoretical without interrogating the values of the patient.[67] If this type of objective approach proliferates within the court, Heywood and Miola's suggestion that a process of de-B*olamisation* has occurred by their own standards would at least be questionable.[68] If on the other hand the doctor must include circumstantial criteria beyond merely biomedical or physical considerations, as Laing argues, this creates uncertainty about the value basis on which doctors should include information.[69] This is of practical importance to medical decision-making as the consumer relationship would remove the ability for doctors to make circumstantial-moral decisions and thus create moral paradigms. The decision made would, by the Supreme Court's definition, be arbitrary and/or paternalistic. One may come to the conclusion that a level of discretion is in some ways inevitable; either in a narrow sense - by allowing the doctor to decide what physical criteria, and treatment are relevant for considerations about materiality - or, in a wider sense, by allowing them to integrate patient characteristics into that decision-making matrix.

Maybe more important is how the judge would evaluate whether the disclosure was reasonable. There seems to be two potential approaches:

> (1) *Bolam*-esque process which would use the evidence to examine the internal basis and logic of the medical decision. A judgement would then set out whether the doctor had correctly identified the material: i) circumstances (either the purely biomedical or biopsychosocial), and ii) scientific evidence, as the basis of constructing the hypothetical reasonable patient, and thus, the objective threshold of material risks.[70]
>
> (2) Alternatively, the judge could independently construct the decision, perhaps using the expert evidence, or empirical studies, and then undertake a comparative assessment of what the doctor should have done in the circumstances. This revisionist approach would of course encourage doctors to second guess the decision of a potential judge, rather than making a based on their view of average patient need in the actual circumstances.[71]

The application of the test in *Montgomery* does little to clarify the correct judicial approach. The Court indicated that the *particular circumstances* for identifying the information needs of the hypothetical

[67] S. Devaney, *et al*, 'The Far-Reaching Implications of *Montgomery* for Risk Disclosure in Practice.' (2018) 24(1) *Journal of Patients Safety and Risk Management* 25-29.
[68] R. Heywood & J. Miola, 'The Changing Face of Pre-Operative Medical Disclosure: Placing the Patient as the Heart of the Matter.' (2017) 133 *Law Q Rev* 296-321, 299
[69] J. Laing, 'Delivering Informed Consent Post-*Montgomery*: Implications for Medical Practice and Professionalism.' (2017) 33(2) *Professional Negligence* 128, 143
[70] See, Chapter 2, Section 2
[71] See for example, *Joyce v Wandsworth HA* **[**1996] 7 Med L R 1. This point was made by J. Montgomery, *Health Care Law* (Oxford University Press, 2003), in relation to *Bolitho*. Also see, R. Mulheron, 'Trumping *Bolam*: A Critical Legal Analysis of *Bolitho*'s "Gloss".' (2010) 69(3) *Camb L J* 609-638, 619-620

patient were simply the risks resulting from birth in addition to the particular risks to a diabetic mother. The risk of shoulder dystocia was between 9-10%, which the Court asserted 'undoubtedly required that it should be disclosed.'[72] However, in antithesis to their previous statement,[73] the Supreme Court went further and argued (without any empirical support) that all mothers with any risk of shoulder dystocia,[74] should be informed of the risk of fourth degree tear, the Zanvanelli manoeuvre or symphysiotomy.[75] As all women to a greater or less extent are at risk of shoulder dystocia when giving birth, this made this category of information in universally material, irrespective of the particularity of the patient's circumstances. On this basis all mothers should be offered a caesarean section.[76] Unhelpfully, the Supreme Court is less ubiquitous about whether, disclosure of other particular risks, such as brachial plexus (1 in 500), cerebral palsy (which the claimant suffered) or death, resulting from shoulder dystocia was required; risks which one could assume would be similarly significant for an expectant mother.[77]

The lack of specification and clarity of logic between types of material information potentially indicate, (as Montgomery and Montgomery argue) decision-making by revisionism (Option 2);[78] where the Supreme Court arbitrarily constructed the *hypothetical mother* to fit in with their case-theory rather than relying on the findings of the trial judge.[79] This post-hoc construction is problematic as it relies on the approach of individual judges to identify contents of information, or treatment options, which should (not) be provided to entire categories of patients (utilising the circumstances of individual cases). This is particularly worrisome, as judges risk creating moral presumptions about groups of patients should think and act - which is then given legitimacy through law.

[72] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 [94]
[73] *Ibid*, [89]
[74] *Ibid*, [94]: "No woman would, for example, be likely to face the possibility of a fourth-degree tear, a Zanvanelli manoeuvre or a symphysiotomy with equanimity.' See this line of thought being followed in *Middleton v Ipswich Hospital NHS Trust* [2015] EWHC 775 (QB)
[75] This is because shoulder dystocia is a potential risk for all mothers (between 0.15-2%): M.G. Hill & W.R. Cohen, 'Shoulder Dystocia: Predication and Management.' (2016) 12(2) *Womens Health (Lond)* 251-261
[76] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 [94]: "The contrast of the risk involved in an elective caesarean section, for the mother [is] extremely small and for the baby virtually non-existent is stark and illustrates clearly the need for Mrs Montgomery to be advised of the possibility, because of her particular circumstances, of shoulder dystocia." See Johnathan Montgomery & Montgomery's analysis where he rightly identified that this approach adopted by the Supreme Court is based on a misperception of the actual risk of CS: J. Montgomery, '*Montgomery* on informed consent: an inexpert decision?' (2016) 42 *J Med Ethics* 89-94, 91. In effect the Supreme Court requires the doctor to abandon the scientific basis of decision-making which grounds the approach which the Defendant followed in the RCOG & NICE Guidelines: Royal College of Obstetricians & Gynaecologists, *Green Top Guideline No. 42. Shoulder Dystocia*. (RCOG, 2012); National Institute for Health and Care Excellence, *Diabetes in Pregnancy: Management of Diabetes and its Complications from Preconception to the Postnatal*. (NICE, 2015)
[77] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [94]
[78] J. Montgomery & K. Montgomery, '*Montgomery* on Informed Consent: An Inexpert Decision?' (2016) 42 J *Med Ethics 89*-94, 89.
[79] *Ibid*, 89-90

(ii) Defensive disclosure

The need to construct a concept of the *reasonable* person's information needs, either globally, or in relation to particularly type or disease or circumstance, requires the adoption of assumptions about the informational needs of the average patient. The construction of the average patient risks making implicit (or even explicit) assumptions about the qualities of the hypothetical patient, particularly, their sex, race, age, sexual orientation, religious beliefs or gender.[80] The assumptive stance rejected by Lady Hale, has the potential to be the primary mechanism by which doctors make informational choices, if the objective limb dominates.[81] These assumptions about informational needs also have potential to discriminate against those patients who are less vocal, empowered, or circumstantially able because of their illness, to rebut the presumptions intrinsic to the objective limb of the *Montgomery* test.

One potential way in which the medical profession might seek to overcome areas of confusion, about: how to construct the objective standard, how to conceptualise the information needs of the prudent patient (in a way that does not potentially place barriers to information), and how to properly facilitate the objective limb, alongside the subjective limb, is to adopt a 'defensive' approach to information disclosure. As Bourne *et al* describes, defensive medicine can occur both positively and negatively. In the positive sense, doctors can provide too much information to avoid liability ('hedging'), in the negative, they can avoid a treatment or certain types of patient ('avoidance').[82] In the particular context of the *Montgomery* standard, 'defensive medicine,' is used to refer to the disclosure of unnecessary information, with the aim of avoiding liability. What information is considered unnecessary will depend on the model of the medical relationship being adopted, and thus, the purpose of information disclosure i.e. to achieve the patient's therapeutic best interests, or to ensure an informed consent. As Lord Justice Irwin noted in *ABC v St George's Health Care NHS Trust*, defensive medicine can result both from enhanced normative rules, but also confusion about the correct medical choice in the absence of prescription.

> I quite accept that the existence of a legal duty to the "third party" as well as to the patient may add to the pressure on the clinician. It will no longer be clear to the clinician which decision will be protective of legal action against him or her. Is it necessarily and inevitably in the public

[80] J. Miola & R. Gilbar, 'One Size Fits All? On Patient Autonomy, Informed Consent and the Impact of Culture.' (2014) 23(3) Med L Rev 375-399. Also, J.Y. Tan *et al*, 'Shared Decision Making among Clinicians and Asian American and Pacific Islander Sexual and Gender Minorities: An Intersectional Approach to Address A Critical Care Gap.' (2016) 3(5) *LGBT Health* 327-334

[81] See for example, C. Yuill, *et al*, 'Women's Experiences of Decision-Making and Informed Choice about Pregnancy and Birth Care: A Systematic Review and Meta-Synthesis of Qualitative Research.' (2020) 20 (343) *BMC Pregnancy and Childbirth* 1-21; R.A. Sanders & K. Crozier, 'How do Informal Information Sources Influence Women's Decision-Making for Birth? A Meta-Synthesis of Qualitative Studies.' (2018) 18 (21) *BMC Pregnancy and Childbirth* 1-26

[82] T. Bourne, *et al*, 'The Impact of Complaints Procedures on the Welfare, Health and Clinical Practice of 7926 Doctors in the UK: A Cross Sectional Survey. (2015) *BMJ Open Access*: (<https://bmjopen.bmj.com/content/5/1/e006687.info>)

> interest that clinicians should be relieved of that pressure? In my view, it is self-evident that there is a public interest in avoiding excessive litigation and in keeping to a minimum what one can call, in shorthand, defensive medicine. However, it seems not necessarily correct, in a situation where patient confidentiality should be waived or, if necessary breached, that the common law should so clearly incentivise obligations in one direction but not the other. It seems to me at least arguable that that may encourage rather than diminish defensive medicine.[83]

The need for guidance and discretion, of course, have to be evenly balanced when constructing rules within laws. An essential method for framing the law, and balancing risks of defensive medicine, is to ensure that there is a clear and agreed purpose to the medical action i.e. in the provision of information.

The concept of 'defensive medicine' emerged sociologically follow the medical litigation crisis within the US. Sociologists, lawyers and economists identified that doctors were providing unnecessary diagnostic tests and treatment to avoid being sued for negligence by litigious patients.[84] McQuade, for example, defined this phenomenon 'as the ordering of treatments, tests and procedures for the purpose of protecting the doctor from criticism rather than diagnosing or treating the patient.'[85] Harris, for example, advocated for 'cost-effective, high quality "defenses" to malpractice.'[86] Within the context of England and Wales, the term defensive medicine has similarly been used to describe actions taken by doctors to avoid litigation. For example, Ortashi *et al*, stated:

> […] the general public is now better informed, they have also become more risk averse, often refusing to accept the usually low probability of adverse outcomes associated with medical care and interventions. At the very least, a 'more defensible' case is created, if litigation were to occur. Such an approach is compounded by the perception that courts have tendency to rely more on data provided by investigations than on claims of experience or medical judgement.[87]

The Summerton observational studies on GP's identified significantly more negative defensive practices, which took place between 1994 and 1999. GP's were significantly more likely to undertake diagnostic testing, refer patients and avoid treating certain conditions at the later date. The Ortashi *et*

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[83] *ABC v St George's Healthcare NHS Trust & Others* [2017] EWCA Civ 336, per Nicol J, at [31]

[84] For example, R.A. Reynolds, *et al*, 'The Cost of Medical Professional Liability.' (1987) 257 *JAMA* 2776-2781; M.K. McClellan, 'Do Doctors Practice Defensive Medicine? (1996) 11 *Q J Econ* 353-390; D. M. Studdert *et al*., 'Defensive Medicine among High-Risk Specialist Physicians in a Volatile Malpractice Environment.' (2005) 293 *JAMA* 2609-2617; R.M. Rodriguez, *et al*, 'A Longitudinal Study of Emergency Medicine Residents' Malpractice Fear and Defensive Medicine.' (2007) 14(6) *Acad Emerg Med* 569-573

[85] J.S. McQuade, 'The Medical Malpractice Crisis – Reflections on the Alleged Causes and Proposed Cures: Discussion Paper.' (1991) 84(7) *J Roy Soc Med* 408-411

[86] J.E. Harris, 'Defensive Medicine: It Costs, but Does it Work.' (1987) 257(20) *JAMA* 2801-2802, 2802

[87] O. Ortashi, *et al*, 'The Practice of Defensive Medicine among Hospital Doctors in the United Kingdom.' (2013) 14 *BMC Medical Ethics* 1-6

al, undertook a survey 202 doctors at South Wales Hospitals.[88] 98% of participants were aware of the concept of defensive medicine, and 78% of the doctor surveyed (n=159) reported practicing one or more forms of defensive medicine[89] and 86% of doctors believed that they were not working in a blame-free culture. 14% of respondents and one in three consultants had direct experience of litigation. However, defensive medicine actually increased the more junior the doctor. Over half of the defensive practices occurred in ordering unnecessary tests (59%).[90] Concerningly, Ortashi *et al*, found that 9% of doctors would refuse to treat high risk patients, and 21% would avoid high risks procedures all together.[91]

Recently, Dr Paula Case has argued that defensive medicine within UK case-law has become a 'jaded cliché.'[92] She criticises the use of defensive medicine as a justification for not enhancing legal standards to protect patient rights. She argues that reference to defensive medicine, actually exists as a bundle of arguments pertaining to the negative impact on medical decision-making in practice, specifically:

(i) defensive medicine is a corruption of doctor's duties;
(ii) defensive medical practices are bad for patients;
(iii) defensive practice in medicine manifest as an unnecessary 'intervention'; and
(iv) the negligence litigation can be isolated as a unique trigger for defensive medicine.[93]

She goes on to identify and justify how the persuasiveness of defensive medicine argument has now fallen out of fashion as a policy consideration in relation to the construction of normative standards. Specifically, that the risk of defensive medicine is empirically unproven, and instead that defensive medicine should be perceived as potentially 'standard enhancing.'[94] She analyses the empirical literature on defensive medicine, and makes the claim that 'there is no empirical evidence of defensive medicine in particular, and that therefore argumentation based on defensive practice in medicine has no

[88] N. Summerton, 'Trends in Negative Defensive Medicine within General Practice.' (2000) 50 *Br J Gen Pract* 565-566; N. Summerton, 'Positive and negative factors in defensive medicine: a questionnaire study of general practitioners.' (1995) 210 *BMJ* 27-29
[89] O. Ortashi, *et al*, 'The Practice of Defensive Medicine among Hospital Doctors in the United Kingdom.' (2013) 14 *BMC Medical Ethics* 1-6. The indicators of defensive medicine included: ordering tests that are probably not clinically indicated to avoid litigation, carrying out interventions or procedures that are probably unnecessary to avoid litigation, arranging unnecessary referrals to other specialties to avoid litigation, prescribing medications to prevent later criticism or litigation, refusing to treat high risk patients to avoid the possibility of litigation stemming from complications, or avoiding high risk procedures to avoid the possibility of litigation stemming from complications.
[90] *Ibid*, 5
[91] *Ibid*. This followed a similar trend in the USA where 48% doctors operating in high risk specialties, such as orthopedics reported that they had taken steps to reduce their practice, by eliminating procedures prone to complications or avoiding patients who had complex medical problems: D.M. Studdert, *et al*, 'Defensive Medicine among High-Risk Specialist Physicians in a Volatile Malpractice Environment.' (2005) 293 JAMA 2609-2617
[92] P. Case, 'The Jaded Cliché of 'Defensive Medical Practice': From Magically Convincing to Empirically (Un)convincing?' (2020) 36(2) *Journal of Professional Negligence* 48-77
[93] *Ibid*, 51-54
[94] *Ibid*, 62. She does add a third rebuttal, but this oddly moves her argument from a review of the use of arguments in law, to a normative approach (to adopt a purposive approach to negligence), which is not sufficiently backed up with case-law examples.

place in negligence jurisprudence.'[95] The crux of the argument within Case's paper rests on her problematisation of the empirical material, which falls into four broad categories[96]

(1) The definition of defensive medicine:

(i) That findings from the US are not equivocal to the findings of the UK, as the US studies identify defensive medicine utilising correlation in proxy phenomenon e.g. the estimated malpractice claim risk which are not directly comparable to the UK nationalised health system. Also, that defensive medicine may be induced in the US because of financial incentives; which makes it difficult to identify motivation which is defensive, rather than economic.[97]

(2) The existence of bias:

(i) That most studies conducted in the UK are authored by clinicians or academics, working at Universities (rather than social scientists). Case suggests that their positions 'might suggest some unavoidable bias in the conduct of that research.'[98]

(ii) That the studies may have been affected by sample bias and survey framing problems

(3) Lack of correlation between the studies:

(i) that there is variation in the 'headline' or overall percentage of doctors is indicative of the studies being unreliable.

(4) Methodological problems:

(i) That the study design relies on *self-reporting* of defensiveness by doctors in surveys and interviews, and are therefore unreliable.

(ii) That quantitative rather than qualitative methodologies are utilised in studies

(iii) That types of defensive disclosures and their causes are not disaggregated within existing research

This author agrees that the US and UK findings on defensive medicine are not sociologically equivocal, however, they are variations on a theme. Indeed, this is unsurprising because of the way that the different systems of healthcare operate. Case attempts to exclude forms of defensive medicine in the UK, by adopting a narrow 'judicial' definition defensive medicine. Particularly, by requiring a linear relationship between the enhanced normative standard as the primary cause of defensive decisions and or practices.[99] The reliance of a legal understanding of defensive medicine, as a way to exclude sociological findings is unconvincing. Case seems to require direct causation between legal standards and outcomes, without recognising the complexity of medical decision-making, or the medical context.

[95] *Ibid*, 50
[96] *Ibid*, 6-75
[97] *Ibid*, 65, relying on A. Jani & A. Papanikitas, "More than my Job is Worth – Defensive Medicine and the Marketisation of Healthcare." In T. Feiler, *et al* (eds), *Marketisation, Ethics and Healthcare.* (Routledge, 2018).
[98] *Ibid*
[99] *Ibid*, 51-53, 60-63, 64-65

Defensive medicine will inevitably manifest differently in varying contexts, for diverse reasons. However, one can still look to generalisable trends, or occurrences, which contain axiomatic or symptomatic content as a basis for diagnosing defensive medicine. These elements or axioms of defensive practices exist within both contexts. Particularly, the general correlation between decision-making and the harmful behaviours of *hedging*, or *avoidance*, which can be linked to a general fear of litigation or complaints (including patient threats, or confusion around normative rules, law, ethics, or avoidance litigation).[100] In relation to financial incentives, and intertwined motives, direct or majority causation are not necessary – as long as there is some causal (direct or indirect) link between the fear of litigation and the unnecessary act, or omission. One should attempt to identify the axiomatic elements of defensiveness, rather than take a linear exclusionary approach to identification. Indeed, taking an exclusive legalistic approach has the potential to exclude or ignore harmful impacts of legal standard on patients.

Second, it is Case fails to explain how academic affiliations could impact the design or conduct of studies and therefore introduce bias.[101] In relation to sample bias, Case argues there could have been elements of 'self-selection' or 'ascertainment bias' – for example, the low uptake in Summerton's work and high incidence of defensive medicine (98%).[102] However, the existing studies used qualitative methodologies which allowed data collection from a statistically significant (and sometimes very large[103]) number of doctors, who operated within different areas of medicine.[104] Case admits:

> Notwithstanding these confessed limitations, 98 per cent of Summerton's 60 per cent sample of GPs identifying with defensive practice is still statistically persuasive, as is the number of participants in Bourne ' s study (7, 926).[105]

Third, variation in headline percentages of self-reported defensive medicine amongst doctors is reflective of the differences between the sample populations – namely GP's, hospital doctors, and the members of the BMA. Indeed, the correlation between doctors operating in a number of context bolsters, rather than undermines the existence of the phenomena. Case admits:

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[100] *Ibid*, 65. See, T. Bourne, *et al*, 'The Impact of Complaints Procedures on the Welfare, Health and Clinical Practice of 7926 Doctors in the UK: A Cross Sectional Survey. (2015) *BMJ Open Access*: (<https://bmjopen.bmj.com/content/5/1/e006687.info>)

[101] *Ibid*, 65

[102] *Ibid*, 66; N. Summerton, 'Positive and Negative Factors of Defensive Medicine: A Questionnaire Study of General Practitioners.' (1995) *BMJ* 210, 28

[103] For example, T. Bourne, 'The Impact of Complaints Procedures on the Welfare, Health and Clinical Practice of 7926 Doctors in the UK: A Cross-Sectional Survey.' (2015) *BMJ Open* (<https://bmjopen.bmj.com/content/5/1/e006687.info>)

[104] For example, Summerton's work on GP's, Ortashi *et al's* work with hospital doctors, and the BMA's work on the general medical population: *Ibid*, O. Ortashi, 'The Practice of Defensive Medicine amongst Hospital Doctors in the UK.' (2013) 14 *BMC Ethics* 42; BMA, *Caring, Supportive, Collaborative: View of Doctors Working in the NHS*. (BMA, 2018)

[105] P. Case, 'The Jaded Cliché of 'Defensive Medical Practice': From Magically Convincing to Empirically (Un)convincing?' (2020) 36(2) *Journal of Professional Negligence* 48-77, 67

> […] whatever the reasons for the variability, we could agree that there is a discernible consensus that at least half the doctors participating in such research report themselves as using defensive practice. The cumulative impact of this body of research may be enough to satisfy a court (if necessary) that defensive practice in medicine is real and is cause for concern.[106]

In relation to methodological problems, Case rightly draws a distinction between *perceptions* of defensiveness, rather than observed evidence of *actual* defensive medical decision-making in practice.[107] However, the argument that self-reporting 'tells us little about the persuasiveness or significance of that defensiveness in their day to day medical judgements' is incorrect – the overwhelming prevalence and variation in the forms of defensive practices identified in the studies are potentially indicative of the significant and complex effect 'fears associated with litigation' may have on medical decision-making. Indeed *perceptions* of having acted defensively may itself form a distinct type of harm being inflicted on (certain) medical professionals – or, indeed, have an impact (explicitly or inchoately) on the form of medical decision-making, patient communication, or wider patient relationship (if not the ultimate decision of the doctor on whether to adopt a form of defensive medicine). Indeed, Case's own study found that doctors sometimes felt that they were operating in a hostile patient environment, that they used defensiveness as a negotiation strategy for aggressive patients, or for those who were particularly anxious or resistant to reassurance, as a way to avoid complaints. While there is not direct causal link between actual litigation, or fear of the law, and defensive behaviour, the growth in patient rights have empowered patients to make threats, and confusion about the law creates uncertainty when treating anxious or uncertain patients. As Case herself recognises these indirect or contributory phenomena should not be ignored.[108] Indeed, she admits, '[t]he cumulative anecdotes in this instance do provide convincing evidence at least of practitioner perceptions that defensive practice in medicine is problematic.'[109]

The utilisation of quantitative methods as a basis for identifying the existence of a phenomenon or type of practice emerging in a sample population is a sound methodology. Collecting explanatory data about why and how defensive medicine has occurred, is better suited to qualitative methodologies. Indeed,

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[106] *Ibid*, 67

[107] *Ibid*. There exists a literature of studies which utilise qualitative rather than quantitative methods, it is uncertain why Case criticises the quantitative methodology of some studies on defensive medicine, but does not engage more strongly with existing qualitative literature. For example, A. Ruston, 'Risk, Anxiety and Defensive Action: General Practitioner's Referral Decisions for Women Presenting with Breast Problems.' (2004) 6(1) *Health Risk & Society* 25; G. McGivern and M. Fischer, 'Medical Regulation, Spectacular Transparency and the Blame Business.' (2010) 12(6) *Journal of Health Organization and Management* 597; A Jain & J Ogden, 'General Practitioners' Experiences of Patients' Complaints: Qualitative Study. '(1999) *BMJ* 1596; J. Robertson, *et al*, 'An Exploration of the Effects of Clinical Negligence Litigation on Practice of Midwives in England: A Phenomenological Study.' (2016) 33 *Midwifery* 55

[108] *Ibid* 67-70. Relying on J. Fanning, 'Uneasy lies the neck that wears the stethoscope: Some observations on defensive medicine.' (2008) 24(2) *Professional Negligence* 93, 99

[109] *Ibid*, 67

Case's study illustrates how the connection between defensive practices and the expansion of normative rules is complex, and relates to the climate of medicine, the changing power structure in the doctor-patient relationship, communication and patient behaviour and complaint history.[110]

Case's most substantive complaint appears to be with a lack of sufficient disaggregation of causes for defensiveness. Case problematises the lack of exactness about the trigger of defensive disclosure.[111] This is unsurprising when she takes a narrow definition of defensiveness, and requires a direct causation between normative rules, and medical decision-making, as the basis of identifying defensive medicine.[112] Case recognises the Otashi and Bourne study goes some way to delineating the types of defensive medicine, and their consequences – identifying the proportion of respondents who have undertaken various defensive actions. However, she emphasises the lack of causation means there is no justification for limiting judicial normativity.[113] This author would argue that it is unnecessary to establish a direct line of causation to take defensive medicine seriously. The link between the form of defensive medicine, it's influences and causes, in the changing contexts and specialisms of the medical profession are unlikely to establish a single standard of care as the primary causative element. However, this does not take away from the ethical responsibilities in attempting to prevent patient harm.[114]

Case's strongest argument is in relation to the frequency and intensity of defensive medicine, collectively and within individual medical decisions. This data is important to making arguments about the proportionality of creating normative standards and the impact on patients in real terms. Case rightly states that the existing qualitative data is not certain about the magnitude of harm as a result of defensive decision-making.[115] However, contrary to Case, this uncertainty about the relationship between causes and harms would lend weight for a more expansive definition of defensive medicine. What one can say is that the occurrence of 264efensivee medicine, as part of the decision-making process, potentially means that doctors are not exclusively orientated towards the teleological ends of that process: in the deontic, if not consequential sense. This author would continue to argue that the burden of proof for deviation from the status quo also rests on those arguing for enhanced legal objectivity and/or normativity.

[110] *Ibid*, 67-69
[111] *Ibid*, 71-74
[112] *Ibid*, 73
[113] *Ibid*, 74
[114] See, D. Ritter, 'When to Act on a Correlation, and When Not to.' (Harvard Business Review, 2014). Indeed, the need to act on correlation, rather than causation has been demonstrated in public health interventions during Covid-19: K. Linka *et al*, 'The Reproduction Number of Covid-19 and its Correlation with Public Health Interventions.' (2020) 66 *Computations Mechanics* 1035-1050
[115] P. Case, 'The Jaded Cliché of 'Defensive Medical Practice': From Magically Convincing to Empirically (Un)convincing?' (2020) 36(2) *Journal of Professional Negligence* 48-77, 74

(iii) The subjective test

Heywood and Miola suggest that the proper way around the conceptual problems of the objective test is a stronger focus on the subjective element, to either enhance or limit the scope of materiality.[116] This was the approach subsequently taken by the Hong Kong Court in *Hii Chi Kok* [117] which argued that the particular patient standard could be activated, by the clear identification of patient values and information need, for example, by the patient asking a question.[118] Whilst this would theoretically work as an 'on switch' for information, it would not prevent the doctor disclosing information which the patient did not want to know, and therefore information that could be potentially harmful. This approach also fails to address the crux of the problem: that the purpose of the particular standard would be to facilitate a distinct type of autonomous decision - an authentic choice. The objective content of disclosure would have the potential effect of altering or influencing patient values meaning that one could not be sure a decision was authentic. If the patient could not receive an authentic choice the purpose of providing additional information according to their particular needs and values would be defeated. This is especially important if the patient has a presentation of a disease outside the norm. Similarly, providing a highly subjective disclosure may have the effect of undermining the purpose of providing an objective content of information; thus, to do so would be actively undermining the ability of the patient to have a rational choice.[119] It may be that the Supreme Court recognised the conceptual conflation at the heart of the test when they try to mitigate the potential pollution of the patient's values.[120] For example, they refer to the GMC guidance, at paragraph 5, which stated:

> The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept their advice. […][121]

Also, paragraph 19 stated:

[116] R. Heywood & J. Miola, 'The Changing Face of Pre-Operative Medical Disclosure: Placing the Patient as the Heart of the Matter.' (2017) 133 *Law Q Rev* 296-321, 302-303

[117] *Hii Chii Kok v (1) Ooi Peng Jin London Lucien; (2) National Cancer Centre of Singapore Pte Ltd* [2017] SGCA 38 [144]; L.V. Austin, '*Hii Chii Kok v (1) Ooi Peng Jin London Lucien; (2) National Cancer Centre*: Modifying *Montgomery*.' (2019) 27(2) *Med L Rev* 339-351, 345

[118] R. Heywood & J. Miola, 'The Changing Face of Pre-Operative Medical Disclosure: Placing the Patient as the Heart of the Matter.' (2017) 133 *Law Q Rev* 296-321, 305. Although one wonders how much further this actually goes from the position in *Sidaway* which required disclosure if the patient identified information need (See Chapter 2, Section 3)

[119] See Chapter 3, Section 3

[120] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [77]-[78], [90]

[121] *Ibid*, [78]: *GMC, Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008), [5]

> You should give information to patients in a balanced way. If you recommend a particular treatment or course of action, you should explain your reasons for doing so. But you must not put pressure on a patient to accept your advice.[122]

This is problematic if the patient and their values are unreasonable or outlandish which make it impossible for the doctor to provide a balanced approach. How, for example, might a doctor disclose the risks of a Covid19 vaccine to a patient who is an anti-vaxxer? Providing an objective content of information may undermine her belief that a vaccine is harmful,[123] however, a subjective disclosure would misinform the patient. Similarly, withholding the vaccine might lead to accusations of negligence despite an authentic informed consent being impossible.

Even if one accepts that the subjective test is fundamentally formative rather than substantive in ensuring patient autonomy, the identification of values and circumstances which are material to the particular patient standard invites another layer of medical discretion. For example, not every aspect of the patients' personality, beliefs or activities may be material but there is a dearth of relevant research. Some patient's circumstances will be so rare that it will require the doctor to adopt experimental or interpretative approaches, which will be in opposition to usual courses of treatment and/or disclosure.[124] Statistical risks once identified will also have to be interpreted in light of the patients' actual medical circumstances. The particular patient standard therefore necessitates an additional layer of medical discretion which is not recognised by the Supreme Court.

Due to the layers of discretion, assessing whether the doctor has fulfilled the subjective standard again invites the potential revisionism, problematised above (Option 2). Depending on the case theory presented by counsel at trial, evidence of the patients' information needs and character can easily be picked to supplement their argument. This allows for the construction of a hypothetical particular patient, rather than determining the relevant evidence based on the authentic patient (warts and all).[125] For example, the first instance judge (Lord Bannatyne) found that:

> The pursuer is a clearly highly intelligent person with a mother who is a doctor and a sister who is a doctor. It seemed to me that if she was not receiving answers in relation to matters, which

[122] *Ibid*, [19]
[123] B. Duffy, *Coronavirus: Vaccine Misinformation and the Role of Social Media.* (The Policy Institute, 2020): (https://www.kcl.ac.uk/policy-institute/assets/coronavirus-vaccine-misinformation.pdf)
[124] The introduction of the Medical Innovation Bill introduced by Lord Saatchi was aimed at removing the fear of liability which acted as a barrier to the particularisation and innovation of treatments. However, it was roundly rejected by both the medical and academic community, see for example: J. Miola, 'Bye-Bye *Bolitho*? The Curious Case of the Medical Innovation Bill.' (2015) 15(2-3) *Med Law Int* 124-154
[125] J. Montgomery & E. Montgomery, '*Montgomery* on Informed Consent: An Inexpert Decision?' (2016) 42 *J Med Ethics* 89-94, 90

> according to her own evidence were of critical concern to her then in my judgement she would not have accepted that situation and would have sought a second opinion or would have asked for a different consultant to be the treating physician. Looking to her whole evidence and the manner in which she gave it I do not think that for a moment she would have accepted not getting answers to questions which she was specifically putting to Dr McL. The view which I have formed of the pursuer did not fit in with the picture she was seeking to present of what had passed between her and Dr McL at the various consultations.[126]

Additionally, the lower court found that the claimant knew that caesarean section was an option.[127] However, the Supreme Court reinterpreted the circumstances of the case to characterise the patient as anxious, and inhibited from attaining information by the paternalistic doctor, apparently falling.[128] As Montgomery & Montgomery argued, the Supreme Court fell 'back onto stereotypes based on: the social and psychological realities of the relationship between a patient and her doctor […] Few patients do not feel intimated or inhibited to some degree.'[129] The Supreme Court went on to argue that the claimant was 'anxious', yet characterised the doctor's decision to not repeat information of potentially serious and potentially life threatening risks as paternalistic.[130] This is inconsistent characterisation of the particular patient. It is unhelpful as it encourages the doctor not to act in good faith in their interpretation of the patient, and thus, abide by the spirit of the subjective standard: to provide patient's at the time with the information they need to make a decision.

6.1.3. Retaining the therapeutic relationship

The Supreme Court adopted the approach of the jurisdiction school to justify a movement to normative standards, by arguing doctors lack any sort of distinct moral expertise in decision-making about materiality. As the previous section has shown, the simplicity of the normative standard betrays the multiple complex layers of technical skill and moral expertise required to identify and communicate material information.[131] As Montgomery & Montgomery argued:

> […] the idea that skills can be broken down into component parts is characteristic of the novice. Expert practice does not separate out the components of judgement but integrates them. The transition from novice to expert is characterised by the tempering of technical knowledge with

[126] *Nadine Montgomery v Lanarkshire Health Board* (2010) CSOH 104, [246]
[127] *Ibid*, [245]; *NM v Lanarkshire Health Board* (2013) CSIH 3, [242]
[128] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [94]
[129] J. Montgomery & E. Montgomery, '*Montgomery* on Informed Consent: An Inexpert Decision?' (2016) 42 *J Med Ethics* 89-94, 90
[130] Ibid, 90; Also see, *NM v Lanarkshire Health Board* (2013) CSIH 3, [41]
[131] For example, (1) the requirement to delineate material information that a reasonable patient would want, (2) the need to ensure that this information is communicated in a comprehensible way so a patient can understand it, and (3) to make sure that the content of the information is not harmful to that particular patient; all of which require combining moral and technical types of information in the circumstances. *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 [85]-[87]

> experiential learning.[132] […] This point has a long philosophical history and was described by Aristotle as 'phronesis' or practical wisdom – enabling judgement to be made about how to act in particular cases.[133] The Court's approach relies, therefore, on a denial of the idea of professional expertise. It works in precisely the opposite direction to those who seek to educate professionals to be experts rather than novices. […][134]

The argument that this type of moral-medical decision-making is neither specialist, nor necessary, is severely weakened by the Supreme Court's reliance on *Consent: Making Decisions Together*[135] for their model of choice. The Supreme Court incorrectly asserted that standard of disclosure in practice, and the approach of the guidance were equivocal: that 'the guidance issued by the General Medical Council has long required a broadly similar approach.'[136] Despite the rhetoric, the previous iteration of guidance was concerned with straddling the divide between the consumer relationship[137] and the therapeutic relationship. The therapeutic relationship of course required exactly this type of *circumstantial-moral* decision-making so the doctor could act in the best interests of her patient.[138] For example:

> (b) The doctor uses specialist knowledge and experience and clinical judgement, and the patient's views and understanding of their condition, to identify which investigations or treatments are likely to result in overall benefit for the patient. The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept their advice. […]
>
> (d) If the patient asks for a treatment that the doctor considers would not be of overall benefit […] after discussion […] they do not have to provide the treatment.[139]

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[132] P. Benner, 'Using the Dreyfus Model of Skill Acquisition to Describe and Interpret Skill Acquisition and Clinical Judgement in Nursing Practice and Education.' (2004) 24 *Bull Sci Technal Soc* 188-199; K. Montgomery, *How Doctors Think: Clinical judgement and the practice of medicine*. (Oxford University Press, 2006). See a similar problematisation about the use of deconstruction of knowledge and expertise in: N.M. Priaulx & M. Weinel, 'Behaviour on a Beer Mat: Law, Interdisciplinarity & Expertise.' (2014) 2 *Journal of Law, Technology and Policy* 361-391; N. Priaulx & M. Weinel, 'Connective knowledge: what we need to know about other fields to 'envision' cross disciplinary collaboration.' (2018) 6 *European Journal of Futures Research* 21.

[133] A. MacIntyre, *After virtue*. (Bloomsbury, 1981)

[134] J. Montgomery & E. Montgomery, 'Montgomery on Informed Consent: An Inexpert Decision?' (2016) 42 *J Med Ethics*-94, 93

[135] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 [77]-[78]; GMC, Consent; patient and doctors

[136] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 [93]

[137] GMC, *Seeking patients consent: the ethical considerations.* (GMC, 1998), [6].

[138] See for example, *Blyth v Bloomsbury Health Authority* [1993] 4 Med LR 151, CA; *Smith v Tunbridge Wells Health Authority* [1994] 5 Med LR 334; *Smith v Salford Health Authority* [1994] 5 Med LR 321; *Lybert v Warrington Health Authority* [1996] 7 Med LR 71 CA

[139] *GMC, Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008), [5]

Dunn *et al*, and Herring *et al*, similarly argued that the requirement that the doctor take 'reasonable care' in their decision-making is indicative of the legal standard being purely therapeutic in nature.[140] The considerations of autonomy would therefore only act as an internal requirement or consideration. However, this is discordant with the both the historical context of the ethical guidance and the general thrust of the judgement. Instead, this thesis argues that the Supreme Court had unwittingly adopted both models of the medical relationship into the law; in the same way as the High Court of Australia in *Rogers v Whitaker*[141].[142] The therapeutic model is serviced by the objective limb of the test and the consumer model in the subjective limb of the test.[143] However, as previously argued, the dual models of the medical relationship existing within the same cause of action is conceptually incompatible as the purpose of the disclosure points in different directions; this has been borne out in the application of *Montgomery*.[144]

6.1.4. Post *Montgomery*: repeating the same mistakes

This section argues that the dual relationship within the standard of care for *Montgomery* has divided the judiciary about which relationship to prioritise. Rather than attempt to straddle the relationship, many of the judiciary have chosen sides. This has created a smorgasbord of judgements that apply diametrically different rules to achieve the aims of either the consumer or therapeutic relationship. This confusion has been exacerbated by a flood of retro-active litigation monopolising on this inconsistency to argue liability under the consumer relationship standard.[145]In the scoping exercise for this Chapter, 46 post-*Montgomery* cases were identified (2015 to 2020) - more than all other periods combined. The amount of case-law has meant the divide in judicial interpretation is much more pronounced.[146] One group of judges adopted a therapeutic relationship as the basis of the standard; placing heavy emphasis on the reasonable patient *in the circumstances* and thus allowing the doctor to contextually interpret what information was in the best interests of the patient. The particular patient standard was then seen

[140] M. Dunn, *et al*, 'Between the Reasonable and the Particular: Deflating Autonomy in the Legal Regulation of Informed Consent to Medical Treatment,' (2019) 27 *Health Care Analysis* 110-127; 112-113; J. Herring, *et al*., 'Elbow Room for Best Practice? *Montgomery*, Patients' Values and Balanced Decision-making in Person-Centred Clinical Care.' (2017) 25(4) *Med L Rev* 582-603

[141] *Rogers v Whitaker* (1992) 16 BMLR 148, 157

[142] See Chapter 3, Section 4

[143] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 [78]

[144] Chapter 3, Section 4

[145] S. Sundar, "Case Based Laws are Turning into 'Emperor's New Clothes." [Electronic response]: D.K. Sokol, 'Update on UK Law on Consent.' (2015) 250 *BMJ* 1481: As Sundar argued: "Imagine a stretch of road where due to high incidence of accidents, the speed limit was reduced from 40 to 30 miles per hour (mph). Imagine the absurdity if police try to retrospectively prosecute everyone who drove at 30 to 40 mph in the past. This is what Montgomery ruling is threatening to do in medical negligence cases. The *Montgomery* ruling is going to open the floodgates form compensation for past actions based on the retrospective application of a case based law by moving the goal posts on the issue of informed consent."

[146] See, Appendix 5. Other judges misapplied the *Montgomery* test completely, and simply applied the conventional *Bolam* standard. These cases will not be discussed, as this thesis would argue that they are wrong in law. For example, *Grimstone v Epsom and St Helier University Hospital NHS Trust*. [2017] EWHC 3756 (QB). See the excellent analysis of this point: L.V. Austin, *Grimstone v Epson and St Helier University Hospitals NHS Trust*: (It's Not) Hip to be Square.' (2017) 26(4) *Med L Rev* 665-674, 668. Also see, *Barrett v Sandwell and West Birmingham Hospital NHS Trust* [2015] EWHC 2627. Thankfully at the time of writing this judgement is being appealed.

as an internal requirement, similar to the judgement of Lord Scarman[147] i.e., that there is a presumption that the patient should receive information so that they can make an authentic autonomous choice, in their best interest's.

The process of judicial analysis adopted the two stage *Bolam* test,[148] plus the requirement to assess whether due weight has been paid to the patient's values: this is termed the *Bolam* plus approach.[149]Another group of judges interpreted the standard of care as facilitating a consumer relationship.[150] The liberal and authentic model of autonomy were then used interchangeably to find liability. This inconsistent approach saw judges' independently delineating materiality based on their preferred model of informed consent, then comparing this content with the information provided by the doctor: a blinked moralism.[151] This approach creates an unknowable judicial standard – as a result liability is almost inevitable – and fails to appreciate that medical discretion is inevitable to a standard of materiality, because of the variable nature of patient circumstances. This thesis will briefly illustrate how the approaches have been applied.

(i) The objective test: *Bolam* plus+

The judiciary have placed emphasis on the *patient in the circumstances* element of the objective test, to reintroduce *circumstantial-moral* decision-making. This discretion allowed the doctor to use the circumstances to delineate what information was in the patient's best interests, thus facilitating the teleological purpose of medicine in the doctor-patient relationship. The judiciary have applied the two stage *Bolam* approach to assess the reasonableness of decision-making.[152]

(a) Stage 1: Internal Assessment

First, the factual and scientific basis of the decision is tested.[153] In *SXX v Liverpool Women's NHS Foundation Trust,*[154] for example, Lady Justice Arden[155] allowed the appeal of the decision of Mr Recorder Elleray QC,[156] where a nurse had overlooked the clinical note which recommended a

[147] See Chapter 2, Section 1; *Sidaway v Board of Governors and Bethlem Royal Hospital* [1985] AC 871, per Lord Scarman at 882-887
[148] See Chapter 2, Section 3
[149] For example, see: *Spence v Hillingdon NHS Trust* [2015] EWHC 1058 (QB); *Tasmin v Barts NHS Trust* [2015] EWHC 3135 (QB); SXX *v Liverpool Women's NHS Foundation Trust* [2015] EWHC 4072 (QB); *Bayley v George Eliot Hospital NHS Trust* [2017] EWHC 3398; *Duce v Worcestershire Acute Hospital NHS Trust* [2018] WEHCA Civ 1307 (COA).
[150] *Webster v Burton Hospitals NHS Foundation Trust* [2017] EWCA Civ 62 (COA); *Lunn v Kanagaratnam* [2016] EWHC 93 (QB); *Thefaut v Johnston* [2017] EWHC 497 (QB); *Hassell v Hillingdon Hospitals NHS Foundation Trust* [2018] EWHC 164 (QB); *Worral v Antoniadou* [2016] EWCA 1219 (COA); *Correia v University Hospital North Staffordshire NHS Trust* [2017] EWCA Civ 356; *Diamond v Royal Devon & Exeter NHS Foundation Trust* [2019] EWCA Civ 585; *Keh v Homerton University Hospital NHS Foundation Trust* [2019] EWHC 548 (QB)
[151] J. Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism? (2007) 15(3) *Health Care Analysis* 235-255
[152] See Chapter 2, Section 3
[153] See also, *Bayley v George Eliot Hospital NHS Trust* [2017] EWHC 3398 (QB), [57]
[154] *SXX v Liverpool Women's NHS Foundation Trust* [2017] EWCA Civ 279 (CA)
[155] *Ibid*, [11]. Although she made the finding on *Bolam* and did not actually mention *Montgomery*
[156] *SXX v Liverpool Women's NHS Foundation Trust* [2015] EWHC 4072 (QB)

caesarean section,[157] and instead gave advice encouraging vaginal delivery. As basis of the decision to offer this advice was factually incorrect, the process of medical decision-making was negligent.[158] In *Duce v Worcestershire Acute Hospital NHS Trust,*[159] on the other hand, the Court of Appeal found that the doctor is not expected to identify or provide information which is not known to the scientific community, or provide pioneering treatments as potential options for treatment. Whilst Dr Singh admitted that he did not specifically disclose the risk of chronic or neuropathic pain directly before surgery, other medical professionals had recommended less invasive treatment to the patient.[160] The claimants' expert also admitted that CPSP was not a known risk of the procedure at the time.[161] The claimant appealed arguing, amongst other things, that the doctor should have applied the subjective patient standard and know that reducing pain was important to the patient. Hamblen LJ stated that:

> what risks were associated with an operation were or should have been known to the medical professional in question. That is a matter falling within the expertise of the medical professional.[162]

The doctor cannot be criticised for not disclosing a risk when he could not reasonably know it existed, as it did not appear in any literature.[163]

The court then has to make an objective decision whether the relevant factors were identified in the circumstances. The Court of Appeal in *Duce* stated that whilst issues were fact specific, this could include, for example:

> Factors of relevance to determining materiality may include: the odds of the risk materialising; the nature of the risk; the effect its occurrence would have on the life of the patient; the importance to the patient of the benefits sought to be achieved by the treatment; the alternatives available and the risks associated with them.[164]

The Court of Appeal in *Jones v Royal Wolverhampton Hospital NHS Trust* similarly stated that considerations could include:

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[157] *SXX v Liverpool Women's NHS Foundation Trust* [2017] EWCA Civ 279 (CA), [7]
[158] *Ibid*, [9]
[159] *Duce v Worcestershire Acute Hospital NHS Trust* [2018] EWCA Civ 1307 (COA)
[160] *Ibid*, [11]
[161] *Ibid*, [50]
[162] *Ibid*, [34]; relying on *Montgomery*,[83]
[163] *Ibid*, [42]
[164] *Ibid*, [35]

> […] its nature and incidence, the claimant's perception of the risk, and then to calibrate such evidence against the possibility of the risk eventuating within a limited time scale, all against the claimant's assessment of the desirability of taking an alternative course of action in light of that risk. It may be in the very nature of these cases that a claimant will always say that he or she would view the risk as material and that he or she would have adopted a different and cautious course of action, but this assumes that the test is exclusively subjective. In my view the court will in some degree apply an objective test and will not be bound to accept inconsistent evidence given by the claimant.[165]

Finally, the court should go on to see whether due weight was placed on different factors within the doctor's decision-making paradigm; obviously paying due regard to the assumption that an autonomous choice will be in the actual patient's best interests. For example, Dingeman J in *A v East Kent Hospitals NHS Trust*[166] assessed whether the need for an autonomous choice was paid due regard within the wider materiality determination. The claimant argued that hospital had been negligent in not offering a chromosomal abnormality test, which she claimed was fundamental to her decision to continue with her pregnancy. The claimant alleged on the objective limb that that the risk was significant, at 1-3 (the experts for the defence, argued that the risk of chromosomal abnormality was less than 1 in 1000).[167] Dingemans J found that materiality was not to be constructed exclusively from statistics, but must also include biopsychosocial considerations drawn from the actual patient's in the circumstances.[168] Taking the patients values into account, the judge still determined that the risk was negligible or background,[169] and concluded a reasonable patient, in the position of Mrs A, would have attached no significance to the level of risk[170] Further, the judge found that the patient could not rely on the particular patient standard as a mechanism to mandate disclosure.[171] The evidence indicated that the claimant at the time was willing to live with a background risk of down syndrome, it could not be said that based on her values she needed to eradicate every risk.[172] The judge found that whilst the risk of chromosomal abnormality, much like shoulder dystocia, was always present, there were no special or indicative facts that would lead an ordinary doctor, in those circumstances, to think that the risk of abnormality was heightened.[173]

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[165] *Jones v Royal Wolverhampton Hospital NHS Trust* [2015] EWHC 2154 (QB), [10]
[166] *A v East Kent Hospitals University NHS Trust* [2015] EWHC 1038 (QB)
[167] *Ibid*, [44]
[168] *Ibid*, [23]
[169] *Ibid*, [84]
[170] *Ibid.* [89]-[90]
[171] *Ibid*, [61] & [102]: "[…] if during the pregnancy I had been told that there was the possibility of B being born disabled I would not have proceeded with the pregnancy", and [103]: "I do not believe in bringing a child into the world if they are going to suffer and unable to lead a full life. If we had the slightest belief that there would be something wrong I would not have proceeded with pregnancy."
[172] *Ibid*, [96]
[173] *Ibid*, [69]

(b) Stage 2: The External Assessment

The external analysis, again, saw the courts look to the expert evidence to see whether the decision was logical and fell within a band of reasonable medical conduct: to the extent that the decision could be said to be in the patient's best interests in the circumstances.[174] The majority of the case-law on this element related to the disclosure of reasonable treatment options.[175] The Supreme Court in *Aintree UH NHSFT v James* had recognised that this was fundamentally a medical decision (albeit that the patients values should weigh heavily).[176] For example, HHJ Worster in *Bayley v George Eliot Hospital NHS Trust*[177] found that the failure to recommend the use of stockings and iliofemoral venous stenting to treat DVT was reasonable given that 'a reasonable competent vascular surgeon in 2008 would not have been aware of the possibility of ilio-femoral venous stenting as an alternative treatment in their circumstances.'[178] Similarly, in *A v East Kent Hospitals NHS Trust* [179]the judge referred to the RCOG guidelines to assess whether the decision not to provide a chromosomal abnormality test was negligent. The judge found that failure to provide the test was reasonable as the doctor had carried out a Doppler scan and foetal abnormality test at 21 weeks, and there were no structural problems.[180] The scientific evidence available in 2009, indicated that it was unnecessary on this basis to offer a further test.[181]

As the doctor was operating under their therapeutic duty, the need to provide information was ongoing.[182] For example, in *Spence v Hillingdon NHS Trust*[183] the claimant was successful in arguing that the surgeon should have informed him of the signs of deep vein thrombosis after surgery, so that he could recognise the risk when it arose. Following *East Kent*,[184] HHJ Collender QC placed emphasis on the need to evaluate what a reasonable patient would want in the actual circumstances of the case – which could not be reduced to percentage thresholds.[185] The judge found that the subjective standard

[174] See for example, *Tasmin v Barts NHS Trust* [2015] EWHC 3135 (QB), per Jay J. at [116]. This seems to be in antithesis to the judgement in *Montgomery v Lanarkshire Health Board* [2015] UKSC, 11, at [94] & [115]-[116].
[175] See for example, *Cameron v Ipswich Hospital NHS Trust* [2018] EWHC 38 (QB), where HHJ Forster QC evaluated whether providing an option of decompression for cauda equina syndrome was reasonable in the circumstances, by evaluating the evidence the doctor used to make his decision [107]-[110] and whether this was (seen externally) as a reasonable medical interpretation [118]-[121].
[176] *Aintree University Hospitals NHS Foundation Trust v James* (2013) UKSC 67, [17]-[22]. This is consistent with *Burke* v *GMC* [2005] EWCA Civ 1003
[177] *Bayley v George Eliot Hospital NHS Trust* [2017] EWHC 3398, per HHJ Worster at [12]-[13]
[178] *Ibid*, [55]-[57] and [99]
[179] *A v East Kent Hospitals University NHS Trust* [2015] EWHC 1038 (QB)
[180] *Ibid*, [70]
[181] *Ibid*, [72]-[74]
[182] *Spence v Hillingdon NHS Trust* [2015] EWHC 1058 (QB), per HHJ Collender QC at [77]: "I accept that, on the fact of it, there is an apparent inconsistency in this case if there was in Mr Spencer's case no duty to warn of the risk of deep vein thrombosis or pulmonary embolism pre-operation to obtain a properly informed consent but there was a duty to inform about symptoms and signs indicative of it. However, I consider that argument unpersuasive. Different considerations are at play. The subject matter of the first is a warning of a remote risk the second is information as to characteristic signs and symptoms indicative of a potentially fatal condition that can be successfully treated if early diagnosed." See also, a duty to advise and follow up on the patient after diagnosis and treatment in: *Gallardo v Imperial College Healthcare NHS Trust* [2017] EWHC (QB)
[183] *Spence v Hillingdon NHS Trust* [2015] EWHC 1058 (QB)
[184] *Ibid*, [44]
[185] *Ibid*, [32]

added a gloss to how the reasonableness of a medical decision was to be assessed. [186] This was an integrated medical judgement. To test the logic of the decision the judge examined the argument of the defendant, the opinions of the expert evidence, and the NICE guidelines. The guidelines recommended that the patient should be given information if they were within a risk category. The defendant argued that hernia repair was not in this category. Utilising *Bolitho*,[187] the judge found that the guidelines were not exclusionary or exhaustive and therefore should have been interpreted purposively rather than strictly. The purpose of the guidelines was to avoid death. Although, a 1 in 50000 chance of deep vein thrombosis was small it was life-threatening[188] and the signs were readily identifiable by an informed patient.[189] It was also 'easy and practical' to provide advice in the circumstances.[190]

(ii) The subjective test: *blinkered moralism*

This section argues that a second group of judges adopted the consumer patient relationship as the basis of interpretation.[191] As the purpose of information disclosure was to ensure an informed consent, the judiciary found themselves best placed to independently define this right rather than using deductive reasoning to analyse the decision actually made.[192] However, there remained disagreement about the model of autonomy that the doctors was facilitating. Some judges prioritised the facilitation of an authentic model of informed consent. For example, the facts in *Thefaut v Johnston*[193] were very similar to those found in *Spencer*,[194] however, Green J took an opposing view to the previous judge. He argued that *Montgomery* is distinct from *Bolam*, and that the doctor had to disclose the information that is 'logically relevant to the appraisal that the patient must perform' given their circumstances.[195] Circumstances would therefore include the patient's actual physical needs, emotions and values i.e., what they considered reasonable. This placed a heavy emphasis on patient values as a means for identifying materiality even under the objective limb. For example, the doctor could not rely on

[186] *Ibid*, [68]: "In light of the *Montgomery* decision already discussed above, I would express the test I should apply to be the Bolam test with the added gloss that I should pay regard to what the ordinary sensible patient would expect to have been told. Put in the form of a question, the test I consider to be, would the ordinary sensible patient be justifiably aggrieved not to have been given the information at the heart of this case when fully appraised of the significance of it?"
[187] *Ibid*, [25]; *Bolitho v City and Hackney Health Authority* [1998] AC 232, per Lord Browne-Wilkinson at 241F-242B & 243 A-D
[188] *Ibid*, [53]
[189] *Ibid*, [78]: '[…] I consider that modern, safe and responsible medical practice should be to give such advice to patients undergoing general anaesthetic […] to inform such patients of the very particular signs and symptoms of those conditions is a precaution that can save lives and should be given."
[190] *Ibid*, [71]
[191] For example, *Thefaut v Johnston* [2017] EWHC 497 (QB) [57] argued that *Chester v Afshar* [2004] UKHL 41, per Lord Hope at [86] is part of law.
[192] R. Heywood & J. Miola, 'The changing face of pre-operative medical disclosure: placing the patient as the heart of the matter.' (2017) 133 *Law Quarterly Review* 296-321, 300.
[193] *Thefaut v Johnston* [2017] EWHC 497 (QB)
[194] *Spence v Hillingdon NHS Trust* [2015] EWHC 1058 (QB)
[195] *Thefaut v Johnston* [2017] EWHC 497 (QB), [54]: "It is common ground between counsel in the present case that the test is a mixture of the subjective and the objective. Logically, and as a matter of policy, it cannot be wholly subjective because this would engage liability in favour of a patient who was irrational or wildly eccentric yet genuine. The test whether "[…] in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk", combines subjectivity with objectivity."

percentages to identify average circumstances or patient need,[196] or even form an objective medical view of what information, if withheld, might causes an objective or 'justifiable grievance.[197] Instead, the doctor had to disclose what a reasonable person would think the actual patient would need to know for an informed consent.[198]

> It is common ground between counsel in the present case that the test is a mixture of the subjective and the objective. Logically, and as a matter of policy, it cannot be wholly subjective because this would engage liability in favour of a patient who was irrational or wildly eccentric yet genuine. The test whether "*[…] in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk*", combines subjectivity with objectivity. (author's emphasis)

The subjective limb was interpreted as going further to require the doctor to consider the authentic values of the patient and their information need, to either enhance or restrict information. [199]

> Paragraph [89] (of *Montgomery*) suggests that the subjective element could extend quite far. It not only deals with the important point that risk cannot and should not inappropriately be reduced to percentages but it seems to treat as relevant in the evidential mix factors such as the effect "*which its occurrence would have upon the life of the patient*" which could reduce a person's mobility and prevent him/her engaging in a favourite sport.[200] (author's emphasis)

The doctor then had a duty to ensure a subjective standard of communication, in a 'comprehensible manner' which was tailored to the 'time and space'[201] of the disclosure, without using percentages. The information was also to be provided in a neutral way, to avoid a false degree of certainty, and hence facilitate the authentic model of autonomy.

This authenticity approach was similarly followed by Dingeman J, in *Hassell v Hillingdon NHS Foundation Trust*.[202] The claimant suffered a spinal cord injury and paralysis as a result of a decompression and disc replacement operation,[203] whilst the operation was not found to be negligent

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[196] *Ibid*, [56]. It is ironic, however, that the judge gave the example of 1 in 1000 chance of occurrence of cerebral palsy, in Tasmin v Barts Health NHS Trust, as an example of a borderline case: *Tasmin v Barts Health NHS Trust* [2015] EWHC 3135 (QB), per Jay J, at [115]; following *A v East Kent Hospitals NHS foundation Trust* [2015] EWHC (QB), per Dingeman J, at [84]
[197] *Ibid*, [62]
[198] *Ibid* [54]-[55] & [80]-[81]
[199] *Ibid*, [55]- [56]
[200] *Ibid*, [56]; *Montgomery* at [89]
[201] *Ibid*, [58]; *Montgomery* at [90]
[202] *Hassell v Hillingdon Hospitals NHS Foundation Trust* [2018] EWHC 164 (QB)
[203] *Ibid*, [14]

the doctor failed to obtain an informed consent.[204] The defendant could not remember the disclosure, but claimed he followed a routine, the consent form listed the potential risk of spinal cord injury[205] and the doctor encouraged Mrs Hassell to do her own research.[206] The risks were repeated before gaining consent to surgery. This included information about ongoing pain, spinal cord injury, and potential weakness,[207] but the doctor did not specifically mention the risk of paralysis.[208] The experts agreed that the risk of paralysis was 1 in 1000[209] and no reasonable body of medical practice would require specific disclosure, only that there was a risk of 'damage [to] the nerves and ankle and feet when referring to cauda equina.'[210] The defendant inferred that risk of weakness was equivocal to paralysis. However, the judge found that although the risk of paralysis would not have been given to an average patient undertaking the treatment, the actual patient 'would have been very concerned about that as the mother of three children in full-time work as head of year.'[211] The objective standard was therefore particularised. The judge also found that whilst one could infer that there was a risk of paralysis from disclosure, a reasonable patient would not have been able to understand this on the day of the surgery.[212] This was negligent as the doctor had a duty to communicate to ensure understanding for an informed consent, which could not be achieved be a reasonable patient at this time.[213] Dingeman J then suggested that the failure of the doctor to regularly disclose the additional potential risks of DVT and pulmonary embolism[214] was also evidence his communication practices were generally poor.[215]

As suggested in the previous section the judgement in *Hassell* is illustrative of the problem of blinkered moralism: of judges making independent assessments of materiality and (un)consciously picking and choosing different models of autonomy as a basis to identify material information.[216] On the one hand the hypothetical patient was particularised so that information is found to be subjectively significant, yet at the same time the judge made findings about the average patient's inability to make autonomous

[204] *Ibid*, [84]
[205] *Ibid*, [35]
[206] *Ibid*, [36] & [72]
[207] *Ibid*, [16]
[208] *Ibid*, [42]
[209] *Ibid*, [53]
[210] *Ibid*, [20] & [54]
[211] *Ibid*, [69] & [10]
[212] *Ibid*, [74]. This is almost in complete antithesis to the finding of the Court of Appeal in *Duce v Worcestershire Acute Hospital NHS Trust*, which recognised that the doctor was not obliged to tell the patient information which was not considered medically relevant (on a *Bolam* standard) by experts at the time.
[213] *Ibid*, [5]
[214] *Ibid*, [36] & [68]
[215] *Ibid* [68] & [73]
[216] Herring *et al* also argue that the judiciary are now obliged to make independent decisions about materiality - rather than analysing the decision-making process which was previously 'all in the doctor's head.' J. Herring, *et al*, 'Elbow Room for Best Practice? Montgomery, Patients' Values, and Balanced Decision-Making in Person-Centred Clinical Care.' (2017) 25(4) *Med L Rev* 582-603, 591-592

choices before surgery.[217] Another patient may, however, need additional and detailed information before treatment. Because of this generalisation those patients may now be ignored.[218]

The additional requirement to facilitate a consumer model of treatment choice, through the requirement to disclose all 'reasonable alternative or variant treatment', in *Montgomery,* has led some judges to construe the information needs of the reasonable patient so widely as to require an exhaustive disclosure.[219] As Herring *et al* argue, this is because the patient is conceptualised as the primary decision-maker who should choose between treatment options.[220] For example, the Court of Appeal in *Webster v Burton Hospitals NHS Foundation Trust*[221] suggested:

> Without intending to summarise the effect of *Montgomery*, in general terms the doctor's obligation (apart from in cases where this would damage the patient's welfare) is to present the material risks and uncertainties of different treatment, and to allow patients to make decisions that will affect their health and well-being on proper information. The significance of the risks and uncertainties, including the possibility of alternative treatment, being sensitive to the characteristics of the patient.[222]

The actual process of medical decision-making for materiality was irrelevant. The Court independently came to the conclusion[223] that all of the options of further investigatory tests/treatments (e.g. an ultrasound or induction[224]) for diagnosis, and the associated risks and benefits of all these options, were material to the particular patient; including 'the increased risk of perinatal (the period around birth) mortality, including ante partum (before delivery) mortality, based on a very small statistical base.'[225] Similarly, in *Lunn v Kanagaratnam*[226], the claimant suffered rare complications as a result of a pace-maker operation and argued that the doctor had failed to provide options other than a pace-maker to treat her fainting condition.[227] HHJ McKenna relied on the GMC guidance to argue that under the

[217] This is a similar approach to Lady Hale who argues that the doctor may not be obliged to offer the pros and cons of all the options, then creates a category of patients which always require disclosure. Thus, the doctor is obliged to provide to provide all options 'where either the mother or child is at heightened risk from vaginal delivery.' *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, per Lady Hale, at [111]
[218] *Hassell v Hillingdon Hospitals NHS Foundation Trust* [2018] EWHC 164 (QB) [5]
[219] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [78], [87] & [95]
[220] J. Herring, *et al*, 'Elbow Room for Best Practice? Montgomery, Patients' Values, and Balanced Decision-Making in Person-Centred Clinical Care.' (2017) 25(4) *Med L Rev* 582-603, 591-592, 586 & 591-592
[221] *Webster v Burton Hospitals NHS Foundation Trust* [2017] EWCA Civ 62 (COA). See also, Kennedy *v Frankel* [2019] EWHC 106
[222] *Ibid*, per Lord Justice Jackson, Lord Justice Simon & Lord Justice Flaux, at [35]
[223] Relying on *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [115]
[224] *Webster v Burton Hospitals NHS Foundation Trust* [2017] EWCA Civ 62 (COA) [17]
[225] *Ibid*, [38]
[226] *Lunn v Kanagaratnam* [2016] EWHC 93 (QB)
[227] *Ibid*, [3]

objective limb disclosure of all options was mandatory,[228] and as the patient was reluctant to accept more surgery, under the subjective limb this indicated that she would wish to be supplied with other options.[229]

In *Diamond v Royal Devon and Exeter NHS Foundation Trust*, the Court of Appeal found that the subjective limb, could not be used to limit the content of the objective limb. For example, the first instance judge found that the defendant was negligent in failing to disclose the particular risk that an abdominal repair might impact future pregnancies.[230] The defendant did not discuss the implications of mesh repair on the chance of pregnancy, because, at the time, the particular patient had expressed no mention of intending to become pregnant in the future. However, the trial judge found (and the Court of Appeal agreed) that the doctor should have assumed that a reasonable woman would want to become pregnant, therefore the doctor should not have excluded it as a risk.[231] This creates a position where the doctor is now obliged to assume that all women in similar circumstances would wish to become pregnant, and therefore receive information, regardless of their actual circumstances.[232] The trial judge also found that Mr Wajed should have mentioned the possibility of primary suture repair[233] despite a finding that 'the reason why Mr Wajed did not mention it was because he himself was convinced, or at least thought highly likely, that a suture repair would fail with the result that the hernia would recur.'[234] On this basis of the judge required the doctor to reject the patient's own particular medical needs as well as values (which placed emphasis on repair and reduction of pain[235]) and instead provide an exhaustive disclosure.[236]

6.2. Medical Ethics

The previous section argued that *Montgomery* resulted in a division between the therapeutic relationship and the consumer relationship. This section argues that reliance on the GMC to create the ethical template that is adopted as the basis of legal duties and standards had created a new type of *Bolamisation*; where the role of standard setting has been handed to the formal sector.[237] The formal sector was entrusted with the ability to create the rational working model as the basis of the law.

[228] *Ibid*, [19] & [63]: "It is common ground that at the material time the relevant GMC guidance to doctors seeking patients' consent made it clear that "*options for treatment or management of a condition, included the option not to treat*" form an essential part of the information to which a patient is entitled."
[229] *Ibid*, [63]
[230] *Diamond v Royal Devon & Exeter NHS Foundation Trust* [2019] EWCA Civ 585 [5] at [31]
[231] *Ibid*, [4]
[232] See, J.M. Manning, 'Oh What an Unholy Mesh! *Diamond v Royal Devon & Exeter NHS Foundation Trust* [2019] EWCA Civ 585.' (2019) 27(3) *Med L Rev.* 519-529, 525-526
[233] *Diamond v Royal Devon & Exeter NHS Foundation Trust* [2019] EWCA Civ 585, [4]
[234] *Ibid*, [4] at [27]-[28], also [8] at [37]-[38]
[235] *Ibid*, [2]
[236] The claimant, rightly, failed on grounds of causation, as pregnancy was not a weighty factor in her determination at the time so she would therefore have accepted the mesh correction regardless. *Ibid*, [9] at [49]
[237] S. Devaney & S. Holm, 'The Transmutation of Deference in Medicine: An Ethico-Legal Perspective.' (2018) 26(2) *Med L Rev* 202-224, 204 & 220-222.

However, raising the GMC guidance to a quasi-legal document has reduced the ability of the GMC to be reactive, and to circumvent the theoretical shortcomings of the law. Indeed, the movement away from the existing model of disclosure had the potential to undermine the legitimacy of the current rules in law and thus place the guidance in conflict with the law. Doctors perceived guidance as equivocal with the law, and thus as mandatory.[238] As the previous chapter argued this was unfortunate, as the rules within the GMC guidance suggested an exhaustive and defensive disclosure.[239]

The section goes on to argue that the semi-formal sector[240] was left to pick up the pieces; and rationalise the confusion created by the reinterpretation of the GMC guidance. This led to a significant increase in guidance.[241] One of the central aims of this guidance seemed to be to set rational and practical limits on the external requirements necessary to facilitate an informed consent.[242] This was essential to guard against the sometimes irrational judicial extension of duties, and standards, in law due to a process of *blinkered moralism*.[243] However, by attempting to pre-empt the development of the law, through specifical of procedures, the semi-formal sector have divided between facilitating the therapeutic and the consumer relationship and between the authentic and liberal model of autonomy. There now exists a plethora of both formulistic, yet contradictory, rules operating in different specialities to facilitate different models of autonomy.

6.2.1. The GMC and *Montgomery:* covert *Bolamisation*[244]

Heywood and Miola argue that the Supreme Court in *Montgomery* took back the reigns from the ethical sector, and particularly the GMC, in setting the standard of care in information disclosure. This is certainly true if one sees control solely as coercive power,[245] however, the theoretical basis of the law was entirely co-opted from the GMC guidance.[246] As Brazier and Miola have previously argued, this is

[238] GMC, 'Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.' (GMC, 2017), 33
[239] Chapter 5, Section 3
[240] For example, Royal College of Obstetricians & Gynaecologists, *Obtaining Valid Consent: Clinical Governance Advice No. 6.* (RCOG, 2015); Royal College of Surgeons, *Consent: Supported Decision-Making A Guide to Good Practice.* (RCoS, 2016); Medical Protection Society, *An Essential Guide to Consent: Advice for the United Kingdom.* (MPS, 2017); The Royal College of Emergency Medicine, *Consent in Adults, Adolescents and Children in Emergency Departments.* (RCoEM, 2018); BMA, *Consent and Refusal by Adults with Decision-Making Capacity: A Toolkit for Doctors.* (BMA, 2020)
[241] GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008)
[242] Royal College of Surgeons, *Consent: Supported Decision-Making A Guide to Good Practice.* (RCoS, 2016); MDU, *Montgomery and Informed Consent.* (MDU, 2018); BMA, *Consent and Refusal by Adults with Decision-Making Capacity: A Toolkit for Doctors.* (BMA, 2020)
[243] See a trend in the case law for example, the requirement to ensure an understanding: *Hassell v Hillingdon Hospitals NHS Foundation Trust* [2018] EWHC 164 (QB), [36] & [68]; *Holdsworth v Luton and Dunstable University Hospital NHS Trust* [2016] EWHC 2878 (QB), [62]; *Worral v Antoniadou* [2016] EWCA 1219 (COA). And even movements for loss of autonomy to been seen as a distinct head of damage: *Correia v University Hospital North Staffordshire NHS Trust* [2017] EWCA Civ 356
[244] J. Keown, 'Doctor Knows Best? The Rise and Rise of "The *Bolam* Test." (1995) *Singapore Journal of Legal Studies* 342-364, 348; M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 90-95
[245] R. Heywood & J. Miola, 'The Changing Face of Pre-Operative Medical Disclosure: Placing the Patient at the Heart of the Matter.' (2017) 133 *Law Q Rev* 296-321, 318-319
[246] GMC, *Good Medical Practice.* (GMC, 2013); GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008)

a form of covert *Bolamisation*, where the judiciary hand over ethical determinations to the medical profession.[247] The result is that the GMC has become, by proxy, legal standard setters, and the judiciary simply ratify their ethical construction. As a number of commentators have recognised, this becomes problematic, as ethics should operate as a 'gold standard', and law should set out the minimum ethical standard.[248] By adopting the GMC's model of consent, the judiciary implicitly adopted the role of specifying and rationalising medical ethics. Whereas, previously, the doctor could look to the GMC guidance for advice, the *Montgomery* judgement blurred the lines between 'suggested' and 'mandatory' rules, as any deviation from the suggested model could be used to find legal liability.[249] The conflation between the role of ethics and law has occurred because the Supreme Court have assumed that the normative rules in the GMC guidance are equivocal to empirical practice.[250] It is unclear how this misapprehension would have occurred when the GMC (as intervenors) had conducted no empirical work as to the equivalency between their guidance and actual practice. [251]

The wholesale adoption of the GMC model remains problematic for medical decision-making for three key reasons:

> (i) the continued conflation between the consumer and therapeutic purpose of disclosure now exists both in law and ethics [252]
> (ii) the failure of the Supreme Court to recognise and substantiate facilitative duties necessary for an informed consent, and
> (iii) the ongoing conceptual confusion as to the appropriate model of autonomy.[253]

Yet, the current ethical model has become ossified, as the GMC remained logically barred from producing new guidance; otherwise they would risk undermining not just the normative, but the empirical, claims of the Supreme Court. As Chan *et al*, rightly argued 'Doctors at the coalface have

[247] M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 93-95
[248] B. Moulton, *et al*, 'From Informed Consent to Informed Request: Do we Need a New Gold Standard?' (2013) 106(1) *J R Soc Med* 391-394. See also, M. Brazier & J. Miola, 'Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 *Med L Rev* 85-114, 100; C. Foster & J. Miola, 'Who's in Charge? The Relationship between Medical Law, Medical Ethics and Medical Morality?' (2015) 23(4) *Med L Rev* 505-530, 514.
[249] S. Forvargue & J. Miola, 'One Step Forward, Two Steps Back? The GMC, The Common Law and 'Informed Consent.' (2010) 36 *J. Med. Ethics* 494-497, 496; *Chester v Afshar* [2004] 4 All ER 587; GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008), 34
[250] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [76]-[80]. A conflation between the normative and sociological: J.L. Montrose, 'Is Negligence an Ethical or Sociological Concept?' (1958) 21(3) *MLR* 259-264.
[251] GMC, *Doctors' Attitudes to Consent and Shared Decision Making*. (2017, GMC), 4.
[252] S. Forvargue & J. Miola, 'One Step Forward, Two Steps Back? The GMC, The Common Law and 'Informed Consent.' (2010) 36 *J Med. Ethics* 494-497, 496; *Chester v Afshar* [2004] 4 All ER 587; GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008), 34
[253] Although see commentators who incorrectly argue that *Montgomery* was a sea-change: C. Dyer, 'Doctors Should Not Cherry Pick what Information to Give Patients, Court Rules.' (2015) 350 *BMJ* H1414; R.S. Chauhan & S.P. Chauhan, '*Montgomery v Lanarkshire Health Board*: A Paradigm Shift.' (2017) 124(8) *BJOG* 1152-1152

received little official direction on how their practice should change in in light of the ruling.'[254] This flies-in-the-face of the assertion of Lord Kerr and Reed, that the risk of defensive medicine was an unlikely and proportionate risk.[255] As previous chapters have already illustrated, conceptual confusion within normative rules, and between the hierarchy of rules,[256] has correlated with excessive disclosure.[257]

6.2.2. The semi-formal sector

The semi-formal sector had to fill in the regulatory vacuum and rationalise the conflicting requirements for decision-making flowing from the didactic medical relationship. However, rather than coming up with a collective approach, the various specialist forums for semi-formal ethics fragmented. For example, the Royal College of Emergency Medicine emphasised the need to make the decision in the patients' best interest according to the *Bolam* plus standard but suggested an exhaustive disclosure to avoid the risk of liability.[258] The Royal College of Gynaecologists ("RCoG"), after being criticised by Lady Hale in *Montgomery*,[259] abandoned a therapeutic approach to identifying patient information need. It now recommends the disclosure of shoulder dystocia, post-partum haemorrhage, and the risk of severe perineal tears to all women irrespective of circumstances.[260] In doing so the RCoG have chosen to ignore the scientific guidelines published by NICE, recommending the disclosure of shoulder dystocia, only when it is clinically indicated (16% of the time[261]).[262] The result is that vaginal birth is

[254] S.W. Chan, *et al*, '*Montgomery* & Informed Consent: Where Are We Now?' (2017) 257 *BMJ* 2224, 2224

[255] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [92]-[93]. A phenomenon which was clearly warned against in previous case-law: *Whitehouse v Jordan* [1980] 1 All ER 650, 658

[256] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship.* (Hart Publishing, 2007) 47-48 & 212

[257] See, Chapter 3, Section 3, Chapter 4, Section 3, Chapter 5, Section 3.

[258] The Royal College of Emergency Medicine, *Consent in Adults, Adolescents and Children in Emergency Departments*. (RCoEM, 2018), 6: "When deciding on what information to provide, the principles of the '*Bolam* test' should be employed; this has subsequently been refined by the *Montgomery* judgement. However, the courts have in the past been critical of responsible bodies of medical opinion, and they are consequently the final arbiter of what constitutes responsible practice. As a result, it is advisable to inform the patient of all significant possible and and/or unavoidable risks however unlikely, the potential benefits of treatment, the risks of procedural failure, details of alternatives to the particular treatment, and the risks incurred by doing nothing."

[259] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, per Lady Hale at [112]-[115]; J. Montgomery & E. Montgomery, '*Montgomery* on Informed Consent: An Inexpert Decision. (2016) 42 *J Med Ethics* 89-94, 91-92

[260] E. Cheung, *et al*, 'Medicallegal Update on Consent: 'The *Montgomery* Ruling.' (2016) 18(3) *TOG* 171-172. "It therefore follows logically that the other 84% of 'unpredicted' incidences of dystocia are obstetric emergences in otherwise low-risk vaginal deliveries. As with other obstetric complications, such as postpartum haemorrhage and severe perineal tears, many occur in women whose only risk is childbirth itself." See RCOG, *Postpartum haemorrhage prevention and management: Green top guidelines No. 52* (RCOG, 2009); RCOG, *Third- and fourth-degree perineal tears, management: Green-top guidelines No.29* (RCOG, 2015)

[261] RCOG, *Shoulder dystocia: Green Top Guideline No.42* (RCOG, 2012)

[262] NICE, *Caesarean section. Nice Clinical Guidelines 132* (NICE, 2011). The guidance has since between updated to require the disclosure of all material risks of a planned vaginal delivery or a caesarean section: NICE, *Appendix: Planned CS compared with planned vaginal birth.* (NICE, 2019): (<https://www.nice.org.uk/guidance/cg132/chapter/appendix-planned-cs-compared-with-planned-vaginal-birth#appendix-planned-cs-compared-with-planned-vaginal-birth>). See, the evidence base: NICE, *4-year Surveillance (2017) – Summary of New Evidence Caesarean Section (2011) NICE Guidelines [CG13* 92*]* (NICE 2017]: (<https://www.nice.org.uk/guidance/cg132/evidence/appendix-a-summary-of-new-evidence-pdf-2736386032>). See the updated guidance: (<https://www.nice.org.uk/guidance/cg132/chapter/1-Guidance>), [1.1.1] & [1.1.2]

to be viewed as a medical process rather than a natural condition[263] and the doctor must embark on a process of defensive obstetrics.[264] The risk of course is that these approaches fall foul of the external assessment of reasonability under the *Bolam* plus+ standard.

(i) Liberal autonomy

Organisations, such as the Medical Defence Union ("MDU"), adopted the consumer relationship, which emphasised the need to provide an objective standard of disclosure. [265] However, the inclusion of biomedical as well as biopsychosocial considerations led to the adoption of an almost exhaustive list of factors which required disclosure; along the lines recommended by the GMC, and the Court of Appeal.[266] The BMA in their consent tool kit[267] for example suggested that:

> You should not withhold any information the patient needs to make a decision, […]. Failure to provide sufficient relevant information could be challenged in law.[268]

Perhaps recognising the futility of their former position, the BMA adopt the same exhaustive approach to disclosure, as the GMC,[269] which suggested that the doctor provide information according to a checklist, to ensure an autonomous choice.[270] The doctor would also have to disclose any additional information according to the 'individual concerns, wishes and values of each patient and their understanding of their condition and prognosis.' [271]

(ii) Authentic Autonomy

Although, the precise specification of duties was rarely aligned, other semi-formal guidelines did suggest a movement towards authenticity as a panacea for confusion.[272] The guidance issued by the

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[263] H. P. Dietz & M. Woodrow, 'Response.' (2017) 19(1) *TOG* 84-85: (<https://obgyn.onlinelibrary.wiley.com/doi/10.1111/tog.12351>) there is some irony in this movement since much of the criticism of the rights school of thought is centred on the inappropriate extension or medicalisation to non-medical areas.

[264] See, G. Goodyear, *et al,* 'Authors' reply' (2017) 19(1) *TOG* 85. (<https://obgyn.onlinelibrary.wiley.com/doi/10.1111/tog.12350>)

[265] MDU, *Montgomery and informed consent.* (MDU, 2018): (<https://www.themdu.com/guidance-and-advice/guides/montgomery-and-informed-consent>).

[266] *Webster v Burton Hospitals NHS Foundation Trust* [2017] EWCA Civ 62 (COA)

[267] BMA, *Consent and Refusal by Adults with Decision-Making Capacity: A Toolkit for Doctors.* (BMA, 2020), 8

[268] *Ibid*

[269] GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008), [9]

[270] BMA, *Consent and Refusal by Adults with Decision-Making Capacity: A Toolkit for Doctors.* (BMA, 2020), 11: For example: (i) The purpose of the investigation or treatment; (ii) Details and uncertainties of the diagnosis; (iii) Option for treatment, including the option of no treatment; (iv) Likely benefits and probabilities of success for each option; (v) Risks and potential side-effects, and adverse outcomes including the treatment not working; (vi) The name of the doctor with overall responsibility for their care; (vii) A reminder that the patient can change their mind about the treatment at any time; (viii) Reasons for any recommended treatment option; and (ix) If relevant, any foreseeable problem that could come to light while the patient is unconscious.

[271] BMA, *Consent and Refusal by Adults with Decision-Making Capacity: A Toolkit for Doctors.* (BMA, 2020), 8

[272] For example, the Royal College of Physicians and Surgeons of Glasgow, have updated their guidance (see, RCPSG, *Medical Consent: More than a signature, for than a form*. (<https://rcpsg.ac.uk/college/this-is-what-we-stand-for/policy/consent>). This has included specific guidance on identifying and using patient values in a process of Shared Decision-making (<https://rcpsg.ac.uk/college/this-is-what-we-stand-for/policy/consent/shared-decision-making>), the provision of good

Royal College of Surgeons ("RCoS"),[273] for example, rejected making assumptions about what information the patient needs, and instead argued that the prudent patient had to be defined in the circumstances of the actual patient.[274] This meant that both the objective and subjective elements of the test were orientated around the patient's actual circumstances and values:

> The judges in the *Montgomery* case held that there was a duty for a doctor to warn a patient of a *material risk* inherent in the treatment and discuss this with them. What constitutes a material risk will vary from patient to patient. Therefore consent has to be patient-specific.[275] (author's emphasis)

In an attempt to pre-empt the iterative development of the law, these groups developed external duties to ensure a substantive authenticity as the basis of an informed consent.[276] For example, they required that doctors:

(1) Identify the relevant values of a patient to make decisions about treatment options and materiality, by communicating with patients effectively to extract these values.[277] The RCoS guidelines, for example, required the doctor to: 'take time to explore the patient's values and wishes about their care and to have sufficient experience to fully understand the risks and benefits that are material to the patient.'[278]

(2) Adopt methods to record the patients' values and thus evidence the logic-basis of their decision-making about options and information disclosure;[279]

Health Literacy and Communication Techniques (<https://rcpsg.ac.uk/college/this-is-what-we-stand-for/policy/consent/health-literacy-and-communication-techniques>) and proper documentation (<https://rcpsg.ac.uk/college/this-is-what-we-stand-for/policy/consent/best-practice-in-documentation>). They refer doctors to A. Coulter & A. Collins, *Making Shared Decisions-Making a Reality: No Decision about me, without me.* (The Kings Fund, 2011). See also the approach taken in British Association of Dermatologists, *Guide to Validating Consent: Dermatology Examinations of Treatment.* (<https://www.bad.org.uk/shared/get-file.ashx?itemtype=document&id=5713>), 6-9

[273] Royal College of Surgeons, *Consent: Supported Decision-Making A Guide to Good Practice.* (RCoS, 2016), [3.4]

[274] *Ibid*, 8, [4.1]: "You should not make assumptions regarding the wishes of a patient and what they might perceive as the best option available. You should not assume that the patient has the same set of values, wishes or life priorities as you would have in a similar situation."

[275] *Ibid*, [4.3]

[276] *Ibid*, 4

[277] *Ibid*, 4[3.3]- [3.4]. Also see, BMA, *Consent and Refusal by Adults with Decision-Making Capacity: A toolkit for doctors.* (BMA, 2020), 11.

[278] *Ibid*, 9, [4.6]

[279] *Ibid*, 4. Also see, The Royal College of Emergency Medicine, *Consent in Adults, Adolescents and Children in Emergency Departments*. (RCoEM, 2018), 2

(3) Utilise patient values to delineate options and information to ensure an authentic autonomous choice.[280] The relevant options,[281] and the material information would vary depending on the values of the particular patient:

> Consent must always be given, and the patient's decision documented prior to any procedure, once the patient has made a decision to go ahead with the procedure. The consent discussion may vary in duration, depending on a range of factors including:
>
> - The complexity or severity of the patient's condition
> - The complexity, risks and range of treatment options and their likelihood of success
> - The patient's level of understanding.[282]

(4) Communicate the information to the patient in a way so that they attain a subjective understanding of information which they can then use it to make a decision based on their own values.[283] The RCoS guidance, for example, required information be presented in a neutral way, to avoid undermining the authentic values of the patient. [284] The guidance also pre-empted *Worral*[285] and *Crossman*, [286] by requiring that disclosure happened over an extended period of time, and thus did not put pressure on patients which could undermine their authentic values.[287] This of course places substantive burdens of time and resources on medical practitioners: requiring that they create a particular type of relationship necessary to have conversations about patient values - through a multiple stage disclosure process.[288] The guidance recognises that

[280] *Ibid*, 10-12
[281] *Ibid*, 8, [4.1]
[282] *Ibid*, 10, [4.8]
[283] *Ibid*, 10-12. Also see, Royal College of Obstetricians & Gynaecologists, 'Obtaining Valid Consent: Clinical Governance Advice No. 6.' (RCOG, 2015), 2: Table 1; BMA, *Consent and refusal by adults with decision-making capacity: A toolkit for doctors.* (BMA, 2020), 5; Also, see Medical Protection Society, *An Essential Guide to Consent: Advice for the United Kingdom.* (MPS, 4 July 2017), 7.
[284] *Ibid*, 8, [4.1]: "You should also ensure that options are presented side by side and that the relative risks and benefits of the different options for treatment are discussed. You should not make assumptions regarding the wishes of a patient and what they might perceive as the best option available. You should not assume that the patient has the same set of values, wishes or life priorities as you would have in a similar situation. When advising a patient which treatment will, in your medical opinion, be the most conducive to the good health of the patient, it is important that the advice given is impartial and factual. Surgeons must not allow their personal views and preferences to have an impact on the description or emphasis given for each of the options. […]."
[285] *Worral v Antoniadou* [2016] EWCA 1219 (COA) [78]
[286] *Crossman v St George's Healthcare NHS Trust* [2016] EWHC 2878 (QB)
[287] Royal College of Surgeons, *Consent: Supported Decision-Making A Guide to Good Practice.* (RCoS, 2016). 10 [4.8]: "Patients should be given enough time to make an informed decision regarding their treatment, wherever this is possible and not adverse to their health. This may require that the discussion takes place over more than one session for particularly complex or life changing decisions. The process of consent should begin well in advance of the treatment, and the amount of time required for each individual stage of the process may vary significantly based on the complexity of the procedure."
[288] *Ibid*, 12

> [t]he reality facing a surgeon in current practice is that time pressure can leave little opportunity to discuss at length the diagnosis or available treatment options. However, this does not change the fundamental legal requirement that surgeons and doctors allocate sufficient time for discussion that will allow them to understand the individual patient and their needs.[289]

The failure of the semi-formal sector to mitigate the additional burdens created by these enhanced requirements, perhaps inevitably invites formulism and tick-boxing of both disclosure, and additional facilitative duties, to evidence the reasonableness of medical actions. Like excessive disclosure, this has the potential to move the focus from the purpose and substance of disclosure onto the form of disclosure.

(iii) The capacity-consent gap

The requirements set out in the semi-formal guidance creates an intimidating quantity of information which the doctor must disclose and the patient must understand, to ensure an informed consent.[290] For the patient, this would require psychological capacities well above the legal standard to be seen as capacitous.[291] The BMA recognised the potential gap between the legal test for mental capacity and the potential requirements of capacity for a legal informed consent,[292] as such they advised the doctor that consent is valid as a long as the patient can:

- Understand in simple language what the medical treatment is, its purpose, nature and why it is being proposed;
- Understand the benefits and risks of the treatment, and any alternative options;
- Understand potential consequence of not having the treatment;
- Retain the information for long enough to use it to make a decision; and
- Communicate the decision (by any means).[293]

This list reproduces the requirements contained in the BMA guidelines on mental capacity published in 1995.[294] However, as Tan and McMillan[295] argued the high thresholds of capacity sat at odds with the common law test in *Re C*,[296] and continues to conflict with the more limited legal test for recognising

[289] *Ibid*, 3.
[290] BMA, *Seeking Patient Consent Toolkit.* (BMA, 2020): (<https://www.bma.org.uk/advice-and-support/ethics/seeking-consent/seeking-patient-consent-toolkit>) "This guidance will provide you with the key legal and ethical considerations you need to take into account when seeking consent for treatment [….] It is not a set of rules or instructions, or substitute for careful reflection and discussion with colleagues.":
[291] s.3 Mental Capacity Act 2005
[292] BMA, *Consent and Refusal by Adults with Decision-Making Capacity: A Toolkit for Doctors.* (BMA, 2020), 5: "Where their decision is 'clearly contrary to previously expressed wishes, or based on a misperception of reality, this may be indicative of a lack of capacity and should be investigated further."
[293] *Ibid*, 5-6
[294] British Medical Association, *Assessment of Mental Capacity: Guidance for doctors and lawyers. A report of the British Medical Association and the Law Society*. (BMA, 1995), 56-66.
[295] J.O.A. Tan & J.R. McMillan, 'The discrepancy between the legal definition of capacity and the British Medical Association's guidelines.' (2004) 30 *J Med Ethics* 427-429.
[296] *Re C (Adult Refusal of Treatment)* [1994] 1 WLR 290

capacity, within the MCA;[297] which requires only that the patient have the bare capacities necessary to consent to treatment within the context of the decision being made.[298] For example, the patient, in this context only needs to understand the salient factors, rather than reach an objective threshold of understanding.[299] The capacities required by the BMA test are also certainly above the standards of consent within the law of battery.[300] The guidance goes on to recommend that the presumption of capacity could be rebutted if: 'their decision is clearly contrary to previously expressed wishes, or based on a misperception of reality, this may be indicative of a lack of capacity and should be investigated further.'[301] Whilst this enhanced test seeks to straddle the divide between a libertarian conception of autonomy in capacity law, and more substantive requirements for an informed consent, this risks undermining respect for patient choices. [302] This is especially concerning in the context of the House of Lords post-legislative Select Committee on capacity, which found:

> The presumption capacity, in particular, is widely misunderstood by those involved in care. It is sometimes used to support non-intervention or poor care, leaving vulnerable adults exposed to risk of harm. In some cases this is because the professionals struggle to understand how to apply the principle in practice. In other cases, the evidence suggests the principle has been deliberately misappropriated to avoid taking responsibility for a vulnerable adult.[303]

6.3. How doctors make decisions post-*Montgomery*

This section will argue that doctors were broadly aware of *Montgomery* and the semi-formal guidance and thus the need to seek an informed consent.[304] However, doctors were less aware of the specifics required by the normative rules, perhaps due to the confusion about which model of the medical relationship the doctor was servicing and the appropriate means for deciding the material information necessary to ensure an autonomous consent. Doctors remained divided between facilitating the therapeutic or consumer relationship. The consumer relationship approache prioritised patient values, however, doctors found that the internal and external requirements were not 'achievable in practice due to the time constraints they work under.'[305] To overcome the conceptual confusion in *Montgomery*, coupled with the sometimes-unachievable requirements of informed consent, some doctors adopted defensive practices such as providing an exhaustive disclosure i.e., listing all of information that could

[297] s. 3(1) Mental capacity Act
[298] *PC and NC v City of York Council* [2013] EWCA Civ 478, [40]; *Heart of England NHS Foundation Trust v JB* [2014] EWHC 342 (COP)
[299] *LBJ v RYJ* [2010] EWHC 2664 (Fam); *PH and A Local Authority v Z Limited & R* [2011] EWHC 1704 (Fam)
[300] See Chapter 3, Section 4
[301] BMA, *Consent and Refusal by Adults with Decision-Making Capacity: A Toolkit for Doctors.* (BMA, 2020), 5
[302] See Chapter 3, Section 2 and Section 3. See also, s. 1 Mental Capacity Act 2005. See for example, *An NHS Trust v P & Anor* [2013] EWCOP 50 (COP); *Heart of England NHS Foundation Trust v JB* [2014] EWHC 342 (COP).
[303] House of Lords Select Committee on the Mental Capacity Act 2005, *Mental Capacity Act, Mental Capacity Act 2005: Post-Legislative Scrutiny*. (House of Lords, 2014), [105]
[304] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 35
[305] *Ibid*, 5 & 34-36

potentially be material. The normative rules have continued to abstract decision-making from the needs of the actual patient, instead focusing doctors on the needs of the legally defined hypothetical consumer patient. Other (particular senior) doctors have (re)adopted the therapeutic process of *circumstantial-moral* decision-making. However, they too identified problems with facilitating a substantive model of liberal autonomy in practice, (even if doing so was in the patients best interests) both due to practical limitations and ongoing conceptual confusions about the purpose and process of informed consent emanating from normative guidance.

6.3.1. The effect of *Montgomery* and the GMC on medical decision-making

Recognising their new quasi-legal role, the GMC, undertook a series of studies to understand both how their 2008 guidance was actually being implemented in practice[306] and the effect that it was having on patient choice.[307] The GMC study on doctors' attitudes found that doctors were familiar with the broad principles of consent,[308] however, few were aware of the *Montgomery* judgement[309] or had ever referred to the GMC's guidance.[310] Doctors had roundly abandoned the GMC guidance as a source of advice; as they viewed it as a regulatory document rather than guidance for practical decision-making.[311] The quasi-legal nature of guidance, meant doctors no longer perceived the GMC as best placed to make gold standard rules.[312] Instead, the study found reliance was placed on the semi-formal sector, as rules were suggestive and tailored to specialised practices.[313] O'Brien *et al* supported the GMC's findings, that a significant proportion of doctors (n=243) were not aware of the legal standard of information disclosure. For example, 35% of doctors were not familiar with *Sidaway*, and 12% were not even aware of the *Bolam* test.[314] Of the doctors that regularly undertook information disclosure only 35% were familiar with *Montgomery*, and 41% were not familiar at all.[315] The GMC study particularly identified that GP's were most unaware of guidance:

[306] *Ibid*
[307] Ipsos MORI, *Attitudes Towards Consent and Decision Making.* (GMC, 2018),
[308] GMC, *Doctors' Attitudes to Consent and Shared Decision Making: Full Research Report for the GMC.* (GMC, 2017), 5. See also, M.L.S. Lie, *et al*, 'Risk Communication in the Hyperacute setting of stroke thrombolysis: an interview study of clinicians.' (2015) 32(5) *Emergency Medicine Journal* 357-363, 10
[309] *Ibid*, 5
[310] *Ibid*, 11
[311] *Ibid*, 33: "I'm afraid that to some doctors the GMC appear as a threat to their livelihood, so they'd much rather source guidance from the MDU and the like who are likely to fight to preserve it." (Psychiatry, less than 10 years qualified, Leeds)
[312] *Ibid*, 32-33: "I think the GMC, for me, should be the short A5, 70 to 100 points, written in that sort of diamond style 'you should do this and minimum proof of consent is this', and that should be the GMC's role. Then the colleges and the Mental Health Commissioner here in Scotland can maybe do the practice guides and the case presentations and the capacity toolkits and all that type of thing. I think the GMC should be like the Ten Commandments and somebody else can do the catechism." (Psychiatrist, more than 10 years qualified, Edinburgh).
[313] *Ibid*, 33. "I use RCOG guidelines when it comes to consent and our college was ahead of the game in the consent from (RCOG guidelines on consenting for hysteroscopy). Also, I use NICE guidelines." (Surgery, more than 10 years qualified, Birmingham).
[314] J.W. O'Brien, *et al*, 'A survey of doctors at a UK teaching hospital to assess understanding of recent changes to consent law.' (2017) 18 *Annals of Medicine and Surgery* 10-13, 11
[315] *Ibid*, 10.

> I probably overlook it because I've been there for such a long time. When you formally come to do it, when I'm doing minor surgery...that's probably the only time I ever record it but most of the time I assume implied consent. I might be shocked in a minute what the proper guidance is. (GP, more than 10 years qualified, Stockport)[316]

Other studies, such as Knight *et al* [317] and McKinnon *et al* [318] found a slightly higher proportion of doctors had knowledge of the law (46.4% and 50% respectively). The increased awareness can be accounted for by the inclusion of comparatively more senior doctors. For example, the Knight *et al* study found that 75% of consultant surgeons knew about the judgement, [319] and 50% of the doctors in the McKinnon survey were at consultant level, and 85% of them know about the judgement. [320] This is concerning, as it indicates that doctors may lack the skills to read and/or interpret judgements after medical school,[321]they may find it difficult to apply knowledge to practice,[322] and are not receiving training during practice.[323]

> Last time I looked at it I was a trainee and, since then, you get a lot of updates and there was a stage, where probably similar, I was interested in all the case law and things around it. But I haven't actually picked up and opened the guidance on it for at least 10 years. (Psychiatrist, more than 10 years qualified, Edinburgh).[324]

> It's amazing how little time is dedicated to something so important that we're expected to do to a high standard, and that's important for the patients because they're having these interventions. The amount of time dedicated to it in Medical School or subsequent training is minimal really. (Surgery, less than 10 years qualified, London)[325]

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[316] GMC, *Doctors' Attitudes to Consent and Shared Decision Making: Full Research Report for the GMC* (GMC, 2017), 12.
[317] S.R. Knight, 'Patient Consent in Post-*Montgomery* Era: A National Multi-Speciality Prospective Study.' (2019) *The Surgeon* 277-283, 282.
[318] C. McKinnon, *et al*, 'Surgical Consent Practice in the UK following the *Montgomery* Ruling: A National Cross-Sectional Questionnaire Study.' (2016) 55 *International Journal of Surgeons* 66-72, 66
[319] S.R. Knight, 'Patient Consent in Post-*Montgomery* Era: A National Multi-Speciality Prospective Study.' (2019) *The Surgeon* 277-283, 282
[320] C. McKinnon, *et al*, 'Surgical Consent Practice in the UK following the *Montgomery* Ruling: A National Cross-Sectional Questionnaire Study.' (2016) 55 *International Journal of Surgeons* 66-72, 67
[321] See for example, GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC*. (GMC, 2017), 17-18. Also, A. Giublini, *et al*, 'The Medical Ethics Curriculum in Medical Schools: Present and Future.' (2016) 27(2) *Journal of Clinical Ethics* 129-145
[322] See for example, P. Vivekananda-Schmidt & B. Vernon, 'FY1 Doctors' Ethicolegal Challenges in their First Year of Clinical Practice: An Interview Study.' (2014) 40 *J Med Ethics* 277-281
[323] See for example, A. Slowther, *et al*, 'Experiences of Non-UK-Qualified Doctors Working Within the UK Regulatory Framework: A Qualitative Study.' (2012) 105(4) *J R Soc Med* 157-165
[324] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 32
[325] *Ibid*, 17

These empirical findings are also legally problematic, as they undermine the claim, made by the Supreme Court that the GMC guidance was representative of actual practice.[326] This lays waste to the suggestion that the guidance had normative force *a priori*. Even after the judgement, McKinnon *et al*[327] found that the normative guidance had little impact on medical decision-making in practice.[328]

Doctors who were aware of the *Montgomery* judgement remained uncertain about the concept of *material risks*, (despite it being adopted from previous GMC guidance).[329] For example, of the minority of doctors that undertake consent regularly, 31% were not actually familiar with the meaning of a material risk.[330] O'Brien *et al*, also found that 64% of doctors were a little uncertain and 18% were very uncertain about what the *Montgomery* judgement meant for decision-making in practice.[331] This lack of understanding may be because only a small number of doctors are tasked with ensuring effective consent so clarifying the appropriate test is not a departmental or institutional priority. [332] For example, 22% of the doctors identified (141 consultants and 104 junior doctors, n=245) provided information disclosure of a monthly basis, and only 23% do so daily.[333] This is a concerning statistic, because it could indicate that doctors no longer see the provision of information as an ongoing therapeutic duty, but as a formulistic event utilised only before major surgery.

Confusion was also particularly centred around the purpose of the medical relationship, and therefore the identification of reasonable treatment options as a foundation for disclosure.[334] The studies identified found wide variation in the options offered between specialist practices. [335] For example, Wiseman *et al* found that 67.8% of patients (n=223) and of doctors (n=14) within outpatient nephrology clinics reported that they received multiple options for treatment;[336] this likely indicates the facilitation

[326] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [77]-[79]
[327] C. McKinnon, *et al*, 'Surgical Consent Practice in the UK following the *Montgomery* Ruling: A National Cross-Sectional Questionnaire Study.' (2016) 55 *International Journal of Surgeons* 66-72, 69
[328] This thesis is aware that this finding may undermine the link between the effect of law and ethics on medical practice, which is the central concern of this thesis. However, the effect of law is not just through direct effect on medical decision-making; as this thesis has argued, the effect of law is also to implement a conceptual model of the medical relationship and informed consent within in medical zeitgeist. These models have been adopted within lower order guidance, within the semi-formal sector, non-formal and academic sectors. Indeed, the GMC study found that doctors relied heavily on the semi-formal sector to rationalise the higher-order normative guidance. GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 5
[329] *Ibid*, 12.
[330] J.W. O'Brien, *et al*, 'A Survey of Doctors at a UK Teaching Hospital to Assess Understanding of Recent Changes to Consent Law.' (2017) 18 *Annals of Medicine and Surgery* 10-13, 10
[331] *Ibid*
[332] *Ibid*
[333] *Ibid*
[334] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [87]-[88]. See the different ways that the 'reasonable options' requirement can be interpreted: J. Herring, *et al*, 'Elbow Room for Best Practice? *Montgomery*, Patient's Values, and Balanced Decision-Making in Person-Centred Clinical Care' (2017) 24(4) *Med L Rev* 582-603, 594-600
[335] S.R. Knight, 'Patient Consent in post-*Montgomery* era: A national multi-speciality prospective study.' (2019) *The Surgeon* 277-283, 277
[336] Although there was disagreement in 32% of encounters about whether choice had been offered to the patient. H. Wiseman, *et al*, 'Do Patients Want Choice? An Observational Study in Neurology Consultations.' (2016) 99 *Patient Education and Counselling* 1170-1178, 1173.

of a consumer model of the medical relationship. However, other studies,[337] such as Knight *et al*, found that less than 30% of patients' were provided reasonable options (either as outpatients or the day of surgery), whilst 20% received no options; indicating a preference for a therapeutic approach to treatment decisions and therefore potentially disclosure of only relevant risks and options. [338]

6.3.2. Medical decision-making: conceptual confusion and barriers to autonomy.

This thesis would posit that the lack of understanding about what amounted to material information was linked to the confusion about the binary standard of care within the *Montgomery* judgement.[339] Doctors remained divided between those who would facilitate an objective or subjective standard of information for an autonomous choice.[340] Some doctors adopted the consumer approach and attempted to facilitate an authentic autonomous choice. Other doctors adopted the therapeutic approach to decision-making and aimed to facilitate a liberal model of autonomy as the basis of disclosure; as this was presumed to be in the patient's best interests. However, both approaches had barriers in practice. Many doctors found that the consumer patient approach was overly burdensome, and patients struggled to meet the responsibilities necessary to make a substantive autonomous choice. The liberal model of autonomy (adopted as the basis of the therapeutic limb of the test) led to highly detailed and generic approaches to disclosure, which caused consent to become a time-consuming tick-boxing exercise (rather than an ongoing and iterative process), with information often overwhelming patients. [341] As Main argues, this division led to 'variation in the quality and quantity of information disclosed in consent consultations.'[342] Knight *et al*, similarly argued that 'the inter-hospital variation revealed that no gold standard exists within the included hospitals and demonstrates that issues regarding the consent process follow the *Montgomery* ruling are widespread.'[343] The substantive requirements of the law and the fear of liability had the effect of exacerbating capacity problems, rather than providing practical guidance. As a result, disclosure became a process of firefighting.

> [...] we're in a time-restricted environment with *Montgomery* case law and all of that about having to work out what the most important factors for that consent process are for that

[337] R. Zarnegar, *et al*, 'Patient Perceptions and Recall of Consent for Regional Anaesthesia Compared with Consent for Surgery.' (2015) 108(11) *J R Soc Med* 451-456., 45; F. Garrad, *et al*, 'Decisions, Choice and Shared Decision Making in Antenatal Clinics: An Observational Study.' (2015) 98 *Patient Education and Counselling* 1106-111, 1109. (It is important to recognise that this study did not directly identify reasons for patient and doctor choice to restricting options.)
[338] S.R. Knight, 'Patient Consent in post-*Montgomery* era: A National Multi-Speciality Prospective Study.' (2019) *The Surgeon* 277-283, 281
[339] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 13
[340] *Ibid*
[341] This would of course indicate that some doctors who stated that they were aware of the Montgomery judgement (93%) were not telling the truth. C. McKinnon, *et al*, 'Surgical Consent Practice in the UK following the *Montgomery* Ruling: A National Cross-Sectional Questionnaire Study.' (2018) 55 *International Journal of Surgery* 66-72, 68.
[342] B.G. Main, 'Core Information sets for Informed Consent to Surgical Interventions: Baseline Information of Importance to Patients and Clinicians.' (2017)18 BMC *Medical Ethics* 29, 31
[343] S.R. Knight, 'Patient Consent in Post-*Montgomery* Era: A National Multi-Speciality Prospective Study.' (2019) *The Surgeon* 277-283, 28

> individual patient and then making sure that those are addressed. I kind of feel like it's a bit of a losing battle for doctors, you can't get it right every time for every patient. (Surgery, less than 10 years qualified, London)[344]

(i) Barriers to the consumer relationship

The majority of, especially younger, doctors supported the consumer patient as the locus of decision-making.[345] However, studies identified found a generally lack of enthusiasm for ensuring that the patients received information to meet their concerns and expectations, necessary for an authentic autonomous choice in practice.[346] The GMC study, for example, found few doctors mentioned tailoring information to the values and circumstances of the actual patient.[347] Whilst the ethical guidance was more explicit in setting out the external requirements necessary to ensure authentic autonomy, [348] the studies identified a number of practical barriers to doctors ensuring this type of informed consent in practice. These barriers are likely to be a locus of liability and patient harm.

(a) Limitation of time on the development of the doctor-patient relationship

Developing a strong relationship with patients is instrumental to identifying the values which are integral to the patient, and thus their preferences for information disclosure. Failure to ensure a robust doctor-patient relationship undermined the ability of the doctor to delineate a material disclosure to meet the information needs of the actual patient.[349] Patients only felt empowered to take on an active role in the decision-making process if they felt doctors were friendly and had time to actively listen.[350] Doctor's, similarly, felt that unless they had the time to develop a relationship of trust with their patients they were unable to actively engage them in a process of shared decision-making. [351] However, the studies identified, found that a lack of continuity of care prevented the development of a trusting relationship:

> So it may be that you do have full consent for something in one treatment but the patient might struggle to get another appointment straight away because there's so much pressure on people coming in. So, yes, I think for simple straightforward things you can do in 10 minutes, but for

[344] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 12
[345] *Ibid*, 14; C. McKinnon *et al*, 'Surgical consent practice in the UK following the Montgomery ruling: A national cross-sectional questionnaire study.' (2016) 55 *International Journal of Surgeons* 66-72; S.R. Knight, 'Patient consent in post-Montgomery era: A national multi-speciality prospective study.' (2019) *The Surgeon* 277-283; [345] C. McIntyre & N. Tolley, 'A critical review of thyroidectomy consent in the UK.' (2019) 66 *International Journal of Surgery* 84-88
[346] M. Bagnall, *et al*, 'Informing the Process of Consent for Surgery: Identification of Key Constructs and Quality Factors.' (2017) 209 *Journal of Surgical Research* 86-92, 90
[347] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC* (GMC, 2017), 11
[348] *Ibid*, 15
[349] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 23.
[350] Ipsos MORI, *Attitudes towards consent and decision making*. (GMC, 2018), 3; N.E. Kassm, 'Trust, the Fragile Foundation of Contemporary Biomedical Research.' (1996) 26(5) *Hastings Center Report* 25-29.
[351] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC* (GMC, 2017), 21

other things you need to bring people back and maintaining that continuity can be difficult. (GP, less than 10 years qualified, Edinburgh).[352]

Doctors have very little time to spend with patients,[353] and may only get to see a patient once; which limits their ability to develop a relationship of trust, where patients are able to disclose personal values as the basis of medical decision-making.[354]McKinnon *et al* found that the majority of patients met with their doctor only twice, and for less than 10 minutes at a time.[355] Night shift doctors, for example, indicated that they must cover a number of wards with very sick patients who they have very limited knowledge, and have no opportunity to gain more insight. However, they are still expected to provide information disclosure and achieve an authentic informed consent, before providing medication, or for phlebotomy.[356]

(b) Failure to recognise patient responsibilities

Doctors identified that many of the external requirements for facilitating an authentic autonomous choice required the patient to take-on additional responsibilities (which were not recognised within the normative rules). For example, to ensure that patients receive information that fits their subjective information need patients were required to have rationally reflected values, and to communicate these values honestly with their doctor. Patients must also have the ability to retain, understand and communicate information according to their second order values.[357] These capacities, again, may be beyond the intellectual sophistication of some patients. [358] The normative rules, however, conceptualise the patient as willing and able to facilitate these requirements, as a basis for establishing corresponding legal duties in the law of negligence.[359] If patients are not reasonable in their responses, however, doctors are placed in a situation where liability is inevitable, if the courts are unwilling to evaluate the actions of the actual patient.[360] The studies, however, demonstrate that patients do not feel that they have any responsibility to either facilitate the consumer relationship, or ensure that they are able to

[352] *Ibid*
[353] *Ibid*,19
[354] For example, O'O Neil, *Autonomy and Trust in Bioethics*. (Cambridge University Press, 2002), 7-20 & 145
[355] C. McKinnon, *et al*, 'Surgical Consent Practice in the UK following the *Montgomery* Ruling: A National Cross-Sectional Questionnaire Study.' (2018) 55 *International Journal of Surgery* 66-72, 68
[356] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 20-21: "I think the nature of our working patterns since[…] the new deal, which is going back quite some time, means that you're not consistently on the ward with the same patients the whole time, you've got many, many more time the amount of patients when you're on nights and weekends, evenings and you don't have the regular doctors, so there might be considerably less continuity for the patients on your home ward or whatever it might be, in inpatient settings anyway."(Mental health, less than 10 years qualified, Leeds).
[357] See Chapter 3, Section 3; G, Dworkin, 'Autonomy and Behaviour Control.' (1976) 6(1) *The Hastings Center Report* 23-28; G. Dworkin, *The Theory and Practice of Autonomy.* (Cambridge University Press, 1988)
[358] s. 3(1), Mental Capacity Act 2005
[359] See *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [75]-[76]; *Darnley v Croydon NHS Trust* [2018] UKSC 50, [28]-[29].
[360] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 14.

make an authentic autonomous decisions. [361] The GMC for example, identified that patients were sometimes unwilling to discuss their values.[362]

> I think some patients actually need more encouragement to hold up their end of the consent process. Some of them just sit back, they understand what you're saying and they're happy to go with the flow. That's okay but sometimes you need to explore it and encourage them to engage with you a bit more and say 'what do you actually think about this?' 'What's your thought about it?' and that sort of brings them up, maybe it prompts them to think in a bit more detail to what they're actually committing themselves to. (Mixed secondary care, less than 10 years' experience, Belfast).[363]

Doherty *et al* found that less than a third of patients felt that they had to engage with the consent process as they simply saw it as a means to an end.[364] If patients refuse or are unable to provide second order desires, as the basis of a disclosure process, this fundamentally undermines the ability of doctors to ensure an informed consent under the authenticity model. Similarly, patients were also sometimes unwilling to ensure their own understanding by asking questions or seeking out information from other sources as the basis of their consent.[365] For example, Powell *et al* found that patients with lung cancer actively avoided information, and expressed the view that knowing the risks would only cause additional and unnecessary worry.[366] The majority of patients in the Doherty *et al* study also did not want to make the final decision about their cancer treatment.[367]

The normative rules provide little normative guidance on how doctors can mitigate this unwillingness without risking liability. Forcing information on patients defeats the purpose of an authentic choice, as it would have the potential of overriding the patients' values. It also has the potential to unduly frighten the patient and thus undermine the doctors' ethical duty to 'first do no harm.'[368] Indeed, doctors argued that some patients complained that they were scare-mongering and asking them to make decisions which they did not feel qualified to make.[369] In these circumstances doctors thought that providing

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[361] *Ibid*, 14.
[362] *Ibid*, 23
[363] *Ibid*, 23
[364] C. Doherty, *et al*, 'The Consent Process: Enabling or Disabling Patients' Active Participation?' (2015) 21(2) *Health (London)* 205-222, 214
[365] *Ibid*, 215: "I think I'm best sticking to that [information from doctors] because when I go on the Internet, I do always come across things that aren't good you know. I think they have me everything I probably needed to know […] so really all I found on the Internet was reiteration of what they had told me. (P5F39)."
[366]H.A. Powell, 'Patients' Attitudes to Risk in Lung Cancer Surgery: A Qualitative Study.' (2015) 90 *Lung Cancer* 358-363,361; C. Doherty, *et al*, 'The Consent Process: Enabling or Disabling Patients' Active Participation?' (2015) 21(2) *Health (London)* 205-222, 217
[367] Ibid, Doherty, *et al*, 213
[368] T. L. Beauchamp and J.F. Childress, *Principles of Biomedical Ethics*. (Oxford University Press, 2013), 150-156
[369] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC* (GMC, 2017),34-36

patients with more information undermined the ability of patients to make an informed decisions.[370] However, patients who did not disclosure their information preferences, and a risk manifested also complained when they had not been told.[371] Doctors are stuck between a proverbial *rock-and-hard-place* as patients neither want to accept the responsibilities or consequences for their decisions.

(c) The independent formation of second order desires

One of the seminal requirements of an authentic autonomous choice are that the value-content and formation of a decision-making paradigm designed independently by the patient. The doctor thus has a duty to ensure this independence or non-control to ensure the integrity of this rationale. However, the studies identified that whilst patients were able to identify values and make decisions about mundane issues relating to their health,[372] when faced with serious or and life-threatening conditions (such as cancer or self-harm) they felt that they did not have the expertise to make decisions in these circumstances.[373] Similarly, some patients wanted to abandon their values and make decisions based on objective medical values; which would undermine the authenticity of their decisions and thus the purpose of the subjective limb of the *Montgomery* test.[374]

The GMC study identified doctors had real difficulty in ensuring that patient's decisions were independent, and not influenced by their family or other external influences.[375] Doctors gave examples where patients were influenced by their families to refuse medication for epilepsy, because 'they believe it is a spiritual' rather a 'medical issues'. Similarly '[s]ome communities (e.g. Somalian) […] believe that there should not be any medical intervention in childbirth so they refuse C-sections and pain relief.'[376] Patients similarly recognised that their families could undermine their own decisions, or confuse them.[377] This problem is exacerbated if patient's preferred their family to act as a conduit for communicating their values, or for breaking bad news.[378] If doctors challenge the authenticity of a decisions they risked creating conflict with carer's or family; which would undermine the relationship between parties, and the profession. However, without supported decision-making patients are at risk of making poor decisions, and if something goes wrong, families are more likely to complain.[379] This

[370] *Ibid*, 36
[371] *Ibid*, 24-25
[372] Ipsos MORI, *Attitudes Towards Consent and Decision Making.* (GMC, 2018), 13.
[373] *Ibid*: "The doctor should guide me to make a decision because that's his field […] and I am sick. I have no knowledge in the area, so he should be able to provide me with all the help I need to make a decision." (Person with limited English), "If it was something complicated, like if I had cancer […] I would think that you would want to put it into the hands of others." (Person living in a care home)
[374] *Ibid*, 14.
[375] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 25-26
[376] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 25-26.
[377] Ipsos MORI, *Attitudes Towards Consent and Decision Making.* (GMC, 2018), 19: "It can make things or decisions more complicated and confusing and [others] might influence your final decision." (Young adult).
[378] *Ibid*, 2
[379] *Ibid*

is an important finding, as the Convention on the Rights of Persons with Disabilities ("CRPD") requires that all patients make supported decisions i.e. so their decisions remain authentic irrespective of capacity. This fails to recognise that the act of supporting a decision could potentially undermine the patients' ability to have authentic autonomous choice.[380]

(d) Irrational values

The GMC study identified wide variations in patients' values and expectations of treatment options; from the objectively irrelevant, to the bizarre and dangerous. These widely varying values could at times not be safely integrated into decision-making frameworks without undermining patient understanding of the actual decision at hand, or offering treatment that was medically inappropriate and objectively harmful.[381] Doctors struggled to provide material disclosure where the values of the patient were irrational, or the doctor could not identify information which might potentially relate to their decision-making paradigm. For example, in the Powell *et al* study, the information patients most wanted to know was how long the surgeon had been practicing and the amount of operations that they had carried out.[382] As result, Doherty *et al* found that doctors regularly fail to represent the patients' values accurately when making decisions about treatment options and materiality.[383] Hamilton *et al*, also found that values of the patient were used to ratify rather than proactively decide the relevance of treatment options. [384] Providing a tailored disclosure may inevitably lead to picking and choosing values and characteristics which are rational and relevant to the decision, rather than representing the irrationality of the patient in the provision of information.[385] Again, the inclusion of an interpretative step creates medical discretion which requires a type of moral decision-making to identify values, and to anticipate how the particular patient might construct those values in their decision-making process.

[380] Art 12, The United Nations Convention on the Rights of Persons with Disabilities (CRPD). See, N. Devi, *et al*, 'Moving Towards Substituted or Supported Decision-Making? Article 12 of the Convention on the Rights of Persons with Disabilities.' (2011) 5(4) *Alter* 249-264; P. Gooding, 'Supported Decision-Making: A Rights-Based Disability Concept and its Implications for Mental Health Law.' (2012) 3 *Psychiatry, Psychology and Law* 431-451.

[381] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 23.

[382] H.A. Powell, 'Patients' Attitudes to Risk in Lung Cancer Surgery: A Qualitative Study.' (2015) 90 *Lung Cancer* 358-363, 361

[383] C. Doherty, *et al*, 'The Consent Process: Enabling or Disabling Patients' Active Participation?' (2015) 21(2) *Health (London)* 205-222, 218. Relying on W.M. Strull, *et al*, 'Do Patients want to Participate in Medical Decision Making?' (1984) 252 *JAMA* 2990-2994; H. Waitzkin, 'Doctor-Patient Communication: Clinical Implications of Social Scientific Research.' (2009) 68 *Soc Sci Med* 2018-2028

[384] D.W. Hamilton, 'Multidisciplinary Team Decision-Making in Cancer and the Absent Patient: A Qualitative Study.' (2016) 6 *BMJ Open* e012559, 6: for example: "Mr Jones (ENT surgeon): He's a very sort of straightforward sort of man, who doesn't worry too much, but he will probably cope with [the diagnosis] very well. But, he needs a lot of radiotherapy.", "Dr Brown: What age is he?", "Mr Jones: He's 87, I mean he's a very good 87."

[385] J. Montgomery & E. Montgomery, '*Montgomery* on Informed Consent: An Inexpert Decision.' (2016) 42 *J Med Ethics* 89-94, 90-91

The studies also found that doctors struggled to delineate between first and second order desires as the basis of decisions about materiality as values and desires changed when patients were confronted with complex, serious and novel decisions.[386] For example, Furber *et al* commented:

> […] David and Paul stated that they wanted the doctor to tell them everything. Yet, when their experiential accounts were analysed, their need for information was not quite as simple as this. David and Paul were ambiguous in their need for information […]. Paul spoke of not wanting to know his prognosis but on another occasion spoke of being informed of his prognosis but he did not like to think about it and then said he was keeping his darkest thoughts about his prognosis to himself. Paul fluctuated between a suspended, uncertain, and active open awareness. Fleeting transitions between various awareness contexts is not uncommon because it is difficult, emotionally, to maintain an active awareness context.[387]

If doctors cannot identify second order desires, then the purpose of providing a subjective disclosure is defeated. The inability to delineate between first and second order desires also made it difficult for doctors to ascertain whether the patient was actually able to make an informed consent.[388] If doctors choose to accept the presumption of capacity, this risked allowing patients without capacity to choose potentially life-altering treatments without intentionality. Whilst doctors could challenge capacity based on the irregularity of the patients' values, the GMC found that doctors were unlikely to challenge a decision if they agreed with patient choices. [389]

(e) Neutral communication

The studies provided evidence, that doctors do make efforts to provide neutral disclosures, to ensure the authenticity of patient decisions. However, the studies found that the resilience of patients varied.[390] Blazeby *et al*, for example, found that the impact of treatment, itself, had the potential to alter patient

[386] L. Furber, 'Patients' Experiences of an Initial Consultation in Oncology: Knowing and Not Knowing.' (2015) 20 *British Journal of Health Psychology* 261-273, 270; P. Kirk, *et al*, 'What do Patients Receiving Palliative Care for Cancer and their Families Want to be Told? A Canadian and Australian qualitative study.' (2004) 328 *BMJ* 1343-1350.
[387] *Ibid*, 270. See support in, D. Feldman-Stewart, *et al*, 'What Questions do Patients with Curable Prostate Cancer Want Answered?' (2000) 20(1) *Medical Decision Making* 7-19; L. Furber, *et al*, 'Investigating Communication in Cancer Consultations: What can be Learned from Doctors and Patient Accounts of their Experience?' (2013) 22 *European Journal of Cancer Care* 653-662.; S. Timmermans, *et al* 'Dying Awareness: The theory of Awareness Contexts Revisited.' (1994) 16 *Sociology of Health and Illness* 322-339.
[388] Ipsos MORI, *Attitudes Towards Consent and Decision Making.* (GMC, 2018), 2
[389] GMC, *Doctors' Attitudes to Consent and Shared Decision Making: Full Research Report for the GMC.* (GMC, 2017), 22: "Yes, if they come up with the same decision as you, you think yes, they've got capacity. If they want to take an unwise decision you think I'm not sure they have capacity." (Mixed secondary care, more than 10 years qualified, Cardiff).
[390] For example, Royal College of Surgeons, *Consent: Supported Decision-Making A Guide to Good Practice.* (RCoS, 2016), 8, [4.1]

values.[391] This is an important findings in relation to *Spencer v Hillingdon*[392] which requires doctor's to provide post-operative disclosure. The problem with this requirement is that information which was material before treatment may not be material after treatment. Hamilton *et al* also found that that the framing of information can have the effect of altering patient perceptions about risk.[393] This thesis would question the efficacy of constructing duties to service a substantive authentic autonomy, which may not be practically achievable if the act of diagnosis, disclosure and treatment actually acts to prevent the patient from achieving an authentic choice.

(ii) Defensive disclosure

Rather than attempting to overcome the conceptual and practical problems arising from the consumer relationships, some doctors adopted defensive disclosure practices as a way of avoiding liability. The GMC study found the consumer model 'was not fully embedded' either into individual practices or within organisations.[394] Decision-making about disclosure was instead 'process-led or driven by defensive practice (i.e. the desire to avoid any legal challenges influencing behaviour, often in a way which is perceived to be negative […], rather than a heartfelt commitment).'[395] This was, similarly, evidenced by the lack of emphasis placed on the facilitative requirements necessary to have an authentic autonomous choice. [396] For example, Bagnall *et al* found that whilst all doctors indicated that they would provide information, 50% of doctors thought that they did not need to ensure patients understood information.[397] One doctor in the GMC study indicated:

[391] M. Blazeby, *et al*, 'Core Information Set for Oesophageal Cancer Surgery.' (2015) 102 BJS 936-943, 941. Relying on, M. Jacobs, *et al*, 'Delphi Survey to Identify Topics to be Addressed at the Initial Follow-Up Consultations after Oesophageal Cancer Surgery.' (2014) 101 *Br J Surg* 1692-1701

[392] *Spencer v Hillingdon Hospital NHS Trust* [2015] EWHC 1058 (QB)

[393] D.W. Hamilton, 'Multidisciplinary Team Decision-Making in Cancer and the Absent Patient: A Qualitative Study.' (2016) 6 *BMJ Open* e012559, 4. For example: "Dr Green: It's a very accurate treatment […] You don't feel anything. You just lie there and then you go home again. […] But, the radiotherapy does cause some side effects and they can be quite nasty. Obviously the aim of the radiotherapy is to try and get rid of this cancer and to do that we have to give quite big doses of the radiotherapy. […] So you skin on the outside will start getting red like it's had a sun burn-type reaction and on the inside it starts getting red and inflamed as well. And that means that you'll start having problems like a sore throat and some problems and your swallowing. […] And that means that you'll need lots of support as you go through the treatment." Compared to: "Dr Goodier: We need to spread it out over six weeks of daily treatment. That means you coming up from home, Monday to Friday, every day for six weeks with just gaps at the weekend. […] We would lie you on a couch on your back, wide awake. […] As the treatment goes through, your body starts reacting to the radiation that we're giving it. […] Everything becomes inflamed and sore. The outside of your skin and the inside of your throat will all become quite red and hot and sore and that's why swallowing will become very, very difficult – probably impossible. Even swallowing your own saliva will be impossible by the time you get to the end of that six weeks.".

[394] GMC, *Doctors' Attitudes to Consent and Shared Decision Making: Full Research Report for the GMC.* (GMC, 2017), 13

[395] *Ibid*,13 & 24-25.

[396] S.R. Knight, 'Patient Consent in Post-*Montgomery* Era: A National Multi-Speciality Prospective Study.' (2019) *The Surgeon* 277-283, 281

[397] M. Bagnall, *et al*, 'Informing the Process of Consent for Surgery: Identification of Key Constructs and Quality Factors.' (2017) 209 *Journal of Surgical Research* 86-92, 90

> There was so many complaints about information or not enough information or wrong information and not involvement in decisions, that we modified our practice and became very defensive." (Mixed secondary care, qualified outside of UK, London)[398]

Making Decision Together was perceived as a form of regulation, which encouraged exhaustive disclosure, due to the recommendation to include both medical and patient values to identify significant information.[399] Doctors began to assemble what they considered to be a core content of information that would cover all potential bases on information need.[400] For example, doctors interviewed by Bagnall *et al* (n=16) recognised that disclosure of details of the procedure, generic risks, benefits and alternative treatments were integral information to ensure informed consent. [401] Greenway *et al* also argued that core information sets were necessary, after finding that all the doctors (n=100) who provided information disclosure for elective spinal operations in a central London neurosurgical department did not disclose the risk of ischaemic neuropathy (which they deemed objectively material).[402] Doctors adopted a cover-all approach to disclosure; to avoid making decisions about preferring medical, or patient values.

> Overall a good emphasis on patient centred care. Like others, I think the real difficulty comes in putting all of this into practice given resource and time limitations. Whilst it is clear from the guidance that consent should be tailored to an individual's needs, realistically I think most doctors would go for a blanket approach to cover the majority of risks in order to be safe and avoid making assumptions on behalf of patients. (Surgery, less than 10 years qualified, London).[403]

[398] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC* (GMA, 2017), 27
[399] *Ibid*, 27: "I think that medico legally they want you to record things… even if they're very rare, if they're very, very significant. So there's like a mismatch between… common and not severe should be talked about but it's actually the rare but important, isn't it?" (GP, more than 10 years qualified, Stockport)
[400] B.G. Main, 'Core Information sets for Informed Consent to Surgical Interventions: Baseline Information of Importance to Patients and Clinicians.' (2017)18 BMC *Medical Ethics* 29; S.R. Knight, 'Patient Consent in Post-*Montgomery* Era: A National Multi-Speciality Prospective Study.' (2019) *The Surgeon* 277-283; O. Brien *et al*, 'A Survey of Doctors at a UK Teaching Hospital to Assess Understanding of Recent Changes to Consent Law.' (2017) 18 *Annals of Medicine and Society* 10-13; F. Greenway, *et al*, 'Consent for Post-Operative Visual Loss in Probe Spinal Surgery: Aligning Clinical Practice with Legal Standards.' (2018) 6 *British Journal of Neurosurgery* 604-609, 607; C. Doherty, *et al*, 'The Consent Process: Enabling or Disabling Patients' Active Participation?' (2015) 21(2) *Health (London)* 205-222
[401] M. Bagnall, *et al*, 'Informing the Process of Consent for Surgery: Identification of Key Constructs and Quality Factors.' (2017) 209 *Journal of Surgical Research* 86-92, 90
[402] F. Greenway, *et al*, 'Consent for Post-Operative Visual Loss in Probe Spinal Surgery: Aligning Clinical Practice with Legal Standards.' (2018) 6 *British Journal of Neurosurgery* 604-609, 604-605
[403] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC* (GMA, 2017), 36

Studies such as Doherty *et al*, [404] Greenway *et al*, [405] Blazeby *et al*,[406] and O'Brien *et al*[407] suggested enshrining this exhaustive list in consent forms. Two out of the three sites that took part in the Lie *et al*, study created a standardised protocol to support decision-making, and a standard script of risks and benefits to be delivered by emergency doctors to stroke patients.[408] One site required a verbatim script to ensure a legal disclosure:

- There is a risk that the treatment will cause bleeding in the brain, causing a worsening stroke. This occurs in 7 out of 100 patients treated and is fatal in 2 of these.
- Despite this, overall, the treatment is much more likely to help than to cause harm.
- Without treatment of 100 people with a stroke, 26 will survive with minimal or no disability – with treatment of 100 people with stroke, 40 will survive with minimal disability[409]

This type of scripted disclosure process, whilst providing a content of information that an average patient might need in the circumstances, fails to tailor the content of disclosure, or communication of those risk to ensure the integrity of patient values, or their understanding. This lack of specification could potentially be harmful to some individuals.[410] The effect of the normative standard in *Montgomery* is therefore self-defeating. The study also identified deviation in the content and framing of these disclosure protocols between sites. [411] The emergence of these pro -forma scripts indicated a propensity for the creation and ossification of silos of divergent, yet potentially unethical practice identified by numerous Inquiries.[412]

[404] C. Doherty, *et al*, 'The Consent Process: Enabling or Disabling Patients' Active Participation?' (2015) 21(2) *Health (London)* 205-222
[405] F. Greenway, *et al*, 'Consent for Post-Operative Visual Loss in Probe Spinal Surgery: Aligning Clinical Practice with Legal Standards.' (2018) 6 *British Journal of Neurosurgery* 604-609, 607
[406] J.M. Blazeby, *et al*, 'Core Information Set for Oesophageal Cancer Surgery.' (2015)102 *BJS* 936-943
[407] O. Brien, *et al*, 'A Survey of Doctors at a UK Teaching Hospital to Assess Understanding of Recent Changes to Consent Law.' (2017) 18 *Annals of Medicine and Society* 10-13, 12. For example, S. Cleeve & J. Curry, 'Attitudes to Consent – A National Surgery.' (2006) 41 *J Pediatri Surg* 368-371; L. Cooper, *et al*, 'Developing Procedure-Specific Consent Forms to Plastic Surgery: Lessons Learnt.' (2016) *J Plast Reconst Aesthet Surg* 10-11; D.K. Sokol, 'Update on the UK Law of Consent.' (2015) 350 *BMJ* h1481
[408] M.L.S. Lie, *et al*, 'Risk Communication in the Hyperacute Setting of Stroke Thrombolysis: An Interview Study of Clinicians.' (2015) 32(5) *Emergency Medicine Journal* 357-363 in pdf pages 1-16, 4 (<https://eprint.ncl.ac.uk/file_store/production/199076/0C08022F-0D7F-411C-BC6E-5667970E5D93.pdf>)
[409] M.L.S. Lie, *et al*, 'Risk Communication in the Hyperacute Setting of Stroke Thrombolysis: An Interview Study of Clinicians.' (2015) 32(5) *Emergency Medicine Journal* 1-16, 9
[410] L. Furber, *et al*, 'Patients' Experiences of an Initial Consultation in Oncology Consultations.' (2015) 20 *British Journal of Health Psychology* 261-273, 263. Relying on L. Furber, *et al*, 'Enhancing Communication in Oncology Outpatient Consultations. Critical Reflections from Doctors.' (2011) 2 *International Journal of Medical Education* 159-169
[411] M.L.S. Lie, *et al*, 'Risk Communication in the Hyperacute Setting of Stroke Thrombolysis: An Interview Study of Clinicians.' (2015) 32(5) *Emergency Medicine Journal* 1-16, 9
[412] See Chapter 1; J. *Montgomery*, 'Law and the Demoralisation of Medicine.' (2006) 26(2) *Legal Studies* 185-210, 189-193

5.3.3. Rejecting the consumer relationship

Many of the studies identified a proportion of doctors who continued to reject the ethics of patient rights, and therefore ignored the law and ethics. O'Brien *et al* for example, argued that the ethical uncertainty around *Montgomery*, and particularly the meaning of *materiality* resulted in the proliferation of the *Bolam* standard in practice. [413] Knight *et al* found that of those doctors who were aware of the *Montgomery* ruling, 31.7% stated that they would make no changes to either their discussion or documentation.[414] McKinnon *et al* similarly found that of the doctors who were aware of the *Montgomery* judgement, only 35% reported that there had been a noticeable change in practice.[415] The study identified that 13% of respondents disagreed or strongly disagreed with requiring an informed consent, and 33% admitting they had not had tailored discussions with patients before surgery;[416] 17% of respondents stated that patients generally could not understand, so they would act in their best interests.[417]

The studies identified a clear correlation between doctors who have knowledge of the *Montgomery* judgement and seniority, and between seniority and rejection of the consumer relationship. The Knight *et al* study found that senior doctors were more aware of the *Montgomery* judgement,[418] and the GMC found senior doctors were more likely to reject the consumer model of the medical relationship.[419] Whilst junior doctors showed more rhetorical support for the consumer model they often did not know about the *Montgomery* judgement, and regularly failed to meet the requirements necessary for an informed consent in practice.[420] For example, Bagnall *et al*, found trainee surgeons (n=8) were less likely to disclose specific risks of surgery (62.5%) compared to senior colleagues (100%), they were less likely to communicate to ensure patient understanding (62.5% v 100%) and were less likely to check understanding and recall (37.5% v 62.5%).[421] Knight *et al*, similarly found that the more senior a clinician, the more likely they were to discuss the benefits, risks and alternatives of treatments, or having no treatment. [422] McKinnon *et al* found that 81% of surgical doctors were aware of recent legal

[413] J.W. O'Brien, *et al*, 'A Survey of Doctors at a UK Teaching Hospital to Assess Understanding of Recent Changes to Consent Law.' (2017) 18 *Annals of Medicine and Surgery* 10-13, 12; L.C. Edozien, 'UK Law on Consent finally embraces the Prudent Patient Standard.' (2015) 350 *BMJ* h2877-h2877

[414] S.R. Knight, 'Patient Consent in Post-*Montgomery* era: A National Multi-Speciality Prospective Study.' (2019) *The Surgeon* 277-283, 280

[415] C. McKinnon, *et al*, 'Surgical Consent Practice in the UK following the *Montgomery* Ruling: A National Cross-Sectional Questionnaire Study.' (2018) 55 *International Journal of Surgery* 66-72, 66.

[416] *Ibid*, 69

[417] *Ibid*, 68

[418] S.R. Knight, 'Patient consent in Post-*Montgomery* Era: A National Multi-speciality prospective study.' (2019) *The Surgeon* 277-283, 279

[419] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 11

[420] *Ibid*, 11-13 & 17-18

[421] J.W. O'Brien, *et al*, 'A Survey of Doctors at a UK Teaching Hospital to Assess Understanding of Recent Changes to Consent Law.' (2017) 18 *Annals of Medicine and Surgery* 10-13, 12

[422] S.R. Knight, 'Patient Consent in Post-*Montgomery* Era: A National Multi-Speciality Prospective Study.' (2019) *The Surgeon* 277-283, 279 & 282

changes (50% of respondents were consultants with 86% awareness).[423] These older doctors continued to recognise the ethical importance of respecting patient autonomy but did so within the context of making decisions about disclosure in the patient's therapeutic interests:

> But I think it's changed over my 35 more years in the trade, is that we are conscious of the bias much more than we were and we are less paternalistic, and we are more willing to accept the patient's point of view and not push and to actually have a dialogue about it. (Surgery, more than 10 years qualified, Birmingham) [424]

The senior doctors who were interviewed saw the consumer relationship as encouraging defensive practices.[425]

> I'm not sure of the value of it. Now after 30 years of just asking what is this consent is about, is it just a legal paper or just a paper to protect me from the MDU, or from a legal point. Yes, we explain the procedure to the patient and don't do anything without consent. But mostly it's about paperwork.[426]

The orientation of decision-making amongst senior doctors is important as they continued to make both the majority of treatment decisions[427] and as Knight *et al* identified, the majority of decisions about the consent process (80% of patients were seen by a consultant surgeon in clinic and 50% on the day of the surgery).[428] This data challenges the assumption made by commentators that the consumer relationship is inevitable, and now acts as the dominant form of the medical relationship,[429] and thus the right to autonomy is trumps when disclosing information.[430]

(i) Reasons for rejection

If the consumer relationship is regularly rejected, despite normative impetus, it is important to identify why this phenomenon is occurring. This review identified six primary reasons for rejection.

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[423] C. McKinnon, *et al*, 'Surgical Consent Practice in the UK following the *Montgomery* Ruling: A National Cross-Sectional Questionnaire Study.' (2018) 55 *International Journal of Surgery* 66-72, 67
[424] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 16-17
[425] S.R. Knight, 'Patient Consent in Post-*Montgomery* Era: A National Multi-Speciality Prospective Study.' (2019) *The Surgeon* 277-283, 279
[426] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMA, 2017), 13
[427] C. McKinnon, *et al*, 'Surgical Consent Practice in the UK following the *Montgomery* Ruling: A National Cross-Sectional Questionnaire Study.' (2018) 55 *International Journal of Surgery* 66-72, 67
[428] S.R. Knight, 'Patient Consent in Post-*Montgomery* Era: A National Multi-Speciality Prospective Study.' (2019) *The Surgeon* 277-283, 282
[429] S.A.M. McLean, *Autonomy, Consent and the Law.* (Routledge, 2010), 31
[430] R. Gillon, 'Ethics Needs Principles – Four Can Encompass the Rest – And Respect for Autonomy should be "First Among Equals." (2003) 29(5) *J Med Ethics* 307-312

First, doctors remained committed to avoiding harm. Whilst some studies have characterised non-disclosure decisions as stubborn paternalism, [431] this is better characterised as an unwillingness, amongst the medical profession, to provide patients with information which is irrelevant and unhelpful, or to undertake defensive practices that will knowingly harm their actual patient.[432] Providing an exhaustive disclosure, may not activate the therapeutic privilege, yet it may undermine the ability of some patients to make rational or authentic choice.[433]

> Good in principle but how practical is it to discuss all the side effects/adverse reactions, including the minor ones? Every medication has a large list of potential side effects and interactions – have we got tome and knowledge to give the accurate information about each potential side effect and how will that empower the patient or will it not just create anxiety and poor compliance? (GP, more than 10 years qualified, Stockport). [434]

Instead, doctors preferred to increase and limit information dependent on the patient's actual needs, choices, and circumstances, attaching proper weight to issues, rather than facilitating an abstract legal construct. [435]

Second, as one doctor in the GMC study commented, the consumer relationship has had the effect of de-personalising the patient and recasting the medical profession as: 'scary horrible technicians who are telling [the patient] that you will die or get paralysed.'[436] Eradicating the internal moral orientation of decision-making reduces doctors to technicians, carrying out functions. Erasing these moral norms also blurs the boundaries between ethical and unethical behaviour within every day practice. Doctors fail to self-regulate and instead are forced to make decisions in both an ethical and moral vacuum. This means that doctors would have no internal moral orientation when making decisions without (knowledge of) detailed rules; this is especially important for junior doctors who have not previously

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[431] C. Doherty et.al, 'The Consent Process: Enabling or Disabling Patients' Active Participation?' (2017) 21(2) *Health (London)* 205-222, 207; referring to I. Kennedy, *Review of the Response of Heart of England NHS Foundation Trust to Concerns about Mr Ian Paterson's Surgical Practice; Lessons to be Learned; and Recommendations*. (Kennedy Review, 2015), 52: "the prevailing culture is one in which the patient is seen as the recipient of whatever is on offer, then consent can come to be seen as some perfunctory exercise […]. Hence, the patient is 'consented', and the doctor can then get on with things, having had to pause as briefly as possible to tick the consent box."

[432] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC*. (GMC, 2017), 13 (Figure 1): "In a way it can't really be [informed consent] because, however much you talk about a prolonged course of treatment, it's very hard to convey." (Mixed secondary care, More than 10 years, Cardiff)

[433] C. Doherty, *et al*, 'The Consent Process: Enabling or Disabling Patients' Active Participation?' (2015) 21(2) *Health (London)* 205-222, 215: "[…] if you did alert patients to all the very rare complications that might occur, you'd have very few people taking you up on the therapies that you're offering."

[434] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC* (GMC, 2017), 36

[435] F. Greenway, *et al*, 'Consent for Post-Operative Visual Loss in Probe Spinal Surgery: Aligning Clinical Practice with Legal Standards.' (2018) 6 *British Journal of Neurosurgery* 604-609, 608. Also see, GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 14 & 24

[436] *Ibid*, 41

been socialised in these internal norms. [437] The consumer relationship therefore has the potential to exacerbate, rather than prevent, the harms identified by Miola,[438] and Kennedy.[439] Doctors therefore continued to perceive their role as a moral profession, and would act in line with the collectively defined standards and practices of their profession. [440]

Third, abandoning the inner moral norms of caring for the patient and acting in their best interests, risked reducing patient trust in the medical profession.[441]Zarnegar *et al* found that 50% of patients felt that providing information had become about protecting the profession from complaints, rather than achieving an informed consent, and as such 65% of patients did not read the consent form before signing.[442] All patients in the Doherty *et al* study similarly thought that consent was a bureaucratic process aimed at defending doctors.[443] Some patients, went as far as to describe the process as 'oppressive' and 'coercive' and stated that it restricted their ability to choose their preferred medical relationship.[444] Undermining trust in the medical relationship has knock on effect of reducing the ability of the doctor to communicate with their patients, and thus to identify their values to ensure an autonomous choice.[445]

Fourth, doctors recognised that normative standards could never facilitate the dynamic and changing nature of patient circumstances and thus information need. Doctors would, inevitably, have to exercise discretion. Discretion necessitated a form of internal moral norms, and orientations, to guide their decision-making.[446] For example, doctors needed to decide: the relevance of issues, the weight to be attached to those issues, and the values that must be prioritised in the circumstances,[447] as well as how to effectively communicate that information to the individual patient.[448] The medical profession cannot

[437] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 43
[438] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship*. (Hart Publishing, 2007),6, 33-34, 38-43, 212
[439] See Chapter 1, Chapter 2, Section 1 and Chapter 3, Section 1. Particularly, I. Kennedy, *Learning From Bristol: The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995*. (Cm 5207, 2001)
[440] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC* (GMC, 2017), 43
[441] *Ibid*, 27
[442] R. Zarnegar, *et al*, 'Patients Perceptions and Recall of Consent for Regional Anaesthesia Compared with Consent for Surgery.' (2015) 108(11) *J R Soc Med* 451-456, 453
[443] C. Doherty, *et al*, 'The Consent Process: Enabling or Disabling Patients' Active Participation?' (2015) 21(2) *Health (London)* 205-222, 216-217
[444] *Ibid*, 217: "I'm signing my life away to say I accept it, it's either that or die, so you really haven't got any option have you? You either do this or you go home unsigned and die. (P23F62)"
"[…] by the time it came to the consent for it was, 'and you need to sign the consent form for the treatment'. By which point nobody's going to say no because if you don't sign it you don't get your treatment. (C1M57)"
[445] See Section 5.3.2. (i)(a)
[446] J.W. O'Brien, *et al*, 'A survey of Doctors at a UK Teaching Hospital to Assess Understanding of Recent Changes to Consent Law.' (2017) 18 *Annals of Medicine and Surgery* 10-13, 12. Also, M.L.S. Lie, *et al*, 'Risk Communication in the Hyperacute Setting of Stroke Thrombolysis: An Interview Study of Clinicians.' (2015) 32(5) *Emergency Medicine Journal* 1-16, 8-9; GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 27-28
[447] *Ibid*, Lie, *et al*, 10. Also, GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMA, 2017), 28
[448] J.W. O'Brien, *et al*, 'A Survey of Doctors at a UK Teaching Hospital to Assess Understanding of Recent Changes to Consent Law.' (2017) 18 *Annals of Medicine and Surgery* 10-13, 12

truly become value-neutral and dispassionate service providers.[449] If the consumer relationship, and thus true *demoralisation* of medical decision-making is impossible in practice, then one must question the legitimacy of any purely normative model.

Fifth, doctors recognised the therapeutic need for patient to have information beyond informed consent. Patient's preferred an ongoing process of disclosure, rather than a single disclosure before surgery. Ultimately, patients preferred a tailored rather than exhaustive disclosure, at a time which suited them. For example, Wiseman *et al* found that in the 32.1% of consultations surveyed, patients were more satisfied where the doctors did not provide exhaustive options.[450] Patients also often wanted information about their condition and treatment, without necessarily taking on the role of decision-maker.[451] Furber *et al* found that patients wanted this tailored approach because they made decisions by balancing their individual need for information against their personal anxiety about prognosis and/or treatment options.[452]

Sixth, a significant minority of patients continued to reject the role of consumer patient.[453] McIntyre and Tolley, for example, found some patients would like to know only the common risks (6.45%), dangerous risks (5.53%), or none at all (1.84%).[454] Other patients rejected their role as decision-maker.[455] For example, the majority (73%) of patient's (n=305) in the Durand *et al* study wanted a shared process of decision-making, and 6% wanted the doctor to exclusively make a decision about renal replacement therapy. As treatment began patients generally wanted to be less involved in future decisions.[456] The GMC study on patient information need also found that some patients did not want to

[449] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 5. Also, S.R. Knight, et al, 'Patient Consent in Post-*Montgomery* Era: A National Multi-Speciality Prospective Study.' (2019) *The Surgeon* 277-283, 281. Relying on A.S. Fink, *et al*, 'Enhancement of Surgical Informed Consent by Addition of Repeat Back: A Multicentre Randomised Controlled Clinical Trial.' (2010) 252(1) *Ann Surg* 27-36

[450] H. Wiseman, *et al*, 'Do Patients Want Choice? An Observational Study of Neurology.' (2016) 99 *Patient Education and Counselling* 1170-1178, 1173-1175

[451] C. Doherty, *et al*, 'The Consent process: enabling or disabling patients'' active participation?' (2015) 21(2) *Health (London)* 205-222, 213-214 & 216. This was identified in the previous Chapters for example: A. Akkad, *et al*, 'Informed Consent for Elective and Emergency Surgery: Questionnaire Study. (2004) 111 *BJOG* 1122-1138 ; A. Akkad, *et al*, 'Patients' Perception of Written Consent : Questionnaire Study.' (2006) 333 *BMJ* 528; H.A. Powell, 'Patients' Attitudes to Risk in Lung Cancer Surgery: A Qualitative Study.' (2015) 90 *Lung Cancer* 358-363, 361

[452] L. Furber, *et al*, 'Patients' Experiences of an Initial Consultation in Oncology Consultations.' (2015) 20 *British Journal of Health Psychology* 261-273,266: "[…] if you get more information then, you can start getting more worried than you might necessarily need to be." (Amy)

[453] H.A. Powell, 'Patients' Attitudes to Risk in Lung Cancer Surgery: A Qualitative Study.' (2015) 90 *Lung Cancer* 358-363, 362

[454] C. McIntyre & N. Tolley, 'A Critical Review of Thyroidectomy Consent in the UK.' (2019) 66 *International Journal of Surgery* 84-88, 68

[455] H.A. Powell, *et al*, 'Patients' Attitudes to Risk in Lung Cancer Surgery: A Qualitative Study.' (2015) 90 *Lung Cancer* 358-363, 360; C. Doherty, et al, 'The consent process: enabling or disabling patients'' active participation?' (2015) 21(2) *Health (London)* 205-222, 213: "I think the decision was this is what we want to give you […] As far as I'm concerned they tell me what's going to happen, I consent to what's going to happen and I sign my signature as consent to that operation […] or whatever I'm having. (P32F68)

[456] M-A, Durand, *et al*, 'Can we Routinely Measure Patient Involvement in Treatment Decision-Making in Chronic Kidney Care? A Services Evaluation 27 Renal Units in the UK.' (2016) 9(2) *Clinical Kidney Journal* 252-259, 257

have a discussion about their treatment, [457] and patients who were most vulnerable, for example those with mental health conditions or in care homes, did not want to make decisions.[458] One patient stated: '[t]he doctor is seen as best placed to make decisions, given their medical knowledge expertise and understanding of what is safest. It is the doctor's role to act in the patient's best interest.'[459] Failing to recognise and accommodate these choices abandons patients to their role as consumer patient.

(ii) Barriers to best interests: liberal autonomy in practice

A liberal autonomous choice was presumed to be in the patients best interest.[460] However as McIntyre and Tolley identified there continued to be confusion about the definition of *relevant circumstances*, and thus the issues which were necessary to consider when attempting to meet the needs of the prudent patient.[461] Specifying how *circumstances* should be defined (by the doctor and/or patient) was practically important as patients and doctors placed different emphasis on relevant factors. For example, Blazeby *et al* found that health professionals (n=185) focused on short-term clinical circumstances and outcomes, particularly technical complications (e.g. Anastomotic leak (8.65/10), in-hospital mortality (8.37) and type of surgery (8.17/10)) as the basis of materiality, whilst patients prioritised practical circumstances and long term benefits of surgery (e.g. cancer reoccurrence (7.88/10), and long term survival (7.8/10)).[462]

The GMC also found that doctors found it difficult to tailor population based data to the particular circumstances of the actual patient; if the data was not equivocal with patient values and circumstances.[463] For example, a national survey of members of the Society of British Neurological Surgeons (n=75) found that 67% 'said they never discuss post-operative visual loss,' for elective prone spinal surgery and 19% said they only do it sometimes, due to a lack of guidelines - despite these being serious risks under the objective standard.[464] This is not an isolated problem: '[t]he rare but significant risk in any procedure are limitless: bilateral supratentorial epidural haematomas, fall from the operating table, cerebellar haemorrhage, seizures, Guillain Barre syndrome, abducens nerve palsy, Horner's syndrome and rhabdomyolysis have all been reported following spinal surgery.'[465] The problem with a

[457] Ipsos MORI, *Attitudes towards consent and decision making*. (GMC, 2018), 2 & 12.
[458] *Ibid*, 41, and 13: "As long as I felt my opinion was being considered properly, I'm happy to leave most involvement to the doctor." (Young adult)
[459] *Ibid*, 12
[460] See Chapter 2, Section 2
[461] C. McIntyre & N. Tolley, 'A Critical Review of Thyroidectomy Consent in the UK.' (2019) 66 *International Journal of Surgery* 84-88, 68.
[462] M. Blazeby, *et al*, 'Core Information Set for Oesophageal Cancer Surgery.' (2015) 102 *BJS* 936-943, 939; R. Zarnegar, *et al*, 'Patient Perceptions and Recall of Consent for Regional Anaesthesia Compared with Consent for Surgery.' (2015) 108(11) *J R Soc Med* 451-456, 457
[463] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC* (GMC, 2017), 4
[464] F. Greenway, *et al*, 'Consent for Post-Operative Visual Loss in Probe Spinal Surgery: Aligning Clinical Practice with Legal Standards.' (2018) 6 *British Journal of Neurosurgery* 604-609, 605 & 607
[465] *Ibid*, 608

lack empirical data about what the circumstances of the reasonable patient (in the UK)[466] and what they would want to know, may mean that doctors are unintentionally providing information that they think that the average patient would want to know, rather than what the average patient actually wants to know.[467]

(a) Lack of time

Doherty *et al* study, found that for patient's adequate time was essential for understanding and feeling satisfied about their decision.[468] However, both doctors and patients reported lack of time had acted as a barrier to communicating information effectively i.e. at a pace and level which would ensure an objective understanding. Doctors also felt limited in their time to clarify understanding, either by testing patient knowledge, or by answering follow-up questions.[469] McKinnon *et al*, found that 49% of consent processes were completed in 10 minutes or less, and 45% up to 30 minutes. Only 24% of respondent patients had protected time for consent discussions and 52% of respondents felt there was not enough time to legally complete the consent process.[470] Knight *et al*, similarly found 55.1% of doctors (n=183) felt that a lack of time and resources prevented an informed consent. [471] The more experienced the doctor the more they saw time as a limiting issue e.g. with 70.6% of consultant surgeons seeing it as a barrier.[472] This is likely because more experienced doctors have more knowledge, and thus potentially identify more material information. The GMC study on patient attitudes also found that patients felt they lacked time to actually understand information and felt under time pressure when communicating to their GP.[473]

Lack of time was identified as a general problem throughout the consultation. Placing more emphasis on achieving an informed consent, may have the effect of reducing time to ensure an adequate diagnosis,

[466] This raises the problem of variation between material information between patient groups. Gathering data on the 'average patient' could have the effect of discriminating along socio-cultural and economic lines. There is also the risk of reliance on data that is not particular to the UK, e.g., Greenway, *et al* argued that doctors could be relying on the guidance published by the American Society of Anaesthesiologists (ASA). The ASA does not provide specific guidance: *Ibid*, 607; also, P. Parame, *et al*, 'Practice Advisory for Perioperative Visual Loss,' (2012) 116 *Anaesthesiology* 274-285

[467] This is a similar finding to C. Doherty, *et al*, 'The Consent Process: enabling or disabling patients'' active participation?' (2015) 21(2) *Health (London)* 205-222, 218.

[468] C. Doherty, *et al*, 'The Consent Process: Enabling or Disabling Patients' Active Participation?' (2015) 21(2) *Health (London)* 205-222, 214: "The doctor explained everything to her and what was going to happen […] we honestly thought the consultation would take about 20 minutes; it took over an hour, now whether that was because we were asking questions […] [that was a] nice feeling, we felt that people had the time. (C7M61)"

[469] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMA, 2017), 12: "[…] we're in a time-restricted environment with *Montgomery* case law and all of that about having to work out what the most important factors for the consent process are for that individual patient and then making sure that those are addresses. I kind of feel like it's a bit of a losing battle for the doctors, you can't get it right every time for every patient." (Surgery, less than 10 years qualified, London).

[470] C. McKinnon, *et al*, 'Surgical Consent Practice in the UK following the *Montgomery* Ruling: A National Cross-Sectional Questionnaire Study.' (2018) 55 *International Journal of Surgery* 66-72, 68

[471] S.R. Knight, 'Patient Consent in Post-*Montgomery* Era: A National Multi-Speciality Prospective Study.' (2019) *The Surgeon* 277-283, 280

[472] *Ibid*, 280

[473] Ipsos MORI, *Attitudes Towards Consent and Decision Making.* (GMC, 2018), 3

or providing good treatment. Commentators rightly argue that focusing on disclosure risks placing the *cart-before-the-horse*; by undermining essential elements of patient care and safety.[474] Whilst one might consider extending the time for consultations, this may not always be possible in the circumstances. [475] A doctor treating a capacitous patient in an emergency department, needing urgent care, may have to disclose a large content of information to ensure a substantive autonomous choice.[476] Spending more time on disclosure may be increasing the patient's risks.[477] The Lie *et al* study, for example, interviewed doctors (n=13) in three acute stroke units; the doctors complained that that achieving a legal consent was sometimes impossible due to the patient's condition.[478] Doctors,

> […] gave accounts of borderline cases where balancing risks and benefits might be difficult for them, let alone the patients. Symptoms may fluctuate over the course of the time window for treatment, adding additional uncertainty. Older patients often suffer multiple co-morbidities and there were those who presented with no clear onset time. These factors complicated diagnosis, risk communication and informed consent. […][479]

To ensure legal consent in the law of battery, doctors had to prioritise disclosing a limited amount of information to ensure legal consent, rather than attempt to achieve an informed consent. [480]

> […] you've just given them this whole raft of information about risks and possible side-effects and this could happen and that could happen and you're almost pushing them into a decision […] because you know you're under time pressure, (DocA05) [481]

[474] The same effect has been found in, P. Coulon-Smith & A. Lucassen, 'Using Biomarkers in Acute Medicine to Prevent Hearing Loss: Should this Require Specific Consent?' (2020) *J Med Ethics* (<https://jme.bmj.com/content/early/2020/07/12/medethics-2020-106106>)

[475] M.L.S. Lie, *et al*, 'Risk Communication in the Hyperacute Setting of Stroke Thrombolysis: An Interview Study of Clinicians.' (2015) 32(5) *Emergency Medicine Journal* 1-16, 6 "It was just coming up to 3 hours and err, I told the family that there was a risk of bleeding, he was at higher risk of bleeding because em because he had diabetes and whatever it was, his blood pressure was a bit high but he was going to be […] from this stroke and err they were very keen to do anything they can. So he actually got, I told them about risk of bleeding and despite the fact that 2 CT's […] which showed that he didn't have any bleeding at all actually he just too a massive brain swelling. When he died the family turned around and said that we had killed him basically." (DocC08), 5

[476] GMC, *Doctors' Attitudes to Consent and Shared Decision Making: Full Research Report for the GMC.* (GMC, 2017), 20

[477] M.L.S. Lie, *et al*, 'Risk Communication in the Hyperacute Setting of Stroke Thrombolysis: An Interview Study of Clinicians.' (2015) 32(5) *Emergency Medicine Journal* 1-16. Also, Ipsos MORI, *Attitudes Towards Consent and Decision Making.* (GMC, 2018), 36

[478] *Ibid* 1-16: "Thrombolysis with recombinant tissue plasminogen activator (rtPA) is an effective early treatment for ischaemic stroke which must be given as soon as possible within a limited time window (up to four and a half hours) from onset of symptoms. However there are risks of bleeding, particularly symptomatic. However there are risks of bleeding, particularly symptomatic intracranial haemorrhage (SICH), which may lead to a worse outcome, including death, than might have occurred without treatment."

[479] *Ibid*, 6: "Because of the nature of stroke, doctors reported facing challenges in predicting the likely outcome with thrombolysis for individual patients, give the probabilistic nature of treatment effectiveness. […]"

[480] *Ibid*, 5

[481] *Ibid*

> […] so in the context of thrombolysis you do actually have to say, we really can't wait for that amount of time to actually do something so, you are pressurising the patient but you have to be honest about that. (DocA07) [482]

Doctors within the GMC study also complained that the substantive test in the law failed to recognise the diverse nature of the patients' medical circumstances. The construct of the consumer, or prudent patient, is grounded on the supposition that patients are making elective decisions, with full capacity, are able to make logical decisions, and have unlimited time.[483] Attempting to follow the guidance can itself lead to distinct harm to the patient i.e. by overloading them with information, causing them unnecessary anxiety, or pushing them into a decision.

> […] we're in a time-restricted environment with *Montgomery* case law and all of that about have to work out what the most important factors for that consent process are for that individual patient and them making sure that those are addressed. I kind of feel like it's a bit of a losing battle for doctors, you can't get it right every time for every patients. (Surgery, less than 10 years qualified, London)[484]

(b) Ensuring an actual understanding

Doctors within the identified studies also raised the problem of patients having sufficient capacity to attain an actual understanding necessary to have an informed consent. The content of information and the technicality of information, necessary to have a rational and balanced decision were beyond the reasonable level of capacity of most patients within the medical setting[485] for a multitude of reasons.[486] For example, Zarnegar *et al* identified that the pressurised environment of the hospital setting and the nature of illness, meant that patients (n=44) struggled to recall risks of shoulder arthroplasty; only 52% of patients could recall two risks of the procedures whilst 25% could recall only one, and for brachial plexus block 20% could recall two risks and 45% could only recall one. [487] However, doctors must also deal with the reality that some patients whilst having a legal capacity to consent will not have the bare ability to retain or understand the content of information necessary for the doctor to ensure a rational

[482] *Ibid*
[483] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC*. (GMC, 2017), 20: "I think there has to be an acknowledgement that this practice, I think it's very good for the patient, it gets them involved and very conscious about what kind of treatment or procedure they're going to get […] if you get a patient with a lot of questions that can take a whole hour, if not a second visit as you said. In intensive care on a Saturday evening with one trainee engaged in something else and myself dealing with the family and another million things happening, there's simply no room for that."
[484] *Ibid*, 12
[485] Ibid, 27
[486] M.L.S. Lie, *et al*, 'Risk Communication in the Hyperacute Setting of Stroke Thrombolysis: An Interview Study of Clinicians.' (2015) 32(5) *Emergency Medicine Journal* 1-16, 10
[487] R. Zarnega, *et al*, 'Patient Perceptions and Recall of Consent for Regional Anaesthesia Compared with Consent for Surgery.' (2015) 108(11) *J R Soc Med* 451-456, 454

decision.[488] For example, Furber *et al* found that some patients could not retain any information after a cancer diagnosis:[489]

> David described how difficult it was to process information during his consultation because he felt 'muddled' and 'a bit slow' and failed to 'listen' because he 'switched off'. When he did not understand what he had been told, he did not seek clarification. He did not explicitly say whether he was switching off as a defence against the emotional response to the content of what he was told, but this is a possible interpretation.[490]

Lie *et al*, through semi-structured interviews with doctors, identified that some patients failed to understand information because of the nature of the illness or disease which requires treatment.[491]

> Erm, the fact that people weren't expecting this to happen, are very shocked and erm, sometimes can't really appreciate that you're saying that they've had a stroke and they're at the moment severely disabled from it. Um, er they've got no experience of what a stroke is. Most people tend to associate strokes with death shortly afterwards. (DocB01).[492]

Doctors comment that they know intuitively that some patients are not going to have sufficient understanding to make the type of autonomous choice conceptualised by the law, [493] yet *Montgomery* argues that doctors must not assume that patients are 'incapable of understanding medical matters.'[494] The only justification for withholding information is if the information will cause serious harm (as defined with hindsight by the courts). The law therefore forces doctors to potentially undertake a defensive disclosure process, as the doctor knows, the patient may not understand or retain information, that the information might potentially confuse (or scare) the patient and therefore would not be in their best interests.[495]

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[488] Which is a legal requirement: *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [90]: "[…] the patient understands the seriousness of her condition, and the anticipated benefits and risks of proposed treatments and any reasonable alternatives, so she is then in a position to make an informed decision."
[489] L. Furber, *et al*, 'Patients' Experiences of an Initial Consultation in Oncology: Knowing and Not Knowing.' (2015) 20 *British Journal of Health Psychology* 261-273, 266: "It wasn't sinking in. I remember some of the stuff as I told my family those details, but some of it was just a bit of a blur. My memory is not great at the moment. Short, short attention span."
[490] *Ibid*, 266
[491] M.L.S. Lie, *et al*, 'Risk Communication in the Hyperacute Setting of Stroke Thrombolysis: An Interview Study of Clinicians.' (2015) 32(5) *Emergency Medicine Journal* 1-16, 5: "[…] depending on what else is happening with them. You don't know whether they're completely taking the information on board. (DocA01)"
[492] *Ibid*, 5
[493] GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008), [34] The GMC state that: 'You should check that the patient understands the terms that you use, particularly when describing the seriousness, frequency and likelihood of an adverse outcomes.'
[494] *Montgomery v Lanarkshire Health Board* [2015] USKC 11, [75]
[495] GMC, *Consent: Patients and Doctors Making Decisions Together*. (GMC, 2008), [10]

(c) Weighing and balancing

Other patients could understand and recall the information but could not attribute proper weight to a risk, as the basis to make rational decision. This could be a problem of basic capacity. For example, if the doctor provides numerous options, with competing benefits and risks then even the most astute patient may struggle to come to a reasoned decision. Blazeby *et al*,[496] for example, undertook a literature review of material information relating to oesophageal cancer surgery. They identified 901 individual pieces of information that were categorised into 67 distinct items which could be disclosed to patients.[497]

In the GMC study, some doctors expressed the view that patients are unlikely to have prior experience of making potentially life-altering decisions about their own health, to be able to appropriately weigh each individual item of information, and balance them proportionately against each other, and then against other options. [498] Blazeby *et al* also identified patients found it difficult to appreciate and balance risks if the risk was not related to practical issues found in their everyday lives.[499]

> It's kind of an understanding of risk, isn't it, and people aren't good at it. So if you're told you have a one in 80 million chance of winning the lottery, you think it will be you so, of course, you also think it will be you that dies from a perforated bowel. So that's a real problem, when you start to use numbers, the logic might go out the window. (Mental health, less than 10 years qualified, Leeds) [500]

McKinnon, *et al*, found that 17% of doctors believed that on average patients generally lack a balanced understanding necessary to make decisions,[501] and Powell *et al* found that some patients who had consented have done so irrationally. For example, patients who agreed to lung removal could not imagine the risk of breathlessness manifesting[502] and some patients actually denied that risks could happen to them.[503]

Studies also found that inability to make rational decisions are not necessarily associated with bare capacity but were related to psychological mechanisms to avoid distress by not listening to, or not

[496] M. Blazeby, *et al*, 'Core Information Set for Oesophageal Cancer Surgery.' (2015) 102 *BJS* 936-943, 939
[497] *Ibid*, 937
[498] GMC, *Doctors' Attitudes to Consent and Shared Decision Making: Full Research Report for the GMC*. (GMC, 2017), 23
[499] M. Blazeby, *et al*, 'Core Information Set for Oesophageal Cancer Surgery.' (2015) 102 *BJS* 936-943, 939
[500] GMC, *Doctors' Attitudes to Consent and Shared Decision Making: Full Research Report for the GMC*. (GMC, 2017), 23
[501] C. McKinnon, *et al*, 'Surgical Consent Practice in the UK following the *Montgomery* Ruling: A National Cross-Sectional Questionnaire Study.' (2018) 55 *International Journal of Surgery* 66-72, 68
[502] H.A. Powell, 'Patients' Attitudes to Risk in Lung Cancer Surgery: A Qualitative Study.' (2015) 90 *Lung Cancer* 358-363, 361.
[503] *Ibid*, 361: Talking about the 2% mortality risk "Them two there could have something wrong with them […] they could have something else wrong with them, like some other disease or something like that which the surgeon didn't know about or nobody's told him about it.' 003 79M" and "Well, I would think in my own case, I'm reasonably fit so I wouldn't expect it to happen to me, on some people that […] don't listen to advice then I would expect them to die as it were."

remembering information. [504] Furber *et al* found that some patients were unwilling to adopt a balanced view of risks and benefits.[505] It is unclear what doctors should do when patients purposefully misinterpret diagnosis, prognosis or risk so that they can hang onto hope.[506]

> "[…] Amy openly talked about the dilemma she faced in needing to know but not wanting to know what was happening to her because too much information might be worrying. This is important because we know that some worry that providing information will worry patients and consequently make paternalistic decisions in favour of protecting the patient from potentially distressing information. This example shows how some patients also orient to this problem, but on receipt of information will shape how they receive and interpret information provided."[507]

For those patients who utilise psychological defence mechanisms, undermining that system, and forcing an understanding can cause psychological harm.[508] Indeed, Ipsos MORI study on patient attitudes, commissioned by the GMC, found that patients felt that they were sometimes being given too much information to understand and make choices. [509] Patients sometimes felt uncomfortable with the responsibility of decision-maker, and worried they would make choices that they would later regret.[510] Whilst doctors acting under the therapeutic privilege could potentially withhold information in the patients best interests, the law needs to be transparent in protecting doctors who do not disclosure to this high objective standard.

(d) Standards of communication

The *Montgomery* judgement required a 'dialogue, the aim of which is to ensure that the patient understands […]'[511] and 'even those doctor who have less skill or inclination for communication, or who are more hurried, are obliged to pause and engage in the discussion which the law requires.'[512] Irrespective of the model of autonomy, the doctor is therefore required to adopt a tailored standard of

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[504] L. Furber, 'Patients' Experiences of an Initial Consultation in Oncology: Knowing and Not Knowing.' (2015) 20 *British Journal of Health Psychology* 261-273, 266: "Patients like David appeared to be using avoidance or denial, possibly to defend themselves from difficult emotions associated with grief and fear. Other patients used different defensive strategies to avoid directly engaging with the knowledge they were given in the consultation. For example, Paul rationalized in an argument that it would not be fair for him to have anything less than another 10 years to live as he had lived and honest and 'by the book' lifestyle. Amy described the shock of being given a diagnosis which prevented her from taking in more information, and she frequently doubted the accuracy of her memory of the consultation."

[505] *Ibid*, 269-70. For example, "[…] Paul wanted to remain positive and did not fully accept information which challenged his outlook and he wanted to beat the odds. David predominately remained in an uncertain awareness context. If he did not know what was happening to him, then he could retain hope for a positive outlook. Furthermore, David did not listen to what he was told and did not seek clarification."

[506] *Ibid*, 267 & 269

[507] *Ibid*, 270; L. Furber, *et al*, 'Enhancing Communication in Oncology Outpatient Consultation: Critical Reflections from Doctors.' (2011) 2 *International Journal of Medical Education* 159-169.

[508] *Ibid*, 268-269

[509] Ipsos MORI, *Attitudes towards consent and decision making*. (GMC, 2018), 25

[510] *Ibid*, 3

[511] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, [90]

[512] *Ibid*, [93]

communication to ensure understanding. Delineating the appropriate model of communication is complex. For example, Bagnall *et al* found that doctors needed to alter communication to fit the patient's culture and education (87.5%).[513] Doctors also had to consider whether the method of communication was clear and unambiguous (50%), that they checked understanding and recall (50%), that they empathised with patients (43.8%), and were mindful of their non-verbal skills or body language (62.5%).[514] Additional barriers about checking understanding were also created if a patient required an interpreter.[515] Patients[516] and doctors[517] placed different emphasis on the importance of tacit forms of communication which are essential to understanding, for example, personability, active listening, and being caring and friendly.

Ensuring an understanding requires a circumstantial and interpretative approach which is in antithesis to the prescriptive regulatory approach to the medical relationship within normative rules.[518] If standards of communication were prescribed this would require highly detailed guidance, potentially specific to patient groups.[519] Worse it could result in stereotyping patients into disease, capacity, emotional or cultural categories. Not only is this discriminatory, it would risk undermining the tailored approach essential to individual patient need. This thesis would argue that medical discretion, and thus moral decision-making, is axiomatic to effective communication. Normative rules therefore have the potential to undermine the patient's ability to attain an understanding for an autonomous choice.

(e) Seek meaningful consent at the appropriate time

The consumer relationship conceptualises informed consent as a one-off event which allows the individual access to a market of medical options.[520] In practice this orientates around disclosure and signing of the consent form, which usually happens before surgery.[521] This conceptualisation of the consent process as an event has been widely adopted. Knight *et al* found the majority of doctors (73%) provided information to patients and *consented them* on the day of their surgery (n=214/289).[522] This is

[513] M. Bagnall, *et al*, 'Informing the Process of Consent for Surgery: Identification of Key Constructs and Quality Factors.' (2017) 209 *Journal of Surgical Research* 86-92, 90
[514] *Ibid*, 90
[515] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC.* (GMC, 2017), 24-25. See also, F. Wood, *et al*, 'Working with Interpreters: The Challenge of Introducing Option Grid Patient Decision Aids.' (2017) 100 *Patient Education and Counselling* 456-464
[516] Ipsos MORI, *Attitudes Towards Consent and Decision Making.* (GMC, 2018), 26
[517] M. Bagnall, *et al*, 'Informing the Process of Consent for Surgery: Identification of Key Constructs and Quality Factors.' (2017) 209 *Journal of Surgical Research* 86-92, 90
[518] Chapter 2, Section 1; D.W. Hamilton, 'Multidisciplinary Team Decision-Making in Cancer and the Absent Patient: A Qualitative Study.' (2016) 6 *BMJ Open* e012559, 4-5
[519] Ipsos MORI, *Attitudes Towards Consent and Decision Making.* (GMC, 2018),24; R. Zarnegar, *et al*, 'Patient Perceptions and Recall of Consent for Regional Anaesthesia Compared with Consent for Surgery.' (2015) 108(11) *J R Soc Med* 451-456, 453
[520] Chapter 3, Section 2 and Section 4. See, J.W. Berg, *et al*, *Informed Consent: Legal Theory and Clinical Practice.* (Oxford University Press, 2001), 167-171
[521] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC* (GMC, 2017), 15
[522] S. Knight, *et al*, 'Patient Consent in the post-*Montgomery* Era: A National Multi-Speciality Prospective Study.' (2019) 17 *The Surgeon* 277-283, 279. Although this may be justified as "a significantly smaller number of clinicians discussed the

problematic as some patients may struggle to provide a fully informed consent on the day of a surgery.[523] Recognising this problem, Green J in *Thefaut v Johnston* argued that the consumer patient is always unable to make an autonomous choice before surgery due to the pressured situation.[524]

> It is routine for a surgeon immediately prior to surgery to see the patient and to ensure that they remain wedded to the procedure. But this is neither the place nor the occasion for a surgeon for the first time to explain to a patient undergoing elective surgery the relevant risks and benefits. At this point, on the very cusp of the procedure itself, the surgeon is likely to be under considerable pressure of time […] and the patient is psychologically committed to going ahead.[525]

This presumption is also problematic as there may be a significant gap between an outpatient appointment and an elective surger; where the patient may change their mind or need more information. If this is the correct approach, the doctor is legally barred from updating understanding for an informed consent. This is especially important in the time of Covid-19 where elective surgeries are being pushed back.[526] More fundamentally, though, this denies individual patients agency to makes decisions and creates a blanket presumption about the time and place patients have capacity to make informed choices. This presumption runs counter to the presumption of capacity within s.1 of the MCA (which is also made clear by the GMC guidelines).[527] The use of law to mitigate the harms of the consumer relationship potentially undermine the liberty of patients and respect for their decisions.[528] In antithesis to the law, the draft GMC guidance now encourages a process of supported patient decision-making through-out the medical relationship, in combination with ratification before surgery.[529]

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procedure on the day of surgery (71.6 vs. 31.7%) […]. Alternatively treatment options, including that of no treatment, were discussed and documented in less than a third of patients, whether in clinic or on the day of surgery."

[523] GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC*. (GMC, 2017), 15: "To go back to the time of consent. In an emergency situation you're pressurised, but I think actually to take consent when a person is in one of those horrible open backed gowns, in bed, with all their clothes off, is not right. Because are they going to say 'hang on, I'm off, give me my clothes back, I really don't want this? No they're not. Whereas if you had done it beforehand, if they turn up, they've had time to think about it, look at whatever information you've given, and I think it is often left until the last minute."(Mixed Secondary Care, more than 10 years qualified, Cardiff)."

[524] *Thefaut v Johnston* [2017] EWCA 497 (QB). Although see *Holdsworth v Luton Dunstable University Hospital NHS Trust* [2016] EWHC 2827 (QB); *Grimstone v Epsom and St Helier University Hospital NHS Trust* [2015] EHC 3756 (QB)

[525] *Ibid*, [77]

[526] Editorial, 'Too Long to Wait: The Impact of Covid-19 on Elective Surgery.' (2021) 3(2) *The Lancet Rheumatology*: (https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913(21)00001-1/fulltext); A. Carr, *et al*, 'Growing Backlog of Planned Surgery due to Covid-19.' (2021) 273(339) *BMJ* 1-2: (<https://www.bmj.com/content/bmj/372/bmj.n339.full.pdf>)

[527] GMC, *Decision Making and Consent: Supporting Patient Choices about Health and Care.* (GMC, 2019), [70]-[71]: "You must not assume a patient lacks capacity to make a decision solely because of their age, disability, appearance, behaviour, medical condition (including mental illness), views, beliefs, apparent difficulties in communicating, or because they make a decision you disagree with or do not understand."

[528] See, Chapter 3, Section 2. See also the GMC response to *Crossman v St George's Healthcare NHS Trust* [2016] EWHC 2878 (QB), [31], which suggests that doctors should respect patient decisions about treatment options when made before surgery: GMC, *Decision Making and Consent: Supporting Patient Choices about Health and Care: Draft Guidance for Consultant.* (GMC, 2019), [61]-[63]

[529] *Ibid*, GMC, [23](g), [98]-[99]

CHAPTER 7: CONCLUSION

This thesis has sought to answer, through empirical reflection: how doctors make decisions about information disclosure in practice; to identify how and why ethical and legal normativity has failed to ensure consistent and safe medical decision-making in practice. Chapter 1 examined how the ideological push for ethical normativity manifest through (what this thesis has termed) the jurisdiction school. The jurisdiction school characterised the process of *circumstantial-moral* decision-making as paternalistic, arbitrary, and non-technical, and argued for legal standards as a way to ensure ethical decision-making.[1] The rights school substantiated these claims in two ways: first, by arguing that internal rules were needed to ensure that doctors paid due regard to patient autonomy when making decisions about material information,[2] second, by requiring that the medical relationship, and thus the purpose of information disclosure, be altered to ensure an informed consent. Patients, they argued, should be characterised as consumers holding the right to make an autonomous choice before treatment.[3] Informed consent required facilitation of one of three (incompatible) models of autonomy: a libertarian, liberal/rational or authentic model.[4] The arguments of the rights and jurisdiction school manifested through three phases of judicial normativity:

1. Chapter 4 examined a period of internal normativity, where doctors were required to disclose significant risks in *Pearce*.[5] This required the doctor to presume that an autonomous choice was always in the patient's best interests.[6]
2. Chapter 5 examined a period of external normativity, where the *Chester*[7] judgement required that information disclosure ensure an informed consent.[8] As the purpose of information disclosure has been altered, a consumer relationship had been adopted.[9]
3. Chapter 6, examined a period where the consumer and therapeutic relationship operated in a binary model within the *Montgomery* judgement.[10]

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[1] Chapter 2, Section 1. For example, I. Kennedy, "The Patient on the Clapham Omnibus." In I. Kennedy, *Treat Me Right – Essays in Medical Law and Ethics*. (Oxford University Press, 1988), 189

[2] Chapter 3, Section 1. For example, *Ibid*, Kennedy, 178-180; S.A.M. McLean, *A Patient's Right to Know: Information Disclosure, The Doctor and the Law*. (Dartmouth, 1989), 7. Also, *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, per Lord Scarman at 886-887

[3] H. Teff, Medical Models and Legal Categories: An English Perspective.' (1993) 9 *J Contemp Health L & Pol'y* 211, 215-216; H. Teff, *Reasonable Care: Legal Perspectives on the Doctor/Patient Relationship*. (Clarendon Press, 1994), 113-116

[4] See, Chapter 3, Section 3

[5] *Pearce and another v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118

[6] Chapter 4, Section 1: *Deriche v Ealing Hospital NHS Trust* [2003] EWHC 3104 (QB)

[7] *Chester v Afshar* [2004] UKHL 41

[8] Chapter 5, Section 1

[9] *Ibid*: *Cooper v Royal United Hospital Bath NHS Trust* [2004] EWHC 3381 (QB); *Birch v United College London Hospital NHS Foundation* Trust [2008] EWHC 2237 (QB); *Webb v Norfolk & University Hospital NHS* Trust [2011] EWHC 3769; *Border v Lewisham and Greenwich NHS Trust* [2015] EWCA Civ 8. However, see, *N M v Lanarkshire Health Board* [2013] CSIH 3; *Al Hamwi v Johnston and Another* [2005] All ER (D) 278; *Burke v GMC* [2005] EWCA Civ 1003

[10] Chapter 6, Section 1: The therapeutic relationship: *Spence v Hillingdon NHS Trust* [2015] EWHC 1058 (QB); *Tasmin v Barts NHS Trust* [2015] EWHC 3135 (QB); *SXX v Liverpool Women's NHS Foundation Trust* [2017] EWCA Civ 279; *Bayley v George Eliot Hospital NHS Trust* [2017] EWHC 3398; *Duce v Worcestershire Acute Hospital NHS Trust* [2018] EWCA Civ

However, medical decision-making throughout these periods did not alter in line with ethical expectation. Medical decision-making under *Pearce* saw doctors interpreting the test literally and only providing patients with significant risks, or attempting to mitigate confusion by providing a highly detailed disclosure, irrespective of patient circumstances and choices.[11] The second period, under *Chester*, similarly saw some doctors providing an exhaustive disclosure which ignored patient choices; this disclosure had the effect of overwhelming patients and undermining their ability to make autonomous choices. Other doctors (and patients) rejected the consumer relationship entirely and continued to act in the patient's best interests using *circumstantial-moral* decision-making.[12] The third period saw younger doctors being more enthusiastic about facilitating patient autonomy, but lacking the skills in practice to ensure an authentic autonomous choice, as the basis of an informed consent.[13] The studies identified numerous barriers to ensuring authentic autonomy, including patient's themselves rejecting information and the role of the consumer patient.[14] This led some doctors to again adopt defensive practices which ignored patient preferences, bombarding them with an exhaustive content of information.[15] Other doctors again re-adopted the therapeutic medical relationship as a way to circumvent patient harm.[16] Over time normativity has fractured the process of medical decision-making horizontally, over the method of disclosure, and vertically, over the purpose of disclosure .

7. 1. The moral diagnosis

The analysis of the identified studies provides six primary reasons as to why the ethical optimums envisaged by the jurisdiction and rights schools of thought failed to ensure a collective and consistent ethical approach to informed consent:

1307 (COA). The consumer relationship: *Webster v Burton Hospitals NHS Foundation Trust* [2017] EWCA Civ 62 (COA); *Lunn v Kanagaratnam* [2016] EWHC 93 (QB); *Thefaut v Johnston* [2017] EWHC 497 (QB); *Hassell v Hillingdon Hospitals NHS Foundation Trust* [2018] EWHC 164 (QB); *Worral v Antoniadou* [2016] EWCA 1219 (COA); *Correia v University Hospital North Staffordshire NHS Trust* [2017] EWCA Civ 356; *Diamond v Royal Devon & Exeter NHS Foundation Trust* [2019] EWCA Civ 585; *Keh v Homerton University Hospital NHS Foundation Trust* [2019] EWHC 548 (QB)

[11] Chapter 4, Section 3

[12] Chapter 5, Section 3

[13] Chapter 6, Section 3; GMC, *Doctors' Attitudes to Consent and Shared Decision Making: Full Research Report for the GMC.* (GMC, 2017), 14

[14] *Ibid*

[15] Chapter 6, Section 3; *Ibid*, GMC, 13; D.W. Hamilton, 'Multidisciplinary Team Decision-Making in Cancer and the Absent Patient: A Qualitative Study.' (2016) 6 *BMJ Open* e012559, 4; S.R. Knight, 'Patient Consent in Post-*Montgomery* Era: A National Multi-Speciality Prospective Study.' (2019) *The Surgeon* 277-283, 281; M. Bagnall, *et al*, 'Informing the Process of Consent for Surgery: Identification of Key Constructs and Quality Factors.' (2017) 209 *Journal of Surgical Research* 86-92, 90; B.G. Main, 'Core Information sets for Informed Consent to Surgical Interventions: Baseline Information of Importance to Patients and Clinicians.' (2017)18 BMC *Medical Ethics* 29; S.R. Knight, *et al*, 'Patient Consent in Post-*Montgomery* Era: A National Multi-Speciality Prospective Study.' (2019) *The Surgeon* 277-283; O. Brien *et al*, 'A Survey of Doctors at a UK Teaching Hospital to Assess Understanding of Recent Changes to Consent Law.' (2017) 18 *Annals of Medicine and Society* 10-13; F. Greenway, *et al*, 'Consent for Post-Operative Visual Loss in Probe Spinal Surgery: Aligning Clinical Practice with Legal Standards.' (2018) 6 *British Journal of Neurosurgery* 604-609, 607; C. Doherty, *et al*, 'The Consent Process: Enabling or Disabling Patients' Active Participation?' (2015) 21(2) *Health (London)* 205-222

[16] GMC, *Doctors' Attitudes to Consent and Shared Decision Making: Full Research Report for the GMC.* (GMC, 2017), 11

1. The normative force of law reduced the scope of medical discretion and encouraged a rigidity in medical decision-making which took the focus away from the actual patient, their values, circumstances, and information need.[17] Fear of litigation led to ossification of decision-making and disclosure practices which neither facilitated patient autonomy, or their best therapeutic interests: a process which Montgomery terms *demoralisation*.[18]

2. Normative rules conflated the philosophical models of autonomy.[19] This was problematic as the duties and methods of decision-making required to facilitate models of autonomy were incompatible. Ethical and legal rules which utilised conflated models then required doctors to provide information which undermined the ability of the patient to have a rational and/or authentic choice. These rules were also problematic for medical decision-making, as doctors could not be sure about the standard of care required in law. This legal uncertainty allowed the judiciary to adopt a process of *blinkered moralism*; where subsequent judicial decisions confused the legal test for materiality.[20] This encouraged doctors to adopt defensive decision-making which has again resulted in exhaustive disclosures. Normative rules are therefore currently manifesting to undermine the substantive models of autonomy which they seek to achieve.[21]

3. The consumer relationship is an ethical model which seeks to facilitate the needs of a hypothetical reasonable patient. This hypothetical patient is not value-neutral; instead, the patient is characterised as capacitous, intelligent, willing, and able to make decisions about elective treatments and the information their need to make a decision.[22] This is the antithesis to empirical reality of the actual patient and their information need. The patients identified within the studies were usually vulnerable in one, or multiple ways; some were unable to reach the substantive level of understanding necessary for an autonomous choice. Creating normative rules which required doctors to provide an objective content of information, or ensure a rational understanding, against the wishes of the patient, is a dignitary harm. Similarly, requiring the medical profession to ensure a substantive autonomy makes liability inevitable if a proportion of those patients are unable to meet the responsibilities necessary for an informed consent.[23]

[17] See Chapter 4, Section 3; Chapter 5, Section 3; Chapter 6, Section 3
[18] J. Montgomery, 'Law and the Demoralisation of Medicine.' (2006) 26(2) *Legal Studies* 185-210
[19] See Chapter 3, Section 3; Chapter 4, Section 1 and 2; Chapter 5, Section 1 and 2; Section 6, Section 1 and 2
[20] See Chapter 6, Section 1: J. Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism?' (2007) 15 *Health Care Analysis* 235-255
[21] See, Chapter 4, Section 3; Chapter 5, Section 3; Chapter 6, Section 3
[22] See, Chapter 3, Section 5
[23] *Ibid*

4. The tort of Negligence has historically sought to judge the actions of a claimant by the rules and standards of a profession.[24] The consumer relationship requires a model of ethical decision-making which has the teleological aim of ensuring autonomous choices.[25] This is a purpose which is diametrically opposed to the moral *purpose* of medicine, and thus the moral norms by which the medical profession operates. Grafting the consumer relationship onto medical decision-making, by creating normative duties and standards in the law of negligence (and particularly by grounding them in patient rights) has undermined the moral and collective frame of reference used by practitioners to weigh, and judge, risks and benefits; thereby, potentially proliferating arbitrary and paternalistic decision-making.[26] Ironically, medical ethics within normative rules has undermined moral decision-making by fracturing the internal morality.[27]

5. Medical ethical guidance has increased rather than clarified philosophical uncertainty by attempting to straddle both the confused models of autonomy, and binary models of the medical relationship.[28] This uncritical adoption of law has exacerbated confusion about the purpose and methods necessary to achieve an informed consent in practice. Division within the formal and semi-formal sector about the philosophical basis disclosure is also problematic as there is no ethical hierarchy between guidance from different sources. Doctors are left to pick and choose what guidance to follow, creating what Miola terms a 'regulatory vacuum.'[29]

6. There remains a dearth of empirical analysis as to how normative rules operate and interact with the underlying moral processes of decision-making, and thus the process of disclosure in practice. If a model of autonomy fails to achieve the optimum end, it has simply been switched out for another, or rules have been made more robust. This has proliferated confusion. It has also catalysed the fracture of collective medical decision-making. Doctors must now choose whether to facilitate a disclosure in the patient's best interest (therapeutic relationship) or autonomy (consumer relationship). If the moral basis of decision-making is fractured and rules are not exhaustive, doctors will inevitably make arbitrary decisions within a moral vacuum.[30]

[24] A. Robertson, 'On the Function of the Law of Negligence.' (2013) 33(1) *Legal Studies* 31-57
[25] See, Chapter 1, Section 1-3; Chapter 3, Section 4
[26] See the deviation and diversity in disclosure practices in Chapter 4, Section 3; Chapter 5, Section 3; and Chapter 6, Section 3
[27] A. MacIntyre, *After Virtue* (Notre Dame University Press, 1981), 175; E. D. Pellegrino & D.C. Thomasma, *The Virtues in Medical Practice*. (Oxford University Press, 1993), 42
[28] See, Chapter 4, Section 2; Chapter 5, Section 2; Chapter 6, Section 3.
[29] J. Miola, *Medical Ethical and Medical Law: A Symbiotic Relationship.* (Hart Publishing, 2007), 18, 38-40, 212-219
[30] *Ibid*

7. 2. A Treatment: The *Re-Moralisation* of Medical Decision-Making

One treatment for the conceptual problems of the consumer relationship might be a call for ethical clarity and consistency: ethical rationalisation. This treatment would require that the conceptually preferred model of autonomy be exhaustively and transparently enshrined in common law. The law would need to recognise distinct facilitative duties of both the medic and patient, and set clear standards. For example, understanding, communication, and rationality, necessary to have an informed consent. This seems to be the approach adopted by the GMC, in their newest draft guidance on consent.[31]

However, the achievability of such an exhaustive approach[32] (and constitutional legitimacy of (quasi) judicial law-making)[33] is questionable. This thesis would argue that an exhaustive approach is also fundamentally flawed as it fails to treat the dislocation between the purpose of law, the philosophical basis of legal rules and the underlying moral process of medical decision-making. Simply, the consumer relationship is not a fit conduit on which to base normative legal rules within the law of negligence. First, it fails to be empirically reflexive of practice. Thus, legal rigidity does not allow the flexibility necessary to the needs of a spectrum of patients. For example, by recognising and accommodating the significant (and consistent) minority of patients who wished to waive information or decision-making authority, and/or a further minority who were (and remain) unable to achieve a substantive autonomous choice because of their capacity, values and/or circumstances.[34] Normative rules contain values and presumptions which risk abstracting the values and needs of the actual patient, by preventing a *circumstantial* approach to identifying and weighing relevant factors within medical decision-making.[35]

Second, rules which facilitate the consumer relationship have the effect of undermining the therapeutic aims of medicine. The effect is that the law distorts the phenomenological processes and practices it is supposed to be regulating. It is fundamentally important that the internal moral norms of decision-making are conceptually consistent so that they can operate in novel circumstances and within a regulatory vacuum. A dynamic shared morality is the only realistic safeguard to ensure that decision-making is not arbitrary or paternalistic. Third, the need for discretion and therefore an internal morality is inevitable. Even when there is normative rules, circumstantial application of those rules invites a

[31] GMC, *Decision-making and Consent: Supporting Patient Choices about Health and Care*. (GMC, 2020)
[32] N. Abrams, 'Scope of Beneficence in Health Care.' In E.E. Shelp (ed.) *Beneficence and Health Care*. (Reidel Publishing Company, 1982), 184-185
[33] J. Montgomery, *et al*, 'Hidden Law-Making in the Province of Medical Jurisprudence.' (2014) 77(3) *MLR* 343-378, 357-360
[34] See Chapter 3, Section 5, Chapter 4, section 3, Chapter 5, Section 3, Chapter 6, Section 3
[35] M.J. Hanson & D. Callahan, *The Goals of Medicine: The Forgotten Issue in Health Care Reform.* (Georgetown University Press, 2000), 34. Also see, N. Abrams, 'Scope of Beneficence in Health Care.' In E.E. Shelp (ed.) *Beneficence and Health Care*. (Reidel Publishing Company, 1982), 184-185

level of discretion, and requires moral norms to fill those gaps.[36] For example, Lord Woolf in *Pearce*[37] created a singular internal consideration that the doctor should usually disclose at least the 'serious risks' of a procedure to a patient, yet as Chapter 4[38] illustrated, despite this meagre rule, commentators and judges were divided as to the legal test; and thus the model of autonomy the standard of care should be facilitating.[39] In practice this uncertainty required medical morality to fill the ethical gaps. In *Montgomery*, for example, the creation of the objective standard created scope for discretion in the definition of the 'circumstances of the reasonable patient.'[40] Similarly, the subjective standard created discretion as to the values, circumstances and needs which are relevant to the particular patient.[41] As the level of normativity increases, so does the level of discretion which must be utilised to apply the rules to real life situations. However, if the philosophical basis of normative rules conflict with the internal moral norms of the profession, this creates confusion, as well as a moral vacuum for decision-making. Whilst case-law has the opportunity to fill this gap, as Maclean argues, the law is a reactive, rather than proactive mechanism, and depends on applications to be made for the law to be updated (and for lacuna to be plugged). [42]

This thesis therefore calls for the *re-moralisation* of medical decision-making through the recognition, by lawyers, of the internal morality, and the distinct therapeutic telos of medical decision-making.[43]

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[36] See this problem in the context of best interest's decision-making under s.4(1) Mental Capacity Act:
M. Donnelly, 'Best Interests, Patient Participation and Mental Capacity Act 2005.' 92009) 17 *Med L Rev* 1-29, 28; H. J. Taylor, 'What Are 'Best Interest'? A Critical Evaluation of Best Interests' Decision-making in clinical practice.' (2016) 24(2) *Med L Rev* 176-205; C. Kong, *et al*, 'An Aide Memoire for a Balancing Act? Critiquing the 'Balance Sheet' Approach to Best Interests Decision-Making.' (2020) 28(4) *Med L Rev* 753-780; J. Coggon, 'Mental Capacity Law, Autonomy, and Best Interests: An Argument for Conceptual and Practical Clarity in the Court of Protection.' (2016) 24(3) *Med L Rev* 396-414. See this problem, for example, in *Re A (Male Sterilisation)* [2000] 1 FLR 549, per Thorpe LJ, at 560. Also see this phenomenon in relation to the welfare considerations under s.3(1) Children Act 1989: H. Reece, 'The paramountcy principle: Consensus or Construct? (1996) *Current Legal Problems* 267; M. Fineman, 'Dominant Discourse, Professional Language and Legal Change in Child Custody Decision-making.' (1988) 101 *Harvard Law Review* 727; J. Herring, "The Welfare Principle and Patients 'Rights.'" In A. Bainham et.al. (eds.) *What is a Parent? A Socio-Legal Analysis*. (Hart Publishing, 1999). See also, S. Choudhry & H. Fenwick, 'Taking the Rights of Parents and Children Seriously: Confronting the Welfare Principle under the Human Rights Act.' (2005) 25(3) *Legal Studies* 453-495; J. Fortin, 'Children's Rights – Flattering to Deceive?' (2014) 26(1) *CFLQ* 51

[37] *Pearce v United Bristol Healthcare NHS Trust* (1998) 48 BMLR 118, 124

[38] See, Chapter 4, Section 1. This internal requirement was in line with the moral presumption that autonomy was in the patient's best interest's and hardly went further than the orbiter set out in *Sidaway*. For example, Lord Diplock argued that: 'No doubt if the patient in fact manifested this attitude by means of direct questioning, the doctor would tell him whatever it was the patient wanted to know.'[38] Similarly, Lord Bridge stated that questions must be answered 'truthfully' and 'fully.'[38] *Sidaway v Governors of Bethlem Royal Hospital* [1985] 1 AC 871, per Lord Diplock, at 895, per Lord Bridge, at 898, and Lord Templeman, at 902.

[39] M. Brazier & J. Miola, Bye-Bye *Bolam*: A Medical Litigation Revolution?' (2000) 8 Med L Rev 85-114, 110; A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5 *Med L Int* 205-230, 313-214; A. Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (Cambridge University Press, 2009), 175

[40] See Chapter 6, Section 1: *Montgomery v Lanarkshire Health Board* [2016] UKSC 11, [87]

[41] *Ibid*

[42] A. Maclean, Autonomy, *Informed Consent and Medical Law: A Relational Challenge*. (Cambridge University Press, 2009), 214: "[…] If an issue is not brought before the courts then the judges cannot address that issue and determine the law's stance. While it may be argued that this means that the law only deal with the most important questions, this is not necessarily the case. The diving force is more likely to be money rather than an important point of principle. On top of this, cases that do reach court must be decided within the common law institutional constraints of precedent and legal policy. Furthermore, any development is likely to be piecemeal and decisions may be inconsistent with each other."

[43] See other calls for remoralisation: S. Chan, 'Remoralising Health Policy.' (2008) *BMJ Opinion*: (https://blogs.bmj.com/bmj/2008/04/07/sarah-chan-remoralising-health-policy/); S. Benatar & R. Upshur, 'Virtues and Values in Medicine Revisited: Individual and Global Health.' (2014) 14(5) *Clinical Medicine* 495-499; D. Reubi, 'Remoralising

This is hardly a novel concept within philosophy; MacIntyre for example, argues '[a]ll 'practices' that have 'any coherent form of socially established cooperative human activity [have] goods internal to that form of activity.'[44] Pellegrino and Thomasma applied this to the context of health, and identified that these moral norms develop through the collective practice of medicine,[45] in combination with the members of the profession carrying out a moral role or function according to the needs of society.[46] Pellegrino and Thomasma argued that the internal morality of medicine should be understood as having a therapeutic telos or purpose, which they termed *Beneficence-in-Trust*.[47] The internal morality, they argue, emerges from the axiological and moral nature of the medical relationship (termed the essentialism approach) .[48] Specifically, (1) the nature of illness,[49] (2) the non-proprietary nature and characteristics of medical knowledge,[50] (3) their professional oaths, and (3) moral complicity[51].[52] The inner morality is therefore: 'a requirement not of a system of philosophy applied to medicine, but of the nature of medical activity.'[53] The medical profession is distinct from other contractual or consumer roles

Medicine – The Bioethical Thought Collective and the Regulation of the Body in British Biomedical Research.' (2013) 11(2) *Social Theory & Health* 215-235

[44] A. MacIntyre, *After Virtue* (Notre Dame University Press, 1981), 175

[45] E.D. Pellegrino & D.C. Thomasma, *The Virtues in Medical Practice.* (Oxford University Press, 1993), 3

[46] *Ibid*, 52-53

[47] *Ibid*, 54. Beauchamp & Childress also recognise this telos or directional virtue as define it as *Caring* - which in some regards is wider than *Beneficence-in-trust* but essentially describe the same thing: an 'emotional commitment to, and deep willingness to act on behalf of persons with whom one has a significant relationship.' i.e., the relationship between the doctor and patient: T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics.* (University Press, 2009), 36. Also, see, M. Conroy, *et al*, Phronesis in Medical Decision-Making: Medical Leadership, Virtue Ethics and Practical Wisdom: Final Report. (AHRC, 2018): (https://www.birmingham.ac.uk/Documents/college-social-sciences/social-policy/phronesis/phronesis-in-medical]-decision-making.pdf>)

[48] *Ibid*, 35 & 53. Although this essentialist view is problematic as it ignores the effect of society and culture on the role of medicine: R.M. Veatch, The Impossibility of a Morality Internal to Medicine.' (2001) 2(6) *Journal of Medicine and Philosophy* 621-642, 628-629. This position also ignores the problem of *medicalisation* of technology which has the potential to distort the role of medicine in society: see Chapter 3, Section 2; M.J. Hanson & D. Callahan, *The Goals of Medicine: The Forgotten Health Care Reform* (Georgetown University Press, 2000), 4-5; E.D. Pellegrino, "Towards an Expanded Medical Ethics: The Hippocratic Oath Revisited." In R.M. Veatch (eds.) *Cross-Cultural Perspectives in Medical Ethics*. (Jones and Bartlett Publishers, 2000), 46

[49] *Ibid*, 42. The medical profession are the only distinct group or profession within society who work exclusively towards the betterment of the distinct phenomenon of illness. Illness creates a vulnerability which forces patients to engage and to trust the doctor in carrying out their specific role as healers. The nature of illness creates a power imbalance which places a de facto moral obligation on the physician, which is distinct from a commercial or consumer relationship, which operates off parity, and exploitation of personal ends. All medical decisions made by individuals, to be classified as medical decisions must be self-effacing: the doctor must attain no benefit. Also, see E.D. Pellegrino & D.C. Thomasma, *A Philosophical Basis of Medical Practice.* (Oxford University Press, 1981)

[50] *Ibid*, 36 & 46. The doctor owes a duty of reciprocity to society due to their exclusive privilege of medical knowledge, and special permissions to dissect, touch, treat and administer medicines to the human body. These are moral obligations and permissions which occur on a society level, beyond a commercial or contractual relationship. Also, E.D. Pellegrino & A.A. Pellegrino, 'Humanism and Ethics in Roman Medicine: Translation and Commentary on a Text of Scribonius Largus.' (1988) 7 *Literature and Medicine* 22-38. For example, see the ethical argument that doctors have a duty to society to treat during the Covid-19 pandemic: D.I. Jeffrey, 'Relational Ethical Approaches to the Covid-19 Pandemic.' (2020) 46 *J Med Ethics* 495-498; H. Malm *et al*, 'Ethics, Pandemics and the Duty to Treat.' (2008) 8(8) *The American Journal of Bioethics* 4-19

[51] *Ibid*, 44. The medical profession is assigned the function of gatekeeper to medical treatment and information. The Law has long recognized that the medical profession will make the final therapeutic decision. *Burke v GMC* [2005] EWCA Civ 1003, per Lord Phillips, [31]. See this argument made in: R. Huxtable, Autonomy, Best Interest and the Public Interest: Treatment, Non-Treatment and the Values of Medical Law.' (2014) 22(4) *Med L Rev* 459-493; G. Birchley, '[…] What God and the Angels Know of Us? Character, Autonomy, And Best Interests in Minimally Conscious State.' (2017) 26(3) *Med L Rev* 392-420, 413-415; J. Keown, 'Euthanasia in the Netherlands: Sliding down the Slippery Slope.' (1995) 9(2) *Notre Dame J.L. Ethics & Pub. Pol'y* 407, 408

[52] *Ibid*, 35 & 53

[53] *Ibid*, 53

and relationships within a market economy as professional duties are essentially moral in nature.[54] Other commentators such as Arras, rejected essentialism and argued that the inner morality is drawn exclusively from the role that medicine plays in society (the social constructionism approach).[55] Society can therefore legitimately limit the role of the medical practitioner or require the doctor to operate within wider societal norms (such as human rights), as long as those laws or norms do not undermine the function of the profession.[56] However, without any internal content, medicine could be misused. [57] Other commentators, such as Miller and Brody, have therefore argued that the content of the internal morality and thus the telos of medicine, have emerged from a combination of the essential nature of the medical act and thus the collective conceptualisation of the medical profession, in conversation with society (the evolutionary approach).[58] As Frith argued, the evolutionary approach is to be preferred as it recognises a substantive moral content of medicine; so that it can be recognised throughout liberal societies, but also acknowledges the empirical and dynamic reality of the role of medicine in society. As the moral values, and purpose, of medicine changes e.g. through for example technology, the function of medical practitioners in society also develops.[59] As the substantive content of the internal morality occurs phenomenologically, it can be identified through empiricism.[60] For example, Hanson and Callahan undertook an international empirical investigation to identify some universal content of the internal morality within liberal societies. [61] Their study identified four core aims of medicine:

(1) The prevention of disease and injury and promotion and maintenance of health
(2) The relief of pain and suffering caused by maladies
(3) The care and cure of those with malady, and the care of those who cannot be cured
(4) The avoidance of premature death and pursuit of a peaceful death.[62]

[54] J.D. Arras, 'A Method in Search of a Purpose: The Internal Morality of Medicine.' (2001) 26(6) *Journal of Medicine and Philosophy* 643-662, 644-650: "[i]n contrast to those engaged in ordinary trades such as selling stamps or repairing auto mufflers, a professional is bound by more stringent duties than those governing contractual relationship within a market economy. Because the relationship between professionals and those they served is asymmetrical with regard to knowledge, power, and vulnerability, lawyers, physicians and nurses have a duty as professionals to subordinate their own self-interest to the welfare of their clients or patients."
[55] *Ibid*, 646
[56] T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics.* (Oxford University Press, 2013), 3; I. Kennedy, "Patients, Doctors, and Human Rights." In I. Kennedy (eds.), *Treat Me Right – Essays in Medical Law and Ethics*. (Clarendon Press, 2001), 387; I. Kennedy, "Patients, Doctors, and Human Rights." In I. Kennedy (eds.), *Treat Me Right – Essays in Medical Law and Ethics*. (Clarendon Press, 2001), 385
[57] M.J. Hanson & D. Callahan, *The Goals of Medicine: The Forgotten Issue in Health Care Reform.* (Georgetown University Press, 2000),16-17
[58] F. G, Miller & H. Brody, 'The internal morality of medicine: An Evolutionary Perspective.' (2001) 26 *Journal of Medicine and Philosophy* 581-599; J.D. Arras, 'A Method in Search of a Purpose: The Internal Morality of Medicine.' (2001) 26(6) *Journal of Medicine and Philosophy* 643-662
[59] L. Frith, "What do we mean by 'Proper' Medical Treatment?" In S. Forvargue & A. Mullock (ed.) *The Legitimacy of Medical Treatment: What Role of for the Medical Exception.* (Routledge, 2016), 34-35
[60] E. D. Pellegrino & D.C. Thomasma, *The Virtues in Medical Practice*. (Oxford University Press, 1993), 53
[61] M.J. Hanson & D. Callahan, *The Goals of Medicine: The Forgotten Issue in Health Care Reform.* (Georgetown University Press, 2000)
[62] *Ibid*, 20-30.

If legal or ethical rules require the doctor to act against the purpose of medicine, for example, by requiring the doctor to make a decision that may cause the patient harm, this places legal rules in direct moral conflict with these central aims of medical decision-making. The treatment for ethical fracture, created by a conceptually conflicting normativity, is for ethicists and lawyers to recognise and empirically identify the substantive content of the internal morality which operates as the basis of medical decision-making, within a given system. If rules are necessary, they must complement, rather than conflict with its moral orientation.[63]

7.3. A Cure: *Bolam* 2.0

One way of ensuring normative rules are always aligned with the internal morality, is to re-adopt a sociological approach to the standard of care for information disclosure.[64]

(i) Immediate benefits

This sociological standard would have the benefit of incorporating and facilitating the *circumstantial-moral* forms of medical decision-making: as doctors would not be orientated or directed by normative rules.[65] This *circumstantial-moral* form of decision-making would allow medical decision-making (particularly patient paradigms) to evolve naturally alongside societal norms; such as the development of patient needs and human rights. Importantly, a sociological standard would avoid the potential harms that are identified by normative rules: stagnation of medical decision-making, tick-boxing, exhaustive disclosure processes, and other forms of defensive medicine, as a way to circumvent confusion about the legal standard. Particularly important is that the method of medical decision-making could readopt a shared therapeutic end – ending the fractured and uncertain forms of medical decision-making which correlate with changes in the law.[66] The principle of autonomy would still be integrated as a consideration within the therapeutic decision-making process, albeit it would limited by the requirement of non-maleficence i.e. an internal form of the rights argument.[67] Ultimately, requiring at least some form of discretion in medical relationship is inevitable – a sociological standard rather than being prescriptive would allow the doctor to tailor disclosure to the needs of the actual patient – beyond an informed consent. Returning to a sociological standard also has the potential to delimit the role of tort law to regulating inter-personal fairness,[68] rather than attempting to use negligence as a system of regulation and compliance.

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[63] See a similar call for empiricism in: T. L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics.* (Oxford University Press, 2019), 439-444
[64] J. L. Montrose, 'Is Negligence an Ethical or Sociological Concept?' (1958) 21(3) *MLR* 259-264
[65] See, Chapter 2, Section 2.
[66] See, Chapter 6, Section 3.
[67] See Chapter 3, Section 1.
[68] For example see, A. Robertson, 'On the Function of the Law of Negligence.' (2013) 33(1) *Ox J Legal Studies* 31-57.

(ii) The construction

The use of a sociological standard in the law of negligence would allow the recognition and facilitation of the internal moral norms of medical decision-making, whilst allowing the judge to review the process decision-making by a process informed and deductive reasoning.[69] This *Bolam* 2.0, would be an explicit two stage test, similar to that applied, albeit implicitly, pre-*Pearce*.[70] Like the original sociological test, it would necessarily require both an internal analysis of the content and method of the medical decision, and include an external evaluation of whether the decision (in its method or consequences) falls within the ethical and legal boundaries of a liberal society.

(a)The purpose of disclosure

First, the internal test would evaluate whether the internal content of the medical decision was reasonable. A decision would only be reasonable if the construction of the decision was orientated towards the ethical aim of act in the patient's best therapeutic interest i.e. in line with the internal moral purpose of medicine. To assess whether the method and purpose of the decision were aligned with this orientation would require the judge to interrogate the adoption of the moral paradigm adopted by the doctor; to delineate the types of information that would relevant to the patient in their particular medical circumstances and context, and the circumstances and values of the actual patient that would justify deviation from these pro-forma disclosures. What amounted to reasonable practice would therefore be contingent on the specialism and expertise of the doctor, and the medical circumstances, place, time and values of the patient. The sociological test, as envisaged, would make the purpose of information disclosure, and the method of judicial evaluation, explicit. Explicitly recognising the beneficent purpose of disclosure, would also mean that the duties inherent within the therapeutic relationship are not artificially separated into component parts.[71]

(b)Internal test: Evaluating patient paradigms

- *Medical decision-making*

As Chapter 1 argued the doctor constructs patient paradigms as an implicit methodology to identify relevant information, and match patients to the type or content of information which they may need given their medical circumstances. These paradigms contain factual, ethical and informational presumptions about what is in the average patient needs in actual patients situation – in essence it is a hypothetical sociological construct from which one can delineate information need. This construct may be informed by the doctor's learned knowledge (i.e. academic or professional training), through observation of other colleagues, or direct experience with patients. In this sense the patient paradigm's

[69] See Chapter 2, Section 3
[70] *Ibid*: *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582, 587
[71] J. Montgomery & E. Montgomery, '*Montgomery* on Informed Consent: An Inexpert Eecision?' (2016) 42 *J Med Ethics* 89-94, 90

are contemporarily negotiated and develop in accordance with the needs of a population of patients. This means that once a patient paradigm is attributed to a patient, the content of the information that they receive is likely to be relevant to the patient's medical needs, medical circumstances, healthcare setting, the time and place of any proposed treatment.

Whilst these paradigms can be explicated and scientifically, the judiciary would need to allow for their nature development. This type of construction of medical decision-making is already facilitated by existing clinical recommendations. For example, the NICE guidance set out key indicators which affect how the patient should be conceptualised (and therefore what information they should receive) in relation to caesarean section.[72] For example, all expectant mothers should be offered the option of a planned caesarean section. As such all mothers require the discussion of information according to their status as pregnant, and the need to go through child-birth. The NICE guidelines require the disclosure that:

- Around 25% to 30% of women have a caesarean birth
- Factors that mean women may need a caesarean section (for example, increased maternal age and BMI)
- Common indications for emergency caesarean birth include slow progression of labour or concern about fetal condition
- Planned place of birth may affect the mode of birth […]
- What the caesarean birth procedure involves[73]

However, the appropriate patient paradigm, and thus the treatment options available to the patient shift, due to her medical presentation. Women are placed in risk categories:

- Category 1: Immediate threat to the life of the woman of fetus (for example, suspected uterine rupture, major placental abruption, cord prolapse, fetal hypoxia or persistent bradycardia.
- Category 2: Maternal or fetal compromise which is not immediately life-threatening
- Category 3: No maternal or fetal compromise but needs early birth.
- Category 4: Birth time to suit woman or healthcare provider. [74]

If a woman is clinically indicated to require a planned caesarean section on any of these bases, an enhanced content of information is recommended in relation to the additional risks of caesarean section.[75] For example:

[72] National Institute of Clinical Excellence, *Caesarean Birth, NICE Guideline [NG192]*. (NICE, 2021), Recommendations, 5-31
[73] *Ibid*, [1.1]
[74] *Ibid*, [1.4.2]
[75] *Ibid*, [1.2]

Maternal short-term (time period: up to 6 weeks)

- Bladder/bowel/ureteric injury
- Major obstetric haemorrhage
- Health related quality of life
- Maternal death

Maternal long-term (at any time after 6 weeks, […])

- Placenta accrete/morbidly adherent placenta/abnormally invasive placenta
- Uterine rupture
- Postnatal depression[76]

The evidence-base and rationale for the construction of the patient paradigm, and thus the content of the information disclosure is similarly set out by NICE.[77]

- *Judicial Decision-Making*

The first requirement of the judge in assessing whether medical decision-making in relation to information disclosure is negligent is to analyse whether the patient paradigm is technically and morally sound. In essence, whether the patient paradigm adopted fell within a spectrum of *reasonable* scientific interpretations. The judge could evaluate the logic of the medical decision-making (whether individual or collectively) which has led to the construction of the patient paradigm. Specifically, whether the clinical characteristics of the patient paradigm are scientifically correct and are supported by a sound evidence base.[78] The judge could also apply their own logic to the construction of the reasonable patient, to see whether a lacuna in existing research might fatally undermine that patient paradigm, and thus the associated disclosure.[79] The judge must also apply their mind to whether the correct ethical balance has been struck between ensuring that patients receive information necessary to promote their autonomy (and right to liberal choice in the provision of alternative treatments), balanced against the principle of non-maleficence; where only relevant information is given, so that the average patient is not be overloaded. To identify existing patient paradigms the defendant can refer to normative ethical guidance, or supporting expert evidence. However, deviation from the conceptualisation of the patient

[76] National Institute for Health and Care Excellence, *Caesarean Birth. [A] The Benefits and Risks of Planned Caesarean Birth*. (NICE, 2021), 7
[77] National Institute of Clinical Excellence, *Caesarean birth, NICE guideline [NG192]*. (NICE, 2021), Rationale and Impact, 35-42
[78] For example see, *Pepper v Royal Free London NHS Foundation Trust* [2020] EWHC 310 (QB), [171]. Also, *Webster v Burton Hospitals NHS Foundation Trust* [2017] EWCA Civ 62, per Simon LJ, at [39]
[79] Similar to the approach taken in *Huck v Cole* (1993) 4 Med LR 393. More recently see, *Robertson v Nottingham Health Authority* [1997] 8 Med LR 1

in specialist normative guidance, without logical or circumstantial, justification may also be indicative of liability. [80]

The judge must also apply their own logic to the construction, and content of the patient paradigm, by asking: whether existing societal circumstances, social or moral norms, or common sense, require the addition or removal of factors in anticipation of average or usual patient information need? For example, a gap in the relevant criteria for consideration could emerge due to the development of technology (e.g. a new treatment), or the context of patient healthcare could have changed. For example, the information patients need in relation to surgery has substantively altered (irrespective of clinical specialism) because of the risks associated with Covid-19.[81] This change in the associated risks of surgery and recouperation, necessitates the information needs of the patient be conceptualised differently, and thus additional information be provided to patients. This common sense, or logical element within the internal test, draws support from existing jurisprudence after *Bolitho*.[82] The *Bolitho* approach allows the judge to identify whether the context in which the patient information paradigm was experientially formed was problematic or flawed (to extent that the doctor's decision-making would be negligent), or the method for attributing a patient paradigm to a patient was illogical.[83] For example in *Lorraine v Wirral University Teaching Hospital Trust*, failure of the doctor to identify PL's previous births, due to not routinely asking patient's whether they had previous births, resulted in the doctors being unaware of a fibroid on the PL's posterior uterine wall during her fifth pregnancy. This fibroid caused an oblique infant position, which risked profound placental abruption or the foreseeable risk of cord prolapse, leasing to asphyxia. In this case the failure to take reasonable steps meant that the doctors did not know the risk profile, and did not take steps to avoid the potential risk by admission of PL. The judge found this approach illogical, and found it should be common sense that a patient be asked about any previous pregnancies.[84] Similarly, in *ARB v IVF Hammersmith*,[85] the judgement of Jay J was overturned because the failure to ensure that the clinic obtained an informed and written consent was illogical.[86] As Heywood argues, recognising the methods and logic by which patient paradigms are formed and attributed, would go some way to ensuring that silos of bad practice are avoided.[87] Requiring this level of analysis of the sources of patient paradigms would also lead to the more rapid identification and

[80] See for example, *M v Royal Berkshire NHS Foundation Trust* [2019] EWHC 2591 (QB)
[81] See, P. S. Myles, 'Mitigating the Risks of Surgery during the Covid-19 Pandemic.' (2020) 396(10243) *The Lancet* 2-3; H. Shanthanna & V. Uppal, 'Surgery during the Covid-19 pandemic.' (2020) 396(10261) *The Lancet* 74; E. Silvapulle, *et al*, 'Risk stratification of individuals undergoing surgery after Covid-19 recovery.' (2022) 128(1) British Journal of Anaesthesia 37-39. See the guidance: Royal College of Surgeons, *Information for Surgical Patients during the Coronavirus Pandemic.* (RCoS, 2021): (https://www.rcseng.ac.uk/coronavirus/recovery-of-surgical-services/tool-3/)
[82] *Bolitho v City and Hackney H.A.* [1998] AC 232, 243; R. Mulheron, 'Trumping Bolam: A Critical Legal Analysis of *Bolitho*'s "Gloss." (2010) 69(3) *Camb L J* 609-638; A. Maclean, 'Beyond *Bolam* and *Bolitho*.' (2002) 5(3) *Med L Int* 205-230
[83] See for example, *ARB v IVF Hammersmith* [2018] EWCA Civ 2803
[84] *Loraine (a child by his mother and Litigation Friend) v Wirral University Teaching Hospital NHS Foundation Trust* [2008] EWHC 1565. Also see, *M v Liverpool Women's NHS Foundation Trust* [2020] EWHC 91
[85] *ARB v IVF Hammersmith* [2019] 2 All ER 1074
[86] *Ibid*, per Nicola Davies LJ, at [56] – [59]
[87] R. Heywood, 'Systemic Negligence and NHS Hospitals: An Underutilised Argument.' (2021) 32(3) *King's Law Journal* 437-465

problematisation of the systemic causes of poor ethical and technical decision-making, through the law of negligence (rather than national inquiry).[88] It is important to note, however, that this type of logical enquiry must not decay into a form of *blinkered moralism*; where judges apply their own technical interpretation, or personal values to either narrow the spectrum of reasonable patient paradigms, or attack the moral basis on which the paradigm was formed, or applied to the patient.[89] As such, any common sense critique must, if possible, be evidence-based. In this sense the judiciary should be required to regulate, rather than specify the optimum conceptualisation of patient information need.

The judge must, next, assess whether the proposed patient paradigm is actually applicable to the patient's situation, at the relevant time. Failure to recognise the salient or essential patient factors will mean that a disclosure will not be sufficient.[90] This requires a detailed interrogation of the facts of the case, particularly: the patient's medical condition, their expressed values, their personal circumstances, the treatment options and clinical capacity available to provide diagnostic and medical procedures. Correct and fair attribution of the patient paradigm, to the actual patient, has the purpose of ensuring that that patient has, at least, the minimum amount of information necessary to make a choice in their best therapeutic interests. The relevant factors, to which the doctor was aware *reasonably aware,* can be ascertained from the witness statements or live evidence of the claimant, the Defendant, relevant witnesses, and contemporaneous evidence such as medical notes. Expert evidence can also be used to identify the material information or factors to which the doctor *should* have reasonably been aware; as a basis to make his assessment about the appropriate patient paradigm (and thus what information to offer the patient). For example, in *M v Royal Berkshire NHS Foundation Trust* the failure of the sonographer to ask appropriate follow-up questions to ensure the mother understood the fetal test she wanted to take, resulted in her first child (AM) being born with Down's syndrome.[91] The claimant brought proceedings for clinical negligence against the defendant's claiming that there were two missed opportunities to identify essential information about the patient which should have led to additional screening. The claimant attended the community midwife, at her GP surgery and 'accepted' all six standards screening tests, including combined screening.[92] Upon attending the sonographer, on the 22nd July, the claimant refused to have a combined test. However, the court found that this decision was made because of a misapprehension about the difference between the booked scan and future combined test.[93] This misapprehension occurred due to the failure of the sonographer to further question the

[88] See, Introduction
[89] See, Chapter 6, Section 1
[90] See, for example, *Webster v Burton Hospital NHS Foundation Trust* [2017] EWCA Civ 62, [10]-[11]
[91] *M v Royal Berkshire NHS Foundation Trust* [2019] EWHC 2591 (QB)
[92] *Ibid*, per Jay J at [5]
[93] *Ibid*, per Jay J at [57]-[59]

claimant, or provide further information, about the difference between the scan and other tests (in line with NHS and or NICE guidelines).[94] Jay J. stated that:

> […] the issue for me is whether her practice was irresponsible, unreasonable and unrespectable, if not illogical, in the light of the duty to take reasonable steps to secure informed consent.[95]

Failure to ask further questions to establish the mother's priorities meant that she did not receive information essential for an informed consent. The test is therefore, that the doctor must take:

> […] *reasonable* steps because I think that in the context of a human system it is impossible wholly to avoid misapprehensions persisting and misunderstandings arising despite the implementation of entirely proper practice by a sonographer. […] what is *reasonable* in this context must absorb a consideration of the issues at stake here. Not merely the birth of a child with Down syndrome a life-changing event for most parents, the steps required to guard against parental choice not being respected are not onerous. What is at issue here is the asking of a limited number of questions to ensure that what may be an unwarranted outcome does not result.[96]

Jay J clarifies that what is *reasonable* in terms of ascertaining the relevant considerations for disclosing information:

> What is reasonable cannot depend on the attributes and characteristics of any particular patient. An examination of the claimant's actual wishes is highly germane to causation (my third issue) but it has no relevance to the second. A reasonable process or system must take into account the fact that patients will naturally vary in terms of their ability, knowledge and capacity to understand.[97]

Lastly, the judge should ensure that the doctor actually provides the correct material information, in line with the patient paradigm (whether experientially or normatively) constructed. Of particular importance, is whether the doctor failed to disclose any material information. This could occur for example, due to a gap in the technical knowledge of the defendant.[98] Whether a full and proper

[94] NHS, *Antenatal Screening – Working Standards for Down's Syndrome.* (NHS, 2007); National Institute for Clinical Excellence, *Antenatal Care for Uncomplicated Pregnancies*. (NICE, 2008)
[95] *M v Royal Berkshire NHS Foundation Trust* [2019] EWHC 2591 (QB), [84]
[96] *Ibid*, [86]
[97] *Ibid*, [87]
[98] See, *Duce v Worcester Acute Hospitals NHS Trust* [2018] EWCA Civ 1308, per Hamblen LJ at [33]. Also, *Webster v Burton Hospitals NHS Foundation* [2017] EWCA Civ 62

disclosure was made could be identified, for example, by comparing the disclosure given with the information specified in guidance documents, or empirical research. Or, if the patient paradigm is experientially formed, whether the relevant considerations and factors identified by the doctor, would have logically led to the provision of the material information that was disclosed to the actual patient. Again, analysing the reasoning of the doctor in identifying material information (risks, benefits, alternatives and advice) requires the judge to evaluate the logic of a decision, and whether there are any gaps in information which the patient would have been entitled. Particularly, the time place, method,[99] magnitude and significance of potential information that was communicated to ensure an understanding requires interrogation.[100]

(c)Internal Test: Circumstantial-moral decision-making

- *Medical Decision-making*

The second step, in medical decision-making about information disclosure, is whether circumstantial factors or patient values which would require the doctor to deviate from the patient paradigm.[101] What amounts to relevant particular circumstances, are themselves contingent on the time, place, needs and values reasonably observed by the doctor, or expressed by the patient. These will need to be weighed up and prioritised by the doctor in the patient's best therapeutic interests. In this sense, the circumstances of the patient can lead to the doctor increasing the amount of information they afford the patient, for example, by requiring specific treatment options, beyond the patient paradigm e.g. if the patient asked follow-up questions. Alternatively, the particular priorities of the patient could limit the information or options that are provided to patient e.g. if the patient expressed a waiver.[102] As argued previously, the patient asking a question, being insistent on a course of action, or waiving information would be indicative of their values (and potentially an autonomous choice), as such it would be in the patients interest's to weigh these considerations heavily when delineating the content of disclosure. These communicative acts, depending on the context, justify the provision or limitation of information.

- *Judicial Decision-Making*

It is for the judge to establish on the facts that deviation from the patient paradigm was reasonable, or should have been undertaken.[103] This would usually be established, on the balance of probabilities by analysis of the communication between the doctor and patient, and the information and knowledge that should reasonably have been available to the doctor at the time. Liability can be found for failing to provide additional information according to the subjective medical needs of the patient; which required the doctor to go beyond the patient paradigm of information. This can include particular or rare medical

[99] See, *Thefault v Johnson* [2017] EWHC 497, per Green J, at [78]
[100] See, *Ollosson v Lee* [2019] EWHC 784 (QB)
[101] See Chapter 2, Section 2
[102] See Chapter 3, Section 1
[103] *Duce v Worcester Acute Hospitals NHS Trust* [2018] EWCA Civ 1308, per Hamblen LJ, at [33]

conditions. For example, in *Webster v Burton Hospital NHS Foundation Trust* on appeal Simon LJ found that the consultant's decision to not investigate and disclose that the rare combination of 'reduced foetal growth velocity, asymmetry and polyhydramnios […] was a matter of serious concern.'[104] This is information that the claimant mother would have needed to know to make an informed decision about the time of birth.[105]

The values and circumstances of the actual patient must similarly be considered as a justificatory basis to deviate from the average content of information disclosure. For example, failure to appropriately answer patients questions about procedures might be indicative of a failure to act in their best therapeutic interests.[106] Alternatively, the judge should evaluate whether the values of the patient would require a restrictive approach to the amount of information; either because the patient has specifically refused information, or their values require that options and information given to the patient are limited.[107] For example, in *Price v Cwm Taf University Health Board*,[108] the claimant argued that the departure from the NICE guidelines, in offering the option of an arthroscopy, had been negligent. The Court of Appeal found that whilst the NICE guidelines indicated that the arthroscopy should not have been offered for treatment of osteoarthritis without mechanical locking, they also stated that guidelines

> […] do not override the need for individual decisions appropriate to the circumstances of the individual patient. After noting that they do not override the need for the appropriate individual decisions the judge then made the statement which is challenged on appeal: "nor is failing to follow the guidelines prima facie evidence of negligence."[109]
>
> […] I agree with the judge that this departure from these guidelines is not prima facie evidence of negligence. Nevertheless what must be right is that the clinical decision which departs from the NICE Guidelines is likely to call for an explanation of some sort. The nature and degree of detail required will depend on all the circumstances. The only relevant question on appeal is whether the particular decision in this case, which does depart from the guidelines, has been adequately explained and justified.

The trial judge found that:

[104] *Webster v Burton Hospitals NHS Foundation* [2017] EWCA Civ 62, [32]
[105] *Ibid*, [38]-[40]
[106] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, per Lord Templeman, at 902
[107] See for example, *Malik v St George's University Hospitals NHS Foundation Trust* [2021] EWHC 1912 (QB)
[108] *Price v Cwm Taf University Health Board* [2019] EWHC 938 (QB)
[109] *Ibid*, [21]

> […] Mr Price was not a typical patient with osteoarthritis in the knee given his comparatively young age (he was 52 at the time of the first arthroscopy) and found that Mr Sharma was reasonably motivated by a desire to postpone carrying out a knee replacement surgery given the implications this might have for Mr Price's employment.[110]

The Court of Appeal, supported the trial judge's findings that it was reasonable for the defendant to depart from the guidelines due to the particular values and needs of the patient.[111]

(d) External test: Social norms and Human Rights

The final element of the judicial test seeks to deal with the problem of *medicalisation.* That is, that the definition of what amounts *beneficence-in-trust,* and thus the purpose of medicine, is defined in the context of societies evolving health need.[112] Deviation from societies need for medicine would therefore be seen as a deviation from the purpose of medicine. Actions which deviate from the purpose of medicine, would fall outside medicine's therapeutic exception, and thus should be conceptualised as a harm.[113] However the societal definition of medicine changes. As Pellegrino and Thomasma argue, the development of medical practice away from the Hippocratic Tradition, has been caused by the development of societal norms.[114] A similar connection between the common morality and the ethical content of principlism is recognised by Beauchamp and Childress.[115] It is widely recognised, for example, that there is a presumption that emphasis should be placed on autonomy – and thus the values and principles of the patient should be weighed heavily.[116] As demonstrated above, this manifests in the requirement that the values and circumstances of the individual patient be taken into account when deciding whether a doctor should deviate from a therapeutic paradigm of the patient. A sociological test within law, would require ready acknowledged of the changing requirements of medicine within society, as well as the dynamic evolution of the acceptable limits of medicine. As Lord Scarman argued:

> The House's task, therefore, as the supreme court in a legal system largely based on rules of law evolved over the years by the judicial process, is to search the overfull and cluttered shelves of the law reports for a principle, or set of principles recognised by the judges over the years but stripped of the detail which, however appropriate in their day, would, if applied today, lay

[110] *Ibid*, [11]
[111] *Ibid*, [22]-[28]
[112] F. G, Miller & H. Brody, 'The Internal Morality of Medicine: An Evolutionary Perspective.' (2001) 26 *Journal of Medicine and Philosophy* 581-599
[113] S. Forvargue & A. Mullock, (eds.), *The Legitimacy of Medical Treatment: What Role of the Medical Exception?* (Routledge, 2016)
[114] E.D. Pellegrino & D.C. Thomasma, *The Virtues in Medical Practice.* (Oxford University Press, 1993), 33. See also, J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship*. (Hart Publishing, 2007), 19 & 20-25
[115] T.L. Beauchamp & J.F. Childress, *Principles of Biomedical Ethics* (Oxford University Press, 2013)
[116] E.D. Pellegrino, Towards a Reconstruction of Medical Morality.' (2006) 6(3) *The American Journal of Bioethics* 65-71; See, E.D. Pellegrino, "Towards an Expanded Medical Ethics: The Hippocratic Oath Revisited." In R.M. Veatch (eds.), *Cross-Cultural Perspectives in Medical Ethics*. (Jones and Bartlett Publishers, 2000), 46

> the judges open to a justified criticism for failing to keep the law abreast of the society in which they live and work.
>
> It is, of course, a judicial commonplace to proclaim the adaptability and flexibility of the judge-made common law. But this is more frequently proclaimed than acted upon. The mark of the great judge from Coke through Mansfield to our day has been the capacity and the will to search out principle, to discard the detail appropriate (perhaps) to earlier times, and to apply principle in such a way as to satisfy the needs of their own time. If judge-made law is to survive as a living and relevant body of law, we must make the effort, however inadequately, to follow the lead of the great masters of the judicial art.[117]

However, the ability for judges to proclaim that a decision falls outside of the boundary of medical practice, occurs only where there is a recognised harm. The law can only, therefore, develop based on the principle of non-maleficence. Axiomatic rules about the boundaries of action in society are readily identified within domestic human rights law and ECtHR jurisprudence, as negative rights.[118] This limited approach to the use of human rights as an axiological structure to limit the harms of *medicalisation*, is concordant with the approach adopted by Kennedy i.e. that human rights only aim 'to set the framework within which such discretion may properly be exercised.'[119]

> I am talking of prima facie rights rather than absolute rights. This is not to deny that absolute rights may be urged by some. Instead, it is to suggest that in everyday practice of medicine by civilised doctors in a civilised doctor in a civilised community, such absolute rights if they exist, are not usually called into play. Thus, the rights we are concerned with are prima facie to be observed, by which I mean that they are to be observed in the absence of any powerful justifying argument which allows them to be overridden.[120]

In the context of judicial analysis, a judge might ask, for example:

(1) Did the information disclosure respect the patients' choices, so that the process did not amount to or lead to inhumane or degrading treatment under Art 3?
(2) Did the doctor provide information to the patient, which failed to respect their decision to waive information, and thus undermine their Art 8 right of self-determination?

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[117] *Gillick v West Norfolk & Wisbech AHA* [1985] 2 All ER, per Lord Scarman, at 419
[118] I. Kennedy, "Patients, Doctors, and Human Rights." In I. Kennedy (eds.), *Treat Me Right – Essays in Medical Law and Ethics*. (Clarendon Press, 2001), 385.
[119] *Ibid*, 387
[120] *Ibid*, 387

(3) Did the doctor provide enough weight to the patients' choice to receive information under Art 8 and therefore have an informed consent to treatment?

Whilst, it is highly unlikely that the need to find liability on a human rights principle will arise in the context of information disclosure, if this approach was adopted more widely, human rights could certainly have a more substantive role in limiting medical action in morally dubious or experimental areas of medicine.[121]

(iii) Differentiation

A key consideration, in relation to the implementation of a sociological standard (and perhaps the central source of critique) is how *Bolam* 2.0 would be different from the judicial test adopted by McNair J in *Bolam v Friern Hospital Management Committee*.[122] Of particular importance is how such a standard could both distinguish and defend itself from the ongoing critiques of the jurisdiction and rights school. Specifically, that a sociological standard leads to medical paternalism, judicial deference and the adoption of the *conventional Bolam* standard.[123] Or, the rights school critique, that medical decision-making will become ethically confused, and cause harm, due to *medicalisation*.[124]

This author would argue, that a novel sociological would differentiate itself in three respects:

(a) Explicitness

Unlike the traditional *Bolam* standard, the proposed sociological standard, would be *explicit* about the necessary connection between how doctor's make decisions and how the law regulates those decisions. This is essential, as this thesis has demonstrated, as the rhetorical aims of normative rules have seldom led to the expected practical outcomes, due to the failure to recognise the method and internal morality of decision-making. Instead, the requirements of judicial evaluation, within the sociological standard, will make clear that the law regulates (rather than legislates to alter) medical decision-making. This is not to say that the law (and thus the judiciary) should be deferential to poor practice. The sociological analysis of this thesis will itself create a basis for critique of existing practice (as well as the effectiveness of law as a mechanism to change those practices). To the contrary, the proposed form and content of the internal and external criteria provide robust and explicit requirements for judicial engagement, and analysis, of medical decision-making. Specifically, the sociological test will make explicit the requirement for: evidence-based sociological and ethical justification for patient paradigms, logical attribution to the patient, and identification of material information. Also, the requirement that

[121] However, see: *ABC v St George's Healthcare NHS Trust and Others* [2020] EWHC 455
[122] Thanks to Professor Robert Heywood, and Dr Melanie Kazarian for raising this to my attention.
[123] Chapter 2, Section 1
[124] Chapter 3, Section 2 and 3

patient values and circumstances be appropriately identified and reasonably weighed to augment an objective content of information. Finally, the risk of paternalism (by individual practitioners or the profession) is mitigated by the requirement that the judiciary evaluate the content, method and consequence of a decision against human rights principles; particularly, Art 5 and Art 8.

(b) Orientation

Unlike the traditional *Bolam* standard, which is silent on the purpose of information disclosure, the new sociological test has a clear orientating principle: that the paramount consideration is to provide information in the patient's best therapeutic interest. This orientating principle, is both sociological compatible with existing practice, and has the potential to rationalise the dual models of the medical relationship currently operating within the law.[125] This principle is unlikely to lead to paternalistic practices, as the best interests of the capacitous patient require that heavy weight is placed on the values and circumstances of patient populations (to construct patient paradigms). The requirement to act circumstantially, also avoids oppressive disclosures. Paternalism, is therefore mitigated by both the internal (as failure to weigh and balance patient values appropriately will lack empirical justification, and likely lead to practical harms) and external (by human rights considerations) elements of the sociological test. In this sense medical principles are properly integrated and balanced within a therapeutically orientated relationship.

(c)Hierarchy

The sociological model also goes some way to avoiding conceptual confusion between normative guidelines by eliminating the conceptual divide between the two forms of the medical relationship; by prioritising the therapeutic orientation.[126] The *Bolam* 2.0 approach also attempts to create clearer hierarchy in relation to medical morality, regulatory ethics, and law; which has been a primary source of conceptual confusion within medical practice.[127] For example, the requirement that patient paradigms be evidence-based, and logical, attempts to properly situate morality above regulatory ethics, and regulatory ethics above normative rules in law. Medical ethics should inform doctors about the proper construction of patient paradigms.[128] However, it should not be restrictive in the sense that deviation is allowed to facilitate the therapeutic needs of the actual patient - their values and circumstances. Moral choices and the overriding therapeutic purpose of decision-making about disclosure, must remain

[125] This is a similar approach to the welfare principle in s.1(1) Children Act 1989, s.1(2) Adoption and Children Act, and s.1 Mental Capacity Act 2005.
[126] J. Montgomery, 'Patient No Longer? What Next in Healthcare Law?' (2017) 70(1) *Current Legal Problems* 73-109
[127] J. Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship*. (Hart Publishing, 2007); C. Foster & J. Miola, 'Who's in Charge? The Relationship between Medical Law, Medical Ethics, and Medical Morality.' (2015) 23(4) *Med L Rev* 505-530
[128] The author is cognisant that this does not deal with the problem of disagreement between tiers of medical ethics.

sovereign to ensure actual patients are centered. Regulatory ethics should inform the law about the proper application of *circumstantial-moral* decision-making, but should not be prescriptive.

(iv) Application

A further contention is the extent to which the readoption of a sociological test will be accommodated by lawyers, the judiciary and medical practice. A full understanding of how this might impact decision-making within these context requires further empirical investigation. However, as this thesis has illustrated, the sociological approach is predicated upon, and facilitative of, *circumstantial-moral* decision-making. This approach has been resilient to normative change, it is practiced by a substantial minority (of particularly senior) practitioners and is utilised in other areas of medical decision-making i.e. diagnosis and treatment. On this basis, one might suggest that remoralisation of medical decision-making - by making explicit existing norms and processes - is unlikely to be problematic for medical practitioners.

More difficult to predict, however, is the likely reaction of lawyers and judiciary. As exemplified above, the methods of analytical enquiry necessary for an explicit sociological standard in *Bolam* 2.0, are regularly being utilised in post-*Montgomery* case-law. However, moving away from the exclusive reliance on patient rights, and the ethical principles of patient autonomy as a way to structure and critique law, will likely prove difficult. Medical law is heavily ingrained into the professional and moral psyche. This orientation is likely to be resilient both within jurisprudence and the legal regulation of the medical profession because of the hidden law-makers (and judicial forms of law-making).[129] But as this thesis has demonstrated, evolution is necessary. Further research on the professional values of lawyers, judicial values, and their respective understanding of law and medical ethics, is essential. Entrenched attitudes might be shifted through cultural change, which could be catalysed by legal and ethical training, and/or interaction with the medical profession, reasserting their moral norms beyond the court-room. Irrespective of *Bolam* 2.0's implementation, lawyers must understand the proper role of law, and process of medical decision-making in medical practice; such an appreciation is essential to avoid patient harm in the future.

[129] J. Montgomery, *et al*, 'Hidden Law-Making in the Province of Medical Jurisprudence.' (2014) 77(3) *MLR* 343-378

APPENDICES

Appendix 1: Studies identified between 1957 - 1997

Date	Reference
1967	P. Ley & M.S. Spelman, *Communicating with the Patient.* (Staples Press, 1967)
1973	M. Reynolds, 'No news is Bad News: Patients' View about Communication in Hospital.' (1978) 1(6128) BMJ 1673-1676
1975	G. Stimson & B. Web, *Going to see the Doctor.* (Routledge & Kegan Paul, 1975)
1976	D.M. Parkin, 'Survey of the Success of Communications between Hospitals Staff and Patients.' (1976) 90(5) *Public Health* 203-209
1977	A. Cartwright, *Patients and their Doctors 1977. A Report on some Change in General Practice between 1964 and 1977 for the Royal Commission on the National Health Service.* (Royal College of General Practitioners, 1977)
1977	J. Lankton, *et al*, 'Emotional Responses to Detailed Risk Disclosure for Anaesthesia: A Prospective, Randomised Study.' (1977) 46 *Anaesthesiology* 294
1978	M. Reynolds, 'No News is Bad News: Patients' Views about Communication in Hospital.' (1978) 1(6128) *BMJ* 1673-1676
1978	J. McIntosh, "The Routine Management of Uncertainty in Communication with Cancer Patients." In A. Davies, *Relationships between Doctors and Patients.* (Saxon House, 1978),
1978	Royal Commission on the National Health Service, *Patients' Attitudes to the Hospital Service.* (Stationary Office, 1978)
1979	C. Hawkins, 'Patients' reactions to their Investigations: a Study of 504 Patients.' (1972) 2 *BMJ* 638-640
1979	J.E. Verby, *et al*, 'Peer Review of Consultations in Primary Care: The use of Audiovisual Recordings.' (1979) ii *BMJ* 1686-1868
1979	H. Dunkelman, 'Patients Knowledge of Their Condition and Treatment: How It Might Be Improved.' (1979) 2(6185) *BMJ* 311-314
1983	T.D. Bunker, 'An Information Leaflet for Surgical Patients.'(1983) 65 *Annuls of the Royal College of Surgeons* 242-243
1983	S.M. Miller & C.E. Mangan, 'Interacting Effect of Information and Coping Style in Adapting to Gynaecological Stress: Should the Doctor Tell All?' (1983) 45 *Journal of Personality and Social Psychology* 223-236
1985	J.J. Ashcroft, *et al*, 'Breast Cancer- Patient Choice of Treatment: Preliminary Communication.' (1985) *J R Soc Med* 43-46

1985	A-L. Caress, 'Patient-Sensitive Treatment Decision-Making? Preferences and Perceptions in a Sample of Renal Patients.' (1985) 3(3) *Nursing Times Research* 346-372
1986	L.M. Wallace, 'Informed Consent to Elective Surgery: The 'Therapeutic Value?' (1986) 22(1) *Soc Sci Med* 29-33
1988	D.J. Byrne, *et al*, 'How Informed is Signed Consent?' (1988) 296 *BMJ* 839-840
1989	J. Morris, *et al*, 'Changes in the Surgical Management of Early Breast Cancer in England.' (1989) 82 *J R Soc Med* 12
1989	G.M. Hawkey & C.J. Hawkey, 'Effect of Information Leaflets on Knowledge in Patients with Gastrointestinal Diseases.' (1989) 30 *BMJ* 1641-1646
1990	L.J. Fallowfield, *et al*, 'Psychological Outcomes of Different Treatment Polices in Women with Early Breast Cancer Outside of Clinical Trials.' (1990) 302(6752) *BMJ* 575-580
1990	S. Gibbs, *et al*, 'Communicating Information to Patients about Medicine: Prescription Information Leaflets: A National Survey.' (1990) 93(5) *J R Soc Med* 292-297
1991	M. Lonsdale & L. Hutchinson, 'Patients' Desire for Information about Anaesthesia.' (1991) 56 *Anaesthesia* 410-412
1992	P.J.D. Dawes, *et al*, 'Informed Consent: The Assessment of Two Structured Interview Approaches Compared to the Current Approach.' (1992) 106 *The Journal of Laryngology and Otology* 420-424.
1993	P.J.D. Dawes, *et al*, 'Informed Consent: Using a Structured Interview Changes Patients' Attitudes Towards Informed Consent.' (1993) 107 *The Journal of Laryngology and Otology* 775-779
1993	D.D. Kerrigan, *et al*, 'Who's Afraid of Informed Consent.' (1993) 306 *BMJ* 298
1993	C. Lavell-Jones, *et al*, 'Factors Affecting Quality of Informed Consent.' (1993) 306 *BMJ* 885
1993	P. Meredith, 'Patients Participation in Decision-Making and Consent to Treatment: The Case of General Surgery.' (1993) 15(3) *Sociology of Health & Illness* 315
1993	K. Luker, *et al*, *Preference for Information and Decision Making in Women Newly Diagnosed with Breast Cancer: Final Report.* (Research and Development Unit, 1993)
1994	K. Chee Saw, *et al*, Informed Consent: An Evaluation of Patients' Understanding and Opinion (With Respect to the Operation of Transurethral Resection of Prostate).' (1994) 87 *J R Soc Med* 143
1994	L. Fallowfield, *et al*, 'Information Preferences of Patients.' (1994) 344(8936) *The Lancet* 1576
1994	P.J. Dawes & P. Davison, 'Informed Consent: What do Patients Want to Know?' (1994) 87(3) *J R Soc of Med* 149
1994	P.J. Dawes 'Informed Consent: Questionnaire Survey of British Otolaryngologists.' (1994) 19 *Clin Otolaryngol* 388

1994	L.J. Fallowfield, *et al*, 'Psychological Effects of Being Offered Choice of Surgery for Breast Cancer.' (1994) 309 *BMJ* 448
1995	S. Ford, *et al*, 'The Influence of Audiotapes on Patient Participation in the Cancer Consultation.' (1995) 31 *European Journal of Cancer* 2264-2269
1995	P. McHugh, *et al*, 'The Efficacy of Audiotapes in Promoting Psychological Well-Being in Cancer Patients: A Randomised, Controlled Trial.' (1995) 71 *British Journal of Cancer* 388-392
1996	S. Ford, *et al*, 'The Influence on Patient Participation in Cancer Consultation.' (1995) 31A *European Journal of Cancer* 2264-2269
1996	K. Beaver, *et al*, 'Treatment Decision Making in Women Newly Diagnosed with Breast Cancer.' (1996)19(1) *Cancer Nursing* 8-19
1996	C. Meredith, *et al*, 'Information Needs of Cancer Patients in West Scotland: Cross Sectional Survey of Patients' Views.' (1996) 313 *BMJ* 724-726
1996	O' Neil, *et al*, 'The Use of an Information Leaflet for Patients Undergoing Wisdom Tooth Removal.' (1996) 34 *British Journal of Oral and Maxillofacial Surgery* 331-334
1996	S. Ford, 'Doctor-Patient Interactions in Oncology.' (1996) 42(11) *Soc Sci Med* 1511-1519
1997	A.P. Armstrong, 'Informed Consent: Are we Doing Enough?' (1997) 50 *Journal of Plastic Surgery* 637-640
1997	P.N. Butow, *et al*, 'The Dynamic of Change: Cancer Patients' Preferences for Information Involvement and Support.' (1997) 8 *Annals of Oncology* 857-863

Appendix 2: Studies identified between 1998 - 2004

Date	Reference
1998	A.L. Caress, *et al*, 'Patient-Sensitive Treatment Decision-Making? Preferences and Perceptions in a Sample of Renal Patients.' (1998) 3(5) *NT Research* 364-372
1998	A. Coulter, *et al*, *Informing Patients: An Assessment of the Quality of Patient Information Materials*. (Kings Fund Publishing, 1998)
1999	A. Towle & W. Godolphin, 'Framework for Teaching and Learning Informed Shared Decision Making.' (1999) 319 *BMJ* 766
1999	R. Brown, *et al*, 'Promoting Patient Participation in the Cancer Consultation: Evaluation of a Prompt Sheet and Coaching in Question-Asking.' (1999) 80(1/2) *British Journal of Cancer* 242-248
1999	S. Ford, *et al*, 'Doctor-Patient Interactions in Oncology.' (1996) 42(11) *Soc Sci Med* 1511-1519
1999	K. Beaver, *et al*, 'Decision-Making Role Preferences and Information Needs: A Comparison of Colorectal and Breast Cancer.' (1999) 2 *Health Expectations* 266-276
2000	H.E. Ellamushi, *et al*, 'Consent to Surgery in a High Risk Speciality a Prospective Audit.' (2000) 82 *Ann R Coll Surg Engl* 213-216
2000	K. Haddow & J.A. Crowther, 'Consent - Who - What, Where, When?' (2000) 58(3) *Healthcare Bulletin* 218 - 220
2000	G.M. Leydon, *et al*, 'Cancer Patients' Information Needs and Information Seeking Behaviour: In Depth Interview Study.' (2000) 320 *BMJ* 909-913
2000	G.M. Leydon, *et al*, 'Faith, Hope and Charity: An In-Depth Interview Study of Cancer Patients' Information Needs and Information Seeking Behaviour.' (2000) 320 *BMJ* 909-913
2000	F.A. Stevenson, *et al*, 'Doctor-Patient Communication about Drugs: The Evidence for Shared Decision Making.' (2000) 50 *Soc Sci Med* 829-840
2000	C. McManus & B. Winder, 'Duties of a Doctor: UK Doctors and Good Medical Practice.' (2000) 9(1) *Quality in Health Care* 14-22, 18-19
2001	S.J. Yardly, *et al*, 'Receiving a Diagnosis of Lung Cancer: Patients' Interpretations, Perceptions and Perspectives.' (2001) 15 *Palliative Medicine* 379-386
2001	V. Jenkins, *et al*, 'Information Needs of Patients with Cancer: Results from a Large Study in UK Cancer Centres.' (2001) 84(1) *British Journal of Cancer* 48-51
2001	E. A. Grunfeld, *et al*, 'Chemotherapy for Advanced Breast Cancer: What Influence Oncologists' Decision-Making?' (2001) 84(9) *British Journal of Cancer* 1172-1178
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2001	V. Jenkins, *et al*, 'Information's Needs of Patients with Cancer: Results from a Large Study in UK Cancer Centres.' (2001) 84(1) *British Journal of Cancer* 48-51.
2001	D. Misselbrook & D. Armstrong, 'Patients' Responses to Risk Information about the Benefits of Hypertension.' (2001) 51 *Br J Gen Pract* 276-279
2001	S.A. Lewin, *et al*, 'Interventions for Providers to Promote a Patient-Centred Approach in Clinical Consultations. The Cochrane Database of Systematic Reviews.' (2001) 4 *The Cochrane Database of Systematic Reviews* 1-63
2002	J. Benson & Britten, 'Patients' Decisions about Whether or not to take Antihypertensive Drugs: Qualitative Study.' (2002) 325 *BMJ* 873, 1-5
2002	F. M. Walter, *et al*, 'Patients' Understanding of Risk: A Qualitative Study of Decision-Making about the Menopause and Hormone Replacement Therapy in General Practice.' (2002) 19(6) *Family Practice* 579-586
2002	A.L. Caress, *et al*, 'A Qualitative Exploration of Treatment Decision-Making Role Preference in Adult Asthma Patients.' (2002) 5(3) *Health Expectations* 223-235
2003	A. Edwards, *et al*, 'The Development of COMRADE - A Patient-Based Outcome Measure to Evaluate the Effectiveness of Risk Communication and Treatment Decision Making in Consultations.' (2003) 50 *Patient Education and Counseling* 311-322
2003	G. Elwyn, *et al*, 'Shared Decision Making: Developing the OPTION Scale for measuring patient involvement.' (2003) 12 *Qual Saf Health Care* 93-99
2003	R. E. Davies, *et al*, 'Exploring Doctor and Patient Views about Risk Communication and Shared Decision-Making in the Consultation.' (2003) 6 *Health Expectations* 198-207
2003	J. Benson, *et al*, 'Keep Taking the Tablets: Balancing the Pros and Cons when deciding to take Blood Pressure Treatment.' (2003) *BMJ* 1314-1315
2003	S. Ford, *et al*, 'What are the Ingredients for a Successful Evidence-Based Patient Choice Consultation? A Qualitative Study.' (2003) 56(3) *Soc Sci Med* 589-602
2004	A. Edwards, *et al*, 'Involving Patients in Decision Making and Communication Risk: A Longitudinal Evaluation of Doctors' Attitudes and Confidence during a Randomized Trial.' (2004) 10(3) *Journal of Evaluation in Clinical Practice* 431-437
2004	A. Edwards, *et al*, 'Patient-Based Outcome Results from a Cluster Randomized Trial of Shared Decision Making Skill Development and use of Risk Communication Aids in General Practice.' (2004) 21 *Family Practice* 347-354
2004	F. M. Walter, 'Women's Views of Optimal Risk Communication and Decision Making in General Practice Consultations about the Menopause and Hormone Replacement Therapy.' (2004) 53 *Patient Education and Counselling* 121-128

2004	A. Akkad, 'Informed Consent for Elective and Emergency Surgery: Questionnaire Study.' (2004) 111 *International Journal of Obstetrics and Gynaecology* 1133-1138
2004	G. Elwyn, *et al*, 'Achieving Involvement: Process Outcomes from a Cluster Randomized Trial of Shared Decision Making Skill Development and use of Risk Communication Aids in General Practice.' (2004) 21(4) *Family Practice* 337-346
2004	A. Edwards, *et.al*, 'Shared Decision Making and Risk Communication in Practice: A Qualitative Study of GPs' Experience.' (2005) 55 *Br J Gen Pract* 6-13

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Date	Study
2005	C. M. Gaston & G. Mitchell, 'Information Giving and Decision-Making in Patients with Advanced Cancer: A Systemic Review.' (2005) 51 *Soc Sci Med* 2252-2264
2005	G. Rowe, *et al*, 'Assessing Patients' Preferences for Treatments for Angina using a Modified Repertory Grid Method.' (2005) 60 *Soc Sci Med* 2585-2595.
2005	A. Akkad, 'Informed Consent for Elective and Emergency Surgery: Questionnaire Study.' (2004) 111 *International Journal of Obstetrics and Gynaecology* 1133-1138
2005	A. Brooks, 'Information Required to Provide Informed Consent for Endoscopy: an Observational Study of Patients' Expectations.' (2005) 37(11) *Endoscopy* 1136-1139
2005	C. Chew-Graham, *et al*, 'Informed Consent? How do Primary Care Professionals Prepare Women for Cervical Smears: A Qualitative Study.' (2005) 61 *Patient Education and Counseling* 381-388
2005	A. Edwards & G. Elwyn, 'Shared Decision Making and Risk Communication in Practice: A Qualitative Study of GP's Experiences.' (2005) 55(510) *Br J Gen Prac* 6-13
2006	M. Dixon-Woods, *et al*, 'Why Do Women Consent to Surgery, even when they do not want to? An Interactionist and Bourdieusian Analysis.' (2006) 62 *Soc Sci Med* 2742-2753
2006	C. Bugge, *et al*, 'The Significance for Decision-Making of Information that is not exchanged by Patients and Health Professionals during Consultations.' (2006) 63 *Soc Sci Med* 2065-2078
2006	A. Akkad, *et al*, 'Patients' Perceptions of Written Consent: Questionnaire Study.' (2006) 333(7567) *BMJ* 528
2006	E.A. Grunfeld, *et al*, 'Advanced Breast Cancer Patients' Perception of Decision Making for Palliative Chemotherapy.' (2006) 24(7) *Journal of Clinical Oncology* 1090-1098

2006	H. El-Wakeel, *et al*, 'What do Patients really want to know in an Informed Consent Procedure? A Questionnaire-Based Survey of Patients in the Bath Area, UK.' (2006) 32 *J Med Ethics* 612-616
2006	A. Edwards & G. Elwyn, 'Inside the Black Box of Shared Decision Making: Distinguishing Between the Process of Involvement and who makes the Decision.' (2006) 9 *Health Expectations* 307-320
2007	A.A. Montgomery, *et al*, 'Two Decision Aids for Mode of Delivery Among Women with Previous Caesarean Section: Randomised Controlled Trial.' (2007) 334(7607) *BMJ* 1305
2007	B. Parsons & M. Kennedy, 'A Review of Recorded information Given to Patients Starting to take Clozapine, a Key Component of Informed Consent.' (2007) 33 J *Med Ethics* 564-567
2007	K. Beaver & K. Booth 'Information Needs and Decision-Making Preferences: Comparing Findings for Gynaecological Breast and Colorectal Cancer.' (2007) 11 *European Journal of Oncology Nursing* 409-416
2008	V. Entwistle, *et al*, ' Involvement in Treatment Decision-Making: Its Meaning to People with Diabetes and Implications for Conceptualisation.' (2007) 66 *Soc Sci Med* 362-375
2007	R. Heywood, *et al*, 'Medical Students' Perceptions of Informed Consent: Qualitative Inquiry and Legal Reflections on Clinical Education.' (2007) 23(3) *Professional Negligence* 151-164
2008	R. Heywood, et al, 'Patients Perceptions of the Consent Process: Qualitative Inquiry and Legal Reflection.' (2008) 2 *Professional Negligence* 104-121
2008	M.C. Weiss & T.J. Peters, 'Measuring Shared Decision Making in the Consultation: A Comparison of the OPTION and Informed Decision Making Instruments.' (2008) 70 *Patient Education and Counseling* 79-86
2008	K. Beaver, et al, 'Information Needs and Decision-Making Preferences: Comparing Findings for Gynaecological Breast and Colorectal Cancer.' (2007) 11 *European Journal of Oncology Nursing* 409-416
2008	S. Audrey, *et al*, 'What Oncologists tell Patients about Survival Benefits of Palliative Chemotherapy and Implications for Informed Consent: Qualitative Study.' (2008) 337 *BMJ* a757
2010	D. Burton, *et al*, 'Shared Decision-Making in Cardiology: Do Patients want it and do Doctors provide it?' (2010) 80 *Patient Education and Counselling* 173-179

2010	R. Heywood, *et al*, 'Informed consent in Hospital Practice: Health Professionals' Perspectives and Legal Reflections.' (2010) 18 *Med L Rev* 152-184
2010	P. Kinnersely, *et al*, 'Interventions Before Consultation to Help Patients Address their Information Needs by Encouraging Question Asking: Systematic Review.' (2008) 337 *BMJ* a485
2010	A.A.B. Jamjoon, *et al*, 'Anaesthetists' and Surgeons' Attitudes towards Informed Consent in the UK: An Observational Study.' (2010) 11(2) *BMC Medical Ethics* 1-7
2011	J. Kai, *et al*, 'Challenges of Mediated Communication, Disclosure and Patient Autonomy in Cross-Cultural Cancer Care.' (2011) 105 *British Journal of Cance*r 918-924
2011	V.A. Entwistle, *et al*, 'How Information about other people's Personal Experiences can Help with Healthcare Decision-Making: A Qualitative Study.' (2011) 85 *Patient Education and Counseling* 291-298
2012	E.J. Robinson, *et al*, 'Do the Public Share Practitioners' View about the Best Evidence?' (2012) 88 *Patient Education and Counseling* 325-329
2012	M. Evans, *et al*, 'Developing a Model of Decision-Making about Complementary Therapy use for Patients with Cancer: A Qualitative Study.' (2012) 89 *Patient Education and Counseling* 374-380.
2012	M.S. Langseth, 'Quality of Decision Making is Related to Decision Outcome for Patients with Cardiac Arrhythmia.' (2012) 87 *Patient Education and Counseling* 49-53
2013	O. Osman, *et al*, 'The Practice of Defensive Medicine Among Hospital Doctors in the United Kingdom.' (2013) 14(42) *BMC Medical Ethics* 1-6
2013	L. Furber, *et al*, 'Investigating Communication in Cancer Consultations: What can be Learned from Doctor and Patient Accounts of their Experience?' (2013) 22 *European Journal of Cancer Care* 653-662
2013	A. Miles, et *al*, 'The Effect of Information about False Negative and False Positive Rates on People's Attitudes towards Colorectal Cancer Screening Faecal Occult Blood Testing (FOBt).' (2013) 93 *Patient Education and Counseling* 342-349
2013	A.G.K. Edwards, *et al*, 'Personalised Risk Communication for Informed Decision Making about Taking Screening Tests (Review).' (2013) 2 *Cochrane Database of Systematic Review* 1-41

Appendix 4: Studies identified between 2015-2019

Date	**Reference**
2015	M.L.S. Lie, *et al*, 'Risk Communication in Hyperacute Setting of Stroke Thrombolysis: An Interview Study of Clinicians.' (2015) 32(5) *Emergency Medicine Journal* 357-363
2015	J. M. Blazeby, *et al*, 'Core Information Set for Oesophageal Cancer Surgery.' (2015) 102 *BJS* 936-943
2015	H. A. Powell, *et al*, 'Patients' Attitudes to Risk in Lung Cancer Surgery: A Qualitative Study.' (2015) 90 *Lung Cancer* 358-363
2015	C. Doherty, *et al*, 'The Consent Process Enabling or Disabling Patients' Active Participation?' (2015) 21(2) *Health (London)* 205-222
2015	L. Furber, *et al*, 'Patients' Experiences of an Initial Consultation in Oncology: Knowing and Not Knowing.' (2015) 20 *British Journal of Health Psychology* 261-273
2015	M.L.S. Lie, *et al*, 'Risk Communication in Hyperacute Setting of Stroke Thrombolysis: An Interview Study of Clinicians.' (2015) 32(5) *Emergency Medicine Journal* 357-363
2015	R. Zarnegar, *et al*, 'Patient Perceptions and Recall of Consent for Regional Anaesthesia compared with Consent for Surgery.' (2015) 108(11) *J R Soc Med* 451-456
2015	F. Garrad, *et al*, 'Decisions, Choice and Shared Decision Making in Antenatal Clinics: An Observational Study.' (2015) 98 *Patient Education and Counseling* 1106-111
2016	D.W. Hamilton, *et al*, 'Multidisciplinary Team Decision-Making in Cancer and the Absent Patient: A Qualitative Study.' (2016) 6 *BMJ* 1-8
2016	M-A. Durand, *et al*, 'Can we Routinely Measure Patient Involvement in Treatment Decision-Making in Chronic Kidney Care? A Service Evaluation in 27 Renal Units in the UK.' (2016) 9(2) *Clinical Kidney Journal* 252-259
2016	H. Wiseman, *et al*, 'Do Patients want Choice? An Observational Study of Neurology.' (2016) 99 *Patient Education and Counseling* 1170-1178
2017	B.G. Main, *et al*, 'Core Information Sets for Informed Consent to Surgical Interventions: Baseline Information of Importance to Patients and Clinicians.' (2017) 18(2) *BMC Medical Ethics* 1-9

2017	M.N. Bagnall, *et al*, 'Informing the Process of Consent for Surgery: Identification of Key Constructs and Quality Factors.' (2017) 209 *Journal of Surgical Research* 86-92
2017	GMC, *Doctors' Attitudes to Consent and Shared Decision making: Full Research Report for the GMC*. (GMC, 2017)
2017	J.W. O'Brien, *et al*, 'A Survey of Doctors at a UK Teaching Hospital to Assess Understanding of Recent Changes to Consent Law.' (2017) 18 *Annals of Medicine and Surgery* 10-13
2017	A. D. Brun, *et al*, 'Factors that Influence Clinicians' Decisions to offer Intravenous Alteplase in Acute Ischemic Stroke Patients with Uncertain Treatment Indications: Results of a Discrete Choice Experiment.' (2017) *International Journal of Stroke* 1-9
2017	F. Wood, *et al*, 'Working with Interpreters: The Challenges of Introducing Option Grid Patients Decision Aids.' (2017) 100 *Patient Education and Counseling* 456-464
2018	Ipso MORI, *Attitudes towards Consent and Decision Making.* (GMC, 2018)
2018	F. Greenway, *et al*, 'Consent for Post-Operative Visual Loss in Prone Spinal Surgery: Aligning Clinical Practice with Legal Standards.' (2018) 32(6) *British Journal of Neurosurgery* 604-609
2018	C. McKinnon, *et al*, 'Surgical Consent Practice in the UK following the *Montgomery* Ruling: A national Cross-Sectional Questionnaire Study.' (2018) 55 *International Journal of Surgery* 66-72
2019	C. McIntyre & N. Tolley, 'A Critical Review of Thyroidectomy Consent in the UK.' (2019) 66 *International Journal to Surgery* 84-86
2019	S.R. Knight, *et al*, 'Patient Consent in the Post-*Montgomery* Era: A National Multi-Speciality Prospective Study.' (2019) 17(5) *The Surgeon* 277-283

Appendix 5: Post *Montgomery* Judgements

1. *Border v Lewisham and Greenwich NHS Trust* [2015] EWCA Civ 8
2. *FM v Ipswich Hospital NHS Trust* [2015] EWHC 775 (QB)
3. *A v East Kent Hospitals University NHS Trust* [2015] EWHC 1038 (QB)
4. *Spence v Hillingdon NHS Trust* [2015] EWHC 1058 (QB)
5. *Connolly v Croydon Health Service NHS Trust* [2015] EWHC 1339 (QB)
6. *Jones v Royal Wolverhampton Hospital NHS Trust* [2015] EWHC 2154 (QB)
7. *Barrett v Sandwell and West Birmingham Hospitals NHS Trust* [2015] EWHC 2627
8. *Shaw v Kovac* [2015] EWHC 3335(QB)
9. *Shaw v Kovac* [2017] EWCA Civ 1028 (CA)
10. *Tasmin v Barts NHS Trust* [2015] EWHC 3135 (QB)
11. *SXX v Liverpool Women's NHS Foundation Trust* [2015] EWHC 4072 (QB)
12. *SXX v Liverpool Women's NHS Foundation Trust* [2017] EWCA Civ 279 (CA)
13. *Grimstone v Epsom and St Helier University Hospital NHS Trust* [2015] EWHC 3756 (QB)
14. *Lunn v Kanagaratnam* [2016] EWHC 93 (QB)
15. *Georgiev v Kings College Hospital NHS Foundation Trust Appeal* [2016] EWHC 104 (QB)
16. *MC v Birmingham Women's NHS Foundation Trust* [2016] EWHC 1334
17. *KR v Lanarkshire Health Board* [2016] CSOH 133
18. *Britten v Tayside Health Board* [2016] 9 WLUK 500
19. *Crossman v St George's Healthcare NHS Trust* [2016] EWHC 2878 (QB)
20. *Worrall v Antoniadou* [2016] EWCA 1219 (COA)
21. *Holdsworth v Luton and Dunstable University Hospital NHS Trus*t [2016] EWHC 2878 (QB)
22. *Webster v Burton Hospitals NHS Foundation Trust* [2017] EWCA Civ 62 (COA)
23. *Malone v Greater Glasgow and Clyde Health Board* [2017] CSOH 31
24. *Thefaut v Johnston* [2017] EWHC 497 (QB)
25. *Correia v University Hospital of North Staffordshire NHS Trust* [2017] EWCA Civ 356 (COA)
26. *Diamond v Royal Devon and Exeter NHS Trust* [2017] EWHC 1495 (QB)
27. *Diamond v Royal Devon and Exeter NHS Trust* [2019] EWCA Civ 585 (CA)
28. *Gallardo v Imperial College Healthcare NHS Trust* [2017] EWHC 3147 (QB)
29. *Bayley v George Eliot Hospital NHS Trust* [2017] EWHC 3398 (QB)
30. *Cameron v Ipswich Hospital NHS Trust* [2018] EWHC 38 (QB)
31. *Hassell v Hillingdon Hospitals NHS Foundation Trust* [2018] EWHC 164 (QB)
32. *LT v NHS Lothian Health Board* [2018] CSOH 29
33. *AH v Greater Glasgow Health Board* [2018] CSOH 57

34. *Rajatheepan v Barking, Havering and Redbridge NHS Foundation Trust* [2018] EWHC 716 (QB)
35. *Duce v Worcestershire Acute Hospitals NHS Trust* [2018] EWHA Civ 1307 (COA)
36. *ML (A child proceeding by his Litigation Friend SL) v Guy's St Thomas' National Healthcare Foundation Trust* [2018] EWHC 2010 (QB)
37. *Clements v Imperial College NHS Trust* [2018] EWHC (QB)
38. *Keane v Tollafield* [2018] EWHC 2064
39. *Richardson v Newcastle upon Tyne Hospitals Foundation Trust* [2018] 12 WLUK 556
40. *Kennedy v Frankel* [2019] EWHC 106
41. *Keh v Homerton University Hospital NHS Foundation Trust* [2019] EWHC 548 (QB)
42. *Ollosson v Lee* [2019] EWHC 784 (QV)
43. *Mills v Oxford University Hospital NHS Foundation Trust* [2019] EWHC 936 (QB)
44. *Price v Cwm Taff University Health Board* [2019] EWHC 938 (QB)
45. *M v Royal Berkshire NHS Foundation Trust* [2019] EWHC 2591 (QB)
46. *Pepper v Royal Free London NHS Foundation Trust* [2020] EWHC 310 (QB).

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