UNIVERSITY OF SOUTHAMPTON

FACULTY OF MEDICINE

School of Primary Care and Population Sciences

The Development of Methods to Assess the Quality of Care in Pain Clinics in England and Wales

by

Dr Catherine Mary Price

Thesis for the degree of Doctor of Medicine (Alt)

[July 2019]

UNIVERSITY OF SOUTHAMPTON

ABSTRACT

FACULTY OF MEDICINE

Population Sciences

Thesis for the degree of MD (Alt)

THE DEVELOPMENT OF METHODS TO ASSESS THE QUALITY OF CARE IN PAIN CLINICS IN ENGLAND AND WALES

Dr Catherine Mary Price

Chronic pain has become a growing public health concern both with respect to its prevalence and unsatisfactory treatment. Of particular concern is the rising number of problems associated with long term opioids for chronic non cancer pain with the USA declaring this a Public Health emergency in 2017.It is essential that pain clinics provide leadership in this area. A recent systematic review of large scale surveys of pain clinics in seven countries described wide variation in standards of care.

Quality improvement in pain management services is also recognised as challenging. In the United Kingdom, several government reviews highlighted the paucity of data on specialist pain services. Evaluating outcomes in routine clinical practice is a significant challenge for specialist pain clinics due to the complexity of interventions provided and the subjective nature of pain.

This work consisted of two methods to measure quality of care. One through development of a patient registry that measured case mix and outcome. This was done twice: firstly, over a four year period in where classifications and outcome measures were developed through the voluntary participation of pain clinics. Secondly, over a further four year period through a National Audit where participation was expected. The other method audited standards of care set by the specialty in the National Audit, quality improvements were made and these were then re-audited.

Overall, the body of work contained in this thesis, which includes population data, content and outcomes of care, suggests that pain clinics are partially meeting the needs of the chronic pain population. All results must be treated with caution due to low recruitment rates from many clinics and low returns of the Patient Reported Outcome Measures (PROMs) in both time periods. The necessary integration with social care is unclear and, based on the limited data from the registries, only 31% of patients had had any form of psychological intervention by 6 months.

There was geographical variation in the provision of multidisciplinary clinics despite no evidence that patients differed in any way. There was evidence of complex patients being seen by the most basic of pain clinics which, in effect, represents a wasted resource. It is likely that there is a high level of unwarranted variation in the provision of services.

There are several methodical improvements that could be made. Firstly, there should be a consensus on datasets and treatment classification. Secondly, is to ensure sufficient patients complete questionnaires. Smaller datasets, slow growth, greater involvement of clinics combined with regular feedback and lengthier support have been suggested based upon others' work. Sustained funding is required to do this and so future work needs to demonstrate cost effectiveness and have wider societal impact e.g. opioid use or Emergency Department use.

Future audits might encompass primary care which would give a better idea of the end to end pathway. Measurement of the level of integration with mental health and social care might help better understand the type of service on offer as would a measure of case mix complexity.

Table of Contents

Table of Tables

Table of Figures

Academic Thesis: Declaration of Authorship

I, Dr Catherine Mary Price.....

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

“The Development of Methods to Assess the Quality of Care in Pain Clinics in England and Wales”

I confirm that:

This work was done wholly or mainly while in candidature for a research degree at this University;
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;
Where I have consulted the published work of others, this is always clearly attributed;
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;
I have acknowledged all main sources of help;
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;
Parts of this work have been published as:

- Griffiths, D.P.G., Mitchell Noon, J., Campbell, F.A. and Price, C.M., 2003. Clinical governance and chronic pain: towards a practical solution. *Anaesthesia*, *58*(3), pp.243-248.
- Hall, G.C., Bryant, T.N., Merrett, L.K. and Price, C., 2008. Validation of the quality of The National Pain Database for pain management services in the United Kingdom. Anaesthesia, 63(11), pp.1217-1221.
- Price, C., de C Williams, A.C., Smith, B.H. and Bottle, A., 2018. The National Pain Audit for specialist pain services in England and Wales 2010–2014. British Journal of Pain, 2019. 13(3); pp185-193.
- Price CM, Williams A C de C, Smith BH, Bottle A. Implementation of Patient Reported Outcomes from Specialist Pain clinics in England and Wales: experience from a nationwide study. European Journal of Pain. 2019: 23;(7);pp1368-1377

Signed: .....

Date: .....

ORCID : https://orcid.org/0000-0003-0111-9364

Acknowledgements

Firstly, I would like to thank Professor Paul Roderick who, as my MD mentor, has generously given me the benefit of his wisdom and experience to help me write this thesis. His support has been steadfast and encouraging at all times. He has also helped further my thinking in this area and helped me move onto new areas of development.

Thank you to Dr Amanda C de C Williams, of University College London, one of my co-authors, for her expertise and knowledge regarding patient and outcomes and her honesty in her feedback. This has helped me raise the standard of this thesis and papers enormously. Her input throughout the National Pain Audit guided it to a successful conclusion.

Thank you to Dr Alex Bottle, of Imperial College London, one of my co-authors and senior statistical advisor. His responsiveness and clear thinking has been invaluable and also helped ensure the National Pain Audit was a success.

Thank-you to Professor Blair Smith from the University of Dundee, who, entirely for altruistic reasons, reviewed the final two papers and has been a supportive and critical friend.

I am grateful to the patients and services who so willingly submitted the data I have used throughout the time that these databases were up and running.

Thanks go to all my co-authors on the four papers presented here: Dr Paul Griffiths, Dr Fiona Campbell, Dr Mitch Noon, Dr Gillian Hall and Laura Merrett.

A massive thankyou to Maggie West my neighbour and friend who bludgeoned me into doing this. Without her I would not have started upon this journey.

Finally, thanks to my family, especially my husband Mark Saville who has left me in peace to get on with writing and then did the proof reading.

My contribution

My contribution to this body of work is as follows:

I performed a baseline survey of all pain clinics in the UK to enquire what was being done about measuring patient outcomes – the lack of a structured approach led to the formation of the PACS database (Pain Audit Collection System).

I analysed all returns on the PACS database for 3 years running and then worked with a biostatistician, Dr Trevor Bryant, at the University of Southampton to internally validate the data.

I collaborated with Dr P Griffith and Dr F Campbell to agree the approach on analysing the data from PACS. Having reviewed the literature I recommended a series of options for acceptable classification of diagnoses. I also researched the optimal outcome measure to be used, recommending the Brief Pain Inventory (BPI). I researched its application to the England and Wales population with qualitative work and factor analysis on its validity under the supervision of Dr Amanda C de C Williams.

I was senior author on the first paper which included agreeing the content to the paper, reviewing drafts and providing information on activity and numbers.

I provided a structured approach to measurement and feedback with PAINDB (PACS version 2).

I obtained funding to work with an epidemiologist on the validation of the initial database Pain Database (PANIDB).

I provided the information on each of the centres and collaborated on the approach with Dr G Hall to externally validate PAINDB.

I obtained funding for a National Pain Audit on behalf of the British Pain Society.

I was clinical lead on the National Pain Audit project, drafting papers on proposed methods for review by the scientific committee. I was also first author on all of the audit reports.

I drafted all of the reports for the National Pain audit and worked with the data analysts and statistician, Dr A Bottle of Dr Foster Research, to review and agree an approach to data analysis.

I was first author on both Paper 3 and 4 which involved writing all of the drafts, analysing data, reviewing drafts and making amendments as needed.

Funding Declaration

- The design and support of software to collect pain clinic information (PACS) was funded by Pfizer through an unrestricted educational grant (formerly Pharmacia)
- The validation of PainDB was funded by a grant from the Liverpool Pain Relief Foundation
- The National Pain Audit was funded by the Health Quality Improvement Partnership

Chapter 1: **Introduction and background**

1.0 History of Pain Clinics

Pain Clinics were established just after the Second World War, mainly in the United States, largely because veterans were surviving, due to improved management of infection and anaesthesia, allowing more complex surgery to succeed. However, for many, they were left with a lot of pain and their quality of life was poor. New approaches to pain relief started with surgeons and anaesthetists doing procedures that interrupted the nervous system such as cordotomy or nerve blocks. Gradually the management of pain took over the practices of many of these professionals. John Bonica is generally credited with opening the first stand-alone pain clinic in the 1950's. Whilst he introduced the concept of multidisciplinary care his ideas did not gain general acceptance until the publication of Melzack and Wall's Gate Theory in 1965 (Melzack and Wall 1965).

Gate Theory provided a scientific basis for the interweaving of neurobiological and psychological approaches in the management of pain. Fordyce successfully introduced operant conditioning programmes for people with chronic pain in the early 1970's (Fordyce et al 1973). The delivery of services for chronic pain, however, remained challenging until George Engel introduced the biopsychosocial framework in the 1970's for long term health issues arguing that internal psychological processes and social determinants of health were equally as important in the management of a long term condition such as chronic pain as biological ones (Engel 1971).

The management of chronic cancer pain diverged from the management of non-cancer pain in the 1970's with the hospice movement and formation of palliative care services. Pain clinics largely emerged to treat long term non cancer pain and remained largely medically staffed by anaesthetists unlike palliative care services which were physician based. The International Association for the Study of Pain (IASP) was formed in 1974 to enmesh the scientific foundations of pain to biological, psychological and sociological approaches to pain. A biopsychosocial approach was recommended for people who were struggling with chronic pain.

The implementation of multidisciplinary pain care and a biopsychosocial approach has remained problematic with little attention paid to the structure and processes of care within pain clinics. In an attempt to address this, the International Association for the Study of Pain (IASP) classified pain facilities into four categories (IASP 2009). However, IASP did not make recommendations as to which patients should attend which facility. Definitions also vary widely as to what is meant by multidisciplinary care, who benefits from multidisciplinary care and how it is best delivered. The result of this is that there continues to be wide variation in the care of patients referred to pain clinics.

Pain clinics treat only a small proportion of people with chronic pain. To date, chronic pain represents a staggering public health burden with it being more common in the socio-economically deprived (Gupta et al 2013). Many pain patients report dissatisfaction with their treatment regimens and there may be inequalities in access. Additionally, many doctors feel inadequately trained to treat chronic pain (Vadivelu 2013). Strategies for addressing chronic pain from a public health perspective include increased education of physicians and the public and improved integration of pain management across disciplines along with better guidance on treatment regimens. Pain clinics should provide leadership on many of these aspects. However, the efficacy of pain clinics has been repeatedly called into question as outlined below raising questions as to whether they are able to perform this task.

The Effectiveness of Pain Clinics

Pain clinics have been heavily criticised in several government reports. The Audit Commission in 1997 raised concerns about the lack of specific guidance on the provision of pain clinics as well as clear funding streams (The Audit Commission 1997). The Commission recommended targets and standards in service contracts. The Clinical Standards Advisory Group (CSAG) report in 2000 highlighted the difficulties in assessing the quality of pain clinic services and also those treating pain in hospitals contrasting this with palliative care services (Clinical Standards Advisory Group 2000). Two key issues were waiting times and lack of multidisciplinary team members. The Group felt they were wandering in a data free zone with nothing on activity, costs, need or outcomes. A maximum waiting time of three months to a new appointment was recommended as well as improved information on need, costs and evidence. However, there were no attempts to benchmark pain services nor to look at whether attending a pain clinic leads to improved outcomes for patients.

Little action was taken to remedy the situation until 2008, with the Chief Medical Officer for England's report on chronic pain "Pain; Breaking through the Barrier" (Department of Health 2008). This highlighted the high prevalence of chronic pain throughout the life cycle and the individual, societal and health care costs due to the lack of a joined-up strategy to manage pain. The report estimated that 7.8 million people had chronic pain and prescription costs were £384 million a year. It drew attention to the impact of pain with 49% experiencing depression, 25% losing their jobs and 16% driven to suicidal thoughts by it . The report found that this situation was exacerbated by long waiting times and lack of a strategic approach to specialist chronic pain services. Some of the problems with trying to improve the situation were related to measurement of pain with little consensus as to what and how pain should be measured. This made ascertaining when care had improved the pain experience very difficult. Seven recommendations to improve services for people with chronic pain were made. These included rapid access to advice, model pathways of care agreed, better epidemiological information, better training of health care professionals and incentives to improve primary care. One recommendation, aimed to address problems with measurement and improvement of specialist pain clinics, was to ensure that all services contributed to a database for chronic pain. A National Audit was felt to be the best way of establishing this as Trusts are obliged to participate. How best to measure the effectiveness of pain clinics poses a real challenge. Pain Clinics are part of a wider system and the patients attending represent only a small proportion of people with chronic pain. Many patients access a wide variety of services and so attempting to ascribe improvement to a pain clinic may be a stretch. However, it is important to ensure that there is some measurement of effectiveness of what is an expensive and scarce resource. There was generally little guidance on what to measure in pain clinics in routine clinical practice.

For an audit to be effective it would need to address three areas - development of a sound dataset to measure quality of care provided, formation of a patient registry to describe the characteristics and outcomes of care and, finally, assessing whether the right people were referred to a service. All of these areas were fraught with difficulty as described below.

An application for a National Audit was made and the project ran for four years. Simultaneously, the Health Survey for England collected detailed data on people with chronic pain (Bridges 2011) – the first time this has been done in England and model pathways were established to guide best practice (Colvin and Rowbotham 2013). These have later been used as a starting point for NICE guidance on chronic pain.

Using the standards derived by the National Pain Audit the Faculty has developed quality standards for specialist pain services making it easier to assess services (Faculty of Pain Medicine

2015). Commissioning guidelines have also been produced for services by the Royal College of General Practitioners and the Faculty (Royal College of General Practitioners 2014). These actions have enabled specialist pain services to be put on a sounder footing.

1.1 My interest in this area

My interest in this came about as a result of being a research fellow from 1996 to 1999 tasked with establishing a research programme for Portsmouth pain services– at the time the largest service in Wessex. It became evident that outcomes for pain services were poorly defined and there was very little data available on the services and the quality of care provided by them. With a small group of like-minded clinicians we founded the Clinical Information Special Interest Group (CISIG) of the British Pain Society (BPS) and set out to provide better information on pain services.

The papers contained in my dissertation describe the journey that we took from piloting and validating a database for services to contribute to running a National Pain Audit for which I became clinical lead. This was a lengthy journey from 1997 to 2014, when the audit ended. The papers describe the methods used to set up a robust clinical database, its validation, transfer of knowledge from this into the National Pain Audit, outcomes and learning from the methods we adopted. The purpose of the dissertation is to reflect upon that journey and review this in the context of current knowledge in order to plan next steps.

1.2 Measurement of Quality of Care

There are many approaches that can be taken to measuring quality of health care. The Health Foundation states that Quality of Healthcare should be measured over six domains (Friebel 2017):

- Effectiveness
- Efficiency
- Equity
- Safety
- Timeliness
- Patient centredness

Quality Metrics should encompass all of these. Donabedian recommended that quality metrics should be grouped into three areas - structure, process and outcome (Donabedian 1965). Outcome measures can be difficult to assess as they can often lag behind improvement. NHS Improvement also recommends that if quality improvement programmes are implemented then a further area should be added - balancing measures (NHS Improvement). These look at the wider system impact or unintended consequences of change such as time off school if surgical policy is to increase the threshold for tonsillectomy. They recommend these are elicited by listening to patients and clinicians concerns about a change.

At the time of Paper 1 there was a focus on pain reduction with pain being the fifth vital sign (JCAHO 2003). However, as it became evident that this was problematic, further recommendations were made by the time of Papers 3 and 4. Some are for specialist care only, (de Meij et al 2018) others have proposed indicators across much of the health care system (Richardson et al 2018, Heath Quality Ontario 2019) with multiple differing indicators being used. However, there is no evidence that these have been put into practice as yet and have not been applied to England and Wales.

1.3 National Audits

The purpose of National Audits is to raise the standard of care through engagement of clinicians in reporting the quality of their care against agreed standards and comparing their service with others. Any National Audit should identify the need for improvement and highlight areas where this should occur (Health Quality Improvement Partnership (HQIP) 2014). Previous research has demonstrated that a national audit can have impact on protocols and clinical practice (Penny and Templeton 1995). The National Pain audit aimed to address deficiencies in care raised by the above reports, develop and measure clear standards of care for patients entering chronic pain services and a suite of Patient Reported Outcome Measures (PROMs), suitable for use in pain clinics. Outcomes from National Audits are published as reports available on the Health Quality Improvement Partnership website. However, not all audits then carry out deeper scrutiny of their methods and outcomes. As part of my thesis I wished to revisit the data from the reports, carry out a more rigorous analysis of the progress through the programme and perform an in depth analysis of the PROMs data.

1.4 My approach

I have included four publications which each individually answer a set of research questions. These are contained in the PICO's below (Table 1:1) . I then gathered these papers together into a single body of work to answer three broader questions as to how to assess the effectiveness of pain clinics.

The four publications covered:

- A description of the Development of the Pain Database collection system (PACS) which developed a minimal clinical dataset over a five year period for pain clinics to address clinical governance needs (Griffiths et al 2003 CP senior author). This described diagnostic and treatment classifications used as well as trialling a PROM – namely the Brief Pain Inventory (BPI) (Cleeland 1989)

- Validation of the items used in the Pain Database through notes comparison with data items (Hall 2008 CP senior author)

- Whether the methods used by the National Pain Audit improved the quality of care provided to people with chronic pain in pain clinics. The variation in care between pain clinics is described in terms of staffing and facilities available and also the case mix of the patients attending them. The re-audit data will be compared to the initial data for evidence of improvement (Price et al 2019). This represents a distillation of 3 reports for a National Pain Audit

- Whether patients attending had improved areas of their health as measured by the National Pain Audit (Price et al 2019)

Whilst the National Pain Audit had already been published as a series of four annual reports, these papers represent a distillation of the knowledge gained and publish, in a comprehensive way, outcomes from the audit.

Table 1:1 PICO's related to four papers:

	Paper 1	Paper 2	Paper 3	Paper 4
Population	Specialist Pain Services	Patients attending Specialist Pain Services from 2003-4 whose PROMs data was captured electronically	Specialist Pain Services	Patients attending Specialist Pain services over a one year period Excluding children less than 12 years old
Intervention	Establishment of a database to collect information on patients	Assessment of the number of data items accurately completed in the database against the written notes	Clear standards to assess the quality of Care set , followed by measures to improve care, followed by a re-assessment	Observational study of the patient journey
Comparator	Nil	Paper notes of all patients who attended pain clinic during the same period	Hospital Episode Statistics (HES) on Pain Clinics Other national surveys of pain clinic facilities (Fashler 2016)	Hospital Episode Statistics (HES) Data on Patients PROMs data from multicentre observational studies of pain clinics
Outcome (s)	Diagnostic Classification Treatment Classification Outcome Measures to be used	Number of completed items across service; identification of services able to complete good returns	Services described against IASP and Royal College of Anaesthetists (RCOA) standards and reported against the systematic review to allow comparison	Completed returns Case mix Outcomes of care Number of questionnaires returned Number of items correctly completed

1.4.1 Research Questions addressed

There were three key areas of uncertainty that were identified when planning the collection of information on the journey of patients through a pain clinic:

1. Measurement of standards of Care (quality assurance)

Measurement of standards of care includes determining what to measure, how best to assess standards of care and whether these lead to an improvement in quality of care.

At the outset there were no comprehensive set of standards to provide quality assurance for pain clinics in the UK. As described above,, IASP produced a classification of clinics (IASP 2009) and made recommendations on waiting times (IASP 2009). There were general recommendations as to waiting times and patient safety in NHS practice. In 2003 the Veterans Association in the USA chose six criteria for a good quality pain system (Kerns et al 2003). These were system outcomes with an emphasis on education, training and connectivity across boundaries. In 2013 the Institute for Clinical Systems Improvement (ICSI) in the USA has also made a series of recommendations to improve processes of care in pain clinics with 15 measurement recommendations (Hooten et al 2013). It is unclear whether these have ever been implemented. The Agency for Healthcare Research and Quality (AHRQ) recommended further methods for long term conditions where care may span several sectors for example, degree of integration between providers (AHRQ 2010). In the management of pain, qualitative work that explores the patient experience has also been recommended in understanding the benefits of treatments and choices that govern these (Barker 2015).

Little work has been done to survey pain clinics and assess the structure and processes of care within them. The German Pain Society led work to measure the structure and processes within pain clinics. They were able to classify pain facilities into five types that included non-specialist services where pain treatment formed a significant element of care. (Müller-Schwefe et al 2016).

In response to the VA standards of care and the Joint Committee on Accreditation of Health Care Facilities recommendations for standards of care in 2003 (Clarke 2003) the VA reported the findings of a quality improvement programme implemented across the system (Cleeland 2003). Services were assessed at two time points on four key variables: standards for pain assessment, a documented treatment plan, patient education and a reduction in pain levels. Three out of four key criteria showed significant improvement with only pain assessment failing to meet standards.

Since that time there has been little evidence of any attempt at quality improvement. Additionally the focus on the use of pain scores has been identified as one of the factors leading to the opioid epidemic in the USA (Baker 2017). Thus it was uncertain which measures should be used to provide quality assurance in pain clinics, what was feasible to collect and what quality improvement interventions were needed in the UK.

2. Patient Registries to assess the patient journey through a service

A number of attempts have been made to form patient registries. Guidance exists on how to form a registry (Glikrich et al 2014). However, as there are many differing types of patient registries a patient registry to monitor the journey through and outcomes of care from pain clinics would need to be fit for purpose. However, at the commencement of this work, and during much of it, very little attention had been paid as to how an effective patient registry might be formed to look at the journey patients made in terms of optimal methods of data collection together with a good understanding of what treatment they had received and whether they had benefited.

Measurement of the effectiveness of pain clinics is not straightforward. Dressler describes two main issues. Firstly, there is a lack of reliable and valid treatment algorithms for chronic pain, meaning that pain practitioners need to develop individualised management plans. Secondly,

that patients often have multimodal pain treatments such as medications, injections, rehabilitation and mental health care with a whole range of possible responses to these (Dressler 2019). Additionally, not all pain treatment facilities are the same.

The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) had published on which areas to measure to research the effectiveness of pain treatments (Dworkin 2005). However, until very recently, there has been little guidance on a minimum clinical dataset appropriate for everyday use in pain clinics.

A systematic review highlighted the importance of using validated Patient Reported Outcome Measures (PROMs) to measure patient care (Holmes 2017). This review highlighted the inadequacies of meta-analyses to assess PROMs as they were too heterogeneous in nature and so a form of meta-ethnography was used instead. The group found that whilst PROMs potentially had a role in managing patients in pain, their impact was limited. The importance of using validated measures that were fit for purpose was emphasised. A variety of PROMs were developed throughout this whole body of work and tested for implementation.

Since this body of work there have been more datasets produced confined largely to a single country (Richardson 2018, Tardiff 2017, Choiniere 2017, Mackay 2016). A systematic review highlighted the lack of consensus around measures used to assess multimodal pain therapy (Deckert 2016). Although considerable work has been done on suitable measures to deploy in routine clinical practice (Kaiser 2018) as yet, consensus only exists on the domains not the actual measures to be used.

3. Patient selection for referral to a service

Chronic pain patients tend to cross the whole health system in a variety of ways. Trying to understand and quantify the “pinball” journey that patients with chronic pain make has been undertaken in a variety of differing ways. Pain clinics have traditionally had long waiting lists which is in part related to funding but also uncertainty about who to refer and when to refer. This is partly as a result of the heterogeneous nature of the chronic pain population but also because of the lack of clarity as to who benefits the most from pain clinic treatments. As described by IASP, delivery can range from single treatments by a single handed practitioner to a range of multimodal treatments delivered by a comprehensive multi-disciplinary team.

In regards to the heterogeneous nature of populations, treatments and facilities, a survey in Germany of Health Service Research projects which looked at a number of differing types of clinical databases found that it was possible to describe the epidemiology, severity and treatment of chronic pain (Hauser 2015). They found over medicalisation of low back pain and generalised widespread pain in the databases that were used. However, data was extremely fragmented with no real linkage possible. Inconsistencies in coding chronic pain subtypes made longitudinal studies to map patient “careers” impossible. Health needs could not be identified from the datasets.

A similar situation exists in the United Kingdom. A review of five general practices’ data for fibromyalgia and low back pain found wide variation in prescribing, high numbers of referrals to secondary care for both newly diagnosed and established chronic pain patients with no consistency as to patterns of referral. The group also highlighted the lack of consistent coding for chronic pain, meaning that they needed to use prescriptions to identify chronic pain patients using a definition of three or more prescriptions (Hart 2015). The many differing types of pain services with differing populations treated and differing goals will have great potential for confusion. As examples, community pain management clinics were established after there was a concerted attempt to shift musculoskeletal services out of hospital in the early 2000’s. These have tended to focus more on self-management of pain and link with social support (Simm 2018). The formation of Independent Sector Treatment Centres (ISTC’s) in England, largely to provide

operative management of musculoskeletal disorders, has also lead to some of these centres providing largely interventional pain procedures. However, there is less of an onus on ISTC's to produce data on outcomes (Royal College of Surgeons 2019). These services may differ widely from multidisciplinary multimodal pain services, yet referrers are unlikely to be able to understand the nuances of the differing services.

Overwhelming social issues may be a feature of some patient presentations. However, services are often poorly equipped to deal with these, being predominantly medically and psychologically focussed. An ethnographic study from the USA of the experiences of care providers described how health care professionals found it exhausting trying to manage people with chronic pain (Webster 2019). This largely occurred when patients had significant social issues as well. The focus has also turned more recently to de-prescribing of opioids. The result was they felt overwhelmed and it lead to depersonalisation of care making de-prescribing even more challenging. As a result, without good guidance, patients may not get the care they need at the right time.

Guidance on when to refer throughout the time that this work was completed was sparse. Low back pain in 2009 (2009) although this was largely rejected by pain physicians. Neuropathic pain guidance for England and Wales (NICE 2013) and general pain guidance for Scotland (Scottish Intercollegiate Guidelines Network (SIGN) 2013) were published right towards the end of this time in 2013. Thus there was little to go on as to whether the right people were being referred to the right services. Given the complexities above this was felt to be highly unlikely.

My research questions for my thesis which covers the development and testing of performance and outcome measures suitable for use in specialist UK pain clinics were:

1. What are the optimal measures that will improve standards of care in pain clinics? This is largely covered by Paper 3.

2. Do we have the right approach to formation of a registry for people attending pain clinics? Papers 1, 2 and 4 cover this area as they describe the development of classification tools, outcome measures, validation and testing on a large scale over a fourteen year period.

3. Are the right people attending the right pain clinics at the right time? This largely looks ta case mix of patients attending pain clinics and is described in depth in Paper 4

To provide clarity on the questions asked in each paper I have constructed PICO's (Table 1:2). Although these are not randomised controlled trials it highlights the different questions being asked in each paper and describes the journey undertaken.

Table 1:2 PICO's for the 3 overarching research questions:

	Q1: Standards of Care	Q2 Patient Registry	Q3 Appropriateness of Referrals to pain clinics
Population	Specialist pain clinics	Patients attending specialist pain clinics	Patients attending specialist pain clinics
Intervention	Application of a suite of standards of care based upon best evidence	Formation of a patient registry Observational study to follow them up	Formation of a patient registry (two time points)
Comparator	Other quality improvement programmes	Other registries	General pain population
Outcomes	Improvement in the structures and processes of care within pain clinics	Pain scores, quality of life and patient experience	Case mix - diagnoses, disease severity , age, sex,

1.4.2 What was the motivation in wanting to answer the research questions?

As a pain clinician I was concerned that unless we were able to demonstrate the value of pain care we would always struggle to get funding to adequately treat patients. Equally it was clear that there was wide variation in the content of pain clinics meaning that patients would receive treatment based upon who they saw rather than what they should get. Several nations had surveyed their clinics using similar criteria. However, no other nation had the opportunity to try to improve pain services at scale, as was afforded by the influence of the English CMO. The Veterans Administration collaborative was perhaps the nearest to this (Cleeland 2003). This support enabled an opportunity for more rapid implementation and support than might otherwise have been the case. The strengths of this were its high profile, the level of research into optimal methods at every stage, a robust governance process and oversight of the project by the main body responsible for ensuring that national audits were of high quality. The co-production of standards, followed by an audit of them, worked well to develop standards further. Good information on specialist pain clinics was provided leading to a public facing website linked to NHS Choices that gave quality ratings to each service. However, the limitations were that it had to cover all pain clinics, rather than be a gradual approach meaning some may not have been ready to participate fully and there was no structure in place for sustainable funding after the grant ran out.

I therefore wished to understand more fully what we had learnt from development of measures and processes to assess the quality of pain clinics, compared with other attempts worldwide to do so. Ultimately I felt that the analysis and learning would support both pain services and registries, which provide oversight of the services, to be funded on a more sustainable basis.

1.4.3 Summary of thesis

This work presents a narrative of how an audit of pain clinics was developed from firstly agreeing a broad set of measures in a small group, refining and testing these, then building this into a national audit. No other nation has attempted to measure the clinical effectiveness of all of its pain clinics nor attempt to form a meaningful registry of pain clinics. The research element was in the development of data items that could meaningfully capture the organisational element of pain services and development of valid data items to measure patient outcome. Implementation of these items was then tested and there was clear learning from this.

Few national audits attempt to measure both organisational elements as well as outcomes of treatment. However, as pain is a highly subjective measure and there was significant difficulty in agreeing what could be usefully measured in pain clinics it was felt that this was an important component of the audit.

Chapter 2 describes the methods involved in all four papers and an overarching view of all of the methods.

Chapters 3 to 8 inclusive contain the four published articles which form the substantive research papers for the thesis. Sandwiched in between Papers 2 and 3 (Chapter 4) is a description of the National Pain Audit and its key findings. The content of each of the four articles is presented as published; however, the format is Microsoft word which differs to the published format. The articles presented in these substantive chapters are referred to throughout the thesis as ‘Paper 1’, ‘Paper 2’, etc. Briefly at the end there is a reflection on the body of work – whether it managed to

achieve its aims, whether it moved on the field of pain management, placing it into context and its limitations.

Chapter 8 reviews the original research questions and assesses whether this body of work answered the overarching research questions. Given this work took place over a long period of time it places the work in context with what was happening at the time as well as looking at what has been learnt since in order to make recommendations as to how to measure the effectiveness of pain care.

Chapter 2: **Methods**

2.1 Approach:

The whole process of developing a systematic way of forming a registry of specialist pain clinics, the structures and processes within, as well as outcomes from them required substantial development. Prior to this, the case mix and treatments within pain services were very poorly described. Outcomes measures to be used in pain research were agreed in 2005 by IASP (Dworkin et al 2005), but there was no international consensus on measures suitable for use at service level throughout the whole time that items were developed throughout the period of this research.

The approach taken was to form a registry of pain clinics seeing NHS patients in England and Wales, assess and benchmark their performance and follow a cohort of patients through the services over a period of a year. These services were also followed up three years later. In the interim there were several steps taken to drive quality improvement in pain clinics. The Department of Health in England commissioned a more detailed population survey of chronic pain patients (Bridges 2011). Best practice patient pathways were developed, widely disseminated and published by the British Pain Society (Colvin and Rowbotham 2013). A commissioning guide for pain services was published through the Royal College of General Practitioners (Royal College of General Practitioners (RCGP) 2014). Various meetings and summits throughout the United Kingdom were organised to raise awareness of these ventures. Draft best practice standards were also published by the Royal College of Anaesthestist's Faculty of Pain Medicine, which were finally published in 2015 (Faculty of Pain Medicine 2015). All of these efforts were linked and facilitated by the Chief Medical Officer for England's report in 2008 (Donaldson 2008). A report was published annually from the National Pain Audit group (Health Quality Improvement Partnership (HQIP) 2017) with a series of recommendations on staffing, content of clinic and measures to improve data quality.

2.2 Developing a Registry of Specialist Pain Clinics and their patients

The purpose of a registry is to establish detailed and standardised information across patients, settings and treatments to understand which factors lead to improved outcomes (Glicklich 2014). Specific outcomes are determined prior to establishing a registry. Standardised information was sought on the features of a pain clinic that were felt to be markers of quality, patients were registered and matched to each clinic. This changed over development of the database in response to validation of data items, national and international guidance and feedback from registry members.

2.2.1 Rationale for the Selection of pain clinics

Many treatment facilities call themselves pain clinics as relief from pain is one of the main aims of any healthcare intervention. However, many focus solely on either a medical model of pain reduction, provide one treatment, for example, chiropractic or acupuncture, or may fail to take into account psychological and social elements of a presentation. With this in mind IASP in 2009 classified pain treatment facilities into four levels (International Association for the Study of Pain 2009). The common factor was that all health care professionals should be trained in the biopsychosocial model

of care and able to weave these into treatment. Education of others should also be a key component of any specialist service. Ideally, this should be multidisciplinary as no single health care professional is likely to be able to fully meet the needs of patients who have complex medical, mental health and social needs. It was felt that even in developing countries much of this was feasible.

IASP describes four levels of treatment facility which are now the common currency for describing pain services:

- A multidisciplinary pain centre has a broad range of clinical staff, patient care services, pain conditions treated, and educational/research activities. It should be part of or affiliated with a higher education and/or research institution.
- A multidisciplinary pain clinic is very similar to a pain centre, but does not have the research and educational commitments of the above.
- A Pain Practice describes a single practitioner. They should be able to easily refer to others and able to recognise when a patient lies outside their expertise.
- Other - this is either a single treatment clinic, for example, a CBT clinic or pain injection facility

As this was a National Health Service audit only services that provided treatments funded by the NHS were included. Currently in England there is a plurality of providers, including ones that were not established as originally part of the NHS, may take NHS patients and be “for profit” enterprises. It was by no means clear that commissioners understood what good practice looked like when commissioning pain services. Therefore it was essential that all providers treating NHS patients were included. This does not apply to Welsh pain services who have a single NHS entity per health board.

Pain services were therefore selected on the grounds of fitting one of the IASP categories and treating NHS patients.

2.2.2 Rationale for selection of the patient population

The patient population attending pain clinics is hugely diverse. It was felt important to capture the full range of people attending pain clinics, as far as it was possible, to gain a better understanding of who exactly is attending pain clinics. It was agreed that all people attending pain clinics should be included in the audit with the exception of children less than twelve years old. This was because the PROMs questionnaire included validated questionnaires that are widely used in the pain population (the Euroqol 5D-3L and Brief Pain Inventory questionnaires). However, their use is not recommended under the age of 12.

2.2.3 Rationale for the selection of Diagnostic Categories

Pain Diagnoses are notoriously difficult to capture. Paper 1 concerned itself largely with addressing treatment classifications. Pain Medicine has only been in existence as a recognised subspecialty in the United Kingdom since 1996 and the Faculty of Pain Medicine was not formed until 2007. Thus classification systems have not been well adapted for use in pain services. At the time, IASP recommended an axial classification and thus diagnostic categories on Diagnosis and treatment were defined via categories of Bodily System, Aetiology, Location and Mechanism of pain. These were based upon the IASP classification of pain syndromes (Merskey and Bogduk 1994). However, feedback from clinicians was that this was not a useful way of describing patients, as the diagnoses could not be benchmarked against similar patient populations and use of four axes was time

consuming and confusing. It was agreed to use a set of terms that had currency throughout healthcare. Options included READ codes, SNOMED –CT and ICD-10. READ codes whilst very detailed are designed to capture the breadth of general practice. SNOMED-CT whilst a very logical data capture system scheduled to be introduced into the UK for many years is still not in widespread use. ICD-10 is the main diagnostic classification system used to describe secondary care patients' diagnoses. However, there are 600 + terms that could potentially be used. The codes also do not match the known epidemiology of chronic non -cancer pain (the main group seen in NHS specialist pain services), nor are the codes grouped in a systematic manner. ICD-10 is used largely for inpatient use, rather than outpatients, where the patients would be seen.
Despite the limitations of ICD-10 it was felt that this was the most useful classification system as clinicians were likely to be most familiar with it and it was the standard coding system in place for secondary care. Services were provided with drop down boxes and shortlists of the most frequently used diagnoses to make data entry easier. Eventually ICD-10 was causing so many difficulties in both the original pilot in 2003 and case mix capture in 2011-12 they also had the option of using free text.

2.2.4 Rationale for the selection of Treatment Categories

Finding an adequate treatment classification for pain clinics proved even more challenging than finding diagnostic categories. OPCS-4 codes are generally used to describe NHS specialist treatments in the UK. However, these are very procedurally based and as with ICD-10, are not grouped in a consistent manner failing to capture the breadth of pain service treatments (e.g. graded hierarchical exposure for the management of fear of movement - usually delivered by specialist physiotherapists). Although some treatments were highly specific to pain no good description exists.

A treatment classification was developed and described in Paper 1. This adopted many of the medical and psychological interventions, but also physical interventions. This classification was eventually taken up by the Department of Health when establishing a Chronic Pain Pathway that would allow rapid access to care and subsequently used for the much larger audit.

2.3 Principles of PROMS questionnaires

PROMs stands for Patient Reported Outcome Measures. They consist of a series of structured questions that are asked of patients in order to understand whether their health has improved as a result of healthcare. They do not measure the process or structure of care. PROMs were introduced routinely into the NHS in 2009 as it was recognised that there was little information on whether health actually improved as a result of an intervention. Prior to this point they were largely used for research purposes to assess the clinical effectiveness of various technologies. The King's Fund recommend four steps when introducing a PROM to measure outcome namely:

- Identify the potential instrument(s) for the setting and assess the evidence base to understanding strengths and limitations
- Pilot the PROM in order to understand how it performs from a perspective of design and statistical analysis
- Review as to acceptability, feasibility and cost effectiveness
- Implement with support and guidance (Devlin and Appleby 2010)

PROMs assume high importance in the assessment and management of chronic pain where the perception of change in health is very important. Outcomes are subjective and thus reliable and valid outcome measures have been developed to measure all aspects of chronic pain.

2.3.1 Development of the PROMs questionnaire for pain services

The initial attempts in 2002-4 were to find a common reliable and validated outcome measure that all clinicians and patients could agree on to capture patient outcomes. The Brief Pain Inventory (BPI) was chosen as the main outcome measure as it included both pain intensity and quality of life (Cleeland 1989). In 2002 it was only used for measurement of outcomes with regards to cancer pain. A qualitative study was therefore done on eighteen patients to investigate its suitability for use in the chronic non-cancer pain population in the UK. Exploratory Factor Analysis was also carried out on the questionnaire. This found that the two factor structure held for this population and that patients generally found the questionnaire relevant although the American phrase “relations” needed to be substituted by “relationships”. In 2004, the original research group confirmed that the questionnaire performed in a very similar way in chronic non –cancer pain compared to cancer pain. (Keller et al 2004). Importantly it is sensitive to change and so can be used to assess treatment effects. More recently it has been found that non-cancer pain patients tend to report greater psychological impact than physical impact when completing the questionnaire compared with cancer pain patients. The diagnoses also seem to impact more greatly (Holen et al 2008).

In the initial data collection with PACS other outcomes measured were adverse events and complications from treatment.

As research into PROMs developed it became evident that a wider measurement of patient experience was needed. Initial data analysis also found that the population attending pain clinics was younger than expected so measures of economic productivity ought to be included. Comparison with other conditions was also felt to be important. When it came to the PROMs data collection within the National Pain Audit the steering committee felt that the EQ5D -3L was the most useful generic measure and was also being used by the National PROMs project. It also has measures of pain, mood and function within it. It had previously been used in chronic pain. Obradovic later reported that the EQ5D, compared to the SF-6D, had greater construct validity and sensitivity to change (Obradovic 2013).

2.4 The Four Papers included

These four papers aimed to answer in a step by step way the following aspects of measuring the effectiveness of pain clinics as described in Chapter 2.

1. Is it possible to get pain clinics to collect information on the patients that they see into a pooled database?
2. How valid is the information from the database?
3. What is the impact of a Quality Improvement Programme on the structure and processes within pain clinics?

4. What can be learned from the implementation of PROMs across all pain clinics in England and Wales?

These papers were then pooled with the aim of answering the following questions:

1. What are the optimal measures that will improve standards of care in pain clinics?
2. Do we have the right approach to formation of a registry for people attending pain clinics?
3. Are the right people attending the right pain clinics at the right time?

Detailed information on methods for the four papers included in this thesis follows:

2.4.1 Paper 1 Initial Testing and Piloting of a Clinical Database (PACS) : "Clinical governance and chronic pain: towards a practical solution "

PACS was an initial attempt to form a Pain Clinic Patient Registry and named the Pain Audit Collection System (or PACS). The purpose of the database was to collect and analyse information on Case Mix and Outcome from specialist pain services. This was an Access based database.

The dataset was derived through the Clinical Information Special Interest Group (SIG) of the British Pain Society (BPS). The officers of the SIG researched potential data items with the author recommending diagnostic and outcome items and the Chairperson deriving a treatment classification as outlined above. The SIG then reviewed recommendations until a consensus was reached.

A software expert then wrote an Access based database to collect the information and designed the front end. This was then tested by the Chair of the SIG for ease of use and then the SIG members piloted it. When happy, this was released to any members of the British Pain Society for use. Support was provided by the software engineer and the SIG officers. A copy of the database was installed on hospital computers and patient data entered into it. Data entry took an average of 7 minutes per patient.

Initially 16 clinics participated and this rapidly grew to 75 clinics. A significant problem was encountered, however, in that Microsoft Access was not upgraded in a uniform way in each Trust. This meant that many clinics could not run upgraded software on their machine and also caused the database to be re-written each time there was no upgrade. A useful feature was that standard reports could be easily generated by clinics and data exported automatically as requested by the researchers for review.

Exported data was analysed using SPSS. This highlighted a large number of missing items and led to Paper 2 i.e. validation of the database. The database also participated in a national registry of all clinical databases (DOCDAT) co-ordinated by the London School of Hygiene and Tropical Medicine (Black and Payne 2003). This helped those working on the database to identify the need for validation of the database as well as to try to improve enrolment of patients and follow-up.

2.4.2 Paper 2 Validation of PACS (renamed PAINDB)

This took a cohort of 37 clinics who entered data in 2003-4 and validated the data by site visits to 30 of them. A random set of patients was generated from the database. For services with a large number of patients (>50 patients p.a.) 40 patient records were generated. This led to 1120 patient records and 2648 visits generated with 80 fields per patient assessed for quality. For those with less than 50 patients p.a. 20 patient records were generated. These records were then compared with paper notes. Ethics approval was needed for this and granted.

A researcher visited each site to compare data entry against entries in the paper notes. The on-site version of PACS was also compared for accuracy in case there were any issues with the export function or problems within the software function on site. Missing visits and missing items were recorded against both for every field. Finally the clinical lead for each service was interviewed to understand individual within clinic processes for recording data.

Key fields which should be recorded every time a new patient attends were selected and the number patients with no entries in these fields counted per clinic.

Data were analysed using Excel as no relationships were investigated.

At this juncture the software became impossible to upgrade and new methods were sought to gather information on pain clinics. The timely publication of the Chief Medical Officer's report enabled a successful application for a National Audit.

2.4.3 Paper 3: The National Pain Audit for Specialist Pain Services in England and Wales 2010-2014

Paper 3 describes the National Audit of pain clinics based in England and Wales. Clinical audit is a quality improvement cycle that involves measurement of the effectiveness of healthcare against agreed and proven standards for high quality, and taking action to bring practice in line with these standards so as to improve the quality of care and health outcomes (HQIP 2011). This was based upon National Audit methodology (HQIP 2016) and supervised by the Health Quality Improvement Partnership. A Donabedian to measure structure, process and outcome from clinics was chosen to measure both organisational aspects and outcomes from clinics. It was expected that a quality improvement programme would be implemented to address any issues found by the baseline audit. Standards were developed from IASP standards on the content of pain clinics and waiting times (IASP 2009). Further standards on safety and quality of patient data entry were also derived from NHS Information Standards and the NHS National Patient Safety Agency (Department of Health 2012). By this time, the Faculty of Pain Medicine had just been given statutory powers and had started to recommend standards of care in pain clinics. These standards and the audit went hand in hand so that a standard was proposed and the audit looked into the feasibility of measurement. By the end of the process it was possible to finalise standards that were then adopted by the Care Quality Commission (Faculty of Pain Medicine 2017).Thus pain clinics had become more visible and the quality of care was measurable.

Clinics were located through multiple methods as outlined in paper 3, as there is a no single way of identifying with confidence all clinics. These included identification of clinics using Hospital Episode Statistics (HES), adverts in specialist journals, searching of NHS Choices which contains information on all NHS providers.

Providers submitted data on the structure and processes of their services through a detailed Excel-based questionnaire containing 317 items. The best returns were when an audit department helped services to complete the forms. Three reports were issued describing the findings - these were combined into one paper to assess at the impact and learning from the organisational audit and quality improvement programme that went with it (Price et al 2019).

Data were analysed based upon a systematic review carried out in 2016 (Fashler 2016). This looked at the experiences of seven countries in surveying their pain clinics as to structure and content including the national audit data. The review recommended seven key areas to assess. For Paper 3, data that were not published from the original reports were used to conform to these recommendations. Additionally comparisons were made between information on pain clinics from HES at that time in terms of throughput and estimates of total throughput made.

2.4.4 Paper 4 Implementation of Patient Reported Outcomes from Specialist Pain clinics in England and Wales: experience from a nationwide study

Paper 4 describes the development of a patient registry of those patients attending pain clinics registered in Paper 3. Paper 4 builds upon the finding from Papers 1 and 2. This formed part of the National Pain Audit, as part of the brief was to develop an instrument to successfully measure patient outcomes in specialist pain clinics. This instrument was then implemented amongst pain clinics who had registered for the audit. This work drew heavily on the learning from the databases described in Paper 1 and 2 although, due to the constraints of the brief, the recommendations from Paper 2 to focus on a small number of clinics who were good data collectors, could not be fulfilled.

From the previous work, it was clear that a web based tool was better placed to register patients than installed software. Patients completed a paper questionnaire both initially and at follow up. Their journey was assessed over a year with follow up at six and twelve months. Collection of the initial questionnaire was done from the clinic and by postal survey thereafter. At that time it was not known how much time the average patient journey was through a clinic. In terms of validated questionnaire of patient outcomes the Brief Pain Inventory (BPI) was again selected with the addition of the EQ5D-3L. This was to enable benchmarking with other health conditions and the concurrent Health Survey for England based upon the whole population. Patient experience of the service was also captured as well as questions developed on work and healthcare resource use.

It was also intended to link this data to the HES outpatient datasets. Benchmarking between providers was also carried out using least squares estimates and standard formulae recommended by the Department of Health when doing this (Department of Health 2012.) The items for this were derived from the data and reviewed by the research group to come up with a final dataset for benchmarking. However, as described in the paper, benchmarking did not prove possible as the data were over dispersed.

Comparisons were made with other nations who had attempted PROMs audits.

2.4.5 Overarching Research Questions: Methods

To answer question one which asked “have we developed the right standards of care to assess pain clinics?” The findings from Paper 3 were compared with other similar quality improvement exercises in pain management (Kerns et al 2003, Richardson et al 2018). The ease and completeness of data

collection was reviewed. These outcomes were reviewed with the question “what makes and effective pain clinic?” in mind.

To answer whether we have the right approach to form a patient registry for people entering pain clinics, papers 1, 2 and 4 were reviewed and the outputs compared with other similar exercises on development and collection of PROMs data worldwide. This primarily has drawn on the experience of Scotland, Canada, Australia and the USA, all of whom have developed substantial programmes to compare and benchmark pain clinics (Richardson et al 2018, Choiniere et al 2010, Tardif et al 2017, Mackey 2016).The learning from these was discussed and recommendations made for future PROMs collection.

For the question “are the right people attending pain clinics?” the population data for those attending pain clinics were compared with the general population data from the Health Survey for England carried out at the same time. Additional literature on the topic since this work was carried out was also included (Hauser et al 2015, Richardson et al 2018).

Chapter 3: **Paper 1**

Clinical governance and chronic pain: towards a practical solution

D. P. G. Griffiths,1 J. Mitchell Noon,2 F. A. Campbell3 and C. M. Price4 Anaesthesia, 2003, 58, pages 243–248

1 Consultant in Pain Management and 2 Consultant in Health Psychology, Royal Cornwall Hospital Trust Truro,
Cornwall TR1 3LJ, UK
3 Consultant in Pain Management, Queens Medical Centre, Nottingham University NHS Trust, Nottingham
NG7 2UH, UK
4 Consultant in Pain Management, Southampton University Hospitals NHS Trust, Southampton, SO16 6YD, UK
Correspondence to: D. P. G. Griffiths
Accepted: 2 December 2002

3.0 **Overview**

The work this paper describes aimed to establish some parameters to measure the work done in pain clinics. This was following some severe criticism of the lack of evidence that anything pain clinic were doing made a difference. As described in Chapter 2, a Special Interest Group (SIG) of the British Pain Society (the Clinical Information SIG) was established to develop classification systems and methods of data collection in order to achieve this. The SIG explored ways to diagnose differing pain syndromes, how best to group treatments and to establish a patient registry that could measure outcomes. This was done through sending out some data collection software with a software engineer to support installation. Data analysis was done by the SIG (largely by the author) and the focus was on enrolling as many sites as possible to get services interested in the collection of data and measurement of outcomes. The SIG worked on this from 1998 to 2005 cumulating in the publication of this paper. The aim of this paper was to describe the development of appropriate data items and findings from participating centres.
Elsewhere, the Veterans Administration (VA) and the Institute for Healthcare Improvement (IHI) in the USA developed a collaborative to improve their system of pain management for Veterans and their families (Cleeland 2003). The collaborative identified multiple barriers to good pain management – patient factors related to reporting of pain, the low prioritisation of the healthcare system given to pain management and poorly trained healthcare professionals. One of the key aims of the collaborative was to ensure adequate monitoring of pain management. This relied on the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards describing pain as the "5th vital sign" and consensus on a set of four standards of care. This was a whole system attempt rather than focussing on specialist providers as was the case with PACS.
At the time there was little agreement on how to classify pain and no agreement on assessment of outcomes. IASP had recommended an axial approach to classification of pain syndromes (Merskey

and Bogduk 1994). However, there were no recommendations as to the standards expected of healthcare facilities. Whilst there was a recognition that the biopsychosocial approach was important, no recommendations had been made as to what to measure and how to measure. A full list of the Dataset is provided in Appendix 1

3.1 Summary

There have been many studies into the effectiveness of single interventions in pain, however, little is known of performance or outcome of pain clinics where treatment often consists of multiple, complex interventions. Many pain clinicians currently experience considerable difficulty in fulfilling the requirements of clinical governance and completing a personal portfolio. There is a clear and urgent need for a viable method of monitoring performance. This study describes a well-developed computer-based system – Pain Audit Collection System (PACS). PACS has been designed by pain clinicians through consensus and its success in uptake suggests that it is a viable method for outcome evaluation. An analysis is provided of outcome data in typical pain clinics. Further work is needed to investigate the utility of this data.

Keywords Pain; chronic, outcomes, audit. Clinical governance. Database; computer.

Chronic pain services address the health concerns of a group of patients whose needs are not met elsewhere in the health service, i.e. pain that has not been relieved by disease-focused treatment. However, many services are poorly resourced and practitioners can be isolated. Little is known about activity levels of pain services or about their performance. There have been some studies of disease severity of patients attending pain clinics (Davies et al 1996, Crook et al 1989) but the information available is limited. Many pain clinic treatments have been evaluated, although not as they are delivered – in the form of multiple interventions. Previous audit has been performed but was of limited scope and duration (McQuay et al 1997). Reports by pain clinicians (Charlton 2002) and both the Audit Commission (Audit Commission 1997) and the Clinical Standards Advisory Group (CSAG 2000) have called for better assessment practices; clinical governance also demands this. Clinical governance is meant to be at the heart of continuous quality improvement within the health service. To facilitate clinical governance at the individual team level, all teams need information on how well they are performing. This should include information on general activity, outcomes and benchmarking (McSherry et al 2002). The Performance Assessment Framework (PAF) is meant to form the cornerstone of clinical governance but is heavily dependent on general hospital databases. However, general hospital systems are inadequate for measuring outcomes; this requires a high-quality clinical database (Rowan and Black 2000).

A recent survey of members of the Pain Society found that only 50% of respondents were able to produce information on outcome from treatment, and only 52% of respondents were confident that they could produce accurate data for clinical governance purposes. These results suggest that many pain clinicians currently experience considerable difficulty in fulfilling the requirements of clinical governance and completing a personal portfolio. There is, therefore, a clear and urgent need for a viable way of doing this.

This study describes a high-quality clinical database that has been designed specifically to meet the needs of pain clinicians in implementing clinical governance and to describe better what pain clinics do. It provides an analysis of results of data from all centres participating. We would argue that, without such a system, the clinical governance concept cannot succeed.

3.2 Methods

3.2.1 Database design

The Pain Audit Collection System (PACS) was designed for the Clinical Information Special Interest Group of the Pain Society. The database is written in Microsoft ACCESS using experience gained from previous pain clinic databases. In order to encourage uptake, the database is distributed free of charge. There are four main areas of data collection –demographic details, pain diagnosis, including pain and quality of life measures, treatment and outcome, including complications.
Diagnosis and treatment information are completed in tick-box form. The remaining information is collected from a single brief patient questionnaire (the Brief Pain Inventory). For experienced users, data entry takes < 5 min for a new patient and < 2 min for follow-up patients. An essential feature of any data collection system is data analysis and feedback. At the local level, the system provides a number of standard reports that allow the clinician to generate summary data in a simple readable format. There is also a data export facility within the database which permits multicentre downloads to be collected and analysed on a yearly basis. Collection of data conforms to the Data Protection Act (1998).
Individual clinician activity, including diagnosis, treatment, complications and outcome, can automatically be transferred to a personal portfolio report. The reports generated by the database provide graphical and / or numerical summaries of changes in outcome measures of pain, function and mood between baseline and discharge. These can also be sent to referrers as part of the discharge summary.

3.2.2 Pain diagnosis

Diagnosis and treatment is defined via categories of Bodily System, Aetiology, Location and Mechanism of pain (Table 1). These are based upon the IASP classification of pain syndromes (Merskey and Bogduk 1994) and that suggested by Woolf (Woolf et al 1998). Read coded terms (NHSIA 1998) are grouped into larger groups of pain syndromes (Table 2). These then map to ICD 10 and OPCS (WHO 1992, NHSIA 1996).

It is vital that the measures used should be multidimensional, easy for patients to understand and complete, easy to score and sensitive to change. The measurement scale found to approximate most closely to these requirements is the Brief Pain Inventory (BPI) (Cleeland 1989), an 11-item numerical rating scale. It is widely described in cancer pain although less so in the general chronic pain population (Radbruch et al 1999). The BPI score is used to determine pain severity and pain interference with physical and psychosocial functioning on initial assessment and subsequent attendances. An interference score > 7 is classified as severe (Serlin et al 995).

3:1 Table of Axial Diagnoses using IASP Diagnostic classification

Bodily system	Aetiology	Location	Pain type
Musculoskeletal	No definite cause	Head, face, mouth	Neuropathic
Alimentary	Trauma	Neck	Nociceptive
Cardiovascular	Surgery	Thorax	Mixed

Endocrine	Infective	Abdomen	Other
Haematological	Inflammatory	Pelvis	
Autoimmune		Low back, spine	
Nervous	Ischaemic	Anal, perineal, genital	
Respiratory	Degenerative	Shoulder, arm, hand	
Skin	Tumour	Buttock, leg, foot	
Urogenital	Mixed	Back and leg	
Reproductive	Metabolic	Multiple sites	
Multiple	Other		

3:2 Table 2 Diagnostic groups used to classify patients

1. Musculoskeletal
    - 1.1 Low back pain
    - 1.2 Neck pain
    - 1.3 Shoulder pain
    - 1.4 Other
2. Neuropathic
    - 2.1 Phantom limb pain
    - 2.2 CRPS
    - 2.3 PHN
    - 2.4 Other
3. Facial / headache
4. Medical disease
5. Visceral
6. Urogenital
7. Cancers
8. Total body pain
9. Other

3.2.3 Treatments

Treatment terms are grouped as shown in Table 3. All categories can be analysed separately.

3.2.4 Outcomes

The definition of successful outcomes in pain management is multifaceted, which avoids the simplistic assumption that success depends solely on a reduced sensory pain score. Outcome measures were defined in terms of number achieving 100% pain relief, 30% pain relief (Farrar 2001) numbers discharged (Audit Commission 2000) and mild pain. Mean pain intensity and pain interference at end of treatment were also calculated. Complications from treatments were classified using categories none, minor and major. Adverse drug reactions are also recorded. A comparison of 2001 data from the first to subsequent visits and eventual discharge was made to determine the outcome of the treatment.

3:3Table 3 Treatment categories.

1. Manual treatments
1.1. Physiotherapy
1.2. Reflexology
2. Complementary therapy
3. Neuromodulation
3.1. TENS
3.2. Spinal cord stimulation
4. Injection therapy
4.1. Local anaesthetic ± steroid
4.1.1. Single block
4.1.2. Infusion
4.2. Neurolytic
4.2.1. Alcohol / phenol
4.2.2. Radiofrequency
4.2.3. Cryotherapy
4.3. Autonomic
4.3.1. Local anaesthetic
4.3.2. Phenol
4.4. Implantable drug delivery systems
5. Medication
5.1. NSAIDS
5.2. Paracetamol
5.3. Opioids
5.3.1. Weak
5.3.2. Strong
5.4. Antidepressants
5.5. Anticonvulsants
5.6. Other
5.7. Topical
5.8. Benzodiazepines
6. Psychology
6.1. Pain management programme
6.2. Individual psychology

3.3 Results

Forty-eight centres participated in the downloading of data. Year 2000 information was available from 43 of 48 pain clinics that submitted data in January 2001. Diagnosis was available for 8387 patients, and 7605 had BPI assessment data. There were 10 412 treatment episodes and 1589 discharges.

Table 4 shows the characteristics of patients attending pain clinics (age, sex, duration of pain, pain severity ratings). There were more women than men, the majority were middle-aged and had severe pain impacting heavily on their lives. The majority of patients attending pain clinics had low back pain (Table 5) although there was some variation between centres. Musculoskeletal pain accounted for the vast majority of pain clinic work. There was a relative minority of patients with neuropathic pain, although this group of patients represent a significant clinical load. Cancer pain was relatively uncommon. Although treatments centred mainly on the traditional _drug and block approach for many pain clinics, there was considerable variation in treatments provided (Table 6).

3:4Table 4 Descriptive clinic statistics.

New patients seen	10 574
Total consultations	25 664
DNA	1259
Mean age (range) 49 (2–95)	
Male: female 2:3	
Duration of symptoms (%)	
< 6 months 761 (7)	
6–12 months 954 (9)	
13–24 months 1166 (11)	
> 24 months 5279 (54)	
Not recorded 1906 (18)	
Average Pain Total [Pmax +Paverage] (range) 14 (12.5–15) Maximum = 20	
Average Pain Interference Total Score (range) 47 (31–53) Maximum = 70	

3:5Table 5 Distribution of diagnostic groups.

Patient Percentage Diagnosis numbers of total (range)
1. Musculoskeletal 6058 74 (33–91)
1.1. Low back pain 3843 63 (5–73)
1.2. Neck pain 783 12 (4–22)
1.3. Shoulder pain 203 5 (4–33)
1.4. Other 1238 20 (4–33)
2. Neuropathic 1361 16 (4–41)
2.1. Phantom limb pain 34 2.50
2.2. CRPS 26 1.91
2.3. PHN 49 3.60
2.4. Other 1252 91.99
3. Facial / headache 211 2.6 (0–12)

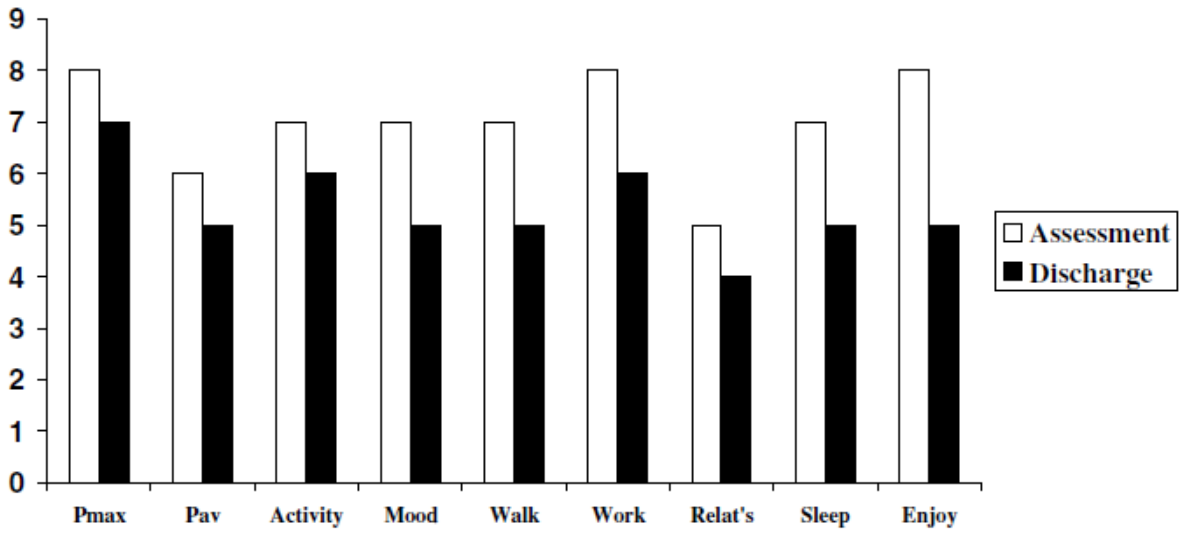
4. Medical disease 119 1.5 (0–4)
5. Visceral 178 2.2 (0–6)
6. Urogenital 93 1.1 (0–8)
7. Cancers 85 1.0 (0–8)
8. Total body pain 95 1.1 (0–5)
9. Other 10 0.12

3:6 Table 6 Treatments given and variation between centres.

Treatment	Total % (range codes treatments between centres)
1. Manual	483 4 (0–17)
2. Complementary	1784 14 (0–17)
3. Neuromodulation	2042 15 (0–41)
4. Injections	5587 42 (0–100)
5. Drugs	2774 21 (0–83)
6. Psychology	516 4 (0–50)

Injection therapy use varied from 0 to 100%. Some centres reported no drug prescribing, which may well reflect lack of data entry. In others, it accounted for almost all the treatments. Psychological treatments generally accounted for a small number of pain treatments, although some centres reported a far higher frequency.

Figure 3.1 Outcome of Care



Outcome is shown in Fig. 1 and Table 7. In Fig. 1 it can be seen that there was a general reduction in all interference and pain scores. Table 7 shows that 60% of discharged patients achieved 30% pain relief. However, the number achieving a 30% change in pain intensity and pain interference was far less, 31 and 39%, respectively, and only 3% achieved 100% pain relief at discharge. Discharge rates

were on average 10% although the rate varied widely across pain centres. Injection complication rates are reported as low with 45 minor and 7 major incidents (4 dural taps and 1 each of: trigger point bowel puncture, bizarre neurological sequelae and severe hypo-tension with phentolamine). Drug complication rates were high for the anticonvulsants with carbamazepine having the highest number of unpleasant side effects (Table 8) although mexiletine had the highest _drop-out rate.

3:7 ***Table 7 Outcome measures.***

Table 7 Outcome measures.

Outcomes	
Number discharged/end of planned treatment	$N = 1589$ (10%)
Average pain relief	39%
Achieved at least 30% pain relief	60%
Achieved 100% pain relief	3%
% achieving mild pain	24%
Improvement in BPI scores by at least 1 SD	30%
Pain intensity:	
Baseline vs. outcome (mean, range, [SD])	Baseline: 14, 0–20, [3.8] Outcome: 11, 0–20, [5]
Pain Interference (mean, range [SD])	Baseline: 47, 8–70, [18] Outcome: 34, 0–70, [19]

3:8Table 8 Drug complications

Table 8 Drug complications.

Drug	Number of complications (%)	Total prescribed	Percentage of total
NSAIDs	0 (0)	281	10.1
Weak opiods	5 (1)	380	13.6
Strong opioids	3 (2)	176	6.3
Antidepressants	40 (4)	1036	37.5
Anticonvulsants	42 (7)	592	21.3
Benzodiazepines	0 (0)	3	0.1
Topical agents	2 (1)	164	6.0
Local anaesthetics	0 (0)	4	0.1
Other	0 (0)	137	5.0
Total	92 (3)	2773	100

3.4 Discussion

Although few specialities have achieved consensus on how to measure performance, the PACS database has been developed after consultation with many pain clinicians and represents a consensus viewpoint. PACS also allows clinicians quickly and easily to obtain the necessary data for their personal portfolio. There is concern, however, about the difficulty in getting good quality data entry. Even those who are committed to the collection of data struggle to do so and this has serious implications for the evaluation of performance as requested by the Department of Health (2000).
The above analysis shows that there is a generally similar case-mix across the UK. Musculoskeletal pain is well recognised as difficult to treat (Woolf 2001) and it is not surprising that many people require help from secondary care pain clinics. Treatment variation is in line with previous studies. The reasons for this variability are not clear, but may reflect a variety of factors such as availability of treatments and both clinician and patient beliefs (Rubenfeld 2001).
The majority of patients on first attendance are at the higher end of the pain and interference scales, which represents a severe impact on several aspects of their lives. Most show an improvement by discharge, although there is notable variability in subjective estimates of relief. Interference with quality of life is more severe than that reported for cancer pain. The database has recently incorporated two further dimensions (pain–now and pain–least) to more fully describe pain intensity.

The overall results demonstrate evidence of a positive effect on pain by visit to a pain clinic. The discrepancy between pain relief and overall change in pain intensity may be explained by several treatments being of temporary benefit. In addition, complete sensory pain relief is hardly ever achieved by attendance at a chronic pain clinic so the other interference items are important to measure as they represent dimensions of an individual's overall pain experience. Several methods of calculating meaningful change in pain treatments have been suggested (Farrar 2001, Turk 2000). The question of what constitutes a significant reduction in pain and disability scores remains to be established, and other measures, such as reductions in other treatments, fewer consultations, return to work and increases in other activities may also be relevant (Oxford 2003). It is also apparent that the BPI, as an outcome measure, is easily completed by patients, simple for clinicians to enter into the database and is sensitive to clinically relevant changes within the pain clinic population. There may be limitations in the measure, when using it on such a large sample on a continual basis, but nevertheless, its very versatility and ease of analysis make it useful. Validation of the BPI in the population under investigation is essential.
Although some pain clinics do achieve high discharge rates, the majority do not. This has implications for waiting lists and government targets – without discharge no new patients can be accommodated. However, the low discharge rate may be understandable in view of clinicians' reluctance to discharge patients who either have not obtained long-term significant benefit in pain and symptom control, or who may have achieved short-term relief, but require further management in the future. Clinicians' criteria for discharge are likely to be subjective and the possibility of objective discharge guidelines perhaps requires further consideration (Audit Commission 1997).

The information provided by the PACS system has a variety of potential uses. Outcomes defined from a national sample, provide a much firmer basis for establishing clinical standards and guidelines. By contributing to the PACS database, clinicians can compare their data and results with their colleagues in other centres. The utility of the data collected, however, is unknown in terms of outcome prediction. PACS represents a process of continuing evaluation of diagnoses, treatments and outcomes with ongoing feedback that monitors the efficacy of pain clinic techniques. This is at the very heart of the clinical governance agenda. However, for clinical governance to flourish there needs to be considerable investment in time and effort. This requires not only the efforts of pain

clinicians, but also a commitment to adequate support from the Department of Health and professional bodies. We hope that this will be forthcoming.

3.5 Acknowledgements

We are grateful to Pharmacia UK for an unrestricted educational grant, which has allowed the development and free distribution of the PACS database and support to the clinical information SIG of the Pain Society. We also acknowledge the considerable development work on the PACS database undertaken by Mr Terry Devine, our technical expert.

3.6 References

Charlton JE. Two for the price of one – is it worth it? Anaesthesia 2002; 57: 1–3.

Cleeland CS. Measurement of pain by subjective report. In: Chapman CR, Loeser JD, eds. Advances in Pain Research and Therapy, Vol. 12: Issues in Pain Measurement. New York: Raven Press, 1989: 391–403.

Clinical Standards Advisory Group. Services for Patients with Pain. 2000.

Crook J, Weir R, Tunks E. An epidemiological follow-up survey of persistent pain sufferers in group family practice and specialty pain clinic. Pain 1989; 36: 49–61.

Davies HTO, Crombie IK, Macrae WA, Rogers KM, Charlton JE. Audit in pain clinics. Changing the management of low back and nerve damage pain. Anaesthesia 1996; 51: 641–6.

Department of Health. Appraisal for consultants working within the NHS. Annexe to circular AL (MD) 5 / 2001.

Farrar JT, Young JP Jr, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 2001; 94: 149–58.
London: Department of Health, 2000.

McQuay HJ, Moore RA, Eccleston C et al. Systematic review of outpatient services for chronic patient control. Health Technology Assessment 1997; 1.

McSherry R, Pearce P, Blackwell P. Clinical governance: a guide to implementation for healthcare professionals. Science 2002.

Merskey H, Bogduk N, eds. Classification of Chronic Pain: Descriptions of Chronic Pain Syndromes and Definitions of Pain Terms, 2nd edn Seattle, WA: IASP Press, 1994.

NHS Information Authority. Office of Population, Censuses and Surveys – Classification of Surgical Operations and Procedures, 4th revision (OPCS-4). http://www.coding.nhsia.nhs.uk/ clin_class/opcs_4asp.

Oxford Pain Internet site. www.jr2.ox.ac.uk/bandolier/ booth/painpag / index.html.

Radbruch L, Loick G, Kiencke P et al. Validation of the German version of the Brief Pain Inventory. Journal of Pain and Symptom Control, 1999; 18: 180–7.

Read terms. http://www.nhsia.nhs.uk/terms.

Rowan K, Black N. A bottom up approach to performance indicators through clinician networks. Healthcare UK 42–6. King's Fund 2000

Rubenfeld GD. Understanding why we agree on the evidence but disagree on the medicine. Respiratory Care 2001; 46: 1442–9.

Serlin RC, Mendoza TR, Nakamura Y, Edwards KR, Cleeland CS. When is cancer pain mild moderate or severe? Grading pain severity by its interference with function. Pain 1995; 61: 277–84.

The Audit Commission. Hospital Services. Anaesthesia under Examination. The Efficiency and Effectiveness of Anaesthesia and Pain Relief Services in England and Wales National Report. London: HMSO, 1997

Turk DC. Statistical significance and clinical significance are not synonyms. Clinical Journal of Pain 2000; 16: 185–7.

Woolf AD, Akesson K. Understanding the burden of musculoskeletal conditions. British Medical Journal 2001; 322: 1079–80.

Woolf CJ, Bennett GJ, Doherty M et al. Towards a mechanism-based classification of pain? Pain, 1998; 77: 227–9.

World Health Organization. The Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems. Geneva: World Health Organization, 1992.

3.7 Reflection

Paper 1 was able to establish some classifications that clinicians were happy with. The treatment classification worked well. However, when it came to data analysis the IASP diagnostic system did not work well - an axial approach with multiple differing ways of grouping patients allowed too many variations and did not describe easily the patients that were being seen. In terms of patient outcomes the BPI, prior to this, had been used only for cancer pain. The BPI's validity was established just prior to its use in PACS for non-cancer pain backed up by qualitative work from the PACS team. However, there was wide variation in recruitment rates and follow-up data was sparse. Whilst this represented a reasonable attempt to set up a patient registry, for all of the reasons listed, it was not possible to say, with confidence, that this was a high quality patient registry.

Unfortunately the software used become gradually less compatible with NHS hardware. The users grew to 75 centres by the end of this period. However, data collection was poor with some centres able to complete most fields and others barely entering data.

Towards the end of this body of work, PACS joined DocDat, a repository of clinical databases run by the London School of Hygiene and Tropical Medicine (Black and Payne 2003). This highlighted the need for input from a statistician and an epidemiologist to ensure the database was of good quality.

This led to support from the University of Southampton biostatistics department and an independent epidemiologist. By the end of this period there were no further registries/databases in operation that assessed outcomes from pain clinics. Treatment classifications were not established. This is perhaps due to the multidisciplinary nature of pain management.

In 2005 IMMPACT was established - this reviewed and agreed a core set of domains and potential PROMs to use in assessing outcomes from pain research and enabled greater consensus in what should be measured from a PROMs perspective. (Dworkin et al 2005).

3.8 Declaration of Authorship for Paper 1

Paul Griffiths : Responsible for study design, choice of methodology, implementation of software; Drafted all versions of the manuscript; Held overall responsibility for manuscript submission and all associated administration

Fiona Campbell : contributed to design of database and items therein. Reviewed methodological design Reviewed drafts of the manuscript

Mitchell Noon : Reviewed drafts of the manuscript, contributed to design of database

Cathy Price: I performed data analysis, developed classification systems, tested outcome measures, agreed and reviewed study design, contributed to literature review and reviewed drafts of the manuscript

All co-authors below confirm the accuracy of the declaration of authorship for paper 4:

Signature **Date**

Paul Griffiths

Fiona Campbell March 18, 2019

Mitchell Noon unable to locate

Chapter 4: **Paper 2**

Validation of the quality of The National Pain Database for pain management services in the United Kingdom

Hall G.C.,[1] Bryant T.N., [2] Merrett L.K.[3] and C. Price [3] Anaesthesia 2008: 63: 11: 1365-2044

1 Consultant, Grimsdyke House, London, UK

2 Director of Information & Computing, School of Medicine, University of Southampton, UK

3 Research Assistant, Pain Clinic, Royal South Hants Hospital, Southampton, UK

4 Consultant in Pain Management, Pain Clinic, Southampton, UK

4.1 Overview

The initial paper focussed on data collection. However, it was evident that there were errors and omissions in the data returns. Validation checks are critical for any clinical database. Both internal and external validity checks are recommended (Gliklich et al 2014). Internal validity checks include Examples of validation include:

- *Piloting and refining data collection methods and dataset change*
- *Building in validation processes at the point of data entry (restricting the responses possible)*
- *Validation by clinical teams (checking of data sent)*
- *Data cleaning*
- *Statistical analyses of data quality (e.g. missing data)*
- *Validation of statistical models and algorithms*
- *Quality assurance and unit testing of analytical code (HQIP 2018)*

Internal validity checks were carried out on the data from the 37 clinics who submitted data in 2003 by the University of Southampton department of biostatistics using Statistics for the Social Sciences (SPSS) computer packages. External validation checks can be done with reference to external sources of information contained in large administrative databases, for example, Hospital Episode Statistics. However, at the time, coding of pain clinic activity was mixed in with anaesthesia activity and thus these types of checks were not feasible. External validation was therefore carried out by visiting as many data collection centres/ as would participate. We aimed to establish how many of the centres were entering good quality data and how useable the whole set of data was in being able to answer the questions about clinic activity and outcomes.

4.2 Summary

Data on specialist pain management is scarce. We evaluated PainDB, a database which aggregates this information from UK pain clinics. PainDB entries for 1120 patients (2648 consultations) were compared to records at 30 pain clinics. Staff were surveyed about normal practice at 28 sites. First consultations (17, 135) on the aggregated PainDB were analysed for 2003 for omissions. Those consultations included on PainDB (54.6%) showed good concurrence with written notes (88.1%), with no pattern for the missing visits. Questionnaire responses were often absent from notes (56%) and diagnosis was most frequently omitted from PainDB (12.4–18.4%). Clinic staff overestimated completeness. Despite commitment, PainDB is currently unsuitable for research or audit. As routine hospital data should provide information on activity, specific questions on severity and outcome could be answered by short-term recording of predefined variables.

4.3 Introduction

As electronic storage of clinical information becomes increasingly common, the resultant databases are used for an ever growing range of clinical and research activities. Although good quality data allows audit in clinical governance as well as research, resource management and decision making in clinical management (Black 2003), previous investigations have shown that unvalidated clinical data sets can be incomplete and unreliable (Fine et al 2003). Thus it is essential to carry out a robust validation of any clinical database prior to use.

Pain management clinics are multidisciplinary in nature with a variety of care pathways options. There is a paucity of data on case mix, activity, treatments and outcomes, and what constitutes a good outcome has been the subject of considerable debate (Turk 1999, Farrar 2000). Without meaningful data to describe the current situation it is hard to move this debate forwards. Within the UK, reviews of these pain services recommend both changes in practice and the monitoring of performance (Audit Commission 1997), while clinical governance requires that teams within Health Services have information on their activity and outcomes.

Although datasets have been described for pain clinics (Rogers et al 2000) little research and no validation has been published from these resources. One potential source of information on pain management is the PainDB (Griffiths et al 2003) collected predominantly by clinicians at pain clinics throughout the UK. PainDB was developed by the Clinical Information Special Interest Group of the British Pain Society (BPS) which is responsible for its maintenance and upkeep. It allows collection of four main types of data across 100 fields: demographics; pain diagnosis (including pain and quality of life measures); treatment and outcome. Developed predominantly as a research and audit tool, it has the potential to provide information on case mix, treatments in outpatients, and outcomes, providing information not always included on standard UK NHS collection systems in outpatients. Data are collected using established coding systems and taxonomies with the majority of participants using a standard software package (Griffiths et al 2003) A new database is created, as

funding permits, on request to members to submit a download to a central site. Further details have been published elsewhere (Griffiths et al 2003).

Before the value of PainDB is understood, it is necessary to evaluate its completeness and quality. The objectives of this study were therefore to validate PainDB against clinic sources and to describe patients in the database.

4.4 Methods

The study received Multicentre Research and Ethics Committee (MREC) Approval from Hampshire and Isle of Wight MREC (04/Q1702/118).

Patient data was collected at 37 pain clinics throughout 2003, and submitted and aggregated into Pain DB during the first half of 2004. Permission for research was requested from clinic staff, chief executives and any other parties as required by each site. An on-site visit was completed at 30 of these 37 clinics; one clinic no longer had data; one had incompatible ID numbers and one visit was abandoned because of repeated flight cancellations. The remaining four practices were not validated because permission for the research could not be obtained from all parties in the time available.

A random sample of patients who consulted during 2003 was generated from PainDB for the 30 participating clinics. This was the most recent complete year of data available and would increase the chance that paper notes were still available. The collection of these data was in 2004. Generation of a cleaned, amalgamated database took approximately 6 months due to the difficulties in amalgamating differing collection systems. For 26 clinics, samples of 40 patients were produced but for four clinics, which had recorded fewer than 50 patients per year, the number was reduced to 20. Participating clinics were sent a copy of the list of patient identifiers (PainDB does not contain identifiable personal information) and asked to identify and provide the notes for these patients. A second list was produced in the same manner and used as a back-up if any notes on the original list were reported to be lost. A printed form of 80 fields was produced from PainDB for each clinic consultation recorded for the selected 1120 patients. Sixteen fields were not validated because either they contained free text and coded data for the same information or it was already known that they contained so little data that validation would not be useful and four further fields were used for identification of the clinic and records by the researcher. This provided a total of 2648 consultations for validation (mean 2.4 per patient). One Research Assistant visited each participating clinic during 2005 for an on-site validation and compared each entry on the PainDB printout, for each consultation, with those in the written notes for completeness and accuracy. In 28 clinics (1030 patients), the written notes were searched for consultations with no printout (so not noted on PainDB) and patients were classified depending on whether any visits were missing and if so which

ones. The PainDB entries were then compared to the clinics' electronic records using the same methodology as the comparison with written notes. This stage was completed to ascertain whether or not conversion during software upgrades and aggregation into PainDB had caused errors.

In the final stage of on-site validation, a senior member of the clinic was interviewed based on a questionnaire designed to collect information on how data were entered onto PainDB. The questionnaire surveyed when and where the data were collected and whether all consultations and patients were included.

The forms generated by the comparison of PainDB with clinic records were scanned and, for every field, the number and percentage with each response was calculated. Further descriptive analyses examined the number of consultations not recorded on PainDB and the responses to the survey on data collection.

The aggregated 2003 PainDB was also investigated for data omissions. Data from 34 clinics and 17 135 patients with a new episode in 2003 were analysed. Three additional clinics with 1466 patients were excluded because patient identification numbers could not be linked across records. The number of patients with no entry for key fields was counted. Nine key fields were chosen as those which should be completed for all new patients and are important for research, and the number of patients with no entry in these fields counted. Treatment is not always initiated at a pain clinic visit so was not included in the analysis. These data are also readily available through the Hospital Data collection systems as they are routinely collected for the purpose of Payment by Results.

4.5 Results

Comparison of PainDB with clinic written records for consultations with no printout (so not noted on PainDB) could be completed for 1030 patients and showed that clinic visits were often not computerised. Only 562 (54.6%) of these patients had all consultations computerised (range 2.5–92.5% across clinics). The number increased slightly when treatment only consultations were excluded (57.2%) or when only consultations dated after the first computerised record were counted (59.8%). This excluded any visits that were made before computerisation was possible. First consultations were recorded more frequently than others, 622 patients (60.4%). Five clinics (17.9%) had all consultations recorded for at least three quarters of patients whereas 11 clinics (39%) had this level of completeness when only first consultations were counted (Table 1).

4:1 Table 1. Number (%) of clinics with every consultation in a treatment episode on PainDB by categories of consultation.

Patients with every consultation on PainDB (%)	All categories of consultations	Only treatment consultations missing*	All consultations after first computerised record†	First consultation
75+	5 (17.9)	7 (25.0)	8 (28.6)	11 (39.3)
50–74	13 (46.4)	11 (39.3)	13 (46.4)	8 (28.6)
25–49	7 (25.0)	7 (25.0)	5 (17.9)	6 (21.4)
<25	3 (10.7)	3 (10.7)	2 (7.1)	3 (10.7)

- *Consultations may not involve physician contact. †Omissions may have been from before computerisation.

For those consultations included, comparison of PainDB with written records showed good agreement across all fields. Of 211 607 data items compared (99.9% possible), 186 436 (88.1%) concurred (including omissions in both). A further 264 (0.1%) were incorrect, six (<0.1%) incomplete and 5795 (2.7%) in the written notes but not in the database. Over all consultations, PainDB included 18 178 (8.6%) entries which were not found in written notes. The validation was not completed for 928 fields (0.4%), for example where written notes were illegible. Comparison of written records with the most recent consultation on PainDB avoided double counting of fields only completed once per patient episode (Table 2). This analysis showed that the essential data items ‘system’; ‘aetiology’; ‘location’ and ‘pain type’ were absent from PainDB more often than other fields, with between 12.4% and 18.4% of first entries missing. Information recorded electronically but not stored in paper format was usually from a patient questionnaire such as the Brief Pain Inventory. Although some patients were reported as receiving as many as ten drugs, most patients had fewer so only the first drug reported is included in the table.

Paper 2
Validation of the quality of The National Pain Database for pain management services in the United Kingdom
4:2Table 2. Comparison of PainDB with paper records for the most recent consultation, number (%).

	Agrees with comparator	Incorrect	In comparator not PainDB	In PainDB not comparator	No. validated*
Sex	1110 (99.2)	3 (0.3)	4 (0.4)	1 (0.1)	1118
Year of birth	1051 (94.0)	2 (0.2)	54 (4.8)	2 (0.2)	1109
Duration of symptoms	1056 (94.4)	4 (0.4)	46 (4.1)	4 (0.4)	1110
System 1st	959 (85.7)	6 (0.5)	139 (12.4)	6 (0.5)	1110
System 2nd	931 (83.2)	1 (0.1)	167 (14.9)	11 (1.0)	1110
Aetiology 1st	895 (80)	0 (0)	200 (17.9)	15 (1.3)	1110
Aetiology 2nd	1099 (98.2)	0 (0)	8 (0.7)	3 (0.3)	1110
Location 1st	890 (79.5)	1 (0.10)	205 (18.30)	14 (1.3)	1110
Location 2nd	1104 (98.7)	0 (0)	3 (0.3)	3 (0.3)	1110
Pain type 1st	889 (79.4)	0 (0)	206 (18.4)	15 (1.3)	1110
Pain type 2nd	1104 (98.7)	0 (0)	3 (0.3)	3 (0.3)	1110
Diagnosis (free text)	1102 (98.5)	0 (0)	3 (0.3)	5 (0.4)	1110

	Agrees with comparator	Incorrect	In comparator not PainDB	In PainDB not comparator	No. validated*
Date Pt. added to system	1107 (98.9)	0 (0)	1 (0.1)	2 (0.2)	1110
Consultation date	1106 (98.8)	2 (0.2)	0 (0)	2 (0.2)	1110
New patient episode	1087 (97.1)	20 (1.8)	1 (0.1)	2 (0.2)	1110
Treatment group 1	1066 (95.3)	17 (1.5)	25 (2.2)	2 (0.2)	1110
Treatment type 1	1015 (90.7)	3 (0.3)	89 (8.0)	3 (0.3)	1110
Site of treatment 1	1012 (90.4)	3 (0.3)	92 (8.2)	3 (0.3)	1110
Treatment 1	1014 (90.6)	3 (0.3)	90 (8.0)	3 (0.3)	1110
Treatment group 2	1025 (91.6)	3 (0.3)	79 (7.1)	3 (0.3)	1110
Treatment type 2	1091 (97.5)	0 (0)	16 (1.4)	3 (0.3)	1110
Site of treatment 2	1093 (97.7)	0 (0)	14 (1.3)	3 (0.3)	1110
Treatment 2	1092 (97.7)	0 (0)	14 (1.3)	3 (0.3)	1109
Complications	1097 (98.0)	0 (0)	10 (0.9)	3 (0.3)	1110

	Agrees with comparator	Incorrect	In comparator not PainDB	In PainDB not comparator	No. validated*
Discharged	1091 (97.5)	6 (0.5)	11 (1.0)	2 (0.2)	1110
Relief from treatment	927 (82.9)	6 (0.5)	47 (4.2)	129 (11.5)	1109
Pain – worst last week	566 (50.6)	2 (0.2)	10 (0.9)	532 (47.5)	1110
Pain – least last week	523 (46.7)	2 (0.2)	10 (0.9)	575 (51.4)	1110
Pain – average last week	524 (46.8)	1 (0.1)	10 (0.9)	575 (51.4)	1110
Pain-right now	523 (46.7)	1 (0.1)	10 (0.9)	576 (51.5)	1110
Activity interference	524 (46.8)	2 (0.2)	10 (0.9)	574 (51.3)	1110
Mood interference	526 (47.0)	2 (0.2)	10 (0.9)	572 (51.1)	1110
Walking interference	527 (47.1)	1 (0.1)	10 (0.9)	572 (51.1)	1110
Work interference	527 (47.1)	1 (0.1)	10 (0.9)	572 (51.1)	1110
Relationship interference	525 (46.9)	1 (0.1)	10 (0.9)	574 (51.3)	1110

	Agrees with comparator	Incorrect	In comparator not PainDB	In PainDB not comparator	No. validated*
Sleep interference	525 (46.9)	1 (0.1)	P10 (0.9)	574 (51.3)	1110
Enjoyment interference	524 (46.8)	1 (0.1)	10 (0.9)	575 (51.4)	1110
Drug start date	652 (58.3)	1 (0.1)	9 (0.8)	448 (40.0)	1110
Drug category 1	1045 (93.2)	0 (0)	25 (2.2)	43 (3.8)	1113
Drug name1	1014 (90.5)	3 (0.3)	90 (8.0)	5 (0.4)	1112
Dosage 1	1001 (89.3)	3 (0.3)	104 (9.3)	5 (0.4)	1113
Adverse Drug Reaction 1	1001 (89.3)	3 (0.3)	104 (9.3)	5 (0.4)	1113

- *Excludes those illegible or not scanned.

Comparison of clinic electronic records with PainDB showed that they were identical in 99% of entries. Across clinics the range was 94–100% of records, with five clinics having less than 99% concurrence. Within these five clinics we found no systematic errors which would suggest a conversion or aggregation problem.

When questioned, 16 clinics (53%) reported that every medical consultation was recorded on PainDB. In one of the remaining fourteen clinics, one of four consultants recorded every clinic consultation. There was an average of 2.8 consultants (range 1–11) per clinic. The majority of the clinics never entered data onto the computer during a consultation (80%). Similarly 70% never entered it directly into the system (rather than from notes) at anytime. In 50% of clinics, staff who saw the patients always or usually entered the data into the system themselves (Table 3).

4:3Table 3. Responses (%) to staff questionnaire about data collection methodology at each clinic.

	Never	Sometimes	Usually	Always	Unknown
Across all clinics and medical staff, is information entered into the computer during the clinic consultation?	24 (80.0)	5 (16.7)	0 (0)	1 (3.3)	0 (0)
Is the information entered directly onto the computer rather than from other records (such as written notes)?	21 (70.0)	8 (26.7)	0 (0)	1 (3.3)	0 (0)
Does the member of staff who saw the patient make the record?	4 (13.3)	11 (36.7)	5 (16.7)	10 (33.3)	0 (0)
If a patient sees another health professional is this entered onto the database?	10 (33.3)	12 (40.0)	6 (20.0)	1 (3.3)	1 (3.3)

Investigation of the nine key fields expected to be completed for all new episodes showed that recording of age and sex was complete in most cases. Omissions were common for the other fields (Table 4).

4:4 Table 4. Number (%) of missing entries for key fields: 17 135 new patients seen in 2003.

Field	Number missing (%)
Age	304 (1.8)
Sex	924 (5.4)
Duration	6094 (35.6)
System affected	6352 (37.1)
Aetiology	6383 (37.3)
Location	5421 (31.6)
Duration	6094 (35.6)
Pain intensity	4396 (25.7)
Pain interference	3630 (21.2)

4.6 Discussion

This is the first time that a pain database has been formally evaluated against original clinic records. It is clear that, while the data included was accurate, many consultations were missing. Consequently use of PainDB for audit would underestimate the workload in most clinics and all research would be limited by potential bias and lack of longitudinal data. There was no pattern to

the consultations which were included which would suggest that, for example, the missing consultations were from before routine use of PainDB. The slightly higher level of recording of first consultations is probably the result of policy at some clinics to focus on these contacts as they give a useful indication of case mix. The study sample was identified from PainDB, so if not all consultations are recorded, there may be additional patients who consult clinics but whose details are never entered onto the system. The results of the staff questionnaire suggest that clinics expected the completeness to be greater. The difference could be because the rate of recording had improved between 2003 and 2005 or possibly because data are routinely recorded when the computer system is accessible, but not when the system is not available, either as the result of technical problems or because the patient is at a site where there is no access. Other clinics may have assumed that only first consultations should be included, if this was their policy. The comparison with the clinics electronic records confirmed that the omissions were not due to transfer problems.

Analysis of the PainDB reflected the on-site validation in that key variables such as aetiology and system are missing for a number of patients. However, there appear to be more 'missing' data than might be expected from the results of the validation. The difference may be due to a missing first consultation with background data not updated later or information such as duration of pain being missing from both the notes and the electronic records.

Previous studies have reported omissions from clinical databases. Validation of an orthopaedic database also found problems with completeness but not accuracy (Barrie and Marsh 1992). An audit study of a cardiac surgery outcomes database reported 25% of essential data elements missing at first validation (Fine et al 2003). More complete recording has been found in general practice databases (Hall et al 1998) which have been successfully used for a variety of research. However, unlike pain clinics, the data included in these resources come from surgeries where the principal record is electronic, not paper based. Electronic records may be the impetus needed before reliable data can be expected from secondary care clinics. External checks are a necessary part of validating any database. However, the process of obtaining the necessary permissions was extremely lengthy (nearly 1 year) and differed between Trusts. Permission to check this data should be obtained at the time of setting up data collection in order to reduce the run-in time to the project.

Given that the UK is moving to an activity-based payment system then it is likely that activity carried out by UK pain management services will be best recorded by existing health care databases (e.g. Hospital Episode Statistics). However, the findings of this study may be relevant no matter what the reasons for data recording, even when those recording the information are confident of good levels of completeness and accuracy. Energies may be best focussed on liaising more closely with information services within an organisation to improve data quality, thus improving the value of routine information on activity from hospital statistics.

Other objectives of PainDB such as the investigation of disease severity and outcome will be less well addressed by general systems so further developments should be focussed in this direction. Our finding that many clinics are routinely recording information of a high quality, but not at every consultation, suggests a commitment to the system. A number of clinics might therefore be willing to follow agreed data collection protocols aimed at recording defined detailed information for brief focused periods, and by those who wish to participate. This strategy could allow investigation of case-mix severity in those clinics which agreed to collect age, sex, diagnosis and Brief Pain Inventory responses for every new patient over a 6-month period. The same information recorded at every visit where a strong opioid was prescribed would provide information on the extent and rationale for their use. Further validation and feedback could ensure quality.

4.7 Conflict of Interest

Gillian Hall has received funding for research and payment for consultancy from a number of pharmaceutical companies and from charities and has no direct stock holding in any pharmaceutical company. Trevor Bryant has received funds from the British Pain Society to prepare the database specification and manage the PainDB web site. Cathy Price has received honoraria from Napp, Janssen Cilag and Pfizer for presentations to clinical meetings, and consultancy from Axon Communications for service redesign. Laura Merrett has no conflict of interest.

4.8 Acknowledgements

The study was funded by the Pain Relief Foundation and Pfizer UK without restriction on publication.

4.9 References

Audit Commission. *Anaesthesia under Examination: The Efficiency and Effectiveness of Anaethesia and Pain Relief Services in England and Wales*. London: HMSO, 1997.

Barrie JL, Marsh DR. Quality of data in the Manchester orthopaedic database. *British Medical Journal* 1992;

Black N. Using clinical databases in practice. *British Medical Journal* 2003; 326: 2–3.

Farrar JT. What is clinically meaningful: outcome measures in pain clinical trials. *Clinical Journal of Pain* 2000; 16: S106–12.

Fine LG, Keogh BE, Cretin S, Orlando M, Gould MM. How to evaluate and improve the quality and credibility of an outcomes database: validation and feedback study on the UK Cardiac Surgery Experience. *British Medical Journal* 2003; 326: 25–8.

Griffiths DPG, Mitchell Noon J, Campbell FA, Price CM. Clinical governance and chronic pain: towards a practical solution. *Anaesthesia* 2003; 58: 243–8.

Hall GC, Luscombe DK, Walker SR. Post-marketing surveillance using a computerised general practice database. *Pharmaceutical Medicine* 1988; 2: 345–51.

Rogers WH, Wittink HM, Ashburn MA, Cynn D, Carr DB. Using the "TOPS," an outcomes instrument for multidisciplinary outpatient pain treatment. *Pain Medicine* 2000; 1: 55–67.

Turk DC. Here we go again: outcomes, outcomes, outcomes. *Clinical Journal of Pain* 1999; 15: 241–3.

Notes:

*Consultations may not involve physician contact.

†Omissions may have been from before computerisation.

*Excludes those illegible or not scanned.

4.10 Reflection

We were partially able to meet our objectives with Paper 2. We were able to establish that if a patient was entered onto the data base then the information at the first visit was completed well but it declined thereafter. However, many patients were not captured which severely limited the representativeness of the database in determining outcome. The issue of monitoring activity was circumvented by the UK moving to a tariff based system which meant hospitals had to focus on getting activity data right. Additionally, as a result of this audit, pain clinic activity was clearly separated from anaesthesia activity by a clear definition of what specialist pain clinic activity consisted of and by promotion of a separate treatment code.

It was clear that considerable work was needed to improve the data entry, suggesting that the database should stay with only a small number of centres to begin with. However, by this time it was no longer possible to run the software due to compatibility issues between NHS computers and Microsoft Access based databases. Data collection therefore ceased in 2007.

It was recommended that there was electronic capture of data into a web tool to obviate interface issues. A differing solution was needed. Application of the UPCARE tool as recommended by HQIP (HQIP 2018) would help users "understand the methods, evaluate the quality and robustness of the data" in PAINDB and future pain databases. This paper therefore enabled greater understanding of the validity of the patient data within PAINDB informing the approach in Paper 4.

4.11 Declaration of authorship Paper 2

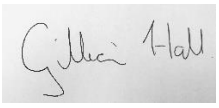
Gillian Hall: Responsible for study design, choice of methodology, drafted all versions of the manuscript, held overall responsibility for manuscript submission and all associated administration

Trevor Bryant: analysed data from the database for outcomes and data quality, converted it into SPSS format, provided data for validation exercise, reviewed and commented on draft manuscript.

Laura Merrett: collected the data, reviewed drafts of manuscript

Cathy Price: I wrote and submitted the grant application, reviewed the study design, provided data for study, supervised researcher, contributed to literature review, reviewed drafts of the manuscript

All co-authors below confirm the accuracy of the declaration of authorship for paper 2:

	Signature	**Date**
Gillian Hall		07MAR2019
Laura Merrett		05/03/2019
Trevor Bryant		06/03/2019

Chapter 5: **Paper 3**

The National Pain Audit for Specialist Pain Services in England and Wales 2010-2014

Dr Cathy Price[1], Dr Amanda C de C Williams[2], Professor Blair H. Smith,[3] Dr Alex Bottle British Journal of Pain 2019.[4] 13;3:185-193

5.1 Overview

In 2010 IASP produced the Declaration on Montreal. This highlighted that very few countries had policies related to pain. This had the effect of lack of prioritisation of chronic pain as an important public health issue. As a result, healthcare professionals were poorly trained and there was poor access to basic pain management strategies. Human rights legislation, however, covers access to pain management as a fundamental human right (IASP 2010).

Accompanying this was a review of national pain policies (IASP 2010). Recommendations were:

- *Access to pain education for health professionals and the general population*
- *Coordination of the care system to ensure timely access to the right support*
- *A quality improvement program to address access and standards of care*
- *A reasonable proportion of direct and dedicated funding for pain research*

Critical Factors to success were:

- *Gathering of evidence on the burden of pain to the nation*
- *Gathering of information on access to care*
- *Development of government policy on pain services*
- *Formation of a broad coalition of stakeholders*
- *A clear plan with timescales to achieve strategic actions*

Sir Liam Donaldson's report (Department of Health 2008) made very similar recommendations. It was noted that this was not official government policy unlike in other countries. Scotland also had a series of government recommendations on how to improve management of pain (Quality Improvement Scotland 2007). Wales had a series of directives on pain which it expected its health boards to follow (Welsh Assembly Government 2008).

[1] Solent NHS Trust, Highpoint Venue, Bursledon Rd, Southampton SO19 8BR
[2] Research Department of Clinical, Educational & Health Psychology, UCL, Gower St, London WC1E 6BT
[3] Department of Population Health Sciences, University of Dundee, Ninewells Hospital and Medical School Dundee DD2 4RB
[4] Dr Foster Unit, Imperial College London, Charing Cross Campus, 3 Dorset Rise, London EC4Y 8EN

The National Pain Audit was recommended as a way of discovering whether those recommendations and directives had been adopted in practice in England and Wales as both participate in the audit programme.

National audits compare against agreed standards and encourage benchmarking between providers. This paper describes the organisational audit that was carried out as part of a national audit. Previous papers had not considered looking at the content of service delivery. However, when we looked at other audits it was clear that this was a vital part of measuring the quality of care delivered by pain services. With this paper we aimed to assess whether there were any signs of improvement by the end of a the complete audit cycle, report the National Pain Audit findings using parameters recommended by a recent systematic review of surveys of pain facilities. This would allow comparisons with other nations pain facilities.

To deliver this over a four-year cycle (2010-14) the audit was divided into four phases

- *Phase 1: Pain service registration and completion of a service questionnaire to the registrant based upon key standards. Organisational standards were benchmarked against each other and against national and internationally agreed standards where they could be ascertained. These were refined by the Scientific Committee.*

- *Phase 2: Case mix information from both the provider clinicians and patients. Also information from patients about the patient journey to a pain service.*

- *Phase 3: Outcomes of care from a patient perspective using validated standard questionnaires and questions developed specifically for the audit by both clinicians and patients.*

- *Phase 4: Re-audit of organisational standards, PROMS data at 12 months after entry using a refined questionnaire based upon the quality of response to the previous questionnaires and existence of safety protocols in the clinics.*

Between Phase 1 and 4 there was a continual feedback process via a public facing website, newsletters and a package of interventions delivered by the British Pain Society and Faculty of Pain Medicine to improve quality of care. This included introduction of standardised clinical pathways, introduction of core standards and service commissioning guidance.

5.2 Introduction

Specialist pain services are an established component of healthcare in most nations. The International Association for the Study of Pain (IASP) provides guidance on standards of care that include the approach, infrastructure and treatment content of such services, and recommended waiting times(IASP 2009, IASP 2010) Treatment should be evidence-based; take into account biomedical, psychological and social factors; be multidisciplinary; and give high priority to safety. Services are further expected to carry out research, evaluation of patient outcomes, and clinical education.

Chronic pain has become a growing public health concern both with respect to its prevalence and to unsatisfactory treatment. Of particular concern are the rising numbers of problems associated with long term opioids for chronic non cancer pain, with the USA declaring this a Public Health emergency in 2017 (Roehr 2017). It is essential that pain clinics provide leadership in this area. A recent systematic review of large scale surveys of pain clinics in seven countries described wide variation in standards of care (Fashler et al 2016). Setting standards has also proved problematic (Baker 2017).

Quality improvement in pain management services is also recognised as challenging (Gordon and Dahl 2004). Issues are the subjective nature of pain, a lack of consensus on treatment and, in the UK, several government reviews highlighted the paucity of data on specialist pain services, including information on the patient population, the types of treatment offered, and their outcomes CSAG 2000, NHS QIS 2007). In 2008, both the Chief Medical Officer (CMO) in England and the Welsh Government recommended several interventions to improve the quality of care for people with chronic pain (Department of Health 2008, Welsh Assembly Government 2008). One recommendation was that all pain clinics should submit data to a national database so that services could be meaningfully compared. National Audits are a recognised way of doing this, aiming to raise the standard of care through engaging clinicians in reporting the quality of their care against agreed standards, and comparing their service with others (Pink and Bromwich 2002). Further recommendations to improve quality included a consensus pathway of care and better understanding of need through data collection via the Health Survey for England. While there are other examples of quality improvement interventions in other jurisdictions, (Kerns 2003, Cleeland et al 2003, Hooten et al 2013) no attempt has been published involving a whole nation's pain services in a quality improvement programme.

A Quality Improvement Programme was implemented in England and Wales and a National Audit funded to support this from 2010-14. Four reports were published over the lifespan of the Audit which have now been combined into two reports (HQIP 2017, HQIP 2013). Some outcomes were reported in the second NHS Atlas of Variation (Public Health England 2011). However, much of the methodology from the audit was not reported and the reports were of each cycle rather than reviewing the whole process. The purpose of this paper is to assess whether a Quality Improvement Programme, based upon government recommendations, which involved the setting of standards for pain clinics, a suite of interventions to improve care, and a re-audit, led to improvement. To achieve this we have reviewed and revised the original data from all four reports, re-presented the data in the format of a recent systematic review of such surveys (Fashler 2016) and explained the methods used to deliver the audit. Additional data not reported in any report includes the number of patients seen and a more complete dataset from providers as 30 missed the deadline for the Follow up

report. The Baseline audit reported by centre rather than by provider which was not in line with reporting requirements and made it difficult to make meaningful comparisons. This paper therefore looks at the impact and implementation of the audit and allows comparisons with other national surveys.

5.3 Methods

5.3.1 Context:

The National Pain Audit's brief was to look at case mix, service organisation, and outcomes of care including patient safety and patient experience within the National Health Services of England and Wales which both provide care free at the point of delivery but differ in waiting times, targets and system integration. The English NHS is delivered based upon competition and choice of providers whereas the Welsh NHS is integrated in delivery. Controversial National Institute of Clinical Excellence (NICE) guidance was produced on low back pain during this period, emphasising the importance of multidisciplinary care and reducing emphasis on medical treatments (NICE 2009).

5.3.2 Quality Improvement Interventions

The CMO of England's and Welsh government's recommendations were reviewed and those deemed feasible were implemented as an improvement programme. This was led by the British Pain Society. The programme consisted of feedback of National Pain Audit results to patients, politicians and policy makers through the Chronic Pain Policy Coalition, regular newsletter updates, development of specific best practice pathways (Colvin and Rowbotham 2013), revised speciality standards (Royal College of Anaesthetists 2015), population data on chronic pain from the Health Survey for England (Bridges 2011) , a roadshow to all regions in England and Wales, commissioning guidance (RCGP 2014), a pain summit that brought together many stakeholders (British Pain Society 2011) and linkage of audit results to NHS Choices, the main public source of information on NHS providers and treatments available in England.

A Donabedian approach was taken to examine organisational structures, care processes and clinical effectiveness (Donabedian 1965). Structure of services and processes of care were measured by direct questions. Both Departments of Health signed off the approaches and reviewed recommendations made and outcomes were assessed by the National Audit oversight board.

Figure 1 shows the complete Quality Improvement Programme and Evaluation which covered the period 2010-14.

5.3.3 Inclusion Criteria – identification of services

During the Baseline Audit (Phase 1) specialist pain services were initially located through searching England's national administrative hospital admission database (HES) to identify services with the

treatment function code 191 for Pain Management, and through British Pain Society newsletters requesting contact. These Services were sent an organisational questionnaire to complete. For the Follow-up audit (Phase 4), the organisational re-audit, the NHS Choices website that hosts all NHS providers in England was searched for mention of specialist pain services, contact was made and a further organisational questionnaire sent. Services were reported by the responsible provider organisation rather than by individual clinics; in line with reporting standards from the Health Quality Improvement Partnership (HQIP).

5.3.4 Exclusion Criteria

Services were excluded if they were clearly non-specialist providers, non-NHS providers, or were unable to self-classify into type of pain facility (IASP 2009).

5.3.5 Audit Standards

Audit Standards were derived from the Royal College of Anaesthetists' General Provision of Anaesthetic Services guidance chapter on Chronic Pain Services (RCOA 2015), IASP guidelines on pain services and waiting times (IASP 2009, 2010) and, for the Follow up Report, the National Patient Safety Agency (Table 1) (Department of Health 2012). Clinicians were asked to assign International Classification of Diseases (ICD-10) diagnostic codes to the primary condition of patients completing the Phase 2 questionnaire. For the additional work on coverage of services population data were calculated from Office of National Statistics tables (ONS 2014).

5.3.6 Data Collection

Data for the items given in Table 1 were collected from providers of pain services via an Excel spreadsheet with sign-off by their audit departments. For consistency, services were analysed by provider in line with National Audit guidance. This produced some discrepancies from the First National Audit report where analysis was by individual clinic.

5.3.7 Data Analysis

Reporting recommendations from the systematic review of multidisciplinary chronic pain treatment facilities were followed (Faschler 2016) and the SQUIRE checklist for quality improvement studies followed ((Ogrinc et al 2015). The χ^2test was used to test for significant differences in important variables. Free text diagnoses were mapped to ICD-codes by national pain coding leads.

5.3.8 Data Validation

Data were compared with HES in England. It was not possible to obtain the Welsh equivalent (Patient Episode Database for Wales). Data were also uploaded to a public facing websites and initial outcomes reported to the clinics. Items were cross-referenced for inaccuracies.

5.3.9 Ethical Considerations

As a Quality Improvement Programme National Audits do not require an ethics review. The use of data and the audit, were overseen by HQIP. The evaluation was overseen by a scientific committee and an independent governance group including lay members.

5.4 Results

Identification of providers and response rates

Figure 2 shows flow through the audit. For the Baseline Audit the first search methodology found 169 clinics, and responses were received from 159 clinics, a 94% response rate. For the Follow-up Audit the follow-up organisational questionnaire we identified services in England using hand searches of NHS Choices. NHS Wales provided a list. These identified 175 providers of specialist pain care in England and Wales, in a variety of settings both in and out of hospital. 146 providers responded to the Follow-up Audit, a response rate of 83%. Nineteen providers identified as having a pain service did not submit a return (10%), and there was uncertainty over the status of another 10 providers who did not respond and it could not be ascertained if they ran a pain service.

Data validation

HES data (England only) identified 133 providers with outpatient data using the specialty code 191: Pain Management. Twenty six providers in the Baseline Audit were not identified through HES but provided specialist pain services. This may have been due to incorrect coding of the clinics. We were unable to cross-check services in Wales using PEDW however the Welsh government had a record of all services.

Standard 1: Clinics were classified according to IASP classification of Pain Clinics

As reported in Table 2, in the Baseline Audit all clinics were able to self-classify using the IASP clinic type classification guideline In the Follow-up Audit 19 (13%) did not self-classify their clinic type

Standard 2: Waiting times should be appropriate and evidence based

Baseline Audit (Phase 1): 80% of clinics in England in the Baseline Audit reported meeting the Government target for England of 18 weeks to first appointment, and 2.5% explicitly did not meet the standard. In Wales, where targets are somewhat different, 50% of clinics achieved 18 weeks for elective waits, with a lower completion rate of 70%. For clinics failing government targets, the median wait was 20 weeks in England and 33 weeks in Wales.

Follow up Audit (Phase 4): IASP waiting time recommendations were used in this round[2] as they have an evidence base for pain and we became aware of the potential consequence of a fine for declaring failing a government target. However, only 49 (38%) of services responded to this. For routine referrals, 25 (43% of those who responded to this question) were able to offer a first appointment within the recommended time of 8 weeks, with a median wait of 15 weeks.

Standard 3: Clinics should be multidisciplinary

The majority of clinics, 111(72%), self-rated themselves as multidisciplinary in the Baseline audit according to IASP criteria, rising to 101 (93%) at the Follow up Audit. (Table 2)

Standard 4: Multidisciplinary pain services per head of population in line with other first world countries

One hundred services, across the range of types of clinic, provided information on numbers of patients seen per annum – an average of 0.25% of the total population in one year in England (Table 3). Adjusting for non-responders (based on the size of the populations they serve and the numbers seen in responding clinics), a rough estimate would be that 0.46% of the population was seen. As only 64% of clinics were multidisciplinary, then 0.25% of the England and Wales population is estimated to attend a multidisciplinary pain clinic every year.

Services also estimated this: 95 services responded to this question, with a mean estimate of 0.3% of the population seen.

Standard 5: Multi-modal Treatments should be available at services

Multimodal treatments are more than one type of treatment being delivered eg physiotherapy and an injection. Ninety three percent of services in the Baseline audit and 97 % in the Follow up audit self-reported they offered multimodal treatment. The types of treatments available are shown in Table 2. Nearly all services provided interventional pain management. In the Follow up audit, 61% reported providing a pain management programme; in the Baseline audit, nearly all services appeared to provide some form of a pain management programme but the question asked about specialist rehabilitation treatments so may be confused with other approaches. Seventy-two percent of those providing pain management programmes had a qualified cognitive behavioural therapy practitioner delivering the programme. Implants (neurostimulation and infusion catheters) were available in 30% of services.

Standard 6: Attributes of pain treatment facilities: Core multidisciplinary staff should be available

It was noted that there was a significant discrepancy between services' self-report and the actual staffing, defined by the audit group comprising at minimum a physician, physiotherapist and psychologist, who together could deliver all major treatment components. Generally, completion rates of questions on staffing levels were high, allowing some understanding of whether staffing levels were matched to need (Table 3). By the time of the Follow up Audit there was significant improvement in the reported availability of the specific multidisciplinary staff needed. Most services

held multi-disciplinary team meetings, and 14% offered multispecialty clinics aimed at the most complex cases.

Standard 7: ICD Codes should be correctly assigned for diagnosis

At the Baseline Audit clinicians were able to assign codes for 6,430 patients (67%). They were unable to code 3,000 patients into diagnostic groups and used free text instead which, when reviewed by the clinical expert group, could nearly all be mapped to a code. It appeared that sometimes clinicians were entering the co-morbidity contributing to chronic pain (e.g. “arthritis”) rather than pain as a condition in itself.

Standard 8: Protocols should be in place to manage risk

This was also reported in the Third Report of the National Pain Audit [16]Of the 121 providers that responded, 53 (44%) reported having a suicide risk assessment protocol. Fifty-three (44%) had a clear process for acting on a wrong diagnosis being made: all providers reported this as a serious untoward event. A process for recording prescribing errors was reported by 114 (94%). One hundred and four services (86%) had pain prescribing guidance, with 94 services (77%) having specific opioid prescribing guidance. Of those providing interventional pain therapy, 88% had a process in place for managing accidental misplacement of an injection, with 92% having a process in place to manage adverse events with interventional pain therapy.

Standard 9: Education to non-specialists and quality improvement programmes should be provided

Most providers met this standard. Ninety-three percent provided a clinical teaching programme for health professionals. Eighty-two percent stated that they carried out a regular audit of clinical practice.

5.5 Discussion

To the best of our knowledge, this was the first time, worldwide, that pain services have gone through an improvement cycle on a national scale. The National Pain Audit managed to characterise most pain clinics in England and Wales in terms of types of clinics, case mix, processes in place to manage risk, patient experience and clinical outcomes. Outcomes from this audit enabled clearer standards to be published and developed for routine inspection by regulators (RCOA 2015).

The quality of service provision improved over the audit period. Sound patient safety procedures are found in nearly every clinic. The proportion of services with reported truly multidisciplinary staffing

rose from 32% at Baseline to 56% at Follow up ($p<0.001$). Hogg in Australia and Peng in Canada, reported that 79% and 39% respectively were multidisciplinary clinics, this was by self-report alone and so it is difficult to draw comparisons (Hogg et al 2012, Peng et al 2007). Multidisciplinary care has been shown to improve general medical inpatient hospital-based outcomes (Fielding et al 2013). Multidisciplinary pain care focusing on self-management skills acquisition has also been found to be effective (Pike et al 2016). This is encouraging and was a key message of the Quality Improvement Programme although may also have been related to national guidance on the management of low back pain. However, professional controversy over the evidence base was not resolved until the production of clinical pathways.

Methodological challenges included difficulties with identifying services: HES data captured many services but at least 11 were missing. Hand searching for clinics on the NHS Choices website and searching for a pain clinic on providers' websites proved to be the best way of identifying clinics. Obligatory use of the relevant specialty code within the national hospital administrative database (HES) would make identification of services much easier. Fashler highlighted the variety of identification methods used by each large pain facility survey; some standardisation is needed to avoid selection bias (Fashler 2016). Considerable liaison was needed to verify eligibility and confirm data. Data availability on an open website proved very useful.

For many services, there was significant discrepancy between their self-description as a multidisciplinary clinic and the staffing required to provide multidisciplinary care. Exact staffing depends on feasibility, potential scope of practice and workforce supply (Conway and Higgins) . At the time only medical staff had a clear, competency-based training programme. No other survey has attempted to assess this and there are no comparators. Given the discrepancy, future surveys ought to ask exactly which staff are present. Using two methods, we estimated that 0.25%- 0.3% of the total population was seen by a multidisciplinary clinic. This is somewhat lower than elsewhere (Fashler 2016); the reasons for this require further research.

Government waiting time targets of 18 weeks in England were largely met by services. However, the maximum waiting time recommended by the IASP for routine cases is 8 weeks, as deterioration is found in some cases from 5 weeks onwards (Lynch et al 2008). A more detailed prioritisation of cases such as that recommended in Norway, based upon condition and complexity may enable clinics to reduce waiting times (Hara and Borchegrevink 2010).

One major difficulty for clinicians was entering diagnostic codes. Perhaps selecting from the 600 ICD-10 codes for long-term pain is simply too overwhelming. The ICD-11 revision has proposed and

tested new codes specifically for chronic pain, which may increase use (Treede 2015). Treatments were also confusing, difficult to classify and require better information standards.

5.6 Summary

A Quality Improvement Programme for specialist pain services in England and Wales was successfully delivered and measured. Sound patient safety processes are in place in nearly every service. Improvement in multidisciplinary provision occurred over the time period. However, waiting times did not improve and coding for diagnoses and treatments require improvement. Future programmes should focus on these areas and ensuring multidisciplinary care continues to grow.

5.7 References:

Bridges S. Chronic pain. Health Survey for England, 2011. https://catalogueicnhsuk/publications/public-health/surveys/heal-surv-eng-2011/HSE2011-Ch9-Chronic-Painpdf 2012. https://catalogue.ic.nhs.uk/publications/public-health/surveys/heal-surv-eng-2011/HSE2011-Ch9-Chronic-Pain.pdf (accessed 10 January 2018)

Cleeland CS1, Reyes-Gibby CC, Schall M, et al. Rapid improvement in pain management: the Veterans Health Administration and the institute for healthcare improvement collaborative *Clin J Pain* 2003;19(5):298-305.

Clinical Standards Advisory Group (CSAG): Services for patients with pain 2000

Colvin LA and Rowbotham DJ I. Managing pain: recent advances and new challenges. *Br. J. Anaesth* 2013; 111 (1);1-3

Conway J, Higgins I. Literature review: models of care for Pain Management. http://www.health.nsw.gov.au/PainManagement/Documents/appendix-3-literature-review.pdf (accessed28 August 2018)

Core Standards for Pain management Services in the UK. Faculty of pain Medicine Royal College of Anaesthestists 2015. http://www.rcoa.ac.uk/system/files/CSPMS-UK-2015-v2-white.pdf . (accessed 28 August 2018)

David W. Baker. History of The Joint Commission's Pain Standards. Lessons for Today's Prescription Opioid Epidemic. *JAMA* 2017;317(11):1117–1118.

Department of Health : Chief Medical Officer's Annual report 2008: Pain: Breaking through the barrier. http://webarchive.nationalarchives.gov.uk/+/http://www.dh.gov.uk/en/MediaCentre/Media/DH_096206 (accessed 28 August 2018)

Donabedian A. Evaluating the Quality of Medical Care. The Milbank Memorial Fund Quarterly 1965;44:3:166-206

Fashler, S.R., Cooper, L., Oosenbrug, E.D et al. Systematic review of multidisciplinary chronic pain treatment facilities. *Pain Research and Management* 2016:1-19

Fielding R, Kause J, Arnell-Cullen V, Sandeman D. The impact of consultant-delivered, multidisciplinary, inpatient medical care on patient outcomes. *Clin Med* 2013: 13(4):344-8.

Getting to GRIPS with chronic pain in Scotland. NHS QIS 2007

Gordon DB, Dahl JL. Quality improvement challenges in pain management. *Pain* 2004;107(1-2):19

Hara KW, Borchgrevink P. National guidelines for evaluating pain - Patients' legal right to prioritised health care at multidisciplinary pain clinics in Norway implemented 2009. *Scandinavian Journal of Pain* 2010 1(1):60-3.

Hogg M. N., Gibson S., Helou A., Degabriele J., Farrell M. J. Waiting in pain: a systematic investigation into the provision of persistent pain services in Australia. *Medical Journal of Australia* 2012;196(6):386–390

Hooten WM, Timming R, Belgrade M et al . Assessment and management of chronic pain. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2013 Nov. p 105

IASP Taskforce Recommendations on Waiting Times: www.dgss.org/fileadmin/pdf/Task_Force_on_Wait-Times.pdf (accessed 28 August 2018)

Kerns R. Improving Care Across Hundreds of Facilities: The Veterans Health Administration's National Pain Management Strategy. In: Joint Commission on Accreditation of Healthcare Organizations. Improving the Quality of Pain Management Through Measurement and Action 2003.

Lynch ME, Campbell F, Clark AJ et al. A systematic review of the effect of waiting for treatment for chronic pain. *Pain* 2008;136(1-2):97-116.

Department of Health 2012:National Patient Safety Agency (Corporate Office) 4-8 Maple Street, London W1T 5HD:www.npsa.nhs.uk /resources/ (accessed 28 August 2018)

NICE Low Back Pain; early management CG88 2009. https://www.nice.org.uk/guidance/cg88 (accessed 28 August 2018)

Office for National Statistics, National Records of Scotland, Northern Ireland Statistics and Research Agency.https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/bulletins/annualmidyearpopulationestimates/2014-06-26 (accessed 28 August 2018)

Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process. BMJ Qual Saf. 2015. PMID: 26369893

Pain Management Services: Planning for the Future - guiding clinicians in their engagement with commissioners file:///C:/Users/cmp1v07/Downloads/RCGP-Commissioning-Pain-Management-Services-Jan-14.pdf (Accessed 19/-8/2018)

Pain Summit Report 2011: https://www.britishpainsociety.org/static/uploads/resources/files/members_articles_pain_summit_report.pdf. (accessed 28 August 2018)

Pain Treatment Services Guideline. International Association for the Study of Pain 2009. http://www.iasp-pain.org/Education/Content.aspx?ItemNumber=1381 (accessed 28August 2018)

Peng P, Choiniere M, Dion D et al. Challenges in accessing multidisciplinary pain treatment facilities in Canada. *Canadian Journal of Anesthesia* 2007;542:977–984

Pike, Andrew; Hearn, Leslie; de C Williams, Amanda C. Effectiveness of psychological interventions for chronic pain on health care use and work absence: systematic review and meta-analysis. *Pain* 157(4):777-785, April 2016

Pink D, Bromwich N. National Institute for Clinical Excellence (Great Britain). Principles for best practice in clinical audit. Radcliffe Publishing, 2002

Public Health England NHS Atlas of Variation volume 2 2011: https://fingertips.phe.org.uk/profile/atlas-of-variation (accessed 28 August 2018)

Roehr B. Trump declares opioid public health emergency but no extra money. *BMJ* 2017;359:j4998

Royal College of Anaesthetists Raising the Standard: a compendium of audit recipes (3rd edition) 2012 http://www.rcoa.ac.uk/index.asp?PageID=477

Service Development and Commissioning Directives, Chronic Non-Malignant Pain. Welsh Assembly Government. June 2008.

The National Pain Audit Reports 2011, 2012 https://www.hqip.org.uk/resource/national-pain-audit-reports-from-2011-to-2012/ (accessed19 August 2018)

The National Pain Audit Third Report https://www.britishpainsociety.org/static/uploads/resources/files/members_articles_npa_2013_safety_outcomes.pdf (accessed19 August 2018)

Treede RD; Rief W; Barke A et al. A classification of chronic pain for ICD-11. *Pain* 2015; 156(6):1003–1007

Figure 5.1 Audit Cycle Undertaken by the National Pain Audit 2010-14

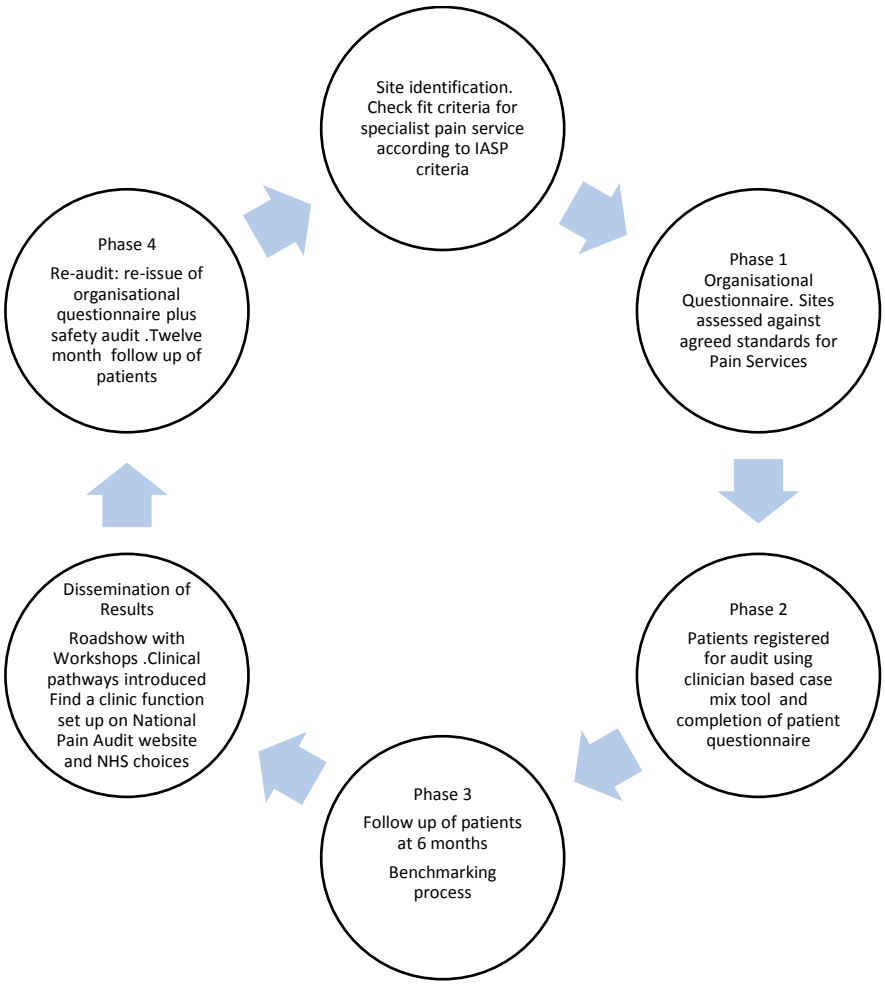
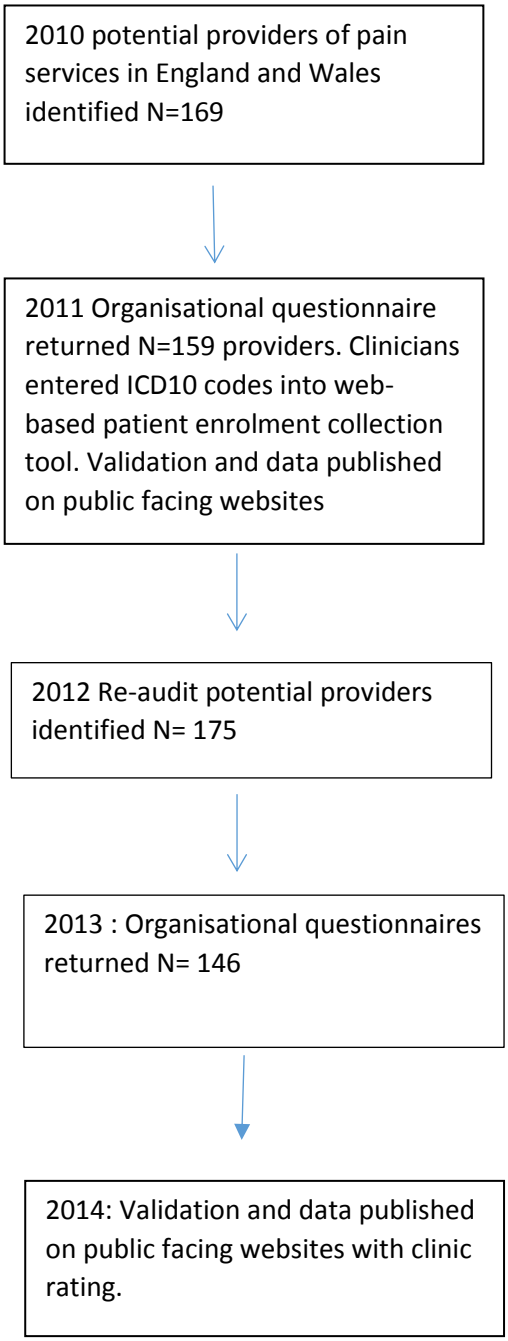


Figure 5.2 Data Collection Flow through the audit



5:1Table 1: Audit Standards assessed by the first National Pain Audit

	Standard	**Indicator Type**	**Justification**	**Reference**
1	Type of Clinic (IASP definition)	Structure	Evidence for multidisciplinary care	International Association for the study of pain guidance (IASP 2009)
2	Waiting times	Outcome	Key performance indicator nationally Evidence for waiting times impact on health	18 week Referral To Treatment Times (Baseline Audit) ASP waiting time standard (IASP2009) (Follow-up Audit)
3	Multidisciplinary staffing	Structure	Internationally Recognised Standard for Pain Services	IASP treatment facilities guidance (IASP 2009)
4	Availability of pain services per head of population	Structure	Key concern worldwide	Systematic Review recommendations (Fashler 2015)
5	Treatments available at Pain services	Structure	Availability of evidence based multidisciplinary care, back up facilities and wider specialist support to the community	British Pain Society Map of Medicine treatment pathways (Colvin and Rowbotham 2013)
6	Attributes of Pain Treatment facilities	Structure	Multidisciplinary Care check that personnel match the definition	Systematic Review recommendations (Fashler 2015)
7	100% patients diagnoses assigned an ICD-10 code	Outcome	Diagnosis Determines Treatment Pathway	NHS Information Standards
8	100% of clinics had protocols in place to manage high risk areas of practice	Process	Standard requirement of NHS providers	National Patient Safety Agency (Department of Health 2012)
9	Education Programme	Structure	As a specialist service , should be providing best practice on managing pain to non-specialists	IASP treatment facilities guidance (IASP 2009)

5:2 Table 2: Types of clinics, staffing and treatments available in pain clinics services at each audit round (N=total number of responses for that section)

	Baseline (2010)	**Follow-up (2013)**	Chi squared test/**P value**
Type of Clinic	**N (%)**	**N (%)**	
Modality-oriented	11 (7)	3 (3)	N/A
Pain Clinic	33 (21)	5 (5)	N/A
Total Non-multidisciplinary	*44 (28)*	*8 (7)*	N/A
Multidisciplinary*Pain Clinic	76 (49)	71 (65)	N/A
Multidisciplinary* Pain Centre	35 (23)	30 (28)	N/A
*Total Multidisciplinary *	*111 (72)*	*101 (93)*	<0.001
Total Clinic Type	***N=155***	***N=109***	
Staffing	**N=124 (%)**	**N=133 (%)**	
Psychologist	60 (49)	80 (64)	0.058
Physiotherapist	67 (54)	89 (67)	0.003
Consultant	89 (72)	113 (85)	0.010
Incomplete responses	40 (32)	20 (22)	
True multidisciplinary staffing (minimum)	39 (32)	75 (56)	<0.001
MDT meetings	70 (56)	117 (88)	<0.001
Treatment Modality	**N=146 (%)**	**N= 116 (%)**	
Interventional procedures	130 (88)	111 (96)	0.049
Implants	43 (30)	31 (28)	0.626
Pain Management Programme	122 **(86)	71 (61)	<0.001

* Minimum staffing of doctor, psychologist, physiotherapist

** may be inaccurate as merged with question on pain rehabilitation in first round

5:3 Table 3. Percentage of patients seen at a pain clinic per total head of population in England

(Source Office of National Statistics: Population Estimates for UK, England and Wales, Scotland and Northern Ireland 2013)

Region	**Number seen in pain clinic**	**Population**	**% seen**
East of England	18043	5,954200	0.303%
East Midlands	6927	4,598700	0.151%
North West	20456	7,103300	0.288%
London	21849	8,416500	0.260%
South West	11253	5,377600	0.209%
South East	17076	8,792600	0.194%
North East	8431	2,610500	0.323%
West Midlands	8577	5,674700	0.151%
Yorkshire and Humber	10083	5,337700	0.189%
England Total	**134223**	**53,865,800**	**0.249%**

5.8 Reflection

Assessing the organisational structure and processes of care of a service is part of any National Audit. To do this required a review of the standards of care set by the Royal College of Anaesthetists. The Faculty of Pain Medicine had just been established and so it served as a useful project for the new Faculty. There was an emphasis on multidisciplinary working and waiting times. This audit then went on to inform the next iteration of the Faculty of Pain Medicine's core standards of care and eventually CQC standards (Faculty of Pain Medicine 2015, 2016).

The audit established how best to identify pain clinics. This involved hand searching each provider on NHS choices and then looking through for mention of a pain clinic. The clinic was directly contacted. Others were picked up through the British Pain Society Newsletter. Many small businesses call themselves pain clinics (e.g. chiropractors) and it took considerable liaison with some to explain why they were not eligible (for example, non NHS, sole purpose was not to treat chronic pain). If this causes confusion to the providers then it must cause confusion to referrers and patients.

However, the spreadsheet proved cumbersome for services to complete and a differing collection method that is perhaps interactive and web-based would be an improvement. Improvement was seen in the increase of multi-disciplinary clinics; however, due to the fact that waiting times are a political issue, with financial penalties for non-compliance, it proved hard to get a real assessment of waiting times. The systematic review by Fashler is a useful platform to standardise data collection both nationally and internationally when planning future surveys.

Quality Standards have to be carefully constructed. The policy recommendation by the Joint Committee on Accreditation of Healthcare Organisations in the USA of Pain as the 5th Vital Sign, although well intentioned, has been widely implicated in the development of the opioid crisis there, forcing providers to mount a response to pain measurement. Any standards used need to be strongly evidence based with an understanding of their impact (Levy et al 2018).

The National Pain Audit only assessed one aspect of the quality of pain care, that is, whether pain services were delivering a reasonable standard of care. The quality standards developed by some other nations cover the whole system recognising the complexity of chronic pain.

Since this time, Scotland has proposed five Quality Standards for Pain consisting of evidence based standards on education, outcome measurement, a medication review, an annual review of pain services and exercise. The structure of the annual review of pain services is based on the approach taken by the National Pain Audit (Richardson et al 2018). However, this is only one section. The state of Ontario in Canada has also proposed 12 Quality statements in a similar vein, adding in ones on assessment and co-ordination of care (Health Quality Ontario 2019). Zidarov considered that, due to the complexity of chronic pain and its ability to span boundaries, the use of quality indicators to measure performance is essential (Zidarov et al 2016).

From a perspective of metrics to assess Quality of Care, as recommended by the Health Foundation (Friebel 2017), the audit can be assessed against these.

- Effectiveness – This was assessed by discharges, PROMS data and impact on emergency visits
- Efficiency – This was not assessed
- Equity – this would assess whether all people had similar access and is assessed to some extent in paper 4

- Safety – this was assessed by asking for copies of protocols in key areas
- Timeliness – this was assessed
- Patient-centredness – patient experience questions were asked in Paper 4

This audit was to assess the structures and processes of how pain clinics work. It did not assess the service from a patient perspective. This is however, a feature of the majority of the National Audits. Some general outcomes were assessed, for example, safety protocols. However, unlike PACS, adverse events were not measured. Feedback from patients on the quality of care provided and patient expectations was asked for.

5.9 Declaration of Authorship for Paper 3

Cathy Price: I was responsible for study design, choice of methodology, drafted all versions of the manuscript, review of all analyses, held overall responsibility for manuscript submission and all associated administration

Amanda C de C Williams: Clinical advice, data analysis for the study and paper. Reviewed the manuscript and commented on drafts

Blair H. Smith: reviewed and commented on drafts of the manuscript

Alex Bottle: Statistical advice for the study and for the audit. Key role in design of the study. Reviewed paper and commented on drafts

All co-authors below confirm the accuracy of the declaration of authorship for paper 3:

	Signature	**Date**
Amanda C de C Williams:		3rd March 2019
Blair H. Smith:		**3rd March 2019**
Alex Bottle		**3rd March 2019**

Chapter 6: **Paper 4:**

Implementation of Patient Reported Outcomes from Specialist Pain clinics in England and Wales: experience from a nationwide study

Short Title: Patient Reported Outcomes from Specialist Pain Clinic in England and Wales

Price CM, Williams A C de C , Smith BH, Bottle A European Journal of Pain. 2019: 23;7:1368-1377

6.1 Overview

This paper took the data obtained from formation of a patient registry as part of the National Pain Audit. It examined the success of implementing the registry, which was based largely on PROMs. This was the first time that PROMs data collection had been attempted from a whole nation's pain clinics.

From the time the initial PACS database was formed and its validity tested, international consensus on the areas that should be measured in chronic pain trials was agreed (IMMPACT 2005). It is expected that any PROMs will cover the six IMMPACT domains for measuring outcome from chronic pain interventions (Dworkin 2005). However, what is also important, is to balance the breadth and quality of data collected with the burden on the patient. Additionally, their utility in measuring outcomes in routine clinics where interventions may be far less clear was unknown.

We aimed to explore the feasibility of implementing a suite of Patient Reported Outcome Measures (PROMs) in terms of recruitment, response rates and completion rates. From this, we were able to make a series of recommendations as to how to best achieve implementation of collection and comparison of PROMs in pain clinics.

The outcome measures selected were based upon IMMPACT guidelines. However, only a few areas were covered by recommended questionnaires (the EQ5D -3L and BPI). There was a balance to be had between the burden of questionnaires and the validity of them. Suitable measures to assess work status, the quality of advice and education from pain services, were not readily available and so were derived through a consensus process with stakeholders.

6.2 Abstract

6.2.1 Introduction

Evaluating outcomes in routine clinical practice is a significant challenge for specialist pain clinics due to the complexity of interventions provided and the subjective nature of pain. This study reports

findings from implementation of Patient Reported Outcomes (PROMs) in pain clinic, in England and Wales, between 2011-2013.

6.2.2 Methods

A paper-based questionnaire was administered at a first appointment in participating centres. This assessed quality of life, experience of health care and health care usage with postal follow-up at 6 and 12 months by the research team. Feasibility was assessed in terms of response rates, completion rates and outcomes.

6.2.3 Results:

Ninety-one (56%) clinics participated, entering 9588 patients (19% of those eligible). For responders there was a 92% item completion rate. The drop-out rate was high, 46% and 19% returned questions at 6 and 12 months respectively. Quality of life at baseline was low, with a mean EQ5D-3L Time Trade Off (TTO) value of 0.32. Amongst responders at 12 months, 92% continued to experience significant pain. For those with planned discharges 30% achieved the Minimal Important Change (MIC) for quality of life. Nonetheless, 70% reported positive experiences of care.

6.2.4 Conclusions:

Patients attending UK pain clinics report an extraordinarily poor quality of life and difficulty with understanding their condition. Problems with PROMs implementation included initial recruitment, follow-up response rates, classification systems and benchmarking. Successful implementation should include use of electronic data capture, feedback and focus on gradual improvement. To achieve this would require extended periods of funding.

6.3 Significance

No nationwide evaluation of the effectiveness of specialist pain clinics had previously been attempted. Comparison of patient outcomes from services enables improvement. This work provides a platform from which to improve methods of routine PROMs capture in pain clinics in order to measure clinical outcomes from pain clinics.

6.4 Introduction

Specialist multi-disciplinary pain services were developed to meet the needs of patients who cannot be managed by a generalist practitioner. Services are expected to assess and treat complex pain disorders by adopting a biopsychosocial approach through various interdisciplinary, multimodal interventions (Gallagher 2005, Turk 2002). Government-sponsored reviews of specialist pain services have highlighted the lack of information on the patient population, treatment offered, and their outcomes.(Department of Health England 2008, Quality Improvement Scotland 2007)

The work of IMMPACT has helped the research community with data collection (Dworkin, Turk et al 2005). There is also consensus on which Patient Reported Outcome Measures (PROMs) should be collected in clinical practice (Devlin and Appleby 2010, Clarke et al 2003, Ashburn 2012, Tauben 2012, Kaiser et al 2017), with broad support from the clinical community (Holmes et al 2017). Currently, however, there is only limited information on the practical implementation of patient-reported outcome measures (PROMs) in pain services. The benefits of PROMS in improving clinical and cost effectiveness have been shown in diverse areas such as cancer care, joint replacement surgery, wound healing and diabetes (Hoque 2015).

In the UK, a clinical registry to collect patient outcomes PACS (Pain Audit Collection System) was established in 2003 and worked well for a small number of services. However, large scale implementation was hampered by incompatibility of software systems, the lack of funding for data analysis and poor quality data from many centres (Griffths, Campbell et al 2003, Hall, Merrett et al 2008). It ceased operation in 2008. Outside the UK other clinical registries have been attempted to a limited extent. In Quebec, Choinere described formation of a patient registry with follow-up at six months using PROMs, but only in 5 tertiary centres (Choinere et al 2017). Tardif described a similar process to PACS in Australia to establish the electronic Persistent Pain Outcomes Collaboration (ePOCC) (Blanchard et al 2017), and this continues to grow. In the USA, the development of PROMIS (Patient-Reported Outcomes Measurement Information System) for capturing patient outcomes (Cella, Yount et al 2010) was then taken up by PASTOR (Pain Assessment Screening Tool and Outcomes Registry) (Cook, Buckenmaier et al 2014). However, no comparison of US centres has been published. Garcia reported successful implementation of PROMs in 316 Spanish pain services, but the use of researchers to recruit and short follow-up times limit its generalisability (Garcia et al 2016).

The UK government funded a National Pain Audit over a four year cycle from 2010 to 2014 in England and Wales (HQIP 2017) to improve specialist pain care Details of clinics and case-mix are described previously (Price 2018). The brief was to develop a robust database that all specialist pain services could submit to (Department of Health 2008). This paper aims to evaluate the feasibility of PROMS collection through formation of a patient registry to over a one year journey, (from 2011-13) in order to inform future data collection across the spectrum of pain clinics in England and Wales, using clinic-based recruitment with postal follow-up by researchers.

6.5 Methods

Study Design and setting

This was a cohort study nested within a National Pain Audit (HQIP 2017) with a focus on assessing the feasibility of data completion and response rates to a PROMS questionnaire. One hundred and sixty-one pain clinics in England or Wales, identified in the National Pain Audit as specialist pain

services (International Association for the Study of Pain 2009), were invited to recruit patients to this PROMs study. Participation in National Audits is expected for National Health Service (NHS) organisations although there are no penalties for non-participation.

Subjects

All children over 12 years old and adult patients in England or Wales attending for the first time during a three-month period between 2011 and 2012 were eligible for inclusion. Patients with cognitive or language difficulties were included if they were able to successfully complete a questionnaire with an interpreter or with help as judged appropriate by the clinic. Patients who declined to complete the questionnaire, or for whom the clinician failed to enter sufficient details on the case-mix tool (see below), were excluded. Support with data collection was provided for the clinics through a series of Frequently Answered Questions on the National Pain Audit webpages and a helpline.

Data Collection Period

The patient-reported outcomes element consisted of three phases. In year 1, while services were being identified and enrolled, the questionnaire and a web tool for clinicians to enter clinical details were assembled and piloted in 12 centres. In year 2 of the audit, each participating clinic was asked to enrol patients over three months of continuous data collection throughout the period of one year at a point when a provider felt most ready to start collection. It was felt that the focused period would maximise the likelihood of collection.
Clinical details were entered into a web tool by the clinician seeing the patient. This was developed by Dr Foster Research UK, the main contractor for the Audit. Each patient completed a paper set of questions that was retained by the clinic and returned to the study team. This cohort was then followed up after 6 and 12 months from entry by direct mailing by post of follow-up questions by Dr Foster Research UK, with patients invited to telephone if they had difficulty. Further reminders to complete the questions were not issued.

Web tool development

An earlier entry of patient data into a Pain Collection System that was Microsoft Access-based (Griffiths 2003) produced problems at interfaces with hospital IT systems, especially when Access was upgraded. A web-based system was therefore developed by the main contractor to enter patient details and case-mix (supplemental data). A pilot of this over a six-month period with 12 clinicians across England demonstrated that clinicians struggled to enter ICD-10 codes, with many refusing to enter data. For this reason, and to ensure maximal uptake of the audit, free text diagnoses were permitted.

Questionnaire Development

The selection of PROMS was guided by the Department of health guidance on PROMS which recommends a generic measure and a disease specific measure. We had previously used the Brief Pain Inventory in the PACS database (Griffiths 2003) after substantial testing of alternatives. The generic quality of life measure EQ5D was selected as it is used by the national PROMS audit (Department of Health 2012).Treatments were grouped based on a previous database PACS

(Griffiths 2003). As in the well-established PROMS Hip and Knee Audits (NHS Digital 2014), a disease-specific scale (the Brief Pain Inventory) and a global scale of health (Euroqol 5D-3L) were chosen. The Brief Pain Inventory (Keller et al 2004, Tan et al 2004) has demonstrated utility in terms of data entry and analysis in UK pain clinics (Hall et al 2008). The Euroqol 5D-3L (EQ5D-3L) has been shown to be relatively responsive in the chronic pain population (Obradovic 2013) and its use enables quality of life comparisons with people with other long-term disabling conditions. Work and healthcare resource questions that elicited data on unemployment, presenteeism and absenteeism were chosen on advice of experts. Ratings of the usefulness of the service and patient satisfaction were developed with patient groups. Personal data collected were age and sex; ethnicity (Office for National Statistics 2011) was collected only for the final follow-up. Patients were also asked what treatment they had received using a classification that had earlier been developed with the Department of Health in relation to waiting times for care pathways (Department of Health 2010). The patient groups and clinicians reviewed and approved the PROMs and a pilot group of 12 sites tested the questionnaire. The final data items are available in Supplementary Table S1.

Data collection and oversight

Piloting at twelve sites indicated that paper-based questionnaires and electronic capture of patient details were the optimal combination to enrol patients. Patients were assigned a unique study Identifier (ID) via the paper-based questionnaire. This ID was then entered into the web tool to collect diagnosis and demographic details. At the end of 3 months, paper-based patient questionnaires were collected by courier from each site. These were scanned, uploaded and linked to the case-mix tool data. Patients were sent follow-up questions at 6 months and 12 months after their first appointment via the research team. Findings were reported in line with STROBE guidance for cohort studies (Von Elm 2008).

Data validation

The number of patients entering the study was cross-referenced with activity returns from the national hospital administrative database for England, Hospital Episode Statistics (HES), for pain clinics during the recruitment period (new patients seen). The denominator was also calculated as the estimated numbers seen by the clinic in three months. The proportion entering the study was then calculated. Patient data were analysed for completeness and a deeper analysis was undertaken to improve follow-up questionnaire design. Questions that were conditional on a previous answer, work-related, or required an opinion were found to be less well answered and so these types of questions were adjusted on the final round.

Data Analysis

Data were uploaded to Excel and SPSS. Diagnostic results were grouped by International Classification of Diseases, version 10 (WHO) chapter, e.g. musculoskeletal pain. Free text diagnoses were mapped to ICD-10 by three clinical members of the National Pain Audit scientific committee.

Mean Time Trade Off (TTO) values for the EQ5D and mean values for Brief Pain Inventory (BPI) subscales of Pain Severity and Pain Interference were reported in line with manuals for both questionnaires. Differences between time points were tested using paired t tests for parametric data. However, as this may not provide a true representation of important changes in patient

outcomes, the Minimal Important Change (MIC) was used to define a good improvement in pain. For the BPI the MIC was defined as a 2 point change in the Pain Severity Scale and a 1 point decrease in mean Pain Interference score (Mease 2011, Matthias 2011, Dworkin 2008); for the EQ5D-3L 0.074 increase in TTO value was used as the MIC value (Walters 2005). EQ5D-3L scores were compared with UK population norms for other conditions (Sullivan 2011).

Pain clinics see a wide variety of cases with some tertiary providers seeing many highly complex cases. Since case-mix may affect outcome, for direct comparison of provider case-mix and outcomes, a case-mix adjustment model was built. Details of this are in Supplementary Information Methods S1.

Funnel plots for the risk-adjusted PROMs were calculated to show variation by unit by change in BPI score and EQ5D-3L TTO value using the Department of Health guidance on case mix adjustment (Supplementary information 1). (Department of Health 2012)

Feedback

A key feature of any patient registry is feedback. Direct feedback to services was limited: results were issued in a series of annual reports and individual clinic outcomes uploaded onto a public facing website (www.nationalpainaudit.org.uk) which linked to NHS choices, the main source of information on healthcare providers in the NHS. Public facing data have been shown to improve quality of data and feedback (Hoque 2015).

Ethical Considerations

There was no transfer of patient identifiable data. The patient questionnaire contained patient details which were scanned in, linked to the Study ID then held separately to their data. Consent was formally sought from patients to link their questionnaire data anonymously with HES Data and, where this was declined, questionnaires were destroyed immediately after data entry. Information was managed by Dr Foster Research UK whose Information Security Management System (ISMS) is certified to ISO 27001:2013 by Certification Europe. A full explanation of Dr Foster Research UK's approach to data management is given on their website (https://www.drfoster.com/company/information-governance/patient-privacy/).

Oversight of the data processes, permissions for the study and handling of data were managed by the Health Quality Improvement Partnership who oversee all contracts for National Audits. (www.hqip.org.uk).

Following completion of the audit, anonimised patient data were uploaded to the UK Government data website (https://data.gov.uk/) by the main contractor, as stipulated by the contract with the Department of Health for each period of collection.

6.6 Results

Flow and numbers

Figure 1 shows the extent of data capture. Ninety-one clinics out of 169 (a response rate of 56%) recruited 9,588 patients. Hospital Episode Statistics data showed that 49,460 patients attended these clinics over a quarter year in 2011-12, giving an overall estimated patient capture of 19%. There was wide variation between clinics in the numbers entered per head of population, with an average of 11 patients per 100,000. No single-modality clinic (ie service offering a single treatment) returned patient level data. Clinics ranged from one seeing 16 patients per year to one seeing 2000, and ranged from single operator pain clinics to tertiary, sub-specialist services. The type of service was not predictive of the response rate. Three returns were spoilt. HES data proved unreliable as a baseline as we discovered significant under-reporting of activity compared to responses in some centres, so it was difficult to truly estimate response rate.

In terms of responders being able to complete the questionnaire, there was a 92% overall item completion rate in both initial and six-month follow-up questions. From the initial set, seven questions were poorly completed, five due to their structure (sub-questions were often missed out). Older (over 75 years) and younger patients (15-25 years) completed questions less well.

By 6 months, patients reported receiving a range of treatments, with 31% having received psychologically based treatments and 60% multimodal care.

Demographics & Case-Mix

Table 1 shows the demographic data collected at different time points. The median age of those entered on the case-mix tool was 54, with 6,158 (64%) being female patients. Two-thirds of patients were reported by clinicians to have musculoskeletal pain.

Both baseline BPI and EQ5D-3L scores suggested severe pain and a very poor quality of life for most respondents (Table 2). The mean BPI score was 6.32/10 for pain intensity, and 6.16/10 for pain interference with life. The mean EQ5D-3L Summary Health Score was 52, and the mean Time Trade-off (TTO) value was 0.32, which is lower than the value for any single condition, suggesting significant levels of multi-morbidity. One thousand six hundred and fifty patients (16%) had a negative TTO value, denoting a quality of life that is “worse than death”. One thousand nine hundred and fifty-six patients (20%) had attended Accident and Emergency Departments looking for help with their pain in the six months prior to being seen.

Patients who responded at 12 months were on average older than those who did not (59 years versus 54 years) and 92% were white British. The ratio of male to female remained the same (65% female to 35% male). Initial BPI scores were very similar (Baseline mean Pain Severity = 6.3, standard deviation 1.2 at 0 months for non-responders , 1.9 for responders , baseline mean Pain Interference 6.6, standard deviation 2.2 for both responders and non-responders). We did not collect data on ethnicity at the outset and so it is unknown whether the ethnic diversity was similar at baseline and follow-up. At baseline, one-fifth reported being able to work, and one-third unable to work; at 12 months one-third were able to work and half unable to do so (Table 2). Twelve per cent were working reduced hours at baseline (Table 2).

Benchmarking outcomes between providers

. The case-mix adjustment model was able to account for 40% of the variability in scores. However, funnel plots were very over-dispersed, i.e. showing more variation than expected purely by chance.

We cannot be sure of the reasons for this over-dispersion, which could include some mix of data noise (data quality issues), unaccounted-for case-mix factors and quality of care, all in unknown proportions. We concluded that the case-mix adjusted model requires further refinement before being used to make fair comparisons between the quality of care at different providers and therefore did not report the funnel plot.

Patient experience of care

Patient-reported experiences of the services at 6 and 12 months are displayed in Table 3. Overall, 70% reported having sufficient information and being involved in treatment decisions. Interestingly, 29% did not want any information on how to manage pain.

Outcomes reported by clinics

Of the 1,799 (19%) who completed both 6- and 12-month follow-up questions, 1,626 (92.9%) continued to have moderate to severe pain at 12 months. Thirty-eight per cent of the cohort who completed the questionnaire had been discharged from the clinic by the end of the study ie at one year. Six per cent did not respond leaving 56% still attending treatment.

For the small numbers completing 12 month follow-up questionnaires, mean BPI Pain Severity and Pain Interference scores and mean EQ5D-3L scores at 6 and 12 months are shown in Table 2. Nearly two-thirds of responding patients reported treatment to be of moderate to good benefit, with only 11% reporting no benefit. There was a statistical improvement in the mean pain specific measure (BPI) at 6 months (mean decrease 0.43 $P<0.001$ in Pain Severity, Mean decrease in Pain Interference 0.41 $P<0.001$). However, by 12 months this was not maintained apart from for those who had been discharged (Mean decrease in Pain Severity for discharged patients 0.68 $P<0.001$ Mean decrease in pain interference 0.76, $p<0.001$). The mean EQ5D-3L TTO value set also showed statistical improvement (mean change -0.03, $p<0.05$) as did the mean EQ5D-3L wellbeing score but this did not reach statistical significance (mean change 2 NS (Table 2).Those in the cohort who were discharged by 12 months had lower initial scores, suggesting they were less severe cases.

The proportions achieving the MIC in Pain Severity and Pain Interference on the Brief Pain Inventory and on the EQ5D-3L at 6 months and 12 months are shown in Table 4. Mean summary health scores were unchanged. Thirty per cent of those discharged achieved the MIC value.

6.7 Discussion

This was a first attempt at implementing PROMs at scale in pain clinics in England and Wales. A sizeable cohort of nearly 10,000 patients was recruited with a large number of participating sites. We were able to measure some key case-mix variables and clinicians found a web tool easy to use. We have reported the findings and lessons from the data collection and analysis, including some limited outcomes relating to clinical effectiveness and patient experience. We found the quality of life of patients attending pain clinics was very poor as reported by the EQ5D-3L, with high use of Accident & Emergency departments. Challenges were disappointing recruitment and response rates; these limit any conclusions that can be drawn regarding outcomes from pain clinics.

The study has several limitations which can be summarised as: low and variable rate of recruitment, low patient response rates at follow up; problems with coding and classification of data into ICD

/treatment groupings and the poor quality of HES outpatient data. Difficulties in recruitment may have been due to clinics not distributing questionnaires or supervising questionnaire completion as well as clinical buy-in to the study. Electronic data capture is now recommended for clinical quality registries (Hoque et al 2017) which should help. Factors that can act as barriers to participation include fear of scrutiny of clinic practices, the additional workload of participating and possible implications for changing practice. (Black and Thompson 1999, Antunes, Harding et al 2014). The expectation that all centres would participate in the study as it was part of a National Audit was not borne out, and our earlier recommendation of sampling only a small number of committed centres, ensuring feedback and growing gradually might well have been more effective (Hall 2008, Hoque et al 2017). However, this may bias responses as the most enthusiastic clinics are also the most likely to complete questionnaires. Additionally, only one time period was permitted to recruit and so we were unable to act upon and improve recruitment strategies. The patient response rate was disappointingly low at 6 and 12 months; many other audits have experienced low response rates (Royal College of Psychiatrists 2012, NHS Digital 2014, Blanchard et al 2017). The National Bowel Cancer Audit found the main factors in poor response rates were being elderly, high deprivation, greater co-morbidity, and being admitted as an emergency (HQIP 2018). The International Society of Arthroscopy Registries recommends a 60% response to PROMS as a measure of an adequate response (Rolfson et al 2016). Providers in the National PROMS Hip and Knee programme were financially incentivised to respond. Public facing feedback, a clear explanation of the goals of the programme to patients, reminders and dedicated staff for PROMS data collection may improve response rates (Rolfson et al 2016). The National Dementia Audit (Royal College of Psychiatrists 2018) recommends greater participation of sites to ensure better response rates. We were aware, however, this was a first attempt and were concerned to not overburden services. Clinicians struggled to classify pain using ICD-10 with 30% of patients having a free text diagnosis initially. The new ICD-11 classification for pain should help (Treede et al 2015). We would recommend tailored support and training for clinicians to enter diagnoses. HES outpatient data proved unreliable which meant that there was no easy denominator to provide numbers seen apart from clinic estimates. Further work with clinics to assist with routine returns on clinic activity to HES together with some monitoring and feedback might improve this. Treatment currently has no recognisable classification system leading to inconsistencies over the study period on how treatments were grouped. Guidance is needed in this area.

We found that the majority of patients were working-age adults with musculoskeletal disorders, with pain having greatest impact on work. That a greater proportion of respondents were women and the majority were working age adults is consistent with other secondary care pain surveys. (Blanchard 2017, Garcia 2016) suggesting our sample is reasonably representative. These findings are similar to cross-sectional surveys reported in Scotland and Canada in terms of age, employment status and quality of life (Health Improvement Scotland 2016, Racine 2014). However, a Norwegian study found 359 patients attending tertiary level clinics enjoyed a much better quality of life reported by the EQ5D-3L - a mean TTO score of 0.53 compared with ours of 0.33 (Vartiainen 2017) - whereas ePOCC reported worse disability scores (BPI Pain Interference mean 7.0). These discrepancies between high income countries with social insurance systems warrant further investigation.

Amongst those responders to the follow up questionnaire, there were some statistically significant improvements in outcomes. Interpretation of these data is limited by the low response rate to follow-up questionnaires and likely bias or possible adverse selection among those who chose to remain in the audit. Depending on the measure, 18% to 25% per cent reported a clinically important improvement (MCID) in pain and quality of life. A study in a single UK tertiary pain centre using the same MIC calculations reported that 16%–23% of patients improved (Shah 2015), a comparable proportion. Others have reported far greater improvement. ePOCC in Australia reported that 68% of

respondents achieved the MIC for Pain Interference (Blanchard et al 2017); a Spanish cohort study (Garcia et al 2016) reported significant reductions in pain and improvement in quality of life. There may be good reason for these differences. Garcia's results may have been affected by exclusion of patients with psychiatric and neurological co-morbidities, Blanchard's results were for those who had completed an episode of care. It is possible that individuals with more severe pain in this study were (a) more likely still be in contact with the pain service and (b) more likely to return a pain-related questionnaire (Smith 2005). We had only a short time frame to collect follow up data which meant only 708 (39%) had completed a care episode and may have differed in treatment received from those remaining. Whilst it is also possible that non-responder dischargees may have improved, non-responders to PROMS tend to be male, socially disadvantaged with poorer literacy so at risk of poorer health outcomes. (Hutchings et al 2012) In future we recommend that only completed care episodes are reported and specific ways to engage these groups are sought.

We were able to explain 40% of the variation in the PROMs scores with the case-mix variables we identified. The remaining 60% variance may be due to a wide range of factors, including the quality of care provided, other case-mix factors, within-person random variation and other un-identified factors. A systematic review in musculoskeletal patients recommended the use of baseline PROM score, age, sex, comorbidities, symptom duration, and surgical history. (Burgess 2018). However, outcomes from diabetes care have been extensively investigated for appropriate case-mix adjustment methods with the conclusion that this is an extremely complex process and ultimately, where multi-morbidity is the norm and it is unclear which characteristics require adjustment, robust models may be impossible to achieve (Calsbeek 2016). Pain care may be similar.

People attending specialist pain clinics experience a very poor quality of life reporting great difficulty in working with what is a long-term condition. The proportion reporting quality of life equivalent to "worse than death" (16%) was very similar to the proportion with neuropathic pain in a recent population study (17%) (Van Heck et al 2014). This level of difficulty and the slow progress through treatment suggest that there is considerable room for improvement in care including improving flow and greater involvement of carers and support agencies. The poor coding and classification systems that exist currently act as barriers to accurate epidemiological data related to chronic pain and prevent the development and implementation of new therapies. Given the current difficulties with chronic pain management this situation urgently needs to change with training for clinicians and coders, and development of a treatment classification.

We were unable to answer the questions as to whether the health of chronic pain patients is observed to improve following input of specialist services in England and Wales and whether we can benchmark services adequately with each other. Collection of PROMs in specialist pain services requires improved methodology before this can be achieved. Based on our previous experience, this might include starting with clinics committed to good quality data collection only (though noting the likely bias), allowing a greater period of follow up to complete episodes and the use of web-based data collection. Sites should take ownership of collection of data and a public facing feedback process should be in place. To deliver this, significant funding is required. However, two reports have emphasised that disease registries more than pay for themselves by improving the quality of care and patient outcomes if they are funded over several cycles to maximise reliability and quality (Larsson et al 2012, ACSHQC 2013). Cost-effectiveness data therefore also should be collected. Case-mix adjustment to allow meaningful comparison between centres needs further research but could include co-morbidities and

important variables that may impact a clinic's outcomes. This would permit identification of high-performing services and drive improvement in care.

6.8 References

Antunes B, Harding R, Higginson IJ, EUROIMPACT. Implementing patient-reported outcome measures in palliative care clinical practice: a systematic review of facilitators and barriers. *Palliative medicine*. 2014 Feb;28(2):158-75.

Ashburn MA, Witkin L. Integrating outcome data collection into the care of the patient with pain. *Pain*. 2012;153(8):1549-50.

ACSQHC. Economic evaluation of clinical quality registries: Final report. Sydney: The Australian Commission on Safety and Quality in Health Care 2016.

Black, N and Thompson, E. Obstacles to medical audit (British doctors speak) .*Social Science & Medicine*. 1999; 36: 849–856

Blanchard M, Tardif H, Fenwick N, Blissett C and Eagar K Electronic
Persistent Pain Outcomes Collaboration Annual Data Report 2016 (2017). Australian
Health Services Research Institute, University of Wollongong.

Burgess, R., Bishop, A., Lewis, M., & Hill, J. (2018). Models used for case-mix adjustment of patient reported outcome measures (PROMs) in musculoskeletal healthcare: A systematic review of the literature. Physiotherapy.

Blyth FM, March LM, Brnabic AJ, Cousins MJ. Chronic pain and frequent use of health care. *Pain.* 2004 Sep;111(1-2):51-8.

Calsbeek H, Markhorst JG, Voerman GE, Braspenning JC. Case-mix adjustment for diabetes indicators: a systematic review. *American Journal of Managed Care.* 2016 Feb 1;22(2):e45-52.

Clarke ME, Kerns R, Craine MH, Markham R, Jones JA et al. National VA Pain Outcomes Working Group: National VA Pain Management Coordinating Committee; VHA Pain Outcomes Toolkit. Department Of Veterans Affairs, 810 Vermont Avenue, N.W. Washington, DC 20420 February 2003).

Choinière, M., M. A. Ware, M. G. Pagé, A. Lacasse, H. Lanctôt, N. Beaudet, A. Boulanger, P. Bourgault, C. Cloutier, L. Coupal, Y. De Koninck, D. Dion, P. Dolbec, L. Germain, V. Martin, P. Sarret, Y. Shir, M.-C. Taillefer, B. Tousignant, A. Trépanier and R. Truchon (2017). "Development and Implementation of a Registry of Patients Attending Multidisciplinary Pain Treatment Clinics: The Quebec Pain Registry." *Pain Research and Management 2017*: e8123812.

Cook KF, Buckenmaier 3rd C, Gershon RC. PASTOR/PROMIS® pain outcomes system (2014): What does it mean to pain specialists? *Pain management*. 2014 Jul;4(4):277-83.

Core Standards for Pain Management Services in the UK . https://www.rcoa.ac.uk/faculty-of-pain-medicine/standards/core-standards Accessed 23/09/2018

Department of Health in England: Chief Medical Officer's Annual report 2008: Pain: Breaking through the barrier.
http://webarchive.nationalarchives.gov.uk/+/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/AnnualReports/DH_096206 Accessed 23/09/2018

Department of Health Elective Care Commissioning Pathways 2010. http://webarchive.nationalarchives.gov.uk/20130104183114/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_121431 Accessed 12/09/2018

Department of Health NHS Outcomes Framework 2012:. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/213711/dh_131723.pdf Accessed 04/11/2018

Department of Health. Patient Reported Outcome Measures (PROMs) in England. The case-mix adjustment methodology 2012. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216507/dh_133449.pdf Accessed 23/09/2018

Department of Health in England 2012: QIPP LTC Year of Care Funding Model Project Team. QIPP Long Term Conditions—Supporting the Local Implementation of the Year of Care Funding Model for People With Long-Term Conditions. London, UK https://www.gov.uk/government/publications/qipp-long-term-conditions-year-of-care-funding-model-early-implementers Accessed 23/09/2018

Devlin N, Appleby J. Getting the Most out of PROMS. The Kings Fund 2010. https://www.kingsfund.org.uk/sites/files/kf/Getting-the-most-out-of-PROMs-Nancy-Devlin-John-Appleby-Kings-Fund-March-2010.pdf Accessed 23/09/2018

Dworkin RH, Turk DC, Farrar JT, Haythornthwaite JA, Jensen MP, Katz NP, Kerns RD, Stucki G, Allen RR, Bellamy N, Carr DB. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. *Pain*. 2005;113(1-2):9-19.

Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, Haythornthwaite JA, Jensen MP, Kerns RD, Ader DN, Brandenburg N. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. *The Journal of Pain*. 2008;9(2):105-21.

Gallagher RM. Rational integration of pharmacologic, behavioral, and rehabilitation strategies in the treatment of chronic pain. *American journal of physical medicine & rehabilitation*. 2005 Mar 1;84(3):S64-76.

García García JA, Hernández-Puiggròs P, Tesedo Nieto J, Acín Lázaro MP, Carrera González A, Soler MJ, Maldonado Vega S. Patient satisfaction with Spanish pain centers: observational study with more than 3,000 patients. *Pain Research and Treatment*. 2016 (2016)

General Medical Council: Good Medical Practice 2013: https://www.gmc-uk.org/guidance/good_medical_practice/partnerships.asp Accessed 23/09/2018.

Griffiths DP, Mitchell Noon J, Campbell FA, Price CM. Clinical governance and chronic pain: towards a practical solution. *Anaesthesia.* 2003;58(3):243-8.

Hall GC, Bryant TN, Merrett LK, Price C. Validation of the quality of The National Pain Database for pain management services in the United Kingdom. *Anaesthesia.* 2008;63(11):1217-21.

Health Improvement Scotland Chronic Pain in Scotland where are we now? 2014 report. http://www.healthcareimprovementscotland.org/our_work/long_term_conditions/chronic_pain/where_are_we_now.aspx.Accessed 23/09/2018

Health Quality Improvement Partnership (HQIP) https://www.hqip.org.uk/wp-content/uploads/2018/08/PROMs-Feasibility-Study-Final.pdf (Accessed 04/11/2018)

Holmes MM, Lewith G, Newell D, Field J, Bishop FL. The impact of patient-reported outcome measures in clinical practice for pain: a systematic review. *Quality of Life Research*. 2017 Feb 1;26(2):245-57.

Hoque DM, Kumari V, Hoque M, Ruseckaite R, Romero L, Evans SM. Impact of clinical registries on quality of patient care and clinical outcomes: A systematic review. PloS one. 2017 Sep 8;12(9):e0183667.

Hutchings, A., J. Neuburger, K. Grosse Frie, N. Black and J. van der Meulen. Factors associated with non-response in routine use of patient reported outcome measures after elective surgery in England. Health Qual Life Outcomes 2012 10: 34 doi:10.1186/1477-7525-10-34

International Association for the Study of Pain: Pain Treatment Services Guideline. 2009. http://www.iasp-pain.org/Education/Content.aspx?ItemNumber=1381 Accessed 28August 2018

Kaiser U, Kopkow C, Deckert S, Neustadt K, Jacobi L, Cameron P, De Angelis V, Apfelbacher C, Arnold B, Birch J, Bjarnegård A. Developing a core outcome-domain set to assessing effectiveness of interdisciplinary multimodal pain therapy: the VAPAIN consensus statement on core outcome-domains. Pain. 2018;159(4):673-83.

Keller S, Bann CM, Dodd SL, Schein J, Mendoza TR et al . Validity of the brief pain inventory for use in documenting the outcomes of patients with noncancer pain. *The Clinical journal of pain*. 2004 Sep 1;20(5):309-18.

Larsson S, Lawyer P, Garellick G, Lindahl B, Lundstrom M. Use of 13 disease registries in 5 countries demonstrates the potential to use outcome data to improve health care's value. *Health Aff* (Millwood). 2012; 31(1):220-7.

Mease, P.J., Spaeth, M., Clauw, D.J., Arnold, L.M., Bradley, L.A., et al. (2011) Estimation of minimum clinically important difference for pain in fibromyalgia. *Arthritis Care and Research* 63(6), 821-826.

National Audit of Psychological Therapies for Anxiety and Depression National Report 2011.http://www.rcpsych.ac.uk/pdf/NAPT%20Report%20amended%20March%202012%20FINAL.pdf. Accessed 23/09/2018.

NHS Digital: Guide to PROMS. http://content.digital.nhs.uk/proms-userguide Accessed 23/09/2018.

Obradovic M, Lal A, Liedgens H. Validity and responsiveness of EuroQol-5 dimension (EQ-5D) versus Short Form-6 dimension (SF-6D) questionnaire in chronic pain. *Health and quality of life outcomes.* 2013 Jul 1;11(1):110.

Office for National Statistics: Final recommended questions for the 2011 Census in England and Wales: Ethnic group. October 2009

NHS Digital: Patient Reported Outcome Measures (PROMs) in England: Special Topic: Rates of Attrition 2013-14. https://digital.nhs.uk/catalogue/PUB20625 Accessed 24/12/2017.

Paper 4:
Implementation of Patient Reported Outcomes from Specialist Pain clinics in England and Wales: experience from a nationwide study

HQIP / Resources / National Pain Audit: Reports from 2011 to 2012. Published Oct 2017. https://www.hqip.org.uk/resource/national-pain-audit-reports-from-2011-to-2012/ Accessed 11/04/2019

Price, C., de C, A. C., Smith, B. H., & Bottle, A. (2018). The National Pain Audit for specialist pain services in England and Wales 2010–2014. British Journal of Pain. https://doi.org/10.1177/2049463718814277
Quality Improvement Scotland: Getting to GRIPS with chronic pain in Scotland. NHS QIS 2007

Racine M, Dion D, Dupuis G, Guerriere DN, Zagorski B,et al . The Canadian STOP-PAIN Project: The Burden of Chronic Pain—Does Sex Really Matter?. The Clinical Journal of Pain. 2014;30(5):443-52.

Rolfson, Ola et al. "Patient-reported outcome measures in arthroplasty registries Report of the Patient-Reported Outcome Measures Working Group of the International Society of Arthroplasty Registries Part II. Recommendations for selection, administration, and analysis" Acta orthopaedica vol. 87 Suppl 1,Suppl 1 (2016): 9-23.

Royal College of Psychiatrists National Audit of Dementia https://www.rcpsych.ac.uk/workinpsychiatry/qualityimprovement/nationalclinicalaudits/thenationalauditofdementia.aspx Accessed 04/11/2018

Shah S, Ho AC, Kuehler BM, Childs SR, Towlerton G et al. Different measures, different outcomes? Survey into the effectiveness of chronic pain clinics in a London tertiary referral center. *Journal of Pain Research*: 2015;8:477.

Smith BH, Hannaford PC, Elliott AM, Smith WC and Chambers WA. The 'number needed to sample' in primary care research. Comparison of two primary care sampling frames for chronic back pain. *Family Practice* 2005; 22: 205–214.

Sullivan PW, Slejko JF, Sculpher MJ and Ghushchyan V. The UK EQ5D scores catalogue. *Med Decis Making* 2011 31: 800.

Susan D.M., Ross, D.C., Yi Q., Qi J., Roger D.et al . (2011)
Estimating Minimally Important Differences for the Worst Pain Rating of the Brief Pain Inventory–Short Form, *J Support Oncol*. 9(2),72-8

Tan G, Jensen MP, Thornby JI, Shanti BF. Validation of the Brief Pain Inventory for chronic nonmalignant pain. *The Journal of Pain.* 2004 Mar 31;5(2):133-7.

Tardif, H., C. Arnold, C. Hayes and K. Eagar "Establishment of the Australasian Electronic Persistent Pain Outcomes Collaboration." *Pain Med* 2017 18(6): 1007-1018.

Tauben D. International Association for the Study of Pain. Chronic Pain Management. Measurement-Based Step Care Solutions 2012:20;8

The Brief Pain inventory User Guide. https://www.mdanderson.org/documents/Departments-and-Divisions/Symptom-Research/BPI_UserGuide.pdf Accessed 23/03/2018

Van Hecke O, Austin SK, Khan RA, Smith BH, Torrance N. Neuropathic pain in the general population: a systematic review of epidemiological studies. *PAIN®.* 2014 Apr 1;155(4):654-62.

Treede RD, Rief W, Barke A, Aziz Q, Bennett MI, Benoliel R, Cohen M, Evers S, Finnerup NB, First MB, Giamberardino MA. A classification of chronic pain for ICD-11. Pain. 2015 Jun;156(6):1003.

Turk DC. Clinical effectiveness and cost-effectiveness of treatments for patients with chronic pain. T*he Clinical journal of pain*. 2002 Nov 1;18(6):355-65.

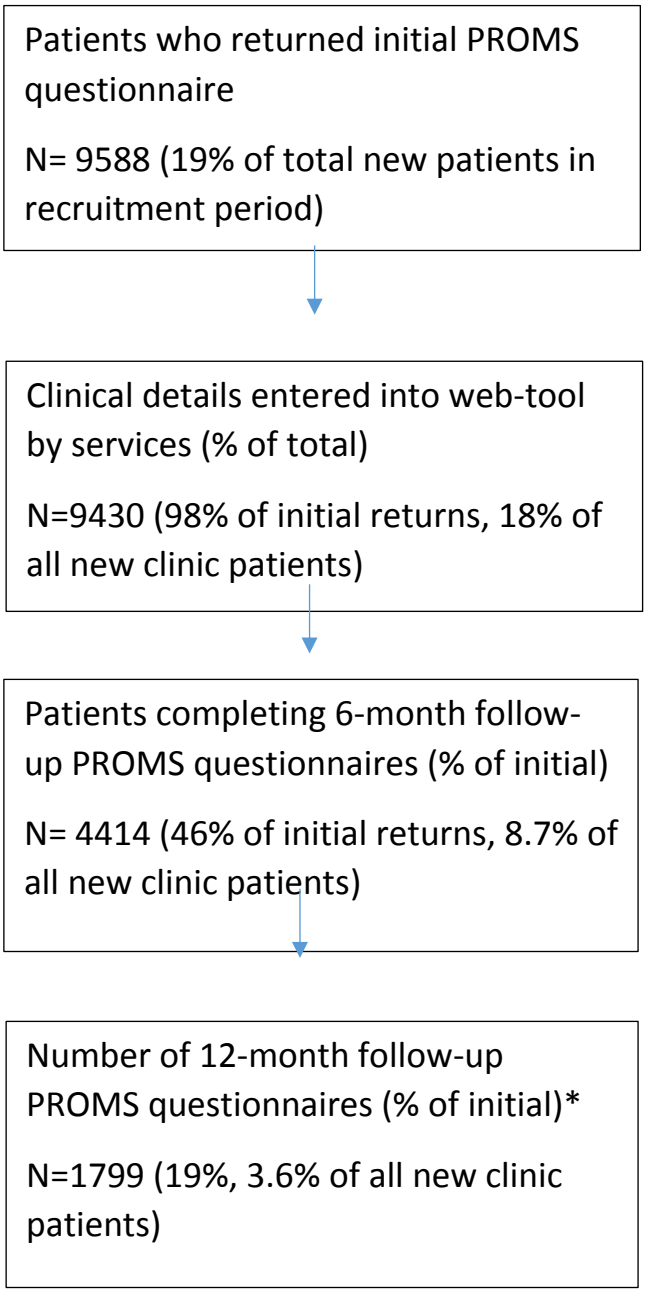
Vartiainen P, Mäntyselkä P, Heiskanen T, Hagelberg N, Mustola S, Forssell H, Kautiainen H, Kalso E. Validation of EQ-5D and 15D in the assessment of health-related quality of life in chronic pain. *Pain.* 2017 Aug 1;158(8):1577-85..

von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, et al . The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *J Clin Epidemiol.* 2008;61(4):344–349

Walters SJ, Brazier JE. Comparison of the minimally important difference for two health state utility measures: EQ-5D and SF-6D. *Quality of life research*. 2005 Aug 1;14(6):1523-32.

World Health Organisation: International Statistical Classification of Diseases and Related Health Problems 10th Revision. http://apps.who.int/classifications/icd10/browse/2010/en Accessed 04/11/2018

Figure 6.1 Patient flow through the study



*only those responding at 6 months were sent a 12-month follow-up questionnaire.

6:1Table 1. Demographic details and case mix for all patients through the audit

	Initial questions N=9684	6-month follow-up N=4337	12-month follow-up N=1777
Age (y) Mean (SD)	54 (16)	60 (16)	59 (15)
Sex M:F	0.36:0.64	0.35:0.65	0.35:0.65
Ethnicity (White British: Other)	n/k	n/k	93:7
ICD-10 diagnosis (%) Back Pain Other MSK Sciatica Other	 26 31 15 28	 27 11 15 37	 28 30 15 27
Discharged from service (%)	N/a	Not asked	708 (38%)

Paper 4:
Implementation of Patient Reported Outcomes from Specialist Pain clinics in England and Wales: experience from a nationwide study
6:2 Table 2 Changes in Patient outcomes over the Study Period (1 year)

	Initial questions N=9684	6-month follow-up N=4337	Mean Difference (CI); P value	12-month follow-up N=1777	Mean Difference (CI); P value
Mean(SD) BPI Pain Severity Score	6.31 (1.90)	5.90 (2.10)	0.43 (0.33-0.51) **p<0.001**	5.98 (2.17)	-0.04 (-0.1-0.05) p=0.45
Mean (SD) BPI Pain Severity Score for those discharged N=708	5.95 (1.96)	N/a		5.26 (2.32)*	0.68 (0.52-0.83) **P<0.001**
Mean BPI (SD) Pain Interference Score (0-10)	6.72 (2.23)	6.26 (2.61)	0.41 (0.30-0.50) **P<0.001**	5.62 (2.68)	0.06 (-0.40-1.60) p=0.25
Mean (SD) BPI Pain Interference Score for those discharged N=708	6.16 (2.32)	N/a		5.4 (2.8)	0.76 (0.59-0.94) **P<0.001**
Mean (SD) EQ5D-3L TTO value	0.32 (0.007)	0.32 (0.011)	0.04 (-0.07-0.16) p=0.49	0.34 (0.19)	-0.002 (-0.17-0.12) p=0.76
Mean Health State EQ5Dl-3L	30	32	3.9 (2.6-5.3) **P<0.001**	30	-1.3 (-2.5-0.76) p=0.051
Mean EQ5D TTO value for those discharged N=645	0.4	N/a		(0.43 *)	-0.031 (-0.05-0.00) **p=0.02**
Mean EQ5D overall health state for those discharged N=676	53	56	2.9 (1.14-4.79) **P<0.05**	55	-2.1(-3.7-3.8) p=0.06
Hospital A&E visits (%) in a 6-month period	1956 (20)	504 (11)		279 (16)	
Work not impacted (%) N=1423	299 (21)	261 (19)		494 (34)	

Reduced work hours (%) N=1383	166 (12)	157 (11)		177 (12)	
Prevented from working if applicable (%) N=1402	477 (34)	469 (34)		738 (50)	
Work question not applicable (%) N=1418	468 (33)	502 (36)		65(4)	

N=Number N/A - discharge data not available A&E = Accident and Emergency

Paper 4:
Implementation of Patient Reported Outcomes from Specialist Pain clinics in England and Wales: experience from a nationwide study

6:3Table 3: Patient experience of care in clinics at 12 months, for patients completing all three assessments (n=1799)

	Yes	No	Do not recall	Total
Given advice on managing pain (%)	1112 (71)	240 (15)	221 (14)	1573
Given information on the risks and benefits of treatment (%)	1124 (67)	299 (18)	257 (15)	1680
Felt sufficiently involved in planning treatment (%)	1202 (71)	500 (29)	0	1702

Table 6:4 *4: Number of patients achieving at least the Minimal Important Change (MIC) in outcomes*

PROMs	6 months	12 months	Discharged at 12 months
BPI Severity (%) (N=707)	499/3404 (15)	272 /1484 (18%	199 (29)
BPI Interference (%)(N=707)	1132/3187 (32)	319/1484 (35)	275 (40)
EQ5D-3L (N=645)	792 /3009(26)	350/1283 (27)	193 (30)

N= Number

6.9 Methods S1

Details on Case –Mix Adjustment Model

Department of Health guidance was followed on case-mix adjustment of the PROMs dataset to produce a model for comparison of sites (Department of Health England 2012). This involves estimation of the impact of differing variables using a Generalised Least Squares fixed effects model. These were selected based upon clinical advice and then tested for statistical significance against the outcome measures (BPI Pain Severity and Pain Interference scores, EQ5D-3L score) using t-tests. Once the variables were selected and the size of their relationship defined with the outcome variables, the adjustment for each patient was calculated using the equation:

$$Q2=\alpha+\beta_1 Q1+x\beta_2+z\beta_3$$

where Q2 =the adjusted outcome score, Q1 the baseline score, $\beta 1$ to 3 the estimated coefficients of the initial score, patient characteristics and other control variables respectively, and z the other control factors

The set of potential variables for the model comprised age, sex, ICD-10 diagnosis code (four categories based on chapter), walking ability (self-rated score from 0 to 10), EQ5D-3L wellbeing score, and type of pain (four categories). Walking ability, age, sex and diagnosis were found to be potential important variables. We therefore adjusted for these. The final model accounted for 40% of the variation in the outcome.

Table 6:5: S2 Data items captured and justification for their inclusion

Item	Rationale	Reference
Case-mix tool		
Age	Standard reporting requirement	N/A
Sex	Standard reporting requirement	N/A
Duration of pain	Standard reporting requirement	N/A
Diagnosis	Standard reporting requirement	International Classification of Diseases (ICD) -10
Ethnicity	Standard reporting requirement	Office for National Statistics 2009
Patient Reported Outcome Measures		
Unemployed due to pain	Main causes of sickness absence	Consensus from stakeholders
Sick leave necessary due to pain	Main causes of sickness absence	Consensus from stakeholders
Brief Pain Inventory	IMMPACT guidance	Dworkin et al 2005
EQ5D score admission to service	Generic Quality of Life outcome measure	Devlin and Appleby 2010

Advice and guidance on managing pain	Good basic medical care expected for a Long term health condition	Consensus from stakeholders
Support to cope with pain	Key outcome measure for long term condition	Department of Health 2012 (QIPP)
Information on risks and benefits of treatment	Good practice	GMC Good medical care 2013
Involvement in planning treatment	Good practice	GMC Good medical care 2013
Education from the service to understand long term pain	Key outcome measure for long term condition	Consensus from stakeholders
Emergency care needed post treatment	Adverse effects of treatment , safety	Dworkin et al 2005
Healthcare resource use	Impact of pain care on NHS resources	Blyth et al 2004

6.10 Reflection

This was the first attempt to implement the collection of PROMs across a nation's pain clinics with the aim of comparing outcomes. Prior to this, PROMs had been collected on a small scale or by researchers. The recruitment and response rates were disappointing. However, they demonstrate the difficulties in attempting to do this. This paper provides better information on implementation at scale than Paper 2. However, the methods used, although they incorporated public facing feedback, were insufficient to achieve high response rates. Options to remediate the situation would either be longer and repeated data collection starting with committed enthusiasts and building up gradually, as recommended in Paper 2, or use incentives as happened with orthopaedic PROMs data collection in the UK. Thus, in terms of setting up a patient registry and asking whether the right patients attended pain clinics, Paper 4 was a good attempt. However, the work lacked sufficient recruitment of sites and return of questionnaires to be able fully to answer the research questions.

Since this time, several nations have established PROMs to measure outcomes in pain clinics. Each of them try to address the issues with implementation experienced by the National Pain Audit. CHOIR (Collaborative Health Outcomes Information Registry) uses an iterative process based upon the PROMIS dataset (Cook 2014, Mackey 2016).So patients will be given a set of questions based upon their answers to previous questions. CHOIR has produced several studies. Their findings include an association between fatigue and social role and that catastrophizing and perceived injustice seem to initiate opioid prescribing (Sturgeon et al 2015, 2016). In contrast to CHOIR, there is less of a focus on data quality in ePOCC's published documents. EPOCC uses four main PROMs to measure outcome with plans to expand these. (Australian Health Services Research Institute 2017). The Scottish government have produced a Minimum Clinical Dataset with additional PROMs being added for specialist services. Currently these are undergoing testing (Richardson 2018). The German Pain Questionnaire (GPQ) uses a core outcome dataset to evaluate the impact of multimodal pain therapy in clinics across Germany. Patients assessed using the PROMs contained with the GPQ have been *divided into responders and non-responders (Donath et al 2018). The Dutch have developed a 21 item questionnaire that includes patient expectations (de Meij 2018). Given these variations, a consensus is needed.*

The Faculty of Pain Medicine in 2019 published guidance on selecting Outcome measures (Faculty of Pain Medicine 2019). It again was based on IMMPACT recommendations rather than assessing whether it was feasible to implement such questionnaires in every day practice. However, it usefully describes the pros and cons of each measure. The Brief Pain Inventory is described as being tested across a wide range of conditions but its factor structure may not be completely robust. The Euroqol 5D-3L has problems in that its baseline score can easily dip below zero for TTO values. This has led to the recommendation that the EQ5D-5L score is used. The EQ5D has demonstrated clinically meaningful change in chronic pain conditions, unlike other generic quality of life measures such as the Short- Form 36 and Nottingham Health Profile.

To completely cover all of IMMPACT domains in a balanced way as to not overburden patients, is not feasible with the current measures available. Further research is especially needed on work items.

6.11 Declaration of Authorship for Paper 4

Cathy Price: I was responsible for the study design and choice of methodology. I drafted all versions of the manuscript. I held overall responsibility for manuscript submission and all associated administration

Amanda C de C Williams: Clinical advice, data analysis for the study and paper. Reviewed the manuscript and commented on drafts

Blair Smith: developed, reviewed and commented on drafts of the manuscript

Alex Bottle: Statistical advice for the study and for the audit. Key role in design of the study. Reviewed manuscript and commented on drafts

All co-authors below confirm the accuracy of the declaration of authorship for paper 4:

	Signature	**Date**
Amanda C de C Williams:		3rd March 2019
Blair Smith:		**3rd March 2019**
Alex Bottle		**3rd March 2019**

Chapter 7: **Discussion of individual papers**

7.0 Overview

When I started this journey as a research fellow in 1997, the best anyone could say about their service and outcomes was that some asked patients whether they were better, worse or the same. Nobody knew what a quality service should look like or how to measure it and worse, nobody knew how patients felt. This was unsurprising as Pain Medicine had just been granted specialty status in 1996. It was to be another 11 years before the Faculty of Pain Medicine was created as a statutory body to set standards for pain services. In the interim, systems were developed to classify pain, pain treatments and measures that services could use. This was in part due to a response to reports on the state of NHS pain services. This thesis has covered the early work that went into developing measurement of the quality of care in pain clinics and the resultant National Audit that lead to clear standards of care and recommendations to improve both quality of care and measurement of it.

The main findings of this body of work were

- Pain Clinics need significant support if they are to continue to compare each other and measure outcome
- Coding and classification of diagnoses and treatments required significant development to permit meaningful measurement of case mix and activity
- Pain Clinics varied widely in staffing and content of treatment but showed improvement following the publication of standards of care by the Faculty of Pain Medicine
- Case-mix analysis found that patients had a very poor quality of life although the reasons for this remain unclear
- Enrolment and follow up of patients requires improved methodology

7.1 How did one paper lead to another?

Paper one was an initial attempt starting from scratch to develop a data collection system that tested classifications of diagnosis, treatment and outcome measures. It became evident that data analysis was an important component of this. Feedback to sites and posters at local and national meetings raised awareness and developed a sense of purpose to the process. Also, the ability to print reports to use as evidence of practice also helped data collection uptake.

However, as the database grew from a few enthusiasts to 75 centres, data analysis became highly challenging, leading to additional funding requirements. It also became evident that quality decreased. A more formal evaluation of quality was needed which lead to paper 2. PACS also joined DOCDAT, a quality assurance project to improve clinical databases (Black and Payne 2002). This highlighted areas needing improvement.

Paper 2 looked at 30 out of the 37 clinics participating in 2003 and compared data entries with paper notes. It proved possible to only visit 30 clinics. This found a large number of missing entries at all levels and concluded that substantial work was needed to improve quality. At this point it became impossible to run the software on Trust computers and alternative methods were sought to develop audit tools. With the CMO recommending that all clinics should contribute to a database, a National

Audit was felt to be the best route to achieve this. The learning from the development of PACS then PAINDB fed into the National Audit.

Paper 3 described the findings of the National Audit of Pain Clinics. This was the first time that anyone had attempted to involve a whole nation of pain clinics in a registry. The lessons learned from the development of PACS/PAINDB were that it was preferable to use widely used classification systems for diagnoses, organisational data should be split from patient level data and the data collection process should not rely on specially installed software. Paper 3 differed from the other papers in that it was a true audit, where clinics were assessed against agreed standards, change was implemented and a re-audit took place. Not all pain clinics took part however, either on the first or second attempt.

Paper 4 described a cohort of patients from the National Audit. This used a recognised case mix classification, drew upon the IMMPACT recommendations of 2005 as to the variety of domains that should be measured for research. It followed 10000 patients who registered over a 3 month period from 91 centres. A web-based tool was used to capture patients. Despite this, both recruitment and follow-up were problematic and many patients were not entered onto the web-tool. By the end of this cohort study it was clear that whilst some services and patients were able to participate, it was clear that differing strategies and sustained development would be needed to engage the rest.

Each paper is now discussed separately to assess the results within the context of the existing literature at the time of publication. It should be noted that sixteen years elapsed between the publication date of the first paper (2003) and the fourth paper (2019), and it is important to evaluate the relevance of each paper's results conditional upon the state of the literature at the time.

7.2 Findings

7.2.1 Paper one Description of the PACS database and outcomes from it

This was the first attempt at developing PROMs for pain services using PACS. The paper describes the development and testing of classification systems for pain clinics. Case-mix was also recorded and outcomes measured. The main findings were

- 43 out of 48 clinics submitted data with 10,574 patients entered - data was reviewed on an annual basis for a period of three years
- most clinics saw musculoskeletal pain
- patients reported a poorer quality of life than those reported by the BPI development group for cancer pain
- the BPI seemed fit for purpose
- Relatively few discharges were recorded - 1589

At the time there was no consensus on how to classify pain diagnoses or treatments nor measure outcome. This paper therefore provided some ideas as to how to do this together with real life testing of those classifications. The main driver to clinicians entering patients was the emphasis on appraisal and being able to produce evidence of their activity. HES data at the time often failed to separate Anaesthesia clinics from Pain Clinics and this database was their only means of evidencing activity.

The main motivation of the group was to provide a vehicle to support members in recording activity in pain clinics and answering the challenges of the Audit commission and CSAG report. The focus was on data collection processes. Now much more formal evidence of activity is required and is usually automatically obtained from electronic paper records. PROMs data has become a prerequisite of holding a contract. The results were helpful as they laid the foundation for future funding and highlighted areas for improvement in methodology.

The strengths of the paper are that it demonstrated that getting information on case mix, activity and outcome could be done. It succeeded in getting a significant minority to clinics to voluntarily submit data so that they could be compared with others. It managed to achieve a description of case-mix and, importantly, classify treatments. Prior to this only OPCS codes were used. These only described medical interventions which, whilst an important component of treatment, form only a part of multidisciplinary care.

The limitations of the paper are that the amount of missing data was significant, however, this could not be easily quantified due to the difficulties in capturing HES data for the same period accurately. It was also evident that the axial system that IASP had recommended did not work well for clinicians with most choosing only one drop down field to describe patients.

7.2.2 Findings of Paper 2

Paper two was a validation of the records held by PACS. By this point it had been named PAINDB to avoid confusion with the imaging library of the same name. At the time, clinical databases were beginning to be recognised and the tariff system for activity was introduced meaning that monitoring activity became much better for acute trusts.

The main findings were

- many records were missing from the database when compared with site visits - first contacts were frequently entered but then follow ups were missing
- The collection system once installed and working correctly seemed to operate well
- The four IASP axes used to describe case mix were completed poorly suggesting that this was not the best way to classify pain.

The strengths of this paper were that it was a clear validation exercise with clear methods and outcomes. Ethics approval and good relationships with the clinicians in the trusts meant that it was possible to visit and check many of the participating centres. Clear conclusions were drawn.

Limitations to this work were that, firstly, it became evident that clinicians often failed to complete fields. Secondly, routine electronic patient records (EPRs) to capture data then transfer for analysis or the use of already existing electronic information already captured by the NHS (e.g. HES data) might be better ways of addressing missing data. It also found that only a small number of clinics entered data well and that it might be better to work with a small number of committed clinics to refine datasets. At the time it was difficult to see what levers could be used to improve data capture beyond this.

A key limitation was that the staff could not identify how many patients were entered into HES due to confusion of specialty coding within HES.

7.2.3 Findings Specific to Paper 3

Paper three covered the development of methodology to form a registry from all pain clinics in England and Wales as well as a re-audit after substantial work was done to address concerns raised by the CMO and the audit. Its main aims were to assess standards set by the Faculty of Pain Medicine. Its main findings were:

- Many specialist pain clinics were multidisciplinary in nature – this had improved by the time of the re-audit
- 0.46% of the population was estimated to be seen annually (in line with other countries)
- Waiting times were in line with whatever government target was set but this was significantly longer than the suggested wait times set by IASP
- Many lacked processes to manage suicide risk and diagnostic issues
- Publishing the data on a publicly facing website lead to feedback from several services and improved the quality of returns.

Outcomes from this audit enabled clearer standards to be published and developed for routine inspection by regulators. Multidisciplinary care became embedded. Limitations to the study were again problems with matching NHS recorded activity against returns in the clinic and the need to hand search to find clinics.

7.2.4 Findings Specific to Paper 4

Paper four covered refinement and testing of PROMs questionnaire.

Just over half submitted paper records. These proved difficult to locate and collect on a national scale. The research team collected data due to the difficulties reported by paper 2. It proved equally as challenging to collect questionnaires from patients directly. If the questionnaires were answered then they were completed well. The web based patient entry system worked well for many clinicians.

The main findings were

- Patients reported an extremely poor quality of life
- Many failed to understand their condition
- Of the small number who completed all three questionnaires about a third improved by the end of a year

The strengths of this paper were that this was a rigorous testing of a PROMs questionnaire for pain services and the content was in line with current recommendations. The paper also highlighted system issues with coding and classifications. HES data did not reflect actual activity, physicians could not describe well the diagnoses with ICD 10 and no clear treatment classification led to variation in grouping and description of activity.

7.3 Limitations

Whilst Paper 2 very clearly recommended working with a smaller number of centres and building up the quality of data returns, the funding restrictions meant that this was not possible with Paper 4. However, it is notable that despite participation in a National Audit being mandatory, many trusts did not submit data.

It may also have been better for services to have followed up patients to obtain returns. Better support of services, reminders and more rapid feedback of outcomes from patients and clinics may have improved returns. Recruitment rates in Paper 4 were low (19%) and could have been improved through the use of web-based systems and reminders. It confirmed that PROMs measurement needs to be embedded through funding for long periods of time as recommended elsewhere (Hickey 2013). Nevertheless, as a first attempt to do this at scale, it provided useful information.

NHS improvement recommends the use of balancing measures across the whole system. Examples include reducing wait times into pain clinics may improve emergency department and outpatient attendances in other services (NHS Improvement). These can be difficult to measure and require data linkage. This was attempted in one centre during the national audit covered by Paper 3 where data from the system and from the audit were managed by one organisation (Dr Foster Research) and showed a reduction in outpatient attendances but not in Emergency Department visits (HQIP 2017). Although attempted data linkage between HES and PEDW was explored, the quality of data was far too poor to do this at scale.

Quality indicators have been developed since this audit was carried out (Richardson et al 2018, Health Quality Canada 2019). However, there is little evidence that there is any consistency of approach to date (Zidarov 2019) and no indicators have been implemented. The National Institute of Clinical Excellence is due to publish guidance on the management of chronic pain in 2020. System indicators should accompany this. These should encompass the metrics recommended by the Health Foundation and NHS Improvement (Friebel 2017, NHS Improvement).

Although patient experience was assessed in line with recommendations, this body of work did not explicitly measure patient expectations. It is known that these are an important mediator of health outcome. Since this work, a 21 item questionnaire has been developed for pain clinics in Holland that explicitly measures expectations (de Meij 2018). Either adoption of this questionnaire or use of elements of it should be considered for future work.

7.4 Discussions Summary

I have critically examined the four papers in the context of the literature at the time of analysis and since the time of each paper's publication. The discussion of each element has been presented serially in the order in which the analysis was undertaken and the importance of each paper to the others has been explained, referring backwards or forwards as appropriate. In their totality, these four papers represent a thesis of work which covers development of a system to assess the quality of care provided by specialist pain clinics in England and Wales over an eighteen year period. This work was driven by multiple reviews of pain clinics highlighting the lack of information on outcomes coming from them. I would conclude that this still remains a significant challenge.

Previous work had consisted of either surveying pain clinic organisational features, without clear standards for guidance or small scale collection of PROMs data to form a patient registry. No one had attempted both simultaneously. We were hoping to identify clinics that met criteria for good provision of standards of care and then compare outcomes between them and those that did not meet those standards. We were able to answer relatively easily whether services were meeting agreed standards of care and would recommend that this survey is repeated from time to time. However, patient recruitment and follow up rates were very low in many clinics making such comparisons very difficult. Further work needs to be done to improve patient returns and ensure that clinics participate in data returns. Nevertheless, this provided a useful start. At the time no other nation had attempted this. Even now only Australia and the USA, via ePOCC and CHOIR, are auditing clinics at scale on a sustained basis.

Gathering information is costly and takes time. Formation of a pain clinic registry which describes each pain clinic according to the standards developed by the National Pain Audit and Faculty of Pain Medicine would be the easiest to achieve. However, this still requires funding to do this work, analyse and feedback data. Whilst data collected for paper 1 (validated in paper 2) and paper 4 had very similar recruitment and follow up rates, there was inbuilt validation for paper 4. This allowed a much greater appreciation of the best methods for data collection and follow up if future audits are to be done.

In the discussion I will answer the questions posed by the PICO's in the introduction. I will then go on to propose optimal methods for improving the quality of care in pain services.

7.5 Research questions review

7.5.1 Have we developed the right measures to assess standards of care in pain clinics?

There are several differing recommendations as to what should be measured as markers of good quality pain care. The Faculty of Pain Medicine in the UK has set standards it expects to be achieved by services. The development of the standards used took place over a long period of time, encompassed feedback from pilot groups, patient groups as well as road testing and validation. However, the gap in funding caused some difficulties as well as being bound by the terms of a national audit.

Measurement was challenging on many levels. Coding and classification of pain diagnoses and treatments proved to be below the level needed to successfully group and describe patients and

activity. Current coding systems in use in the UK are ICD-10 for diagnosis and OPCS for treatments. Neither have had significant input from the speciality to ensure meaningful classification systems are developed. ICD -11 which will be released shortly offers significant improvement for diagnosis (Treede et al 2015) but there needs to be a consensus on treatment classification and on describing multimodal care.

Data Collection

Originally all data was captured electronically by Microsoft Access based software. However, it became very clear that this was not sustainable as constant maintenance of the data base was needed, increasing costs substantially. By the time of the national audit case mix data was collected by a web-tool which proved very successful. Less successful was the paper based questionnaire - a switch to electronic data capture is recommended (Hoque 2017).

Data analysis

Data was largely descriptive and easy to report. The validation work also was straightforward, we used a systematic review reporting methods to analyse the data for Paper 3. Patient level data for Paper 4's case mix adjustment was insufficient to build a robust model for use.

Dissemination

Others have looked at the effectiveness of quality improvement programmes for pain management services (Kerns et al 2008, Cleeland et al 2003, Hooten et al 2013). Ivers et al highlighted that the impact of audit and feedback on patient care was limited. They did identify some factors that led to greater impact such as one to one, written and verbal feedback more than once (Ivers et al 2014). Brehaut has also recommended ways to improve the quality of feedback given (Brehaut et al 2016). This includes repeated feedback, simplifying messages, being done locally, added into a care pathway and peer delivered.

For an audit to have impact, measurement and feedback needs to be done more than once, feedback is shared with managers and any areas requiring remediation are acted upon. The limitations of such national ventures need to be recognised. We chose regional roadshows to inform local teams of the outcomes of the audit, as well as highlight areas of the care pathways that could be improved. However, implementation of these areas was dependent on the attendees' ability to effect change in their organisations. Whilst the outcomes of all national audits are fed back to Trusts and they are obliged to follow this up with services, the level of engagement varies widely. An individualised pack to services, together with verbal feedback to the local clinical audit lead on outcomes, would have probably had greater impact.

As pain clinics vary so greatly in content and case-mix, it may be preferable to develop differing criteria to assess the standards of care in differing settings. For example, the Austrians have set standards across a whole range of services who treat pain with a rising level of competency expected and also defined the relationship between medical and psychological treatments (Jaksch et 2017). An audit in Germany in 2012 on what was contained in pain services found a reasonable concordance with what was delivered especially with regards psychological treatment (Nagel et al 2012).

This question was answered by Paper 3. Overall, due to the close collaboration between The British Pain Society, Faculty of Pain Medicine and the National Pain Audit team, it was relatively straightforward to establish standards of care and then measure them. It also proved relatively easy

to use the systematic review's analysis allowing comparison with others. Most providers returned a questionnaire and it was possible to see some changes by the time of the second audit. It is important to go beyond self-report in some areas, for example, in terms of staffing content and waiting times. Asking actual staff proved a far better measure of measuring a multi-disciplinary approach than self –rating. Waiting times have such political ramifications it may be better to be really precise, for example, to ask "on this day what was your waiting time for..?"

7.5.2 Do we have the right approach to formation of a registry for people attending pain clinics?

Recruitment and Follow up

Standardised Questionnaires were taken from the IMMPACT recommendations for domains to measure in chronic pain trials (Dworkin 2005). Although patients were able to complete the questionnaires the number of responders was disappointing but similar in response rate to other audits when such methods were used as discussed in Paper 4. This suggests the main problem was with the method of data capture, although it is unknown whether questionnaire burden was too great. The questionnaires were carefully piloted beforehand with patient groups, although this was to an already engaged population. As a result of the low response, the audit failed to deliver on an effective method for measuring outcome of care from a patient perspective. The data items themselves were well answered. However, response rates for follow up were very low and the audit seemed to exclude minority groups. New methods need to be investigated to improve this, as outlined in Paper 4, starting slowly with services who are committed along with improved feedback to centres and patients, use of electronic data entry and a longer period to allow returns.

Since this work was carried out, a Spanish study, published in 2016, managed to retain 90% of its patients (Garcia et al 2016). However, response was measured at 3 months rather than 6 or 12 months; we presume this was when patients were followed up in outpatients. Chronic pain often fluctuates widely in intensity, with patients initially reporting a response to treatment then reverting to previous levels. We therefore did not feel a 3 month follow up was sufficient to gauge response to care, nor would it encompass reliably multidisciplinary treatments, such as a course of physiotherapy, which usually extends over several months. EPOCC in Australia has been going since 2013. After four years, 20% of patients had finished a care episode and submitted an outcome measure (Blanchard et al 2017).

Measurement of health outcomes

These papers explored methods to analyse health outcomes from pain clinics, which allow benchmarking with others, particularly the use of MIC to determine success, which has also been used by the ePOCC registry in Australia (Blanchard et al 2017).
Hoque highlighted the importance of measuring variables that have a clear economic impact (Hoque et al 2017), for example, the Australian joint registry demonstrated a decrease in revision hip replacements. Such markers of success in pain management might be an overall reduction in the prescription of strong opioids or urgent care visits. Guidance exists on management of medicines (NICE 2017).These would have a clear cost benefit and potentially justify funding of a patient registry for specialist pain clinics to improve pain outcomes and should be included in any future venture. The recommendation is that outcomes are measured for services, contributing and not contributing

to a registry, using a stepped wedge design and that the benefit of a service joining a registry is then quantifiable.

VAPAIN recommended a very similar set of domains - pain intensity, pain frequency, physical activity, emotional wellbeing, satisfaction with social roles and activities, productivity (paid and unpaid, at home and at work, inclusive presentism and absenteeism), health-related quality of life and patient's perception of treatment goal achievement (Kaiser et al 2018) . It is likely that similar difficulties in response rates will be found unless alternative methods are chosen to collect data from patients.
The EQ5D-3L TTO value set is known to overestimate the degree of difficulty that patients have in the UK population (Lamers 2007). This means that although 16% of patients reported that they would be better off dead, this may not represent a true reflection. The EQ5D-5L is a more robust instrument and it also has easily available algorithms to measure TTO values and so would recommend this if the EQ5D was to become commonplace in pain clinics. We would recommend using the proportion achieving the minimally important difference (MID) to assess change (Dworkin 2008, Walters 2005). Given the multiple variables associated with outcomes, case-mix adjustment may not be a useful goal although more research could be done on this. Whilst the benchmarking data set has since been applied to measure structure and processes within pain clinics, the patient questionnaire developed for the study has not been, suggesting it did not achieve its goal of producing a suite of measures that pain clinics would routinely use.

EPOCC in Australasia developed a dataset to compare specialist pain services over the period of several years starting first with a pilot in three centres, followed by refinement by the ePOCC working group (Tardiff et al 2017). The dataset was selected based upon the multidimensional nature of pain, ease of completion and with availability in other languages and cost. Eighty–six data items were agreed. Outcome areas were collected at baseline, at the end of treatment and six months afterwards. An electronic collection system was used for PROMs data. From the reports provided, it is unclear what the overall recruitment rate is. The recruitment rate should be reported to give an idea of the success of capturing data.

More recently, core minimum datasets have been developed and tested elsewhere. In Scotland the approach has been to develop a core set with 12 data items and then a more in depth set (Optimal dataset) for services who are able to collect this (Richardson et al 2018). This approach, however, has not been adopted nor tested as yet.

These are isolated examples of datasets in use across a nation. In North America, despite the introduction of the PROMIS dataset, most healthcare professionals are still not using a consistent dataset to record outcome (Zidarov 2019). Given that considerable experience now exists on the development of datasets and collection of them, an international consensus on data items to collect in a patient registry, together with better development of work outcomes, should be achievable.

Thus, Papers 1, 2 and 4 contributed to the development of patient registries in pain clinics by being early contributors to the field. Paper 1 developed classification systems and demonstrated that services would contribute to a registry if it were available. The validation of the database in Paper 2 was important as it highlighted that there needed to be a gradual recruitment of centres into a registry. This was adopted by ePOCC and CHOIR and is more likely to assure quality. However, due to the nature of a national audit which expects recruitment in all pain clinics, it was not feasible to take this approach and although more centres were recruited in Paper 4 than Paper 1, the follow-up was very poor and overall recruitment in many centres was low. This approach demonstrates that for a National Pain Audit to succeed, it would require sustained funding over many years. It also confirms

that paper-based questionnaires are unlikely to be well completed. A much smaller dataset is also recommended.

7.5.3 Are the right people attending pain clinics*?*

The Chief Medical Officer for England in 2011 suggested that Chronic Pain should become a "High Street Disease" with rapid access to advice from specialists and generally greater understanding of chronic pain by health care professionals (British Pain Society 2011). This section reviews what is known about the general health needs of the chronic pain population and the variation in care and outcomes from specialist pain clinics. It considers the role of primary care and whether this body of work was able to reliably identify the right patients to attend pain clinics. In order to do this it is important to understand the health need of the population and the evidence base for treatment within a pain clinic.

Chronic Pain Population needs

Health needs are "those that can benefit from health care or from wider social and environmental changes". The individual or identified population must have capacity to benefit from health, social or environmental intervention. A population health needs assessment is an objective and valid method of tailoring health services (Wright et al 1998). Some economists also argue that a health needs assessment must also include priority setting as needs almost always outstrip supply (Donaldson and Mooney 1991). Thus this work should have identified those patients who had capacity to benefit from pain clinics.

Gupta et al publishing in the wake of the emergence of the opioid epidemic in the USA highlighted the enormous burden imposed by chronic pain and lack of treatment especially in the vulnerable and economically disadvantaged. They highlighted the poor knowledge amongst doctors as to how to treat chronic pain, lack of integration across disciplines and lack of monitoring of prescriptions (Gupta et al 2013). Thus it is unlikely that patients will be reliably identified to attend pain clinics.

In 2011, the Health Survey for England added an additional module to ascertain the size and nature of the chronic pain population, as well as understand which services patients had accessed for their pain. This was carried out concurrently with the Audit (Bridges 2011). Both used EQ5D data to look at quality of life allowing for comparison. The survey found that more women than men reported chronic pain (31 per cent of men and 37 per cent of women). The prevalence of chronic pain increased with age (14 per cent of men and 18 per cent of women aged 16-34 to 53 per cent of men and 59 per cent of women aged 75 and over). The poorer households reported more chronic pain (40 per cent of men and 44 per cent of women in the poorest households compared to 24 per cent of men and 30 per cent of women in the richest). Chronic pain was not more prevalent in one region of the UK compared to another. The vast majority of the population (70% or men, 68% of women) reported little interference with their quality of life. Those with more severe pain also reported multi-morbidity (using the Chronic Pain Grade I to IV) and their health as generally poor. Mental well-being was also poor in the more severe cases. The more severe pain grades were more likely to have attended a specialist pain clinic (61% of men and 54% of women).

Since the time of this body of work there has been more work to better characterise the needs chronic pain sufferers. The HUNT study in Norway, which carried out a population survey over four years, found that there was only an 8% chance of recovery from chronic pain if moderate to severe pain was present (Landmark et al 2018). Pain severity, widespread pain, pain catastrophizing,

depression and poor sleep were significant predictors of future moderate to severe chronic pain, both among subjects with and without chronic pain at baseline.

In a review of the known epidemiology of chronic pain, nineteen risk factors were listed as being associated with the development of chronic pain (Mills et al 2019). The authors recommend that these risks are managed within a biopsychosocial framework rather than a medical one. With this level of complexity, it is unsurprising that clinicians can feel ill-equipped to deal with chronic pain.

In Germany there was an attempt to link databases together to get a better idea of the whole chronic pain population needs. However, they met multiple barriers. These included diagnostic inconsistencies leading to poor coding and fragmentation of data from various databases. They concluded that this was currently an impossible task (Hauser 2015). This may be easier to achieve in the UK in the future where there is the UK Clinical Practice Research Datalink and a more consistent coding practice across the NHS. The fragmentation of data from health insurance companies, old age pension insurances, clinical institutions and population surveys with inconsistencies in diagnosing or encoding chronic pain, impeded the carrying out of significant longitudinal studies. It is hoped that the new coding classifications for pain will enable important questions to be answered such as the cost effectiveness of therapy for pain and potential starting points of a treatment pathway. Three systematic reviews in Germany, using large health insurance databases, found that medical treatments and opioids were over prescribed compared to guidelines (Houses et al 2014, Wolff et al 2011). If pain clinic scan be reliably identified in large databases this may be an alternative method to answer whether the right people are getting into pain clinics.

In Scotland, a Health Needs assessment was carried out as part of the Scottish Public Health Network. The assessment identified that across the care pathway there was wide variation in treatments delivered (Mellor 2018). Data again was highlighted as problematic. A READ code was developed for chronic pain with the intention of overcoming this. However, as yet, its use has not been widespread

In order to ensure that population needs are met, Mackey highlighted that it is important to differentiate “people with high-impact chronic pain from those who sustain normal activities although experiencing chronic pain.” He defined high impact chronic pain as “associated with substantial restriction of participation in work, social, and self-care activities for six months or more.” If these people can be identified then they should be moved into specialist services to meet their needs (Mackey 2016). However, finding this group through database searches in primary care such as is used with other common chronic diseases, is fraught with difficulty due to coding difficulties and the quality of data kept on people in pain in primary care. In the USA, CHOIR was introduced to fulfil this purpose.

Patients attending pain clinics should therefore be the high-impact chronic pain group. This work did indeed find that patients referred reported severe pain, extremely low quality of life and a significant impact on work. However, it is not known how many patients should have been referred and were not due to the lack of primary care data.

Characteristics of the Population reaching UK pain clinics

The Health Survey for England suggested that only two thirds of the most severe cases are reaching specialist pain clinics. The majority of respondents who completed the follow up questionnaire were older and Caucasian which may not be representative. This body of work did not collect the presence of multi-morbidity. As the majority had low back pain and the EQ5D look up table suggests that the TTO value is near 0.7 for the general back pain population, it can be assumed that the majority also have multi-morbidity leading to poor quality of life rather than for just back pain alone. For psychological co-morbidities, only anxiety/depression was assessed via the EQ5D with two thirds reporting this. As psychosocial factors are important in pain persistence and its severity then interventions that address these for the chronic pain population are important. As the majority attending pain clinics were of working age, then it would be expected that welfare support, employment support and housing would be important areas that services should link with. A further study might establish whether this is the case.

Variation in Content of Services

Paper 3 demonstrated that there are differing types of pain clinics in existence in the UK

The types of clinic as classified by IASP are:

- Single modality (one treatment) service
- Pain Practice – this is a single handed practitioner
- Multidisciplinary Pain Clinic
- Multidisciplinary Pain Centre

The gold standard is a multidisciplinary clinic or centre to meet the needs of patients with chronic pain who have experienced a significant impact of pain on their lives. Both advanced methods of pain relief and rehabilitation are available in these types of services. The more severe cases need to be seen by staff with the right skills and capacity to impact outcome.

There was wide variation in the provision of multidisciplinary care with only 32% able to fulfil criteria for this at the commencement of the audit rising to 56% by the end. There was also wide variation in the provision of multidisciplinary care across the country. Thirty one per cent of clinics were a single-handed pain practice - it was evident that a whole range of patients attended this type of clinic- those with a high level of need may benefit very little from this type of service. The audit also found that the most disabled and distressed (scoring 3 on EQ5D scores) constituted 8% of the population seen in pain clinics - these were evenly spread across services. Germany has adapted the IASP classification to represent facilities in Germany more meaningfully which should be considered as an option in the United Kingdom (UK) (Muller-Schwefe et al 2016).

This variation was also found by Dressler who suggested that the lack of clear evidence based guidance was a factor in being able to assess the quality of care delivered in pain clinics. This was not due to a lack of effort, moreover, that to assess and plan a treatment, a practitioner needs to take into account the response to medication, injections, rehabilitation and mental health care. All of these have individual evidence based pathways but when combined in the management of patients with chronic pain who may require all of or some of these pathways, the evidence base was lacking (Dressler et al 2019). This could be a focus of future work.

Outcomes from care in pain clinics

Paper 4 suggested that for the small number of patients who were discharged and completed follow up questionnaires (7% of the original cohort), there was a statistically significant improvement in general quality of life and pain related quality of life. This translated into a clinically significant improvement in pain interference for 40% and a general improvement in quality of life for 30%. These numbers are small and must be interpreted with extreme caution.

Paper 3 found that 70% patients attending specialist pain clinics reported being involved in decisions about treatments and being supported to manage their pain. These papers did not assess patient preferences and this has only been studied to a limited extent in chronic pain. A study of 348 patients with low back pain found that patient preferences are highly individual with most preferring conservative treatment although some may wish to wait for their preferred treatment (Klojgaard et al 2013). It is not known whether this correlates with severity of pain.

Primary Care and Referral Pathways

It is clear that there is wide variation in care in specialist services. What is not known is whether there is also wide variation in the management of chronic pain in primary care services. It is also unclear whether primary care practitioners can reliably identify those who might benefit the most from a co-ordinated multidisciplinary service. The reasons for this may lie partially in the lack of feedback to primary carers as to who is benefitting from pain clinics. The knowledge of primary care practitioners about chronic pain is low (De Ruddere et 2014). Given the variation in pain clinics, the confusion that this must cause to referrers and added to this the variation in care provided by primary care, it is surprising that any patients are accurately channelled to the right service for them. During the time that patient data was being collected, best practice pathways were established for a variety of chronic pain conditions. This, together with revised NICE guidance on low back pain (NICE 2016) and neuropathic pain (NICE 2019) as well as IASP guidance (Finnerup et al 2015) on specialist treatment for neuropathic pain may have addressed knowledge in primary care. Further research could determine whether these pathways are now being followed.

This body of work therefore was able to partially answer the question, “are the right people getting to pain services?” The pain questionnaires would indicate that the more severe cases are being seen. Additionally, patients reported they benefit from pain services through feeling supported. However, as the follow up rate was so poor in both Papers 1 and 4, it was not possible to answer whether the patients referred were actually benefitted from services. Thus these papers were able to partially answer this question in terms of case mix but not in terms of outcome.

7.6 Conclusions

Overall, this review of population data, content and outcomes of services, suggests that pain clinics are partially meeting the needs of the chronic pain population it should be targeting. However, many are either not referred or do not attend and the necessary integration with social care is unclear. Only 31% had had any form of psychological intervention by 6 months. These conclusions are drawn from Paper 4 and thus must be interpreted with caution due to the low recruitment rate and low follow-up rate results.

Not all specialist pain clinics are the same with a sizable proportion unable to deliver effective care based upon their staffing. There was evidence of complex patients being seen by the most basic of pain clinics, which in effect represents a wasted resource. It may be better that a single expert provides advice and support to primary care e.g. in reducing opioid prescribing, rather than

attempting to take on complex patients. There was geographical variation in the provision of multidisciplinary clinics despite no evidence that patients differed in any way. Thus it is likely that there is a high level of unwarranted variation in the provision of services, meaning that the right patients do not get to the right clinics. If it were possible to link HES and PEDW data, the impact of pain clinics on the whole healthcare system could be measured (Balancing measures). However, the quality of this data was far too poor to enable this.

The factors in primary care causing variation in referral include : lack of coding of chronic pain, lack of a consensus on who the more severe cases are, poor knowledge of chronic pain, the complexity of chronic pain being a biopsychosocial condition and lack of clear referral pathways. The factors in secondary care pain services causing variation in referral include: lack of standardised treatment facilities in terms of staffing and treatment content, lack of measurement of outcome, lack of clear evidence as to who benefits the most from specialist pain clinic care, variation in mental health and social care support and lack of feedback to primary care. Currently, there are only 8 specialised services that are able to deal with the most complex cases with 3 being in London. Given the co-morbidity with mental health conditions, pain clinics may achieve better outcomes by greater integration with mental health and social services.

To answer did a National Audit improve quality of care in pain clinics the answer must be to only a limited extent? Due to the subjective nature of pain PROMs are a necessity to measure outcome. However, involving a whole nation's clinics sacrifices quality for quantity. This meant that Friebel's measures of quality of care were only answered in a limited way. Effectiveness, efficiency and degree of patient-centredness could not be answered due to the low follow up rates. Timeliness of treatment, safety and equity were partially assessed. Responders tended to be older and white, not fitting the profile of those who attend pain clinics. Measures of safety did identify some risk management protocols were in place, although there were gaps. This could have included recording of adverse events as was the case for PACS. Timeliness of access was well measured. However, this only covered time to first assessment and not necessarily definitive treatment.

7.7 Future Research

There are many potential areas that may benefit from further research and development to improve the effectiveness of any pain clinic registry. Firstly, a consensus on treatment classifications would ensure greater consistency when describing clinic activity. Secondly, and probably the most problematic area, is to ensure sufficient patients complete follow-up questionnaires. Research should be done into the optimal methods for collection and also the point at which the number of questions become too burdensome. Greater involvement of clinics on an ongoing basis combined with regular feedback might improve this. Sustained funding is required to do this and thus any future registries should collect data on outcomes which have a wider societal impact e.g. opioid use, Emergency Department use. Given the multiple variables associated with outcomes, case-mix adjustment may not be a useful goal, although more research should be done on how best to achieve this. An international consensus on datasets and optimal methods of collection based upon the work carried out by this audit and others since, is very much needed.

Health outcomes may improve if greater integration of pain services is achieved with mental health and social care. Additionally, a measure of complexity might help define the types of interventions patients may benefit from. Measurement of these two factors might usefully add to descriptions of services. Agreement on who benefits the most from pain clinics is needed. Understanding patient

expectations and experiences may help better define service provision as well as measurement of their delivery.

Future audits might encompass primary care which would give a better idea of the end to end pathway. This has been carried out with the National Diabetes Audit which extracts data from GP systems as well as measurement of important variables in diabetic foot care and inpatient care. This would not be without its challenges as primary care patients are not well captured by the READ coding system with too many options in place.

This work was the first of its kind worldwide. Much has been learnt through the process of researching optimal methods to deliver an audit and form a patient registry. Other countries have built upon this work and it is hoped that the United Kingdom can re-establish a patient registry on an ongoing basis for the future benefit of all patients and be able to repeat the standards set by this audit to continually improve the quality of care provided by pain clinics.

Appendices

Appendix 1 Data Items for the Original PACS database (Paper 1)

Unique Database ID number

Age

Duration of pain

Diagnosis

- *Bodily system*
- *Aetiology*
- *Location*
- *Pain type*

Treatments

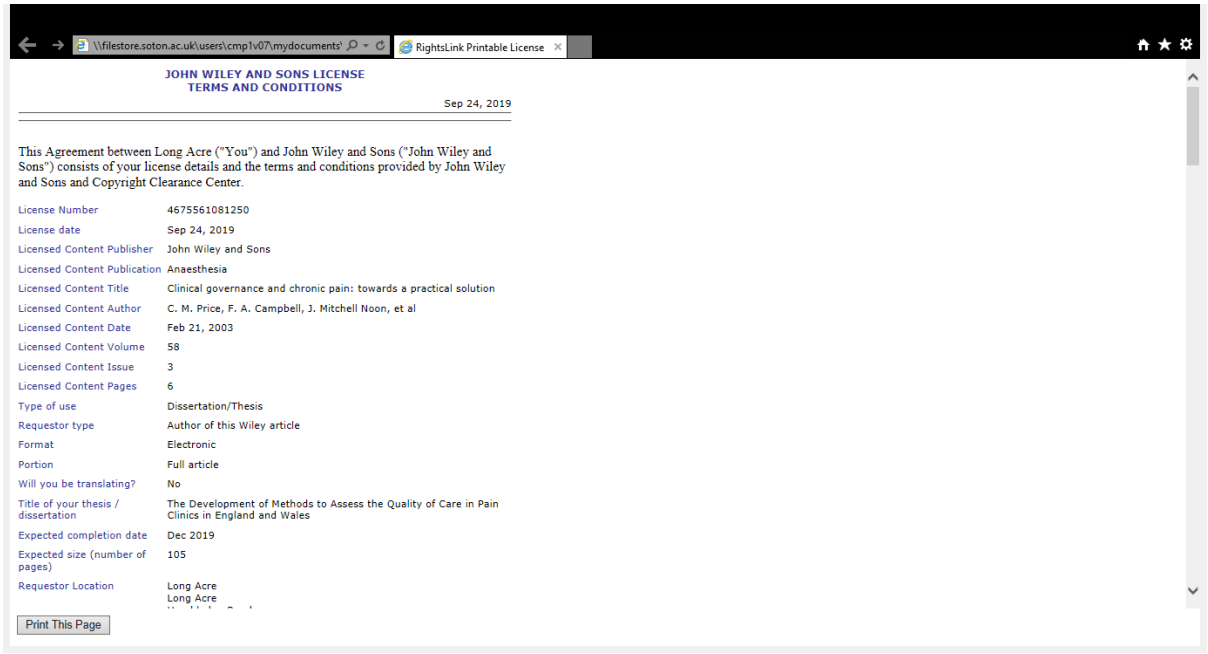
- *Manual treatments*
- *Complementary therapy*
- *Neuromodulation*
- *Injection therapy*
- *Medication*
- *Psychology*

Pain Measure

- *Brief Pain Inventory Pain Intensity*
- *Brief Pain Inventory Pain Interference*

Appendix 2 Permissions to reproduce each of the papers

Paper 1



\\filestore.soton.ac.uk\users\cmp1v07\mydocuments\ RightsLink Printable License

JOHN WILEY AND SONS LICENSE TERMS AND CONDITIONS

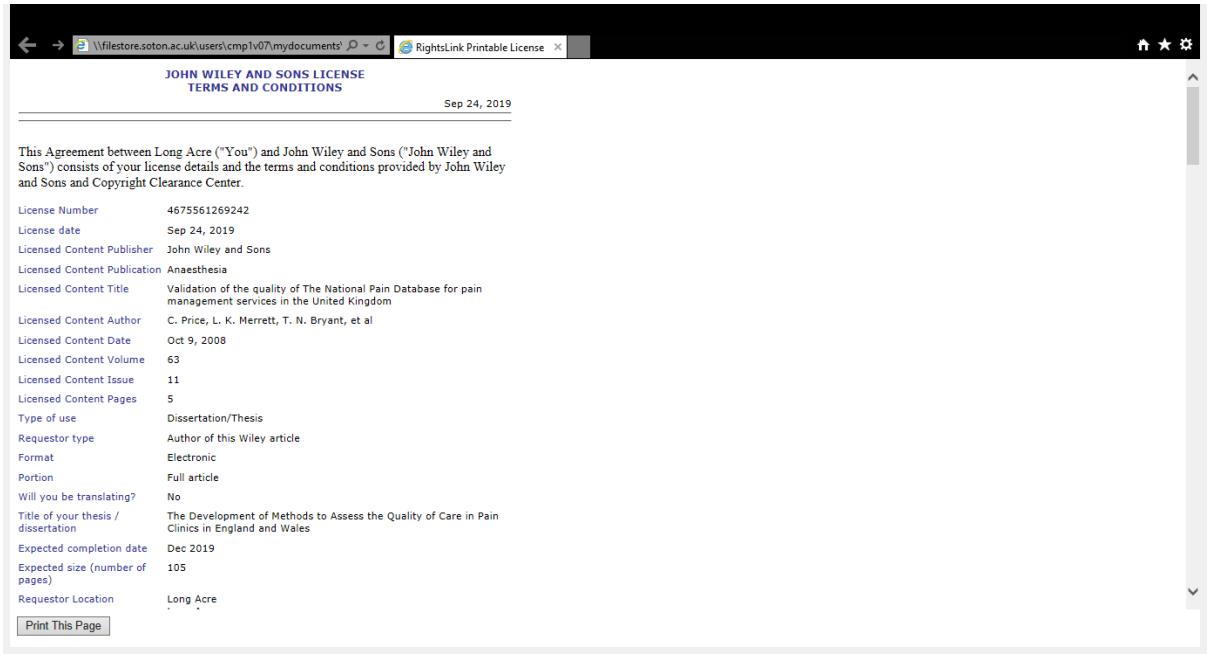
Sep 24, 2019

This Agreement between Long Acre ("You") and John Wiley and Sons ("John Wiley and Sons") consists of your license details and the terms and conditions provided by John Wiley and Sons and Copyright Clearance Center.

License Number	4675561081250
License date	Sep 24, 2019
Licensed Content Publisher	John Wiley and Sons
Licensed Content Publication	Anaesthesia
Licensed Content Title	Clinical governance and chronic pain: towards a practical solution
Licensed Content Author	C. M. Price, F. A. Campbell, J. Mitchell Noon, et al
Licensed Content Date	Feb 21, 2003
Licensed Content Volume	58
Licensed Content Issue	3
Licensed Content Pages	6
Type of use	Dissertation/Thesis
Requestor type	Author of this Wiley article
Format	Electronic
Portion	Full article
Will you be translating?	No
Title of your thesis / dissertation	The Development of Methods to Assess the Quality of Care in Pain Clinics in England and Wales
Expected completion date	Dec 2019
Expected size (number of pages)	105
Requestor Location	Long Acre Long Acre

Print This Page

Paper 2



\\filestore.soton.ac.uk\users\cmp1v07\mydocuments\ RightsLink Printable License

JOHN WILEY AND SONS LICENSE TERMS AND CONDITIONS

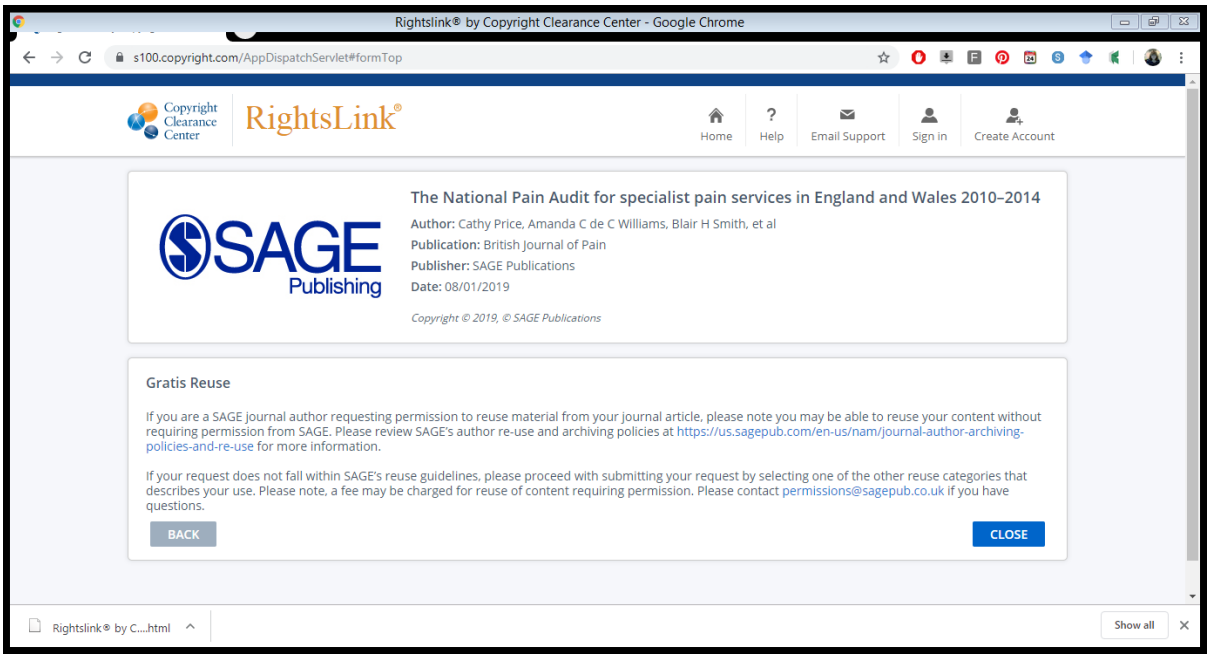
Sep 24, 2019

This Agreement between Long Acre ("You") and John Wiley and Sons ("John Wiley and Sons") consists of your license details and the terms and conditions provided by John Wiley and Sons and Copyright Clearance Center.

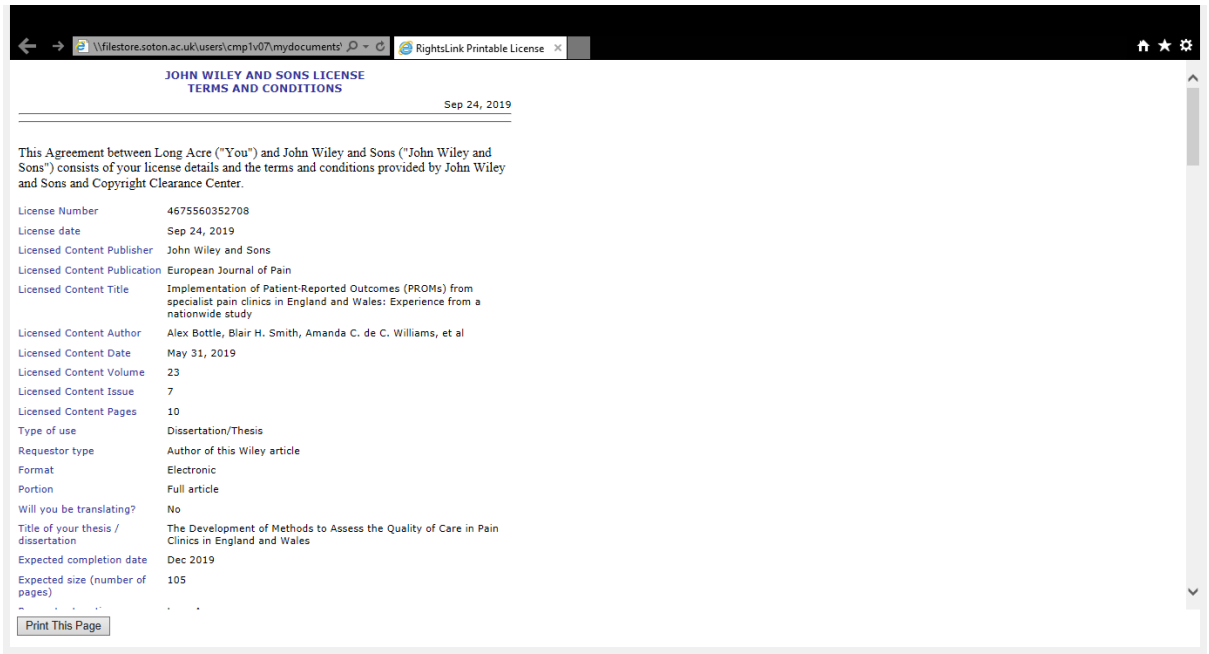
License Number	4675561269242
License date	Sep 24, 2019
Licensed Content Publisher	John Wiley and Sons
Licensed Content Publication	Anaesthesia
Licensed Content Title	Validation of the quality of The National Pain Database for pain management services in the United Kingdom
Licensed Content Author	C. Price, L. K. Merrett, T. N. Bryant, et al
Licensed Content Date	Oct 9, 2008
Licensed Content Volume	63
Licensed Content Issue	11
Licensed Content Pages	5
Type of use	Dissertation/Thesis
Requestor type	Author of this Wiley article
Format	Electronic
Portion	Full article
Will you be translating?	No
Title of your thesis / dissertation	The Development of Methods to Assess the Quality of Care in Pain Clinics in England and Wales
Expected completion date	Dec 2019
Expected size (number of pages)	105
Requestor Location	Long Acre

Print This Page

Paper 3



Paper 4



Glossary of Terms

BPI	Brief Pain Inventory
BPS	British Pain Society
CHOIR	Collaborative Health Outcomes Information Registry
CSAG	Clinical Standards Advisory Group
E.g.	For example
ePOCC	electronic Persistent Pain Outcomes Collaboration
EPR	Electronic Patient Record
EQ5D-3L	Euroqol5D-3L
FPM	Faculty of Pain Medicine
GPQ	German Pain Questionnaire
HES	Hospital Episode Statistics
HQIP	Health Quality Improvement Partnership
HSE	Health Survey for England
IASP	International Association for the Study of Pain
ICSI	Institute for Clinical Systems Improvement
I.e.	that is
IHI	Institute for Health systems Improvement
IMMPACT	Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials
ISTC	Independent Sector Treatment Centre
JCAHO	Joint Commission on Accreditation of Healthcare Organizations
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NPSA	National Patient Safety Agency
ONS	Office of National Statistics
PACS	Pain Audit Collection System
PAF	Performance Assessment Framework
PAINDB	Pain DataBase

PASTOR	Pain Assessment Screening Tool and Outcomes Registry
PROMIS	Patient-Reported Outcomes Measurement Information System
PROMs	Patient Reported Outcome Measures
RCGP	Royal College of General Practitioners
SIG	Special Interest Group
SIGN	Scottish Intercollegiate Guidelines Network
SPSS	Statistics Package for the Social Sciences
UK	United Kingdom
VA	Veterans Administration
VAPAIN	V alidation and A pplication of a patient relevant core outcome set to assess effectiveness of multimodal PAIN therapy

Bibliography

ACSQHC. Economic evaluation of clinical quality registries: Final report. Sydney: The Australian Commission on Safety and Quality in Health Care 2016. https://www.safetyandquality.gov.au/sites/default/files/migrated/Economic-evaluation-of-clinical-quality-registries-Final-report-Nov-2016.pdf Accessed 10/11/2019

AHRQ (2010). Care Coordination Measures Atlas. Rockville, MD: Agency for Healthcare Research and Quality

Antunes B, Harding R, Higginson IJ, EUROIMPACT. Implementing patient-reported outcome measures in palliative care clinical practice: a systematic review of facilitators and barriers. Palliative medicine. 2014 Feb;28(2):158-75

Ashburn MA, Witkin L. Integrating outcome data collection into the care of the patient with pain. Pain. 2012;153(8):1549-50

Audit Commission. Anaesthesia Under Examination: The Efficiency and Effectiveness of Anaethesia and Pain Relief Services in England and Wales. London: HMSO, 1997.

Australian Health Services Research Institute. EPOCC Annual Data Report 2017. https://ahsri.uow.edu.au/content/groups/public/@web/@chsd/documents/doc/uow255219.pdf Accessed 03/11/2019

Baker DW. History of The Joint Commission's Pain Standards. Lessons for Today's Prescription Opioid Epidemic. JAMA 2017;317(11):1117–1118. doi:10.1001/jama.2017.0935)

Barker KL.How can qualitative research be utilised in the NHS when re-designing and commissioning services? British Journal of Pain February 2015 vol. 9 no. 1 70-72

Barrie JL, Marsh DR. Quality of data in the Manchester orthopaedic database. British Medical Journal 1992; Jan 18;304(6820):159-62.

Black N, Payne M. Directory of clinical databases: improving and promoting their use. BMJ Quality & Safety. 2003 Oct 1;12(5):348-52.

Black N. Using clinical databases in practice. British Medical Journal 2003; 326: 2–3.

Black, N and Thompson, E. Obstacles to medical audit (British doctors speak) .Social Science & Medicine. 1999; 36: 849–856

Blanchard M, Tardif H, Fenwick N, Blissett C and Eagar K Electronic Persistent Pain Outcomes Collaboration Annual Data Report 2016 (2017). Australian Health Services Research Institute, University of Wollongong

Brehaut JC, Colquhoun HL, Eva KW, et al. Practice Feedback Interventions: 15 Suggestions for Optimizing Effectiveness. Ann Intern Med. 2016 Mar 15;164(6):435-41

Bridges S. Chronic pain. Health Survey for England, 2011. https://catalogueicnhsuk/publications/public-health/surveys/heal-surv-eng-2011/HSE2011-Ch9-Chronic-Painpdf Accessed 10 /1/2018

British Pain Society 2011. Pain Summit Report https://www.britishpainsociety.org/static/uploads/resources/files/members_articles_pain_summit_report.pdf. Accessed 28 August 2018

Burgess, R., Bishop, A., Lewis, M., & Hill, J. (2018). Models used for case-mix adjustment of patient reported outcome measures (PROMs) in musculoskeletal healthcare: A systematic review of the literature. Physiotherapy 2019 Jun;105(2):137-146.

Calsbeek H, Markhorst JG, Voerman GE, Braspenning JC. Case-mix adjustment for diabetes indicators: a systematic review. American Journal of Managed Care. 2016 Feb 1;22(2):e45-52

Charlton JE. Two for the price of one – is it worth it? Anaesthesia 2002; 57: 1–3.

Choinière, M., Dion, D., Peng, P., Banner, R., Barton, P.M., Boulanger, A., Clark, A.J., Gordon, A.S., Guerriere, D.N., Guertin, M.C. and Intrater, H.M., 2010. The Canadian STOP-PAIN project–Part 1: Who are the patients on the waitlists of multidisciplinary pain treatment facilities?. Canadian Journal of Anesthesia/Journal canadien d'anesthésie, 57(6), pp.539-548

Choinière, M., M. A. Ware, M. G. Pagé, A. Lacasse, H. Lanctôt, N. Beaudet, A. Boulanger, P. Bourgault, C. Cloutier, L. Coupal, Y. De Koninck, D. Dion, P. Dolbec, L. Germain, V. Martin, P. Sarret, Y. Shir, M.-C. Taillefer, B. Tousignant, A. Trépanier and R. Truchon (2017). "Development and Implementation of a Registry of Patients Attending Multidisciplinary Pain Treatment Clinics: The Quebec Pain Registry." Pain Research and Management 2017: e8123812

Clarke ME, Kerns R, Craine MH, Markham R, Jones JA et al. National VA Pain Outcomes Working Group: National VA Pain Management Coordinating Committee; VHA Pain Outcomes Toolkit. Department Of Veterans Affairs, 810 Vermont Avenue, N.W. Washington, DC 20420 February 2003)

Cleeland CS. Measurement of pain by subjective report. In: Chapman CR, Loeser JD, eds. Advances in Pain Research and Therapy, Vol. 12: Issues in Pain Measurement. New York: Raven Press, 1989: 391–403

Cleeland CS1, Reyes-Gibby CC, Schall M, et al. Rapid improvement in pain management: the Veterans Health Administration and the Institute for Healthcare Improvement Collaborative Clin J Pain 2003;19(5):298-305

Cleeland CS1, Reyes-Gibby CC, Schall M, Nolan K, Paice J, Rosenberg JM, Tollett JH, Kerns RD Rapid improvement in pain management: the Veterans Health Administration and the institute for healthcare improvement collaborative. Clin J Pain. 2003 Sep-Oct19 (5):298-305

Clinical Standards Advisory Group (CSAG): Services for patients with pain 2000

Colvin L. A. and Rowbotham D. J. Managing pain: recent advances and new challenges. Br. J. Anaesth 2013;111 (1);1-3

Conway J, Higgins I. Literature review: models of care for Pain Management. http://www.health.nsw.gov.au/PainManagement/Documents/appendix-3-literature-review.pdf (accessed28 August 2018)

Cook KF, Buckenmaier 3rd C, Gershon RC. PASTOR/PROMIS® pain outcomes system (2014): What does it mean to pain specialists? Pain management. 2014 Jul;4(4):277-83

Crook J, Weir R, Tunks E. An epidemiological follow-up survey of persistent pain sufferers in group family practice and specialty pain clinic. Pain 1989; 36: 49–61

Davies HTO, Crombie IK, Macrae WA, Rogers KM, Charlton JE. Audit in pain clinics. Changing the management of low back and nerve damage pain. Anaesthesia 1996 Jul;51(7):641-6.

De Ruddere, L., Goubert, L., Stevens, M.A.L., Deveugele, M., Craig, K.D. and Crombez, G., 2014. Health care professionals' reactions to patient pain: impact of knowledge about medical evidence and psychosocial influences. The Journal of Pain, 15(3), pp.262-270

Deckert S, Kaiser U, Kopkow C, Trautmann F, Sabatowski R, Schmitt J. A systematic review of the outcomes reported in multimodal pain therapy for chronic pain. European Journal of Pain. 2016 Jan;20(1):51-63

Declaration of Montreal. International Association of the Study of Pain 2010.https://www.iasp-pain.org/DeclarationofMontreal Accessed 03/11/2019

de Meij N, Köke A, Thomassen I, Kallewaard JW, van Kleef M, van der Weijden T. Quality indicators to assess quality of pain clinic care from the perspective of patients with chronic pain: development, usability, comprehensibility, and psychometric quality of the QiPPP questionnaire. Pain. 2018 Dec 1;159(12):2593-605.

Department of Health in England: Chief Medical Officer's Annual report 2008: Pain: Breaking through the barrier
http://webarchive.nationalarchives.gov.uk/+/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/AnnualReports/DH_096206 Accessed 23/09/2018

Department of Health Elective Care Commissioning Pathways 2010.
http://webarchive.nationalarchives.gov.uk/20130104183114/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_121431 Accessed 12/09/2018

Department of Health in England: QIPP LTC Year of Care Funding Model Project Team. QIPP Long Term Conditions—Supporting the Local Implementation of the Year of Care Funding Model for People with Long-Term Conditions. London, UK:2012
..https://www.gov.uk/government/publications/qipp-long-term-conditions-year-of-care-funding-model-early-implementers Accessed 23/09/2018

Department of Health NHS Outcomes Framework 2012:.
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/213711/dh_131723.pdf Accessed 04/11/2018

Department of Health. Appraisal for consultants working within the NHS. Annexe to circular AL (MD) 5 / 2001. London: Department of Health, 2000

Department of Health. Patient Reported Outcome Measures (PROMs) in England. The case-mix adjustment methodology 2012

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216507/dh_133449.pdf Accessed 23/09/2018

Desirable Characteristics of National Pain Strategies. International Association of the Study of Pain 2010. https://www.iasp-pain.org/DCNPS?navItemNumber=655 Accessed 03/11/2019

Devlin N, Appleby J. Getting the Most out of PROMS. The Kings Fund 2010.
https://www.kingsfund.org.uk/sites/files/kf/Getting-the-most-out-of-PROMs-Nancy-Devlin-John-Appleby-Kings-Fund-March-2010.pdf Accessed 23/09/2018

Donabedian A. Evaluating the Quality of Medical Care. The Milbank Memorial Fund Quarterly 1965;44:3:166-206

Donaldson C, Mooney G Needs assessment, priority setting, and contracts for health care: an economic view. BMJ. 1991 Dec 14; 303(6816):1529-30

Donath C, Geiß C, Schön C. Validation of a core patient-reported-outcome measure set for operationalizing success in multimodal pain therapy: useful for depicting long-term success?. BMC health services research. 2018 Dec;18(1):117

Dressler AM, Gillman AG, Wasan AD. A narrative review of data collection and analysis guidelines for comparative effectiveness research in chronic pain using patient-reported outcomes and electronic health records. Journal of pain research. 2019;12:491

Dworkin RH, Turk DC, Farrar JT, Haythornthwaite JA, Jensen MP, Katz NP, Kerns RD, Stucki G, Allen RR, Bellamy N, Carr DB. Core outcome measures for chronic pain clinical trials: IMMPACT recommendations. Pain. 2005;113(1-2):9-19

Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, Haythornthwaite JA, Jensen MP, Kerns RD, Ader DN, Brandenburg N. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. The Journal of Pain. 2008;9(2):105-21

Engel GL (1977) The need for a new medical model: a challenge for biomedicine. Science 196:129–136

Faculty of Pain Medicine: Outcome measures : 2019 https://www.rcoa.ac.uk/system/files/FPM-outcome-measures-2019.pdf

Faculty of Pain Medicine: Core Standards for Pain Management Services in the UK. Faculty of Pain Medicine Royal College of Anaesthestists 2015. http://www.rcoa.ac.uk/system/files/CSPMS-UK-2015-v2-white.pdf . (accessed 28 August 2018)

Faculty of Pain medicine: Key Standards in Pain medicine 2016. https://www.rcoa.ac.uk/system/files/FPM%20CQC%20key%20standards.pdf

Farrar JT, Young JP Jr, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. Pain 2001; 94: 149–58.

Farrar JT. What is clinically meaningful: outcome measures in pain clinical trials. Clinical Journal of Pain 2000; 16: S106–12.

Fashler SR, Cooper LK, Oosenbrug ED, Burns LC, Razavi S, Goldberg L, Katz J. Systematic review of multidisciplinary chronic pain treatment facilities. Pain research and management. 2016;2016.

Fielding R, Kause J, Arnell-Cullen V, Sandeman D. The impact of consultant-delivered, multidisciplinary, inpatient medical care on patient outcomes. Clin Med 2013: 13(4):344-8.

Fine LG, Keogh BE, Cretin S, Orlando M, Gould MM. How to evaluate and improve the quality and credibility of an outcomes database: validation and feedback study on the UK Cardiac Surgery Experience. British Medical Journal 2003; 326: 25–8.

Finnerup NB, Attal N, Haroutounian S, McNicol E, Baron R, Dworkin RH, Gilron I, Haanpää M, Hansson P, Jensen TS, Kamerman PR. Pharmacotherapy for neuropathic pain in adults: a systematic review and meta-analysis. The Lancet Neurology. 2015 Feb 1;14(2):162-73

Fordyce WE, Fowler RS, Lehmann JF, De Lateur BJ, Sand PL, Trieschmann RB. Operant conditioning in the treatment of chronic pain. Archives of physical medicine and rehabilitation. 1973;54(9):399-408

Friebel R Health Foundation 2017. Measuring quality of health care in the NHS: Giving a voice to the patients. https://www.health.org.uk/blogs/measuring-quality-of-health-care-in-the-nhs-giving-a-voice-to-the-patients (accessed 17 November 2019)

Gallagher RM. Rational integration of pharmacologic, behavioral, and rehabilitation strategies in the treatment of chronic pain. American journal of physical medicine & rehabilitation. 2005 Mar 1;84(3):S64-76

García García JA, Hernández-Puiggròs P, Tesedo Nieto J, Acín Lázaro MP, Carrera González A, Soler MJ, Maldonado Vega S. Patient satisfaction with Spanish pain centers: observational study with more than 3,000 patients. Pain Research and Treatment. 2016 http://doi.org/10.1155/2016/7829585

Gliklich R, Dreyer N, Leavy M, eds. Registries for Evaluating Patient Outcomes: A User's Guide. Third edition. Two volumes. (Prepared by the Outcome DEcIDE Center [Outcome Sciences, Inc., a Quintiles company] under Contract No. 290 2005 00351 TO7.) AHRQ Publication No. 13(14)-EHC111. Rockville, MD: Agency for Healthcare Research and Quality. April 2014. http://www.effectivehealthcare.ahrq.gov/ registries-guide-3.cfm. Accessed 11/04/2018

Gordon DB, Dahl JL. Quality improvement challenges in pain management. Pain 2004;107(1-2):19

Griffiths DP, Mitchell Noon J, Campbell FA, Price CM. Clinical governance and chronic pain: towards a practical solution. Anaesthesia. 2003;58(3):243-8.

Gupta A, Weber N, Duwell M. Implementing a public health approach to the management of chronic pain in the USA. Pain management. 2013 Jul;3(4):315-9

Hall GC, Bryant TN, Merrett LK, Price C. Validation of the quality of The National Pain Database for pain management services in the United Kingdom. Anaesthesia. 2008;63(11):1217-21

Hall GC, Luscombe DK, Walker SR. Post-marketing surveillance using a computerised general practice database. Pharmaceutical Medicine 1988; 2: 345–51

Hara KW, Borchgrevink P. National guidelines for evaluating pain - Patients' legal right to prioritised health care at multidisciplinary pain clinics in Norway implemented 2009. Scandinavian Journal of Pain 2010 1(1):60-3

Hart OR, Uden RM, McMullan JE, Ritchie MS, Williams TD, Smith BH. A study of National Health Service management of chronic osteoarthritis and low back pain. Primary health care research & development. 2015 Mar;16(2):157-66

Häuser W, Neugebauer E, Petzke F. Healthcare services research on pain in Germany. A survey. Schmerz 2015: 29(5):469-70

Health Improvement Scotland: Chronic Pain in Scotland where are we now? 2014http://www.healthcareimprovementscotland.org/our_work/long_term_conditions/chronic_pain/where_are_we_now.aspx. Accessed 23/09/2018

Health Quality Improvement Scotland. Getting to GRIPS with chronic pain in Scotland. NHS QIS 2007

Health Quality Improvement Partnership (HQIP) 2018. Understanding Practice in Clinical Audit and Registries tool: UPCARE-tool. A protocol to describe the key features of clinical audits and registries

Health Quality Improvement Partnership (HQIP) 2011. New Principles of Best Practice in Clinical Audit', Radcliffe Publishing,

Health Quality Improvement Partnership (HQIP) https://www.hqip.org.uk/wp-content/uploads/2018/08/PROMs-Feasibility-Study-Final.pdf (Accessed 04/11/2018

Health Quality Ontario 2019: Draft Quality Statements Chronic pain. https://www.hqontario.ca/portals/0/documents/evidence/quality-standards/qs-chronic-pain-clinical-guide-1810-en.pdf

Health Quality Improvement Partnership/ Resources / Best Practice in Clinical Audit 2016 https://www.hqip.org.uk/resource/best-practice-in-clinical-audit/#.Xb7N6lX7TIU

Health Quality Improvement Partnership/ Resources / National Pain Audit: Reports from 2011 to 2012. Published Oct 2017. https://www.hqip.org.uk/resource/national-pain-audit-reports-from-2011-to-2012/ Accessed 11/04/2019

Health Quality Improvement Partnership 2013. The National Pain Audit Third Report https://www.britishpainsociety.org/static/uploads/resources/files/members_articles_npa_2013_safety_outcomes.pdf (accessed19 August 2018)

Hickey GL, Grant SW, Cosgriff R, Dimarakis I, Pagano D, Kappetein AP, et al. Clinical registries: governance, management, analysis and applications. European Journal of Cardio-Thoracic Surgery. 2013 Jan 30;44(4):605-14.

Hogg M. N., Gibson S., Helou A., Degabriele J., Farrell M. J. Waiting in pain: a systematic investigation into the provision of persistent pain services in Australia. Medical Journal of Australia 2012;196(6):386–390

Hølen JC, Lydersen S, Klepstad P, Loge JH, Kaasa S. The Brief Pain Inventory: pain's interference with functions is different in cancer pain compared with non-cancer chronic pain. The Clinical Journal of Pain. 2008 ;24(3):219-25

Holmes MM, Lewith G, Newell D, Field J, Bishop FL. The impact of patient-reported outcome measures in clinical practice for pain: a systematic review. Quality of Life Research. 2017 Feb 1;26(2):245-57

Hooten WM, Timming R, Belgrade M, Gaul J, Goertz M, Haake B, Myers C, Noonan MP, Owens J, Saeger L, Schweim K, Shteyman G, Walker N. Assessment and management of chronic pain. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2013 Nov. p 105

Hoque DM, Kumari V, Hoque M, Ruseckaite R, Romero L, Evans SM. Impact of clinical registries on quality of patient care and clinical outcomes: A systematic review. PloS one. 2017 Sep 8;12(9):e0183667

Houses W, Schmutzer G, Henningsen P, Brähler E (2014) Chronic pain, pain and satisfaction of those affected with pain treatment in Germany. Results of a representative population sample. Pain 28: 483-492

Hutchings A, Neuburger J, Frie KG, Black N, van der Meulen J. Factors associated with non-response in routine use of patient reported outcome measures after elective surgery in England. Health and quality of life outcomes. 2012 Dec;10(1):34.doi:10.1186/1477-7525-10-34

IASP Taskforce Recommendations on Waiting Times 2010: www.dgss.org/fileadmin/pdf/Task_Force_on_Wait-Times.pdf (accessed 28 August 2018)

International Association for the Study of Pain: Pain Treatment Services Guideline. 2009. http://www.iasp-pain.org/Education/Content.aspx?ItemNumber=1381 Accessed 28August 2018

Ivers NM, Grimshaw JM, Jamtvedt G, et al. Growing literature, stagnant science? Systematic review, meta-regression and cumulative analysis of audit and feedback interventions in health care. J Gen Intern Med. 2014 Nov;29(11):1534-41

Jaksch W, Likar R, Folkes E, Machold K, Herbst F, Pils K, Stippl P, Lettner S, Alfons M, Crevenna R, Wiederer C. Qualitätssicherung der schmerzmedizinischen Versorgung in Österreich: Klassifikation schmerztherapeutischer Einrichtungen. Wien Med Wochenschr. 2017:349-58

Joint Commission on Accreditation of Healthcare Organizations (JCAHO) . Improving the Quality of Pain Management Through Measurement and Action 2003. https://www.npcnow.org/system/files/research/download/Improving-the-Quality-of-Pain-Management-Through-Measurement-and-Action.pdf Accessed 17//1/2019

Kaiser U, Kopkow C, Deckert S, Neustadt K, Jacobi L, Cameron P, De Angelis V, Apfelbacher C, Arnold B, Birch J, Bjarnegård A. Developing a core outcome-domain set to assessing effectiveness of interdisciplinary multimodal pain therapy: the VAPAIN consensus statement on core outcome-domains. Pain. 2018;159(4):673-83

Keller S, Bann CM, Dodd SL, Schein J, Mendoza TR et al . Validity of the Brief Pain Inventory for use in documenting the outcomes of patients with noncancer pain. The Clinical journal of pain. 2004 Sep 1;20(5):309-18

Kerns R. Improving Care Across Hundreds of Facilities: The Veterans Health Administration's National Pain Management Strategy. In: Joint Commission on Accreditation of Healthcare Organizations. Improving the Quality of Pain Management Through Measurement and Action 2003.

Kløjgaard ME, Manniche C, Pedersen LB, Bech M, Søgaard R. Patient preferences for treatment of low back pain—a discrete choice experiment. Value in Health. 2014 Jun 1;17(4):390-6

Lamers LM. The transformation of utilities for health states worse than death: consequences for the estimation of EQ-5D value sets. Med Care. 2007;45(3):238–44

Landmark T, Dale O, Romundstad P, Woodhouse A, Kaasa S, Borchgrevink PC. Development and course of chronic pain over four years in the general population: The HUNT pain study. European Journal of Pain. 2018 Oct;22(9):1606-16

Larsson S, Lawyer P, Garellick G, Lindahl B, Lundstrom M. Use of 13 disease registries in 5 countries demonstrates the potential to use outcome data to improve health care's value. Health Aff (Millwood). 2012; 31(1):220-7

Levy N, Sturgess J, Mills P. "Pain as the fifth vital sign" and dependence on the "numerical pain scale" is being abandoned in the US: Why?. British Journal of Anaesthesia. 2018 Mar 1;120(3):435-8

Lynch ME, Campbell F, Clark AJ et al. A systematic review of the effect of waiting for treatment for chronic pain. Pain 2008;136(1-2):97-116

Mackey S. Future directions for pain management: lessons from the institute of medicine pain report and the national pain strategy. Hand clinics. 2016 Feb 1;32(1):91-8

Mathias SD, Crosby RD, Qian Y, Jiang Q, Dansey R, Chung K. Estimating minimally important differences for the worst pain rating of the Brief Pain Inventory-Short Form. The journal of supportive oncology. 2011;9(2):72-8

McQuay HJ, Moore RA, Eccleston C et al. Systematic review of outpatient services for chronic patient control. Health Technology Assessment 1997; 1

McSherry R, Pearce P. Applying Clinical Governance in Daily Practice. Clinical governance: a guide to implementation for healthcare professionals. 2002:60.

Mease, P.J., Spaeth, M., Clauw, D.J., Arnold, L.M., Bradley, L.A., et al. (2011) Estimation of minimum clinically important difference for pain in fibromyalgia. Arthritis Care and Research 63(6), 821-826

Mellor R. Health Care Needs Assessment of Adult Chronic Pain Services in Scotland 2018. https://www.scotphn.net/wp-content/uploads/2017/04/2018_10_11-Chronic-pain-HNA-Final.pdf Accessed 03/11/2019

Melzack R, Wall PD (1965) Pain mechanisms: a new theory. Science 150:971–979

Merskey H, Bogduk N, eds. Classification of Chronic Pain: Descriptions of Chronic Pain Syndromes and Definitions of Pain Terms, 2nd edn Seattle, WA: IASP Press, 1994.

Mills SE, Nicolson KP, Smith BH. Chronic pain: a review of its epidemiology and associated factors in population-based studies. British Journal of Anaesthesia. (2019):123(2) ;e273-e283..

Müller-Schwefe GH, Nadstawek J, Tölle T, Nilges P, Überall MA, Laubenthal HJ, Bock F, Arnold B, Casser HR, Cegla TH, Emrich OM. Structure of pain management facilities in Germany: Classification of medical and psychological pain treatment services-Consensus of the Joint Commission of the Professional Societies and Organizations for Quality in Pain Medicine. Schmerz (Berlin, Germany). 2016 Jun;30(3):218-26

Nagel B, Pfingsten M, Brinkschmidt T, Casser HR, Gralow I, Irnich D, Klimczyk K, Sabatowski R, Schiltenwolf M, Sittl R, Söllner W. Structure and process quality of multimodal pain therapy. Results of a survey of pain therapy clinics. Schmerz (Berlin, Germany). 2012 Dec;26(6):661-9

National Clinical Audit Quality Assessment. Overview of the self-assessment survey: “audit of audits” Report to the Healthcare Quality Improvement Partnership 19 December 2014. https://www.hqip.org.uk/wp-content/uploads/2018/02/audit-of-clinical-audits-national-report.pdf. Accessed 11/04/2019

National Institute for Clinical Excellence 2017. Key Therapeutic Topic 21. Medicines Optimisation in Chronic Pain https://www.nice.org.uk/advice/ktt21

National Institute for Health and Care Excellence CG 173. Neuropathic pain in adults: pharmacological management in non-specialist settings 2013. https://www.nice.org.uk/guidance/cg173 Accessed 03/11/2019

National Institute for Health and Care Excellence CG 88 Low back pain in adults: early management 2009. https://www.nice.org.uk/guidance/cg88 Accessed 03/11/2018

National Institute of Clinical Excellence .Neuropathic pain in adults: pharmacological management in non-specialist settings Clinical guideline [CG173] July 2019 https://www.nice.org.uk/guidance/cg173/chapter/Update-information Accessed 26/11/2018

National Institute of Clinical Excellence. Low back pain and sciatica in over 16s: assessment and management NICE guideline [NG59]: November 2016. https://www.nice.org.uk/guidance/ng59 Accessed 26/11/2018

National Patient Safety Agency (Corporate Office) 4-8 Maple Street, London W1T 5HD:www.npsa.nhs.uk /resources/ (accessed 28 August 2018)

NHS Improvement: Quality, Service Improvement and Redesign Tools: A model for measuring quality care. https://improvement.nhs.uk/documents/2135/measuring-quality-care-model.pdf (accessed 17 November 2019)

Public Health England: NHS Atlas of Variation volume 2 2011: https://fingertips.phe.org.uk/profile/atlas-of-variation (accessed 28 August 2018)

NHS Digital: Guide to PROMS. http://content.digital.nhs.uk/proms-userguide Accessed 23/09/2018

NHS Digital: Patient Reported Outcome Measures (PROMs) in England: Special Topic: Rates of Attrition 2013-14. https://digital.nhs.uk/catalogue/PUB20625 Accessed 24/12/2017

NHS Information Authority. Office of Population, Censuses and Surveys – Classification of Surgical Operations and Procedures, 4th revision (OPCS-4). http://www.coding.nhsia.nhs.uk/ clin_class/opcs_4asp

Obradovic M, Lal A, Liedgens H. Validity and responsiveness of EuroQol-5 dimension (EQ-5D) versus Short Form-6 dimension (SF-6D) questionnaire in chronic pain. Health and quality of life outcomes. 2013 Jul 1;11(1):110

Office for National Statistics, National Records of Scotland, Northern Ireland Statistics and Research Agency.https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/bulletins/annualmidyearpopulationestimates/2014-06-26 (accessed 28 August 2018)

Office for National Statistics: Final recommended questions for the 2011 Census in England and Wales: Ethnic group. October 2009

Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process. BMJ Qual Saf. 2015. PMID: 26369893

Oxford Pain Internet site. www.jr2.ox.ac.uk/bandolier/ booth/painpag / index.html

Pain Treatment Services Guideline. International Association for the Study of Pain 2009. http://www.iasp-pain.org/Education/Content.aspx?ItemNumber=1381 (accessed 28August 2018)

Peng P, Choiniere M, Dion D et al. Challenges in accessing multidisciplinary pain treatment facilities in Canada. Canadian Journal of Anesthesia 2007;542:977–984

Penney GC, Templeton A Impact of a national audit project on gynaecologists in Scotland. BMJ Quality & Safety 1995;4:37-39

Health Services Research Institute, University of Wollongong.

Persistent Pain Outcomes Collaboration Annual Data Report 2016 (2017). https://ahsri.uow.edu.au/content/groups/public/@web/@chsd/documents/doc/uow255219.pdf

Pike, Andrew; Hearn, Leslie; de C Williams, Amanda C. Effectiveness of psychological interventions for chronic pain on health care use and work absence: systematic review and meta-analysis. Pain 157(4):777-785, April 2016

Pink D, Bromwich N. National Institute for Clinical Excellence (Great Britain). Principles for best practice in clinical audit. Radcliffe Publishing, 2002

Price CM, C. de C. Williams A, Smith BH, Bottle A. Implementation of Patient-Reported Outcomes (PROMs) from specialist pain clinics in England and Wales: Experience from a nationwide study. European Journal of Pain. 2019 Apr 26

Price, C., de C Williams, A. C., Smith, B. H., & Bottle, A. (2019). The National Pain Audit for specialist pain services in England and Wales 2010–2014. British Journal of Pain. 13;3:185–193. https://doi.org/10.1177/2049463718814277

Quality Improvement Scotland: Getting to GRIPS with chronic pain in Scotland. NHS QIS 2007

Racine M, Dion D, Dupuis G, Guerriere DN, Zagorski B,et al . The Canadian STOP-PAIN Project: The Burden of Chronic Pain—Does Sex Really Matter? The Clinical Journal of Pain. 2014;30(5):443-52.

Radbruch L, Loick G, Kiencke P et al. Validation of the German version of the Brief Pain Inventory. Journal of Pain and Symptom Control, 1999; 18: 180–7.

Read terms. http://www.nhsia.nhs.uk/terms.

Richardson C , Laskawska M, Berlouis K, Cameron P, Colvin L, Smith BH. Data and Measurement for Chronic Pain Services. A Project to Inform National Pain Service improvement. Draft Progress Report 2018.http://www.nhsresearchscotland.org.uk/uploads/tinymce/National%20Outcomes%20Summary%20Report%20-%20pain.pdf

Roehr B. Trump declares opioid public health emergency but no extra money. BMJ 2017;359:j4998

Rogers WH, Wittink HM, Ashburn MA, Cynn D, Carr DB. Using the “TOPS,” an outcomes instrument for multidisciplinary outpatient pain treatment. Pain Medicine 2000; 1: 55–67.

Rolfson, Ola et al. “Patient-reported outcome measures in arthroplasty registries Report of the Patient-Reported Outcome Measures Working Group of the International Society of Arthroplasty Registries Part II. Recommendations for selection, administration, and analysis” Acta orthopaedica vol. 87 Suppl 1,Suppl 1 (2016): 9-23

Rowan K, Black N. A bottom up approach to performance indicators through clinician networks. Healthcare UK 42–6. King’s Fund 2000

Royal College of Anaesthetists: General Provision of Anaesthetic Services: Good Practice in Chronic Pain Management 2012

Royal College of Anaesthetists. Raising the Standard: a compendium of audit recipes (3rd edition) 2012 Royal College of Anaesthetists https://www.rcoa.ac.uk/ARB2012

Royal College of General Practitioners https://www.rcgp.org.uk/-/media/Files/CIRC/Chronic-pain/RCGP-Commissioning-Pain-Management-Services-Jan-14.ashx?la=en Accessed 27/10/2019

Royal College of General Practitioners: Pain Management Services: Planning for the Future - guiding clinicians in their engagement with commissioners 2014 file:///C:/Users/cmp1v07/Downloads/RCGP-Commissioning-Pain-Management-Services-Jan-14.pdf (Accessed 19 August 2018)

Royal College of Psychiatrists National Audit of Dementia https://www.rcpsych.ac.uk/workinpsychiatry/qualityimprovement/nationalclinicalaudits/thenationalauditofdementia.aspx (Accessed 4 November 2019)

Royal College of Surgeons Press Statement April 2016:https://www.rcseng.ac.uk/news-and-events/media-centre/press-releases/assuring-standards-independent-sector/ Accessed 02/11/2019

Rubenfeld GD. Understanding why we agree on the evidence but disagree on the medicine. Respiratory Care 2001; 46: 1442–9

Scottish Intercollegiate Guidelines Network Management of Chronic Pain 2013.https://www.sign.ac.uk/sign-136-management-of-chronic-pain.htm

Serlin RC, Mendoza TR, Nakamura Y, Edwards KR, Cleeland CS. When is cancer pain mild moderate or severe? Grading pain severity by its interference with function. Pain 1995; 61: 277–84

Shah S, Ho AC, Kuehler BM, Childs SR, Towlerton G et al. Different measures, different outcomes? Survey into the effectiveness of chronic pain clinics in a London tertiary referral center. Journal of Pain Research: 2015;8:477.

Simm R, Barker C. Five years of a community pain service solution-focused pain management programme: extended data and reflections. British Journal of Pain. 2018 May;12(2):113-21

Smith BH, Hannaford PC, Elliott AM, Smith WC and Chambers WA. The 'number needed to sample' in primary care research. Comparison of two primary care sampling frames for chronic back pain. Family Practice 2005; 22: 205–214

Sturgeon JA, Carriere JS, Kao MC, Rico T, Darnall BD, Mackey SC. Social disruption mediates the relationship between perceived injustice and anger in chronic pain: a collaborative health outcomes information registry study. Annals of Behavioral Medicine. 2016 Jun 20;50(6):802-12

Sturgeon JA, Dixon EA, Darnall BD, Mackey SC. Contributions of physical function and satisfaction with social roles to emotional distress in chronic pain: a Collaborative Health Outcomes Information Registry (CHOIR) study. Pain. 2015 Dec;156(12):2627

Sullivan PW, Slejko JF, Sculpher MJ and Ghushchyan V. The UK EQ5D scores catalogue. Med Decis Making 2011 31: 800

Tan G, Jensen MP, Thornby JI, Shanti BF. Validation of the Brief Pain Inventory for chronic nonmalignant pain. The Journal of Pain. 2004 Mar 31;5(2):133-7.

Tardif, H., C. Arnold, C. Hayes and K. Eagar "Establishment of the Australasian Electronic Persistent Pain Outcomes Collaboration." Pain Med 2017 18(6): 1007-1018

Tauben D. International Association for the Study of Pain. Chronic Pain Management. Measurement-Based Step Care Solutions 2012:20;8

The Audit Commission. Hospital Services. Anaesthesia Under Examination. The Efficiency and Effectiveness of Anaesthesia and Pain Relief Services in England and Wales National Report. London: HMSO, 1997

The Brief Pain inventory User Guide. https://www.mdanderson.org/documents/Departments-and-Divisions/Symptom-Research/BPI_UserGuide.pdf Accessed 23/03/2018

Treede RD, Rief W, Barke A, Aziz Q, Bennett MI, Benoliel R, Cohen M, Evers S, Finnerup NB, First MB, Giamberardino MA. A classification of chronic pain for ICD-11. Pain. 2015 Jun;156(6):1003-1007

Turk DC. Clinical effectiveness and cost-effectiveness of treatments for patients with chronic pain. The Clinical journal of pain. 2002 Nov 1;18(6):355-65

Turk DC. Statistical significance and clinical significance are not synonyms. Clinical Journal of Pain 2000; 16: 185–7.

Turk DC. Here we go again: outcomes, outcomes, outcomes. Clinical Journal of Pain 1999; 15: 241–3.

Vadivelu N, Mitra S, Hines RL. Undergraduate medical education on pain management across the globe. AMA Journal of Ethics. 2013 May 1;15(5):421-7

Van Hecke O, Austin SK, Khan RA, Smith BH, Torrance N. Neuropathic pain in the general population: a systematic review of epidemiological studies. PAIN®. 2014 Apr 1;155(4):654-62.

Vartiainen P, Mäntyselkä P, Heiskanen T, Hagelberg N, Mustola S, Forssell H, Kautiainen H, Kalso E. Validation of EQ-5D and 15D in the assessment of health-related quality of life in chronic pain. Pain. 2017 Aug 1;158(8):1577-85

von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, et al . The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin Epidemiol. 2008;61(4):344–349

Walters SJ, Brazier JE. Comparison of the minimally important difference for two health state utility measures: EQ-5D and SF-6D. Quality of life research. 2005 Aug 1;14(6):1523-32

Webster F, Rice K, Katz J, Bhattacharyya O, Dale C, Upshur R. An ethnography of chronic pain management in primary care: The social organization of physicians' work in the midst of the opioid crisis. PloS one. 2019 1;14(5):e0215148

Welsh Assembly Government. Service Development and Commissioning Directives, Chronic Non-Malignant Pain. June 2008

Wolff R, Clar C, Lerch C, Kleijnen J (2011) Epidemiologie von nicht tumorbedingten chronischen Schmerzen in Deutschland. Schmerz 25(1):26–44

Woolf AD, Akesson K. Understanding the burden of musculoskeletal conditions. British Medical Journal 2001; 322: 1079–80

Woolf CJ, Bennett GJ, Doherty M et al. Towards a mechanism-based classification of pain? Pain, 1998; 77: 227–9

World Health Organization. The Tenth Revision of the International Statistical Classification of Diseases and Related Health Problems. Geneva: World Health Organization, 1992

Wright J, Williams R, Wilkinson JR. Development and importance of health needs assessment. BMJ. 1998;316(7140):1310-3

Zidarov D, Visca R, Ahmed S. Type of clinical outcomes used by healthcare professionals to evaluate health-related quality of life domains to inform clinical decision making for chronic pain management. Quality of Life Research. 2019 May 28:1-1

Zidarov D, Visca R, Gogovor A, Ahmed S. Performance and quality indicators for the management of non-cancer chronic pain: a scoping review protocol. BMJ Open. 2016;6(2):e010487. doi:10.1136/bmjopen-2015-010487