University of Southampton

Faculty of Environmental and Life Sciences

Health Sciences

Supporting shared decision making when cancer can’t be cured

by

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Abstract

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Shared decision making (SDM) involves patients and clinicians working together to reach a decision that is best for the patient. It is particularly important in the setting of incurable cancer, where it may be necessary to balance the risks and side effects of treatments with the benefits of increased survival or quality of life. Decision making conversations may include detailed discussions of complex information, and patients must be able to understand and process the information they have been given in order to weigh up the options. Health literacy (HL) plays a fundamental role in achieving SDM, yet is not always accounted for when interventions to support the process are developed. This PhD sets out to 1) explore and better understand the issues for SDM in incurable cancer, focussing on the particular challenges faced by those who experience difficulties with HL, and 2) identify the components of an intervention to support SDM in this setting.

Guided by the Person Based Approach to Intervention Development, this Thesis describes four distinct phases of work carried out during the PhD study. They include a systematic review of the role of HL in cancer care, a series of interviews with patients diagnosed with incurable cancer suspected of experiencing difficulties with HL, an online survey of NHS healthcare professionals involved in decision making with patients with incurable cancer, and two expert panel meetings, one involving patients and carers and another with healthcare professionals. Findings from each phase informed the next and were ultimately synthesised and refined to form three overarching challenges for SDM in the context of incurable cancer and HL difficulties. These were used to devise of a set of guiding principles, from which a team based complex intervention to support SDM was developed.

The overarching challenges identified for SDM in this setting included the persistence of traditional paternalistic clinician-patient roles, dealing with the emotional hurdles associated with a diagnosis of incurable cancer, and practical issues resulting from an imperfect system. A team based, complex intervention aimed at preparing patients, training teams and creating a supportive environment has been developed to overcome many of these barriers and improve SDM in this setting.

Shared decision making is complex, and the emotional burden of an incurable cancer coupled with difficulties processing information make it all the more challenging to achieve in clinical practice. To better support SDM in this setting, it will be important to consider this combination of socio-cultural, emotional, and system-related barriers when developing future interventions.

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Research Thesis: Declaration of Authorship

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I 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.

I confirm that:

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2. Where any part of this thesis has previously been submitted for a degree or any other qualification at this University or any other institution, this has been clearly stated;
3. Where I have consulted the published work of others, this is always clearly attributed;
4. Where I have quoted from the work of others, the source is always given. With the exception of such quotations, this thesis is entirely my own work;
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Signature: Date:

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Definitions and Abbreviations

CNS	Clinical nurse specialist
DNACPR	Do Not Attempt Cardio-Pulmonary Resuscitation (order)
GMC	General Medical Council
HCP	Healthcare professional
HL	Health literacy
HLD	Health literacy difficulties
NHLD	No health literacy difficulties
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PBA	Person Based Approach
PPI	Patient and public involvement
SDM	Shared decision making

Chapter 1 Introduction

1.1 Overview and rationale for project

Based on clinical experience and borne out of several challenging interactions with patients, this project was conceived with the overall aim of supporting shared decision making (SDM) by patients with incurable cancer. Reflecting on some of those difficult conversations, it became apparent that incomplete understanding about their clinical situation led to some patients struggling through treatments discordant with their priorities, or they experienced greater distress and conflict when difficult decisions needed to be made. Involving patients more actively in decisions about their care and throughout the course of their disease therefore seemed to be one way of improving some of these experiences. An initial scoping search of the literature highlighted a crucial step in this process of sharing decision making is that the patient understands their current situation, the aims and potential risks of treatments put forward, and the possible alternatives (Makoul and Clayman, 2006). This relies on health literacy (HL), which has been linked directly to outcomes as well as playing a vital role in SDM (Berkman *et al.*, 2011a; Edwards *et al.*, 2012; International Union for Health Promotion and Education, 2018). This first chapter therefore provides an overview of SDM in the setting of cancer that cannot be cured, followed by a discussion of the definitions, conceptualisations, and tools to assess HL.

Based on this initial understanding of the existing literature, Chapter 2 outlines the underpinning methodology and approach taken in this project. It includes an overview of the study design as well as the chosen definitions and frameworks on which the work is based. Using the Person-Based Approach to intervention development (Yardley *et al.*, 2015) and given the vital role of HL in decision making, a first step was to explore the role of HL in the oncology setting and the impact this has on patients. Chapter 3 details a systematic review exploring this further using a mixed studies approach. Despite the project's overall focus on incurable cancer, the review incorporates all stages and tumour sites, as many patients receive care initially in the curative setting before transitioning to a more palliative approach, and there are similarities between experiences, regardless of treatment intent. The review set out to determine the wider impact of HL in this setting, as well as exploring its role in decision making.

The next step was to discover more about the interplay between heath literacy and decision making, focussing on the palliative oncology setting. Chapter 4 describes a qualitative interview study designed to learn more about this from those who have experienced difficulties with HL, exploring these issues from the perspective of patients with incurable cancer.

In order to gain a better understanding of the views and experiences of healthcare professionals towards SDM in incurable cancer, and consider how their approach changes when they suspect a person might have lower HL, a survey of healthcare professionals was subsequently carried out, presented in Chapter 5. This provided an important alternative perspective and offered insights into some of the experiences described by patients.

Findings from these three pieces of work were then brought together and considered alongside a commonly used model for SDM in Chapter 6, and presented to a panel of expert patients, carers, and healthcare professionals (Chapter 7). Common discussion points from these meetings and areas for improvement were summarised and used to inform a set of guiding principles, from which the components of a complex intervention to support SDM in practice were developed (Chapter 8). Finally, Chapter 9 includes a discussion of the contributions made by this work and some of its limitations.

For the purpose of this PhD study, the terms ‘incurable cancer’ or ‘cancer that cannot be cured’ refer to those for whom treatment or care is delivered with palliative intent, not with the aim of cure, but to control the disease or improve quality or length of life. Individuals with cancer are largely referred to as patients, the reasons for which are discussed in Section 2.4.3.

This chapter will now go on to describe the challenges and decisions faced by patients diagnosed with cancer and explain the importance of person-centred care in the cancer setting. Following this, the two main areas of interest for the PhD, SDM and HL, will be set out. Definitions, conceptualisations, and their relevance to the wider healthcare setting will be discussed, and the importance of each will be considered in the context of cancer care.

1.2 Challenges faced and decisions to be made

Patients diagnosed with cancer face many new challenges and are often required to process large amounts of complex new information in a relatively short time. Despite significant improvements in survival over the past 40 years, with 50% of people with cancer now living for at least ten years (Cancer Research UK, Accessed 24/03/2023), many still consider cancer to be a death sentence (Quaife *et al.*, 2015). Pre-diagnosis, people may not realise their symptoms could be due to cancer, and almost 20% of cancer diagnoses are made during an emergency presentation to hospital (Public Health England, 2020). The process of diagnosis itself requires investigations and procedures which may be unfamiliar, particularly to someone who has had limited experience of or contact with the healthcare system. Subsequently receiving a diagnosis of cancer is, very often, life changing and unexpected.

For those who have the option of radical treatment with the aim of long-term cure, there may be a need to consider surgery, radiotherapy, chemotherapy, or more novel therapies such as immunotherapy or targeted treatments, and such decisions are often time critical. The need for adjuvant treatments given after surgery or radiotherapy to reduce the risk of a cancer returning is often based on possible rather than proven personal risk. The treatments themselves carry their own dangers and toxicities. Decisions must take account of personal circumstances, immediate and long-term priorities, and may have wider implications on employment, finances, and fertility, amongst others. Additional challenges arise when patients are carers themselves, and must factor in their responsibilities and the impact of treatment schedules and toxicities when weighing the options. Such decision making can therefore be extremely complicated.

Unfortunately, some patients diagnosed with cancer at an earlier stage will develop progressive disease, and others will be diagnosed when the cancer is already advanced. At this point, curative treatment is rarely an option, and the focus is instead on controlling the disease, to prolong survival and improve symptoms and quality of life. Systemic treatments, such as chemotherapy, targeted treatments, and immunotherapy, may be required to treat disease at multiple sites, with potential for unwanted side effects which may lead to hospital admission or even result in death. Based on the specific characteristics of their tumour, certain treatments may be an option for some patients but not others, requiring explanation of the complex scientific justification for this, while newer, less familiar treatments such as immunotherapy have different toxicity profiles to more well-known chemotherapy side effects. These side effects can be more complex to manage and may not be considered cause for concern by patients without careful counselling. Combination treatments involving chemotherapy alongside radiotherapy or immunotherapy are more complicated still, and the duration of treatment for different protocols can vary greatly.

If effective, palliative anticancer treatments can greatly improve symptoms, quality, and length of life. However, some will experience significant toxicities. It is not possible to determine exactly how a given treatment will affect each individual, and it can be very difficult for both patients and clinicians to navigate this uncertainty. Patients, their families, and healthcare teams must discuss and explore the available treatment options, balancing risks and benefits of each. The choice is often not binary, and patient priorities must be factored in.

Alongside or alternative to these treatment options is the careful management of symptoms, addressing each as they arise and endeavouring to maintain quality of life without the added toxicities anticancer treatment approaches might bring. This alternative of symptom control or palliative care might be seen as ‘doing nothing’ and not really considered an option by some patients, whereas for others it can be preferable to the regular hospital visits, tests, and side effects ‘treatment options’ bring.

When conventional treatments have been exhausted, and often before this point, clinical trials might be considered, requiring cautious discussion about possible benefits of participation and expectations of experimental treatments. As the disease progresses further still, difficult conversations around cardiopulmonary resuscitation and preferences for end of life must be broached, to ensure further management is appropriate and as in line with an individual’s wishes as possible. Decisions must balance patient preferences with what is medically achievable. Clear, compassionate communication, ensuring good understanding of the situation from the perspective of both patient and clinician is crucial to facilitate this.

This work sets out to learn more about how to support patients through this difficult time. Though aimed primarily at supporting SDM in the palliative setting, some elements will also consider those with earlier stage disease. In the systematic review, for example, all adults with cancer will be considered, as patients may face several of the same challenges regardless of treatment intent, and many will initially receive care with the hope of cure before requiring a more palliative approach. As outlined above, however, significant differences in the types of decision do exist, with a focus on improving quality or length of life rather than pursuit of cure in later stages, and other aspects of the study will focus solely on those with incurable cancer.

1.2.1 The role of person-centred care in the oncology setting

The Health Foundation describes person-centred care as a concept that ‘*supports people to develop the knowledge, skills and confidence they need to more effectively manage and make informed decisions about their own health and health care. It is coordinated and tailored to the needs of the individual. And, crucially, it ensures that people are always treated with dignity, compassion and respect’* (Health Foundation, 2014). Given the challenges faced by those with cancer, the oncology setting appears particularly suited to this approach. An important element setting it apart from what may be the standard expectation of good care, is that patients are supported to develop their knowledge, skills and confidence to participate in a partnership with their healthcare provider - a move away from just following doctor’s orders (Health Foundation, 2014). This is relevant to care delivered in the United Kingdom, as the NHS strives to shift its approach towards more personalised and person-centred care, offering patients greater choice and control, and supporting people to manage their own health as outlined in the Long Term Plan (NHS England, 2019a). The strategy to address this is set out in The Comprehensive Model for Personalised Care (NHS England, 2019c), with SDM the first of six key components for how personalised or person-centred care will be delivered in practice.

1.3 Shared decision making

1.3.1 Defining SDM

SDM can be defined as *'a process in which clinicians and patients work together to clarify treatment, management or self-management support goals, sharing information about options and preferred outcomes with the aim of reaching mutual agreement on the best course of action'* (Coulter and Collins, 2011). As described by Charles, Gafni and Whelan (1997), *'it takes at least two to tango'*, for SDM to happen. It requires a willingness on the part of both the patient and clinician to share the decision-making process, and may involve other members, such as the patient's family and friends, or additional healthcare professionals providing differing expertise. The process cannot be fully shared without this cooperation. Provision of information is another key prerequisite for SDM (Charles, Gafni and Whelan, 1997) as the patient cannot otherwise be expected to weigh up their options and make a decision.

Taking this further, Makoul and Clayman (2006) identified several additional elements of SDM, of which some were considered essential to the process. These include defining/explaining the problem to be addressed, presenting the options, discussing the pros and cons, identifying the patient's values/preferences, discussing the patient's ability/self-efficacy, sharing the doctor's knowledge/recommendations, checking/clarifying understanding, making or explicitly deferring decision, and arranging follow up of the decisions made. In a recent systematic review, 40 models of SDM were identified (Bomhof-Roordink *et al.*, 2019b), of which half were based on existing models, including Makoul and Clayman (2006) and Elwyn *et al.* (2012) (discussed further in 1.3.4), and 14 were informed by empirical data. The elements described in each were clustered into overarching components of SDM, of which none were present in all models. The commonest components included 'describe the treatment options', in 88%, followed by 'make the decision' (75%) and 'patient preferences' (65%). 'Create choice awareness' (55%), 'tailor information' (65%) and 'learn about the patient' (53%) were commoner in more recent models, with 'provide a recommendation' becoming less common and present in only 10% of models since 2018, reflecting the evolution of SDM over time. Thus, SDM goes beyond the more traditional and established practices, whereby clinicians are seen as the only source of knowledge. The model chosen to frame this work (Elwyn *et al.*, 2017) is discussed in 1.3.4.

1.3.2 Outcomes of SDM

SDM is considered an ethical imperative and important for good quality care, but has also been associated with various outcomes. In one systematic review, 95 unique patient outcomes were explored across 39 included studies (Shay and Lafata, 2015). Based on their conceptual model

(Figure 1), adapted from previous frameworks linking communication and health, outcomes of SDM can be classified into three groups: affective-cognitive, behavioural, and physiological.

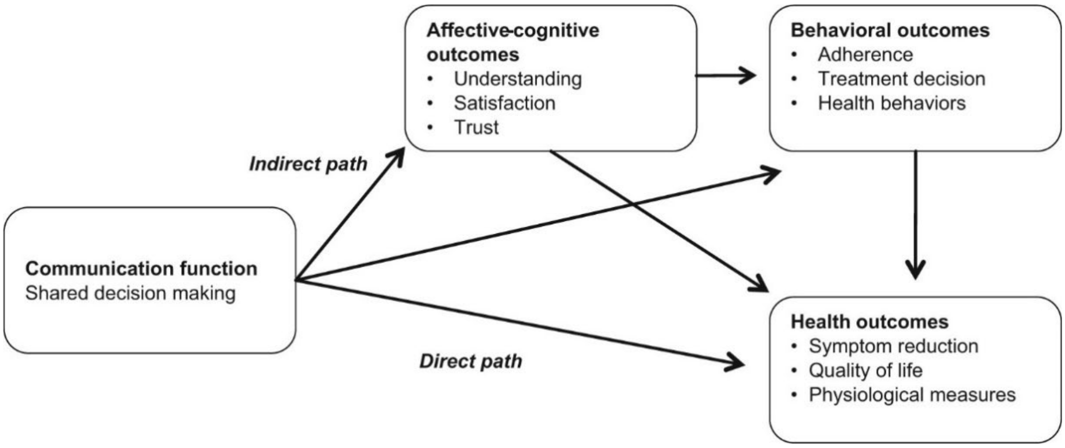


Figure 1 – Conceptual framework linking SDM to patient outcomes (reproduced from Shay and Lafata (2015) with permission from SAGE Publishing)

Fifty-one percent of outcomes studied were affective-cognitive, including patient satisfaction, decisional conflict, and anxiety about the illness. Behavioural outcomes made up 28%, including treatment decision making and adherence, whilst health outcomes included self-ratings of health, quality of life and depressive symptoms. Across all outcomes, 43% of the studies reported a positive significant association with SDM, though this varied depending on whether SDM was patient-reported, observer reported, or clinician reported (Shay and Lafata, 2015). The review did, however, highlight the lack of research exploring the link between SDM and health outcomes, also noting the high proportion of studies measuring SDM with self-report (85% of included studies).

Beyond these more proximal outcomes, Elwyn, Frosch and Kobrin (2016) hypothesise that further distal and distant outcomes of SDM may include improved patient and clinician experiences, and lead to safer, more cost-effective healthcare, with reduced use of resources and better health outcomes.

Such findings demonstrating the positive outcomes associated with SDM and potential for long term gains provide justification for its incorporation into routine clinical care.

1.3.3 Guidelines supporting SDM in the NHS

Given the range of benefits associated with SDM and the overall move towards a more person-centred approach to care, the principles of SDM have been incorporated into all NICE guidelines (National Institute for Health and Care Excellence (NICE), 2020) and have featured prominently in the recently updated GMC guidance on consent (General Medical Council, 2020). Newly published NICE guidance on SDM draws on a commonly used model (the Three Talk Model, discussed below) and outlines recommendations to support the routine use of SDM within the NHS (National Institute for Health and Care Excellence (NICE), 2021).

The changes to such guidance highlight a shift in the way healthcare is delivered, from a more paternalistic, healthcare-driven approach towards a partnership with patients, with greater emphasis on choice and higher expectations for patients to be involved in and take responsibility for matters relating to their health (NHS England, 2019c).

1.3.4 SDM models

Many models of SDM exist (Bomhof-Roordink *et al.*, 2019b), with one of the most commonly used being the Three Talk Model (Elwyn *et al.*, 2012). The model, which has informed many subsequent models, comprises three steps: 'choice talk', 'option talk', and 'decision talk'. In 'choice talk', patients are made aware options exist, that individuals will have different preferences, and there is an element of uncertainty. In 'option talk', the available options are listed and described, with clear explanation of risks and benefits. Decision support tools may be used and understanding checked. The final step, 'decision talk', involves eliciting the patient's preferences and moving to a decision, which may need to be deferred to a later point. These three steps contribute to the process of deliberation and lead to a decision. An important aspect of this approach is the delivery of information to ensure patients are well informed when making decisions.

The model was used as the basis for the UK's Making Good Decisions in Collaboration (MAGIC) SDM programme (Joseph-Williams *et al.*, 2017) which ran from 2010-2013. The first design and testing phase ran across two sites (Cardiff and Newcastle) in several clinical areas including general practice and head and neck cancer, whilst the second phase aimed to demonstrate that SDM could become part of routine clinical care. Interactive skills training workshops for clinical teams based on the Three Talk Model improved skills and promoted positive attitudes towards SDM which persisted beyond the end of the project (Joseph-Williams *et al.*, 2017).

Following on from this programme, SDM was observed during routine care of patients with chronic kidney disease and early stage breast cancer in two of the original participating services (Joseph-Williams *et al.*, 2019). The authors compared observed practices to the Three Talk Model, and found all stages were present in the consultations. Additional elements were identified, including a distinct preparation phase which took place before 'choice talk'. Importantly for participants with breast cancer, this included support and reassurance following diagnosis. Presentation of options was tailored during the consultation as information was shared between patient and clinician, and the role of significant others in contributing to decision making was noted. Based on the Three Talk Model (Elwyn *et al.*, 2012), a more complex, descriptive model

'Implement-SDM' incorporating these observations was subsequently developed. Comparing the two models, the authors suggest they likely serve different purposes. Whilst the Implement-SDM Model reflects observations of clinicians already trained and skilled in SDM as part of the MAGIC programme, the more concise three-talk model *'makes it easier for learners to understand the key skills that should be displayed during an SDM discussion with a patient, without becoming overwhelmed by the range of influences on that discussion'* (Joseph-Williams *et al.*, 2019).

The Three Talk Model was updated in 2017 (Figure 2) following a consultation process (Elwyn *et al.*, 2017). Changes included renaming the first step to 'team talk', distinguishing it from 'option talk', and emphasising the patient's involvement and need to provide support in the decision-making process. This step was further developed to include eliciting patient goals to guide the process. The existing linear model was reformed to a bi-directional circular process, and prompts were added to illustrate its use in practice.

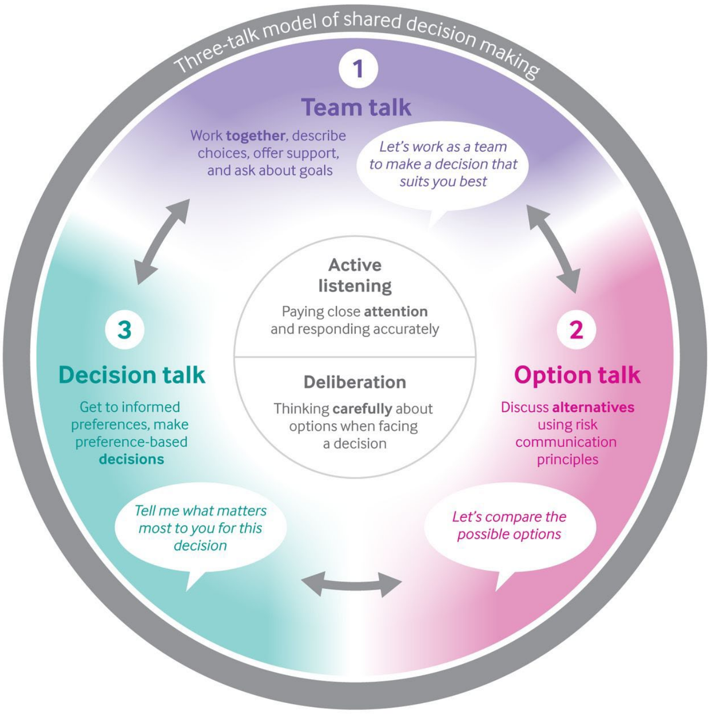


Figure 2 – Three talk model for SDM. Reproduced from A three-talk model for SDM: multistage consultation process, Elwyn, G. et al, 359: j4891, 2017 with permission from BMJ Publishing Group Ltd

The review by Bomhof-Roordink *et al.* (2019b) identified two models designed for use in oncology settings. One, the Shared Decision Making Communication Process (Kane *et al.*, 2014) draws on existing communication frameworks, and takes account of policy, community and healthcare organisation level influences on SDM, as well as considering interpersonal level influences such as patient and provider background characteristics, knowledge, attitudes, skills and emotions. The other, developed based on patient, non-patient, clinician and researcher interviews, highlights the importance of time outside consultations for patients to consider options, consult others or seek further information as an essential part of SDM in oncology (Bomhof-Roordink *et al.*, 2019a). It emphasises the patient role, requiring them to be open about their thoughts and consider their options, and requires clinicians provide a treatment recommendation as part of the process. The challenges posed by such requirements are discussed later in the context of this PhD's findings.

1.3.5 Measures of SDM

In order to establish current practice and examine the effects of interventions aimed at improving SDM, it is important to be able to measure it. Many measures of SDM exist and can be grouped according to whether they are patient, clinician, observer reported, or a combination. A recent systematic review (Gärtner *et al.*, 2018) identified 40 instruments assessing the process of SDM, of which 25 were originally developed or revised versions, and 15 were translations. The majority were observer based (18/40), followed by patient reported (16/40), provider reported (4/40) or mixed (2/40).

Whilst the new NICE guidance includes a recommendation for further research into the best ways to measure the effectiveness of SDM in different contexts, it does not suggest an accompanying measure for use in NHS practice (National Institute for Health and Care Excellence (NICE), 2021). Three commonly used validated measures are, however, given as examples for use in NHS England's Summary Guide for Shared Decision Making (NHS England, 2019b). They include a single item (item 28) from the GP patient survey run by Ipsos on behalf of NHS England (NHS England, 2018), the CollaboRATE tool, which consists of three questions completed by patients after a clinical encounter (Elwyn *et al.*, 2013), and the nine item SDM Q9 questionnaire, which can be applied to preference sensitive decisions (Kriston *et al.*, 2010). All are relatively short, self-report measures, which can feasibly be used in a busy clinical setting to establish and monitor SDM in practice.

1.3.6 Barriers and facilitators to SDM

Despite evidence of the benefits and efforts to increase SDM, barriers to implementation exist and have been explored from the perspective of both healthcare professionals and patients. A systematic review of 38 studies identified the commonest barriers reported by healthcare professionals were time constraints, lack of applicability due to patient characteristics, and the clinical situation (Légaré *et al.*, 2008). As noted by the authors, this suggests healthcare professionals use judgements about patients to assess suitability for SDM rather than exploring and discussing preferences for involvement, i.e., the more paternalistic approach SDM seeks to move away from. There may also be assumptions patients do not want to take part in SDM and prefer to defer to the clinicians' expertise. Such attitudes present a key barrier for SDM, which will only happen if fully supported and offered by the clinician, even when the clinician is concerned it may not be in the patient's interests. This highlights the need to incorporate approaches directed towards healthcare professionals when considering how best to support SDM, to change the culture around healthcare decision making, and make SDM the rule rather than a model to use in specific circumstances with the 'right' patients. Where it is truly the case that a patient does not want to be involved, this decision should itself be informed, and it is still important the clinician has a good understanding of the patient's priorities, so they may act in their best interests (National Institute for Health and Care Excellence (NICE), 2019b).

More recent reviews focussing on SDM in screening programmes (Hernández-Leal *et al.*, 2021) and in older patients with multiple chronic conditions (Pel-Littel *et al.*, 2021) have identified similar barriers in these contexts. Organisational factors such as limited time and turnover of staff impeding development of the patient-doctor relationship were reported, as were patient factors such as poor HL or cognitive impairment affecting understanding, and perceived preference not to participate in SDM. Ill health was reported as a barrier in both reviews. In the context of screening decisions, healthcare professionals' attitudes, knowledge and perceived competence to involve patients in decision making were also reported barriers (Pel-Littel *et al.*, 2021).

A further review by Joseph-Williams, Elwyn and Edwards (2014) considered barriers from the patient perspective and similarly found time was a prominent issue, with patients feeling rushed, or concerned about taking up clinicians' time. Patient characteristics were also important, and included those that were non-modifiable, such as poor health or cognitive impairment, as well as factors that could be modified or mitigated for, such as education level or age. Such personal and situational factors, amongst others, were considered to influence two key contributors to the individual's capacity to participate in SDM: knowledge and power (Joseph-Williams, Elwyn and Edwards, 2014). Although knowledge and understanding of the options are key to enabling SDM, patients also need 'power', or the confidence and permission to take part in the decision, otherwise SDM cannot go ahead. These elements are incorporated into modern definitions of HL (discussed further in section 1.4), and the two concepts are closely linked.

1.3.7 Interventions to support SDM

One approach to supporting SDM has been through the development and use of decision aids: tools designed to provide information to patients on the pros and cons of different treatment options and support them to actively participate in decision making. Hundreds of decision aids now exist, with one inventory listing over 750 (Ottawa Hospital Research Institute, 2022). Tools range from visual guides or tables comparing treatments side by side, to question prompt lists encouraging patients to explore their options with clinicians providing their care, as well as more complex, multi-component interventions.

A Cochrane review of decision aids for people facing treatment or screening decisions identified 105 randomised controlled trials comparing use of a decision aid to usual care or alternative interventions (Stacey *et al.*, 2017). Decision aids were defined as *‘interventions designed to help people make specific and deliberated choices among options (including the status quo), by making the decision explicit and by providing (at the minimum) information on the options and outcomes relevant to a person's health status as well as implicit methods to clarify values’.* Fifty different decisions were studied, the most common relating to prostate and bowel cancer screening, with a small number exploring cancer treatment decision making. Outcomes associated with use of decision aids included attributes related to the choice made (increased knowledge, accuracy of risk perceptions, and congruency between informed values and care choices) and attributes related to the decision-making process (reduced decisional conflict, indecision about personal values, and the proportion of people passive in decision making). Other outcomes included behavioural (choices e.g., of elective surgery, screening, and adherence to medication), health-related (general, condition specific outcomes e.g., symptoms, other health outcomes, anxiety, depression) and health system effects (such as cost and resource use, and consultation length). Decision aids were found to increase participants’ knowledge, accuracy of risk perceptions, and congruency between informed values and care choices compared to usual care, whilst decreasing decisional conflict, indecision about personal values, and the proportion of people passive in decision making. Participants who used a decision aid were equally or more satisfied with their decision and the decision-making process, and no adverse effects were reported (Stacey *et al.*, 2017). The review identified few studies exploring the use of decision aids in patients with lower HL, despite this being a group that might be expected to find it harder to participate in SDM.

Specifically evaluating the impact of SDM interventions on disadvantaged groups, including those with lower literacy, a systematic review and meta-analysis by Durand *et al.* (2014) assessed the effectiveness of interventions including at least 50% of people from such groups. Disadvantaged groups were defined as *“all people who are socially disadvantaged in respect of: 1) poverty/socioeconomic status; 2) ethnic minority status; 3) education/literacy level or 4) geographical location (areas described as disadvantaged/or medically underserved), using the author set criteria”.* The breakdown of studies in each group was: minority ethnic group (n = 6); low literacy/low education minority ethnic group (n = 6); low literacy group (n = 1); low socioeconomic status, including low literacy and/or minority ethnic groups (n = 4); medically underserved (n = 2). All outcomes directly relevant to SDM were included in the meta-analysis, and qualitative outcomes relating to acceptability of the interventions were included in the narrative analysis. Although none of the 19 included studies assessed the effect of an intervention on HL itself, five out of seven studies comparing disadvantaged and higher literacy/socio-economic groups reported a narrowing of disparities between the groups in terms of knowledge, decisional conflict, uncertainty, and treatment preferences, suggesting SDM interventions were more beneficial to disadvantaged groups than to those in higher literacy/socio-economic groups. As the studies were heterogenous, and the overall quality low, reflecting the lack of randomised controlled trials addressing this issue, the authors highlight the need to interpret these results with caution. Despite this, it is important to ensure those who are already disadvantaged are not left further behind, and although historically few interventions were developed with HL in mind (McCaffery *et al.*, 2013), this provides justification for further work to develop tools accessible to a diverse range of audiences.

Despite findings demonstrating beneficial patient outcomes relating to the use of decision aids, evidence for the effect of interventions to increase SDM by healthcare professionals is limited due to the variability and quality of existing studies (Legare *et al.*, 2018). Although a previous update of this systematic review suggested greater benefit from interventions involving both patients and healthcare professionals (Légaré *et al.*, 2014), it is unclear from this more recent update how future interventions would be best targeted.

1.3.8 SDM in oncology

1.3.8.1 SDM in palliative oncology

SDM is particularly important in the oncology setting, where there may be multiple options for anticancer treatment or more symptom-directed approaches, often no right or wrong answers, and the potential for significant impact on a patient's quality of life (Charles, Gafni and Whelan, 1997). In the context of cancer treatment, SDM may itself be positively associated with quality of life (Kashaf and McGill, 2015). Although the evidence in this review from 17 studies was limited due to their largely cross-sectional design and the variety of quality-of-life assessment measures precluding meta-analysis, there was no evidence to suggest SDM should not be used in this setting.

While the majority of patients with advanced cancer wish to play an active role in decision making (Gaston and Mitchell, 2005; Hitz *et al.*, 2013; Noguera *et al.*, 2014; Tricou *et al.*, 2018; Yennurajalingam *et al.*, 2018), clinicians may underestimate the degree to which patients want to be involved in such decisions, sometimes wrongly perceiving they would prefer their clinician to make the decision for them (Bruera *et al.*, 2001; Elkin *et al.*, 2007). Barriers to SDM in this setting are discussed further in section 1.3.8.2.

In the palliative oncology setting, Brom *et al.* (2017) examined how four steps of SDM were used in a longitudinal study of decision making about second and third-line chemotherapy. The steps, proposed by Stiggelbout, Pieterse and De Haes (2015) (Figure 3), are similar to those in the Three Talk Model, with the division of 'decision talk' into two distinct steps (3 and 4).

1. The professional informs the patient that a decision is to be made and that the patient's opinion is important
2. The professional explains the options and the pros and cons of each relevant option
3. The professional and patient discuss the patient's preferences; the professional supports the patient in deliberation
4. The professional and patient discuss patient's decisional role preference, make or defer the decision, and discuss possible follow-up

Figure 3 - Four steps of SDM (Stiggelbout, Pieterse and De Haes, 2015)

Following 14 patients with advanced cancer over time, they found that although the participants reported satisfaction with decision making, the steps themselves were rarely followed in practice, with limited and unequal discussion about available options and lack of elicitation of patients' wishes and concerns.

To further explore the importance of these issues and using the Three Talk Model as a framework, the following section provides an overview of some considerations for SDM in palliative oncology.

1.3.8.1.1 Team talk

An important first stage in SDM is identifying there is a decision to be made and explaining there is a choice, with no 'best' option, as this will differ from person to person depending on their situation, preferences, and priorities. Yet patients may be unaware a decision needs to be made (Nelson *et al.*, 2020) or a choice exists (Elit *et al.*, 2003; LeBlanc *et al.*, 2018). This may arise through unintentional or intentional omission of information (Brom *et al.*, 2017; Nelson *et al.*, 2020), or through misinterpretation of the conversation (LeBlanc *et al.*, 2018).

It is also important to establish goals and expectations of treatment. Efforts must be made to ensure patients have an accurate understanding of their situation, yet prognostication is challenging for both patients and healthcare professionals. In one prospective study of 1018 patients with advanced cancer no longer undergoing active treatment, Gwilliam *et al.* (2013)

found doctors', nurses' and MDT predictions of prognosis were accurate only 56.3%, 55.2% and 57.5% of the time, and patients' predictions were significantly less accurate than any of the clinical groups (52.1%). All parties were over-optimistic in their estimates (Gwilliam *et al.*, 2013). This overestimation of prognosis was associated with an increased likelihood of favouring life extending treatment in another prospective cohort study of 917 patients with advanced lung cancer and colon cancer (Weeks *et al.*, 1998). Conversely, Mack *et al.* (2010) found, in a study of patients with advanced cancer who had failed first line therapy, that those aware of the terminal nature of their illness were more likely to prefer symptom-directed care. These findings are particularly important considering some patients who receive life extending treatment will experience poorer quality of life, and greater physical and psychological distress than those who do not, without necessarily experiencing prolonged survival (Mack *et al.*, 2010).

1.3.8.1.2 Option talk

Benefits and risks of the options available to the patient must be discussed, along with their respective probabilities. As an example, trifluridine/tipiracil is an oral chemotherapy for third line treatment of metastatic colorectal cancer. This treatment offers a median overall survival benefit of around 2 months compared with placebo for patients with advanced disease (Shitara *et al.*, 2018). It is therefore important this potential benefit is balanced against the requirement for regular hospital visits, blood tests, side effects and the possible need for hospital admission as a consequence of toxicity. Yet despite life prolongation being an important goal of treatment for both patients and their oncologists (Rand *et al.*, 2016; Mieras *et al.*, 2020), information given to patients about the survival benefit of treatment is often vague or lacking (Audrey *et al.*, 2008), hindering any possibility of fully informed decision making.

An important risk of cancer treatments is hospitalisation, which must also be considered and discussed. The risk of hospitalisation following a diagnosis of advanced cancer is high. In one study, 71% of individuals (n=25,032) with breast, colorectal, non-small cell lung cancer, and pancreatic cancer from a cancer registry in the USA required admission in the first year, and 16% were hospitalised three or more times (Whitney *et al.*, 2017). When looking specifically at patients receiving treatments, a study of 500 older adults (>65 years) with cancer receiving chemotherapy for any stage disease found 23% required hospitalisation during the course of their chemotherapy, with 53% experiencing at least one grade 3 (severe) to 5 (fatal) toxicity according to the Common Terminology Criteria for Adverse Events (CTCAE) v3.0 (Hurria *et al.*, 2011). A similar rate of 58% grade 3-5 toxicity was found in the smaller (n=250) validation study of their chemotherapy toxicity predictive model (Hurria *et al.*, 2016), with rates up to 70% in their high-risk group. In work for another predictive model, developed for patients with advanced cancer receiving palliative chemotherapy, the rate of hospitalisation of an insured population in the USA (n=3606) within the first 30 days of chemotherapy treatment was 15% (Brooks *et al.*, 2019). These figures highlight the risk of hospitalisation due to chemotherapy toxicity, and the importance of full disclosure to patients so they may make an informed decision about whether to proceed.

Another significant risk is that of death, not only as a direct result of, but also in proximity to receipt of chemotherapy. Data from a population based study in the UK highlighted 30 day mortality rates of 7% in those receiving palliative chemotherapy for breast cancer, and 10% for patients receiving palliative chemotherapy for lung cancer (Wallington *et al.*, 2016). One example of such a treatment is docetaxel, a NICE approved option for patients with advanced lung cancer who have relapsed after prior chemotherapy. In an early randomised study of patients with lung cancer by Shepherd *et al.* (2000), the response rate to docetaxel in pre-treated patients was 7%, with an improvement in median survival to 7.0 months compared with 4.6 months in the arm receiving best supportive care. The median number of 21-day cycles was four, equivalent to three months of treatment, during which time patients will have undergone three weekly hospital assessments, blood tests and infusions, as well as managing any side effects from the treatment itself. As one in ten may die within 30 days of such treatment, it is important patients are aware they have a choice, and efforts are made to ensure choosing treatment, and all that it entails, is in line with their priorities as they approach the end of their lives.

In addition to the receipt of treatment itself, palliative chemotherapy at the end of life is also associated with higher rates of cardiopulmonary resuscitation, mechanical ventilation and late hospice referrals, as well as increased likelihood of dying in intensive care and lower likelihood of death at home or in a patient's preferred place (Wright *et al.*, 2014).

Beyond the acute and life-threatening toxicities, significant longer-term problems may also arise from anti-cancer treatments. Peripheral neuropathy is one example, which may become permanent and impair a person's ability to work or continue hobbies. This can potentially have significant financial implications, causing additional worry at this difficult time, or have the opposite effect than intended and negatively impact quality of life.

Establishing understanding of treatment, including its intent, is therefore hugely important, yet studies have identified that many patients have expectations of cure from palliative intent treatment (Weeks *et al.*, 2012; Tricou *et al.*, 2018). If patients have such expectations and perceive their condition to be less serious than it is, this is likely to influence their decision making, and may lead to patients choosing aggressive treatments as opposed to more symptom-directed approaches aimed more towards maximising quality rather than quantity of life.

Although many treatments for advanced cancer can lead to much better outcomes than those detailed above, it is important the positives are balanced with these significant risks, and the patient has been able to process and understand what they have been told so they may reach a genuinely informed decision about their treatment.

1.3.8.1.3 Decision talk

Efficacy and toxicity are priorities often shared by clinicians and patients when making treatment decisions, yet patients have additional considerations, such as family responsibilities, or how treatment will fit into day-to-day life, which will also influence their decisions (Rocque *et al.*, 2019). As well as establishing understanding of their situation, it is therefore important clinicians elicit patients' values and priorities, in order to support them in reaching a decision. Studies have shown this is not always achieved (Brom *et al.*, 2017; Pilote *et al.*, 2019), meaning important priorities may be left undiscussed when patients do not have the confidence to raise the issue themselves.

While some patients may be clear and able to move forward with a plan, others may need more time to reach a decision, which can be challenging in a pressured healthcare environment. As the majority of patients with advanced cancer wish to take an active role in decision making, efforts must be made to support patients to deliberate, help them establish their preferences and reach an informed decision.

1.3.8.2 Barriers and facilitators to SDM in oncology

Having justified the need for SDM in palliative oncology practice, it is important to consider why this is not always achieved. A systematic review of studies from the USA identified three main barriers to SDM in oncology: uncertainty or lack of consensus in the treatment decision, patient concern regarding adverse effects and poor physician communication through imbalanced discussion of the options available or use of medical language (Covvey *et al.*, 2019). Elicitation of patient preferences and positive physician behaviours that helped build trust facilitated SDM, and the important role of family, friends, groups, and others was highlighted. The review drew on quantitative and qualitative data, but the inclusion only of studies from the USA may limit generalisability to different healthcare systems and cultures.

Considering communication in more detail, Thorne, Oliffe and Stajduhar (2013) identified several significant challenges in a study of 60 patients with cancer, of whom 40 had advanced disease. Participants expected clinicians to respond to their individual cues, though participants' responses to similar communication styles differed, highlighting the need for tailored approaches to suit the individual. Calm and compassionate communication encouraged coping for one participant, yet evoked fear in another as they realised the seriousness of their situation. Participants also expressed different information needs, with some actively seeking and questioning to become more informed, and others wanting limited responses to questions they had asked. Personalisation is therefore important to facilitate patient engagement in SDM.

Exploring SDM in advanced cancer from the clinician's perspective, De Snoo-Trimp *et al.* (2015) sought the views of specialists treating patients with recurrent glioblastoma and identified several barriers resulting from clinicians' attitudes. These included focussing on treatment as the better option and steering patients towards this, making assumptions about patient priorities rather than explicitly asking for them, and preferring to take responsibility for the decision given their greater knowledge about the disease and treatments (De Snoo-Trimp *et al.*, 2015). Clinician preferences regarding patient involvement differed depending on the line of treatment, with more weight given to patient opinion in later lines of treatment, likely as a result of changes to the risk: benefit ratio as options become more limited. Whilst this expertise is clearly important, such paternalistic attitudes are not aligned with SDM and need to be addressed for person-centred care to move to the fore of standard clinical practice.

Another important factor in this setting is that of psychosocial influences, and the role negative emotions may play in patient understanding. This is particularly relevant to discussions surrounding a diagnosis of incurable cancer. Derry, Reid and Prigerson (2019) considered findings from behavioural and applied clinical research relevant to this setting. They highlight how anxiety and distress may affect not only how the patient processes the information they are given, but also the way their clinician communicates with them, perhaps withholding information they deem will cause further upset. This may lead to inaccurate understanding of prognosis and the patient's clinical situation, which in turn may influence SDM. The authors suggest this may explain why some efforts to improve comprehension through informational interventions alone, without considering wider psychological factors, have not led to better prognostic understanding.

1.3.8.3 Interventions to support SDM in the oncology setting

One means of supporting SDM is through the use of decision aids. The Ottawa Hospital Decision Aid Library Inventory contains over 750 items, of which 160 relate to cancer treatment decision making (Ottawa Hospital Research Institute, 2022). However, despite the range of tumour sites, treatment options and complex decisions to be made, only five are specifically targeted to patients with advanced or recurrent disease.

Reviews of decision aids in early stage prostate (Violette *et al.*, 2015; Martínez-González *et al.*, 2019) and breast cancer (Waljee, Rogers and Alderman, 2007) suggest such tools may lead to improved knowledge, increased satisfaction and quality of life and, in breast cancer, may influence treatment decision making. These reviews were however limited by heterogeneity of intervention designs and outcome measurement, and a lack of data from randomised controlled trials. Considering only randomised controlled trials, but across patients with breast, prostate, colorectal and lung cancer, Spiegle *et al.* (2013) found decision support interventions (including decision aids, question prompt lists and consultation recordings) increased knowledge and question asking, but did not have a significant effect on satisfaction, anxiety or decisional conflict. Common across the reviews were that intervention designs varied, few were used during the clinical encounter and a range of outcomes were studied, making meta-analysis difficult.

Specifically focussing on advanced disease, Gaston and Mitchell (2005) reviewed interventions to improve information giving and understanding. These included recordings of clinical consultations or simplified information summaries, and those designed to increase patient participation in decision making, such as question prompt lists and coaching. Interventions were generally well received and did not appear to increase anxiety, but there were few randomised controlled trials and the studies tended to be small, limiting further conclusions. Three further recent systematic reviews have looked at aids for supporting SDM in patients with advanced colorectal and lung cancer (Spronk *et al.*, 2019), metastatic breast cancer (Spronk *et al.*, 2018) and advanced cancers (Tapp and Blais, 2019). They identified 12, seven and 16 aids respectively, with some overlap, but many were already unavailable at the time the review was conducted. Tapp and Blais (2019) found sufficient information to allow full evaluation of only eight aids, and five of these scored poorly on accessibility of the language used as the authors did not assess or report the readability of their tools. Despite increasing interest in SDM, few randomised trials were identified in these more recent reviews.

1.3.9 Summary and next steps

SDM is an area of growing importance as practice moves from more traditional paternalistic approaches towards person-centred care. Many barriers to implementation exist, with some easier to overcome than others. Fundamental to SDM is that patients have the information they need to be able to weigh up their options and have the confidence and opportunity to be able to take part in the decision-making process.

Interventions have been shown to improve SDM outcomes, and appear particularly effective in disadvantaged groups, including those with lower HL. As HL plays such a vital role in SDM, and those who experience HL difficulties may have the most to gain from supportive interventions, the next section will discuss the concept in greater detail.

1.4 Health literacy

1.4.1 Defining HL

Health literacy has been variably defined since the term was first used in the literature in the 1970s, with differences reflecting the approach taken, be it from a public health or medical viewpoint, and a developing understanding of the wider concept and its interactions with health and outcomes (Okan *et al.*, 2019). Whereas earlier definitions emphasised the skills of the individual, more recent definitions have acknowledged the role of wider society in developing HL (Okan *et al.*, 2019) and aim to portray what is now considered a much more complex concept of HL.

Seeking to identify existing definitions and conceptual frameworks, Sørensen *et al.* (2012) conducted a systematic review as part of the European Consortium Health Literacy Project, and highlighted several key themes. A new definition resulting from this work aimed to provide a comprehensive and overarching definition of HL: *"Health literacy is linked to literacy and entails people's knowledge, motivation and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course" (Sørensen et al., 2012).* The authors note this definition can be amended to reflect a more individualised rather than public health approach by using the terms "being ill, being at risk and staying healthy". On the basis of this new definition, and taking into account the existing frameworks in the literature, the authors then developed a new conceptual model (Sørensen *et al.*, 2012) and accompanying HL measure (Sørensen *et al.*, 2013) (see 1.4.3), validated in 8000 patients across eight European countries (Sørensen *et al.*, 2015).

Though built on the existing literature and incorporating elements of previous definitions, Squiers *et al.* (2012) note this definition includes knowledge as an integral component of HL, which others consider a separate construct, and which they themselves include as background factor affecting acquisition of HL skills in their own conceptual framework. The definition focuses on the individual in isolation rather than considering the context they find themselves in, but does take a longer view of HL beyond the immediate situation and considers its role throughout an individual's life.

Another widely used definition from the WHO reads: *"Health literacy refers to the personal characteristics and social resources needed for individuals and communities to access, understand, appraise and use information and services to make decisions about health. Health literacy includes the capacity to communicate, assert and enact these decisions"* (World Health Organization, 2015). In a Position Statement from a working group of global experts on HL including authors of several pre-existing definitions, a similar definition refers to personal competencies and situational resources, acknowledging HL is context specific and does not solely rely on an individual's abilities (International Union for Health Promotion and Education, 2018). It does not assume a pre-existing level of knowledge but suggests every individual has the potential to acquire the knowledge they need to make decisions about their health. Beyond being able to make informed decisions, it is about being able to articulate and put them into motion, having the assertiveness and confidence to do so. It also offers the possibility for interventions to support patients and improve HL.

1.4.2 HL frameworks

A key conceptualisation of HL is that proposed by Nutbeam (2000), who described HL as an outcome of education and communication activities, with potential to lead to greater patient empowerment. Drawing on this broader understanding rather than solely referring to the application of literacy skills to a healthcare setting, Nutbeam outlined a three-level model of HL based on an existing general literacy classification and detailing what increasing HL might offer.

The first level is functional HL, which refers to the transmission of health information to a patient, resulting in increased knowledge and compliance with directed activities such as taking medication as prescribed, or participating in screening programmes. These actions generally lead to personal gain but have wider implications for service delivery and use of resources. The second level, termed interactive HL, builds on the first and refers to the development of personal skills. Through opportunities for skill development, individuals become better able to use knowledge they have gained, and act independently with increased confidence. The third level, critical HL, describes benefits to the wider community, through increased social and political action as a result of greater personal and community empowerment. Cognitive ability and general literacy skills are required, but the development of HL also relies on exposure to information, which is influenced by personal and social skills as well as self-efficacy.

Nutbeam has subsequently described two distinct views of HL, as either a 'risk' or an 'asset' (Nutbeam, 2008). The 'risk' approach is largely associated with work in the clinical domain, exploring the impact of HL on individual and health system outcomes, where low HL is seen as a risk factor that must be compensated for. The 'risk' model outlines how an initial assessment of knowledge and skills is made (considered in this approach to be an individual's HL) within an organisation sensitive to the needs of those with low HL. This leads to delivery of tailored health information and improved HL sensitive communication by healthcare professionals, which in turn enhances patient capabilities for self-management and increased compliance, ultimately resulting in better health outcomes.

In the 'asset' approach, developed from work in public health, HL is a means of increasing patient empowerment through development of skills. As in the risk model, an initial assessment of knowledge and capability is made, which leads to delivery of tailored education and communication. This results in increased knowledge and capability, self-management skills and social advocacy, in line with the levels of HL outlined above, and leads to improved HL as the outcome of these interventions. Changed health behaviours and social influence are a consequence of this better developed HL, and in turn lead to improved health outcomes on the societal as well as individual level.

The choice of approach taken may influence the HL assessment tools used, how and what outcomes are measured, and may guide strategies to support or develop HL in different settings.

Sørensen *et al.* (2012)'s review brought together existing definitions and models of HL, and therefore the different disciplines from which they arose, identifying 17 definitions and 12 conceptual models. Taken from the viewpoint of HL as an asset, these were then combined to develop the Integrated Model of Health Literacy (Figure 4). Four dimensions of HL were included incorporating Nutbeam's levels of HL (Nutbeam, 2000): accessing/obtaining, understanding, processing/appraising and applying/using information relevant to health. These dimensions are applied to three health domains of healthcare, disease prevention and health promotion, spanning from the narrower clinical view of HL to the broader public health perspective. This HL process is shown to be influenced by personal, situational, societal, and environmental determinants, leading to outcomes from health service use to equity and sustainability.

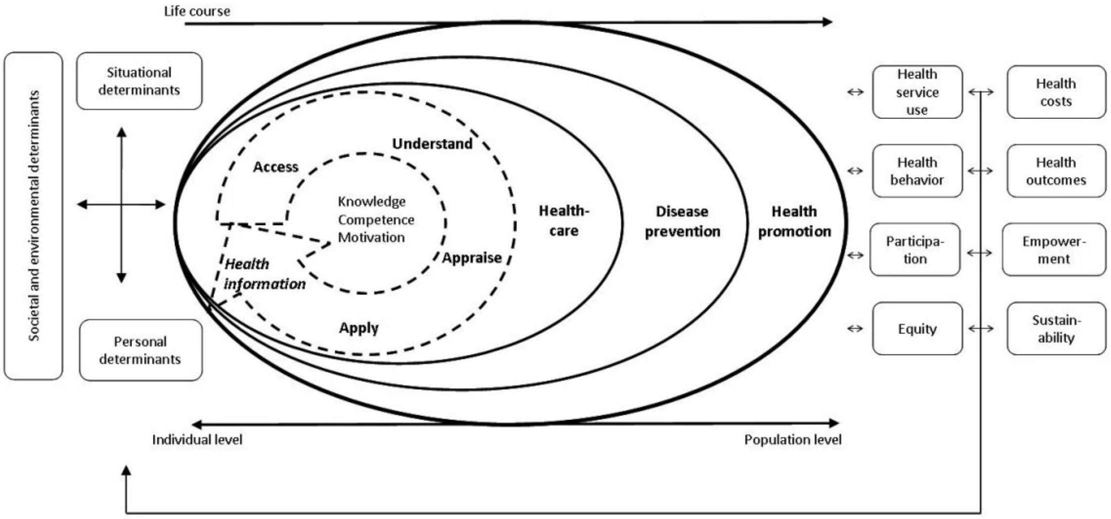


Figure 4 – "Integrated model of health literacy" by Sørensen *et al.* (2012), used under CC BY 2.0

Although this complex model gives an overview of HL processing as applied to different contexts, the focus remains primarily on the ability of the individual to apply a set of skills, with limited discussion of internal and external influences which may facilitate or inhibit this process.

A further model, the Health Literacy Pathway Model (Figure 5), was developed from longitudinal interviews with participants who had a long-term health condition (Edwards *et al.*, 2012). HL was viewed as an asset, and as both a process which developed over time and an outcome. Through development of HL, individuals become more informed about their condition, are able to take a more active role in consultations and can participate in SDM.

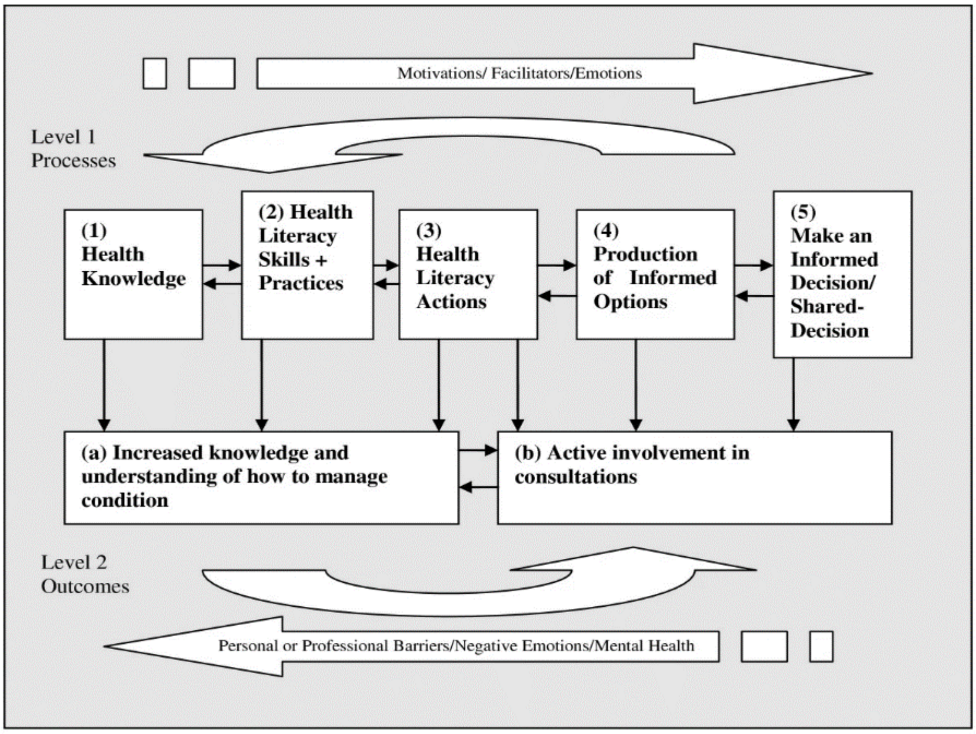


Figure 5 – "The Health Literacy Pathway Model" by Edwards *et al.* (2012) used under CC BY 2.0

The model lends greater consideration to the motivations and barriers to the development of HL, including personal characteristics and healthcare professionals' influences.

The extent to which the models described in this section incorporate aspects of articulating and asserting decisions, a key component of more recent definitions of HL, varies. In Nutbeam's conceptualisation, whilst functional HL equates to knowledge and health actions such as taking a medication appropriately, interactive HL is recognised by the development of skills and ability to use this knowledge and act independently (Nutbeam, 2000). The focus in this model is on the individual's skills, capabilities, and independent actions, with less emphasis on shared interactions such as in a consultation setting, and the issue of asserting decisions is not directly addressed. The later 'asset' view, however, considers how these health literacy skills are an outcome of health education, that can be developed to increase capability, enable confident interactions with healthcare providers, and support greater empowerment, thus facilitating individuals to more assertively articulate their decision making (Nutbeam, 2008). In Sørensen *et al.* (2012)'s model, the competency of 'applying' information refers to being able to communicate and use information to maintain and improve health. The process of developing these competencies generates knowledge and skills to make informed decisions and comply with medical advice. The authors describe that advancing health literacy allows for personal empowerment, but whilst there is acknowledgement of social and environmental determinants of HL, including culture and societal systems, there is limited discussion of how an individual might articulate and assert (or not) the decisions made. Finally, in the Health Literacy Pathway Model, making an informed/shared decision follows the development of skills, knowledge, and empowerment along the HL pathway. Patients may take HL actions including contributing to knowledge exchange in consultations during stage three of the pathway, but increased active involvement in consultations (which may include articulating and asserting decisions) is presented as an outcome resulting from progression along these health literacy stages, rather than an integral component of the pathway itself (Edwards *et al.*, 2012). Whilst prominent in recent definitions of HL (International Union for Health Promotion and Education, 2018), the inclusion of individuals' ability to communicate and assert their decisions is variable in these models, and may provide some explanation for the lack of representation of this part of the definition in many HL measures (discussed further below).

These conceptualisations of HL demonstrate its close relationship to SDM, highlighting the precursors necessary for SDM to take place and potential influences on this process. Further discussion of the models used to frame this work can be found in section 2.4.

1.4.3 Assessing HL

As the concept of HL has evolved with increasing understanding of its complexity and role in health, so too have the tools designed to assess it. Despite the earlier origins of the concept, the first widely used tools did not appear until the 1990s. These tools, which were direct measures of personal reading and comprehension skills, remain the most highly used and are often employed as gold standard comparators in validation studies of new tools (Berkman *et al.*, 2011b; Okan *et al.*, 2019). The Rapid Estimate of Adult Literacy in Medicine (REALM) is a word recognition test developed to identify patients with limited reading skills (Davis *et al.*, 1991). It consists of 66 words used in healthcare settings to be read aloud by the patient, with scores equated to reading grade, and takes less than five minutes to administer. It has been shortened to a seven word version, the REALM-SF (Arozullah *et al.*, 2007) and adapted for use in several healthcare settings (Health Literacy Tool Shed, 2020).

The Test of Functional Health Literacy in Adults (TOFHLA) comprises 67 items based on hospital materials, incorporating a numeracy component as well as reading comprehension, and takes about 20 minutes to administer (Parker *et al.*, 1995). Again, a short form exists, the S-TOFHLA, which is administered over a maximum of 12 minutes (Baker *et al.*, 1999). Scores are grouped into inadequate, marginal, and adequate HL.

These two measures attempt to objectively define an individual's level of HL, with the practical aim of identifying patients with low literacy in the clinic (Davis *et al.*, 1991; Parker *et al.*, 1995). However, as the field developed, there were growing concerns about the negative impact such measures could have on patients, namely feelings of shame at unmasking low literacy which may have been kept hidden by the patient (Parikh *et al.*, 1996).

Around ten years later, two further and now commonly used tools were developed (Chew, Bradley and Boyko, 2004; Weiss *et al.*, 2005). The Newest Vital Sign (NVS), developed with rapid administration in mind, consists of a picture of an ice cream label, which patients are asked to interpret in response to six questions primarily assessing their numeracy skills (Weiss *et al.*, 2005). The average time to administer was just under three minutes in the validation study, with both English and Spanish versions available. The NVS has since been adapted and validated for use in the UK (Rowlands *et al.*, 2013).

Chew, Bradley and Boyko (2004) took a different approach, aiming to develop quick screening questions to be used discretely in clinic, rather than the traditional test-based tools. From an initial pool of 16 questions, three self-report questions, with Likert scale responses, were identified as the strongest when compared to the S-TOFHLA: "How often do you have someone help you read hospital materials?", "How confident are you filling out medical forms by yourself?" and "How often do you have problems learning about your medical condition because of difficulty understanding written information?". The questions were individually able to identify inadequate HL, but were less effective at finding the group of patients with inadequate or marginal HL (as opposed to adequate), and their performance was not improved by using the questions in combination (Chew, Bradley and Boyko, 2004).

Moving away from these brief screening tools, Pleasant and McKinney undertook a consensus seeking process to gauge expert opinion and provide direction for future efforts to develop new measures of HL. They found the existing tools to be lacking, and there was consensus that new measures, grounded in theory and validated in representative, broad populations were needed (Pleasant and McKinney, 2011). Thus, as the field of HL developed, with greater understanding of the concept and acknowledgment that proficiency in HL requires more than the ability to read and understand text and numbers, the definitions and measures followed suit.

The Health Literacy Questionnaire (HLQ) and European Health Literacy Survey Questionnaire (HLS-EU- Q) address some of the problems with previous tools. The HLQ was developed by Osborne *et al.* (2013) using the WHO definition of HL (World Health Organization, 2015). Following a workshop discussion with experts and patients, an existing HL measure, the Health Literacy Management Scale (HeLMS), was reviewed and several concepts found to be missing. A new tool (the HLQ) was developed, taking into account concepts from the mapping process, then refined and tested. The exact wording was altered after testing, creating a need for further validation, and leaving a 9 category self-report questionnaire (Osborne *et al.*, 2013). Scales can be used independently, or combined, and mean scores used to compare groups with cluster analysis used to identify respondents with similar profiles.

Development of the HLS-EU-Q was based on a conceptual model and definition of HL discussed earlier in this chapter (see 1.4.1 and 1.4.2) and used a Delphi process, focus groups, pre-testing and expert consultation to generate the self-report questionnaire designed to measure HL in populations (Sørensen *et al.*, 2013). A 47-item version of core HL items and an 86-item version including antecedents and consequences of HL were developed, with the 86-item questionnaire validated in a study across eight European countries (Sørensen *et al.*, 2015).

There is some concern about the use of subjective, self-report assessment tools in determining a person’s HL, as there is no direct assessment of skills, and there is therefore potential for individuals to give inflated responses, either intentionally or through lack of awareness of difficulties (Nguyen, Paasche-Orlow and McCormack, 2017). Yet such measures can be beneficial, avoiding the need for test-like conditions and for ease of delivery. In a systematic review comparing the two types of measure, only four fair quality studies were identified, and found mixed results (Kiechle *et al.*, 2015). As the authors note, this is perhaps unsurprising given the variability in what the tools are actually measuring, their purpose, and the cut-offs used to determine HL levels.

Numerous other tools are available, covering different aspects of HL, in specific settings, with varying methods of delivery and administration times. According to one database of measures, there are over 100 validated English language tools (Health Literacy Tool Shed, 2020). As there is no perfect ‘one size fits all’ tool, the choice for a particular purpose will therefore depend on the context and focus of the planned work.

1.4.4 Prevalence of HL difficulties

The prevalence of lower HL can vary widely and depend on the measure used. In the European Health Literacy survey validating the HLS-EU-Q, 12.4% of the total 8000 participants were found to have ‘inadequate’ HL (scores of 0-25/50). This reflected a range in prevalence across countries, from 26.9% in Bulgaria to 1.8% in the Netherlands (Sørensen *et al.*, 2015). When also considering those with ‘problematic’ HL (scores of >25–33), the prevalence increased to almost 50% in the total sample.

In the UK, a city-wide study using the objective NVS (Protheroe *et al.*, 2017) reported a prevalence of 52% limited HL (n=1046), while a recent population based survey (n=2309) using two domains of the self-report HLQ (Simpson, Knowles and O’Cathain, 2020) found 19.4% had some difficulty reading written health information and 23.2% had difficulty discussing health concerns with healthcare providers. Lower HL was associated with increased age, lower formal education, poorer self-rated health, greater deprivation, and lack of internet access (Protheroe *et al.*, 2017; Simpson, Knowles and O’Cathain, 2020). The authors of both note the study designs may have led to an underestimation (Simpson, Knowles and O’Cathain, 2020) or overestimation (Protheroe *et al.*, 2017) of the prevalence of lower HL for the general UK population, and the true value may therefore lie somewhere in between.

1.4.5 Impact on healthcare outcomes

HL has been associated with important healthcare outcomes across several conditions. A review by Berkman *et al.* (2011a) included 96 good or fair quality studies directly measuring HL and comparing participants in relation to a health-related outcome. All were observational, and a range of HL measures was used. The authors found moderate evidence for increased emergency health service use and lower use of preventive services by people with lower HL. There was moderate evidence for an association between lower HL and poorer ability to demonstrate taking medications appropriately, poorer interpretation of health messaging, and poorer health status among older patients. Strong evidence supported an association between lower HL and higher all-cause mortality in older people.

More recent systematic reviews have focussed on specific conditions, finding associations between lower HL and poorer diabetes specific knowledge (Al Sayah *et al.*, 2013), and increased mortality and hospitalisation for people with heart failure (Fabbri *et al.*, 2020) and chronic kidney disease (Taylor *et al.*, 2017). Such reviews have generally relied upon observational studies of varying quality using a variety of HL measures.

1.4.6 Relationship with SDM

The concept of HL is closely linked to SDM, and based on existing HL definitions and theoretical frameworks, individuals with higher HL may therefore be expected to be more able to process information and weigh up their options, communicate their preferences, and be in a better position to participate in SDM.

Those with lower HL have been found to want a less active role in decision making compared to those with higher HL (McCaffery *et al.*, 2013), which, the authors suggest, may be due to a lack of awareness that involvement is an option. This was noted in a study comparing views of a decision aid for bowel cancer screening, where attendees of literacy classes, presumed to have lower HL, appeared unfamiliar with the concept of informed choice, and were unsure why screening was presented as optional and something to deliberate over (Smith *et al.*, 2008). These views were subsequently explored in greater depth through interviews involving individuals with higher and lower education levels which assessed HL using the NVS and TOFHLA (Smith *et al.*, 2009). Seventeen of 41 participants in the lower education group had lower HL as assessed by the NVS (score <4/6), whilst 24 had higher HL (score of ≥4/6). The authors found those with lower education described their involvement as giving consent to treatment, putting greater weight on their doctor’s recommendation rather than actively participating in decision making, and were more likely to involve and seek support from friends and family. Although the authors found the greatest differences were between educational groups, they note there were few participants with very low HL skills, and all had adequate HL as assessed by the TOFHLA.

1.4.7 HL and the social determinants of health

The social determinants of health consist of the conditions in which we are born, grow, live and age that determine our health status (Nutbeam and Lloyd, 2021). They include structural determinants and conditions of daily life (including access to health care, schools, and education), conditions of work and leisure, homes, communities, towns, or cities, and account for health inequities within and between counties (Commission on Social Determinants of Health, 2008). Given its association with a range of health outcomes, HL has been considered a social determinant of health, which, in contrast to many of the other determinants, is potentially modifiable. This relationship is discussed in a review by Nutbeam and Lloyd (2021), who explore the evidence for the direct and mediating effects of HL, and use this to consider how to improve HL. In an analysis of a large European dataset (n=8102), Pelikan, Ganahl and Roethlin (2018) sought to determine whether HL acted as a direct social determinant of health, as a mediator between other determinants and health, or as a moderator of the effect of other determinants of health. They found comprehensive HL, as measured by the HLS-EU-Q, acted as a direct determinant of health when taking into account demographic and socio-economic variables including gender, age, education, self-perceived social status, and perceived financial deprivation. Using a different measure of HL, however, the NVS, the effect was non-significant. The moderating and mediating effects of HL were more variable and limited to specific countries, and the authors therefore concluded comprehensive HL primarily impacts health as a direct determinant, with only part of its impact through moderation or mediation of other determinants of health (Pelikan, Ganahl and Roethlin, 2018).

Stormacq, Van den Broucke and Wosinski (2018) provide further evidence for the mediating role of HL between socio-demographic factors and socioeconomic status (education, income, occupation, and perceived social status) with health disparities. They found people with low educational attainment were significantly more likely to have low HL, and this showed a gradient depending on the level of education. The authors noted, however, that several studies found a proportion of people across education levels had limited HL, and this is therefore not a perfect correlate. Lower HL was found to be related to lower income in two studies, unemployment/retirement in one study, and lower subjective social status in another. Race/ethnicity was also shown to have an influence, with 11 studies reporting higher odds of limited HL in African American/Black or Latino/Hispanic people than white people. HL was found to have a mediating role between various socio-demographic factors and health related outcomes, determinants of health-related behaviours, such as information recall and health related knowledge, health related behaviours, such as medication adherence and unhealthy behaviours, and use of healthcare services. The authors conclude that disadvantaged social or socioeconomic status (primarily educational attainment, income, occupation, and race/ethnicity) contribute to low HL, and HL in turn plays a partial mediating role between social and socioeconomic factors and health disparities. The potential for improving HL to reduce disparities is therefore highlighted: *"Interventions that aim to increase HL or that take people's low HL level into account will not lift people from disadvantaged socioeconomic conditions but can be considered as a 'midstream' strategy to reduce the impact of 'upstream' socioeconomic determinants on 'downstream' disparities in health." (Stormacq, Van den Broucke and Wosinski, 2018).* As is common in HL research, the review was limited by the variety of measures used to determine HL and reliance on observational and cross-sectional study designs.

1.4.8 Challenges of HL research

As discussed throughout this chapter, several challenges exist when conducting HL research. Differences in conceptualisation have arisen as work has developed within different disciplines, resulting in different definitions, models, and tools to assess HL. Tools may be used to screen HL through patient self-report, or measure it through test-like questions, and may assess only some aspects of the recent conceptualisations of HL or attempt to capture a more rounded understanding. Thresholds to divide those with 'lower' or 'higher' HL also vary. The approach taken may influence strategies to support development of HL or address any perceived deficits. Such variation makes it more difficult to compare studies and draw solid conclusions.

1.5 Project research questions

1. What are the barriers to SDM in the context of lower HL and incurable cancer from the patient and healthcare professionals' perspective?
2. What approaches and strategies might facilitate SDM in the palliative oncology setting for those with lower HL?
3. What combination of approaches/strategies/components might constitute a feasible complex intervention designed to support SDM for patients with incurable cancer and lower HL?

1.6 Summary and next steps

SDM is important in the oncology setting, particularly in the context of incurable disease, where decisions are preference-sensitive, and treatments may carry high risk for low potential benefit. Further work is needed to establish how best to support patients through the difficult decisions they must make.

Given its close links with SDM, HL is likely to play a key role, and should be accounted for when considering interventions to support patients in this setting. It is difficult to see how patients can be actively involved in decision making, or indeed, provide fully informed consent, without good understanding of their clinical situation and options available to them.

The next chapter will therefore set out the approach used to further understand these issues, and the steps taken to work towards developing an intervention to support SDM by patients with incurable cancer.

Chapter 2 Methodology and study design

The previous chapter explored the importance of SDM, barriers to its implementation and introduced and discussed the concept of HL. It also outlined supporting literature demonstrating the need for further work exploring the specific issues for SDM in the context of lower HL when cancer can't be cured.

This next chapter describes the basis for the development of the study, and provides an overview of the study design, with the aims, objectives, and key methodological considerations for each phase. It also includes a discussion of the key definitions, frameworks, and overall approach used to frame the study.

2.1 Research perspective

2.1.1 Personal background and philosophical stance

When discussing the research methodology used throughout this project, it is helpful to consider how my professional experiences have influenced the decisions made. I am a medical oncology registrar and have completed three out of four years of specialty training, taking time out of programme to undertake this doctorate.

I received my medical degree 11 years ago and have worked in the NHS since, rotating through several different hospitals and medical specialties. Throughout my training, the emphasis has been on practising evidence-based medicine, and this is particularly true in oncology. In routine clinical practice, multidisciplinary teams work together to make recommendations in line with evidence-based clinical guidelines which are constantly changing to keep up with the active pace of cancer research. Guidelines are developed following rigorous review of quantitative data from the latest clinical trials, and the interpretation and explanation of these results are an important part of an oncologist's role. Randomised controlled trials seek to demonstrate the effect of one treatment over another, tightly controlling for variables to find answers to be applied to all patients with the same characteristics in the same setting. Given this evidence, a treatment may be deemed effective or not, and used as a basis for clinical practice. Such conclusive evidence of cause and effect is important when discussing treatments and would not be obtained through using qualitative research methods seeking the views of small numbers of individuals who had received the treatment.

Despite this tight control achieved by randomised controlled trials, there is huge variability evident in clinical practice. Two patients may have tumours with very similar characteristics, yet may develop different patterns of metastatic disease, or have different responses to the same treatment. One may tolerate treatment much better than another patient of a similar age, or experience worse side effects than someone many years their senior. Others’ attitudes may influence their approach to decision making or appear to relate to their experience of treatment, and some patients just seem to be particularly lucky or unlucky. Taking a positivist stance, such individuals might be considered outliers, paid little further attention. Yet a constructivist approach could explore this further, gaining insight into the experiences of individuals, learning about the issues from the patients’ perspective and unearthing the unquantifiable influences that may account for some of these differences. Such an approach can help us better understand and support the patients sitting across from us in clinic. However, as highlighted above, these experiences can differ widely, according to factors such as disease site, geographical location, personal circumstances, and the findings from one study may not apply to all patients everywhere.

Alternative to the positivist or constructivist approaches, pragmatism acknowledges the uses and benefits of both quantitative and qualitative methods and has applicability to day-to-day oncology practice by considering both perspectives. As a result, this is the approach taken in this project, discussed in further detail below.

2.1.1.1 A pragmatic approach

Rather than taking the view either that there can only be one objective truth, or that there is no single objective reality and all inquiry is subjective, pragmatism accepts *‘there are singular and multiple realities that are open to empirical inquiry and orients itself toward solving practical problems in the ‘‘real world’’’* (Yvonne Feilzer, 2010). Pragmatic research is intended not to most accurately reflect reality, but to be useful, questioning what and who the research is for (Yvonne Feilzer, 2010). Morgan (2007) draws some key comparisons between qualitative, quantitative, and pragmatic approaches (Figure 6).

	Qualitative approach	**Quantitative approach**	**Pragmatic approach**
Connection of theory and data	Induction	Deduction	Abduction
Relationship to research process	Subjectivity	Objectivity	Intersubjectivity
Inference from data	Context	Generality	Transferability

Figure 6 - A Pragmatic Alternative to the Key Issues in Social Science Research Methodology (Morgan, 2007)

Whereas the qualitative approach might strive to draw conclusions purely from the data, and the quantitative approach might be driven entirely by existing theory, pragmatism moves between the two, acknowledging existing theory will have an influence, yet there is more to be learnt from the data themselves. The process of moving back and forth between induction and deduction provides opportunities to further the knowledge gained from one approach by exploring it through the other (Morgan, 2007).

Pragmatism can also address the issue of subjectivity or objectivity, accepting no research can be entirely subjective, nor the researcher entirely removed from the process and therefore completely objective. Instead, the researcher must share an understanding with both the participants and those who read the research outputs (Morgan, 2007). Rather than the polarised views of the two traditional approaches, in pragmatism *'there is no problem with asserting both that there is a single "real world" and that all individuals have their own unique interpretations of that world'* (Morgan, 2007).

The final comparison Morgan considers is whether the research findings apply only to the context in which they were obtained (qualitative approach), or whether they are universal and apply to all (quantitative approach). The pragmatic approach considers instead how what has been learnt in one setting can be useful to another and what factors affect this (Morgan, 2007).

By moving away from these opposing views, pragmatism allows the researcher to draw on the methods most suited to answer the research questions, to generate useful knowledge and a rounded understanding of the subject under investigation, and hence is well suited to exploring the issues raised in this study.

2.1.2 Development of the study

As discussed in section 1.1, this study began with an initial problem identified through clinical experience and has been undertaken with the aim of developing a practical means to improve the experience of patients with incurable cancer, through supporting SDM. Pragmatism fits well with this aim of undertaking research useful for solving a real-world problem and supports the use of a range of different methods to gather data and inform the intervention development process.

There are many published approaches to the development of interventions in the healthcare setting (O'Cathain *et al.*, 2019). While some focus on optimising efficiency or ensuring interventions will be used in the real world if effective, others are notable for their in-depth involvement of the end user as a partner in the process, or for combining existing evidence or theory as a basis for the intervention. An example of this latter approach is the Medical Research

Council's guidance on Developing and Evaluating Complex Interventions (Craig *et al.*, 2008), which emphasises the importance of developing interventions systematically using evidence and theory, and outlines four stages, including development, feasibility/piloting, evaluation and implementation. Due to the time and resource limitations for this PhD study, it was not anticipated that progress would be made beyond the intervention development stage.

Further guidance on this initial development stage was later proposed following a consensus study of intervention developers and wider stakeholders (O'Cathain *et al.*, 2019), which set out to identify the key actions needed for successful healthcare intervention development. These actions include planning the development process, involving stakeholders, bringing together a team, reviewing published evidence, drawing on existing theories, articulating programme theory, undertaking primary data collection, understanding context, attending to future implementation, and designing and refining. They are not followed step by step but are revisited throughout the development process, and the key underlying principles are that the process is dynamic, iterative, creative, open to change and forward looking. As part of 'planning the development process', the authors suggest developers must decide between following a published approach to intervention development or undertaking a pragmatic self-selected set of actions. Where a published approach is used, experts recommend these are applied flexibly to the specific context (O'Cathain *et al.*, 2019).

As this was the first time I had undertaken a project to develop a healthcare intervention, it seemed sensible to follow a tried and tested published approach, whilst still allowing decisions about methods to be pragmatic. Although I had some initial ideas, I did not already have a specific intervention, and it was important the process involved target users. To this end, with the overall project aim in mind, and to both provide further structure for the research process and increase the likelihood of developing an successful intervention, the Person-Based Approach to intervention development was adopted (Yardley *et al.*, 2015). This approach seeks an understanding of the issues facing both parties and combines it with existing theory, ultimately working towards the development of an intervention that will be acceptable, feasible, and more likely to lead to behaviour change and improved outcomes for patients (Yardley *et al.*, 2015).

Within the taxonomy of approaches to intervention development, the Person-Based Approach fits in the category of target-population centred approaches, alongside user-centred and human-centred design (O'Cathain *et al.*, 2019). All of these approaches strive to develop interventions that meet users' needs, but the Person-Based Approach goes beyond this, combining an in-depth understanding of users with theory and evidence based design, leading to the development of an intervention that is relevant and engaging (Yardley *et al.*, 2015).

Within this approach, decisions about the methods used have been pragmatic, focussing on the research questions to be answered at each stage and choosing the most appropriate research design to address them (Kaushik and Walsh, 2019). Having established the overall aim for the project, early reading identified HL as an important contributor to SDM. Quantitative methods were used to identify the scale of the issue and associated outcomes in clinical practice, providing justification for the concept to remain a key focus of the project, whilst qualitative methods have been used to understand the challenges faced by patients, allowing identification of practical issues to be addressed in future interventions.

Analysis has been both deductive and inductive, drawing on existing knowledge and theory and accepting this will influence interpretation, whilst also allowing the opportunity for new issues or themes to arise. Throughout this project, consideration has been given to the most practical and appropriate ways of obtaining the required information to answer the research questions, ultimately aspiring to making tangible improvements for patients, whilst ensuring quality is maintained.

2.2 Person-Based Approach

The Person-Based Approach comprises three main stages: Intervention Planning, Intervention Optimisation, and Mixed Methods Process Evaluation (Morrison *et al.*, 2018). In addition to utilising theory and evidence-based approaches, the Person-Based Approach seeks a thorough understanding of the issues from the users' perspectives (Yardley *et al.*, 2015).

Importantly for this study, the approach has been successfully used in the development of a web-based intervention to promote physical activity in people with type-2 diabetes, which was specifically tailored to and developed using feedback from users with lower HL (Rowsell *et al.*, 2015). In a subsequent randomised trial of the intervention comparing two versions of the same content, users reported high levels of satisfaction, with higher diabetes knowledge scores achieved by those who used an interactive rather than solely text-based version of the website (Muller *et al.*, 2017). Although not assessed at baseline, there was no significant difference in knowledge after using the intervention between those with higher and lower HL, and attitudes and intentions toward physical activity increased for both HL groups.

The above example provides support for using the PBA in this setting, as well as targeting interventions towards those who may have lower HL. However, as the authors note, the number of participants with low HL as assessed by a single screening question was small (67/1005, 6.7%) and it is not known whether this group would have benefitted from the intervention to the same degree.

For this study, having established the overall aim of supporting SDM for people with incurable cancer, and identifying the key role of HL within this, the next steps were to identify what was already known about the subject and begin to explore some of the issues from the users' perspective. These steps form part of the Intervention Planning stage of the Person-Based Approach.

2.2.1 Intervention Planning

The first stage of the Person-Based Approach entails planning, with identification of key behavioural issues, needs and challenges the intervention must address (Yardley *et al.*, 2015). To achieve this, four pieces of work were planned: a systematic literature review, qualitative patient interviews, a survey of healthcare professionals and discussion of the findings and possible interventions with panels of patients, carers, and healthcare professionals.

An overview of the study design and further details of the methods chosen are given in the following sections.

2.3 Overview of study design

Table 1 provides an overview of the phases of work undertaken during this PhD study, including the aims and objectives for each, informed by the previous study phase.

Table 1 - Overview of study design including aims and objectives of each study phase

	Mixed studies systematic review	**Patient interviews**	**Healthcare professional survey**	**Expert panel meetings**
	Chapter 3	**Chapter 4**	**Chapter 5**	**Chapter 7**
Aim	To bring together the literature relating to HL in cancer care, to improve understanding of the challenges associated with HL in this context, and efforts already made to address them, and provide an overview of the subject that would inform the intervention development process.	To explore the experiences of and challenges faced by patients lower HL receiving care for incurable cancer, acknowledging the implications COVID-19 will have for future care delivery, and consider how best to support decision making for this patient group.	To understand healthcare professionals' views and approach to SDM in the context of incurable cancer, with a focus on HL	To discuss the key issues and intervention components identified through this work, consider existing interventions, and determine which aspects are likely to be most useful and achievable in this setting
Objectives	1. To identify which outcomes relate to limited HL in patients with cancer 2. To identify the prevalence of limited HL in patients with cancer 3. To identify what qualitative studies have explored the role and consequences of HL in patients to access, understand, appraise, and use information and services to make decisions about health 4. To explore what interventions have been developed or tested to support patients with limited HL in this setting	1. To understand the experiences and decision making of patients with lower HL receiving care for incurable cancer in the NHS 2. To identify particular challenges faced by patients with lower HL whilst receiving care for incurable cancer 3. To make recommendations about how best to support this patient group in clinical practice.	1. To understand the views and experiences of healthcare professionals towards SDM in the context of incurable cancer 2. To explore the barriers to SDM in incurable cancer reported by healthcare professionals 3. To explore how perceived lower HL affects how healthcare professionals approach SDM with patients with incurable cancer 4. To identify what strategies might be useful to support SDM for patients with incurable cancer and lower HL	1. To review key summary findings from systematic review, qualitative interviews, and healthcare professional survey 2. To discuss possible components for an intervention based on these findings 3. To review existing interventions 4. To consider which intervention components are likely to be most useful, engaging, and achievable in this setting and which to prioritise for future interventions

2.3.1 Mixed studies systematic review

The first piece of work undertaken was a systematic review of the role of HL in cancer care. Given the close association between HL and SDM, the review set out to look at the outcomes associated with HL in the oncology setting, including those relating to SDM, as well as understand the scale of the issue, and explore what interventions had been developed to support HL in this setting.

2.3.1.1 Aims and objectives

The overall aim of this review was to bring together the literature relating to HL in cancer care, to improve understanding of the challenges associated with HL in this context, and efforts already made to address them, and provide an overview of the subject that would inform the intervention development process.

In addition to considering the prevalence and clinical relevance of HL in oncology, the review also sought to identify what interventions had been developed to support HL in this setting, to begin to get an idea of what might or might not be effective. To achieve this, four objectives were identified:

1. To identify the prevalence of limited/lower HL in patients with cancer
2. To identify which outcomes relate to limited HL in patients with cancer
3. To explore the role and consequences of HL, reported by qualitative studies, as patients with cancer access, understand, appraise, and use information and services to make decisions about health
4. To explore what interventions have been developed or tested to support patients with limited HL in this setting

Figure 7 demonstrates how these four objectives combine to provide a comprehensive overview of HL in cancer care.

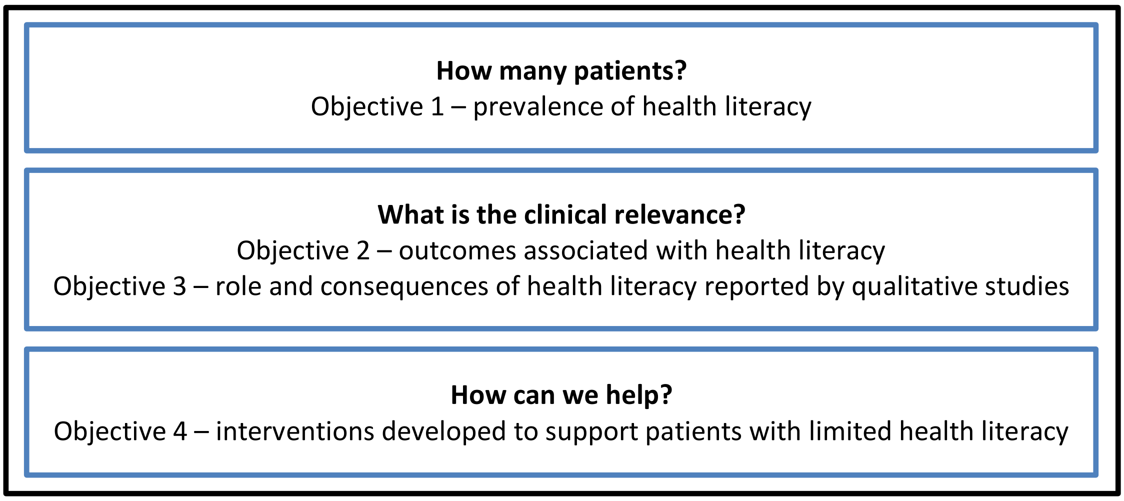


Figure 7 – Diagram demonstrating how the mixed studies objectives in this review combine and apply to the clinical context

2.3.1.2 Review design

To achieve the review's aims and objectives, a mixed studies approach was used. Beyond determining the kind of evidence available on a subject through a scoping review, which may also draw on different study designs, *'mixed methods systematic reviews are designed to answer a question or questions based on the synthesis of evidence from for example qualitative, and quantitative research'* (Peters, 2020). By combining quantitative and qualitative data, the mixed studies approach can produce useful results for decision makers and support guideline development (Lizarondo, 2020).

A convergent synthesis approach (Hong *et al.*, 2017) was chosen, allowing data to be collected separately for each review objective. The qualitative and quantitative studies could then be synthesised separately without transforming the data, before being integrated. From this, it was possible to explore the role of HL in terms of measurable or quantifiable outcomes, to understand the experience from the patient perspective, to see how these interact with each other and provide evidence for possible approaches for intervention development.

As an initial scoping search identified few studies looking specifically at incurable disease, and as many patients eventually develop progression even if initially commenced on a curative pathway, studies looking at all cancer stages were therefore included in this phase of the work.

Further detail on the methods used for the review can be found in Section 3.2, page 54.

2.3.2 Qualitative patient interviews

The second piece of work aimed to obtain qualitative data from the target patient group – those with lower HL and incurable cancer. The method and design considerations are discussed in the following sections, while further detail on interview procedure and analysis is given in Chapter 4.

2.3.2.1 Aims and objectives

The main aim was to explore the experiences of and challenges faced by patients with lower HL receiving care for incurable cancer, acknowledging the implications COVID-19 will have for future care delivery, and consider how best to support decision making for this patient group. The objectives were:

1. To understand the experiences and decision making of patients with lower HL receiving care for incurable cancer in the NHS
2. To identify particular challenges faced by patients with lower HL whilst receiving care for incurable cancer
3. To make recommendations about how best to support this patient group in clinical practice

2.3.2.2 Choice of data collection methods

When considering the research method to use, Ritchie and Lewis (2003) suggest making an initial decision between naturally occurring and generated data. This should take into account the research questions and consider factors such as context, whether recounting of the research phenomenon is likely to be sufficiently detailed, accurate or complete, whose interpretation is paramount and practical accessibility issues. In this case, the natural context was less important, and descriptions provided by participants were considered likely to be sufficient. A key element of the work was to learn about participants' experiences from their own perspective rather than through interpretation of an observed encounter, and generated data collection methods offered this opportunity. Finally, the work was planned during the COVID-19 pandemic when there were significant restrictions on social contact, with limitations on the number of people present in clinic rooms and many consultations delivered virtually, therefore use of observational methods would not have been possible during this time.

Having established that generated data collection methods could meet the research aims and be carried out in line with COVID-19 restrictions, the next consideration was which method to use based on the type of data sought, the subject area and the nature of the study group (Ritchie and Lewis, 2003). The focus of this work was on individuals' experiences, taking account of participants' individual circumstances. Exploration of an individual's decision making process and their diagnosis are personal, and issues relating to HL can be difficult to discuss given the associated stigma. Additionally, and again, given the COVID-19 restrictions, facilitation of focus groups would have been incredibly difficult, particularly for a group who might have limited access to technology. For these reasons, individual interviews were the chosen method of data collection.

A semi-structured interview approach was selected to address the specific research questions, allowing for further probing and exploration of other topics as they arose. The topic guide was developed drawing on theoretical frameworks (Nutbeam, 2000; Edwards *et al.*, 2012) and piloted prior to use. Interview questions were designed to explore the information giving process, participants' understanding of their situation and treatments offered, experiences of decision making, and challenges faced by participants.

2.3.2.3 Recruitment

Early study designs involved screening patients to identify lower HL, with targeted recruitment of individuals for interview, however, this was changed in light of restrictions introduced during the pandemic, and participants were instead identified by healthcare professionals.

Although recruiting participants in this way made it possible to identify those who might have the relevant experience, by drawing on the healthcare professionals' knowledge of their patients, this approach had its own limitations. Clinicians may have acted as gatekeepers, perhaps protecting some patients from the additional burden of participating in a research study at this difficult time. Clinicians may have been selective in those they referred, protecting the researcher from patients perceived to be 'difficult', or choosing only those they felt would make a useful contribution. They may also have felt uncomfortable labelling people as having lower HL or may have lacked confidence identifying them as such. It will also have been important not to risk damaging the healthcare professional's relationship with their patients. To address some of these concerns, efforts were made to reassure teams about the level of involvement required by both clinicians and participants, and to emphasise the focus not on identifying individual deficiencies, but to explore how to improve the system itself.

Successful recruitment also depended on buy in from healthcare professionals, which will have been influenced by their interest in the topic and its perceived importance, as well as the additional workload. In designing the study, efforts were made to minimise the burden on clinicians beyond identification of participants and making an initial approach. Given their competing clinical commitments, healthcare professionals may also have forgotten about the study, and reminders were communicated in person and by email, with brief summaries available for easy reference.

Finally, in addition to the above considerations, healthcare professionals were under additional pressure during the COVID-19 pandemic and recruiting participants to this study may not, understandably, have been a top priority for them at this time.

Despite these potential issues, the clinicians involved facilitated the successful recruitment of twenty-one individuals with suspected lower HL. This is a significant achievement and would not have been possible without their help.

2.3.2.4 Patient and public involvement

Patient and public involvement (PPI) was sought to help support development of participant information materials and interview topic guides. It was particularly important to include those who had faced difficulties with HL, in order that their experience of the materials might reflect that of the potential participants, and to stimulate modifications making the materials more accessible and easier to understand. Identification of such individuals was challenging, as members of established PPI groups might be expected to have higher HL and greater confidence communicating about health-related issues. However, two individuals were ultimately identified. One was a member of a local PPI group present at a meeting where the study was discussed, who had experienced difficulties understanding information when acutely unwell with a non-malignant life-threatening illness. The other was a patient known to myself and Amélie Harle, who we suspected had been experiencing difficulties understanding and processing the complex information given about their incurable cancer. Both contributors provided input through review of the participant information documents and summary video, and by piloting the consent process and interview schedule. Changes were made to all materials in response to this feedback. One of the members, keen on the idea of a summary video, highlighted an issue with access, as they had no means of receiving or playing the video at home. This prompted a search for an alternative means of sharing it, and ultimately led to the solution of recordable video cards which could be sent to potential participants by post.

2.3.2.5 Ethical considerations

Given the subject and patient group to be studied, a number of ethical issues were considered during the development of this part of the study.

As participants might experience feelings of shame or discomfort when discussing issues relating to literacy/HL and any perceived deficits in this area, these terms were avoided. The focus was instead placed on deficiencies in the system rather than on any individual, and exploring how processes could be improved.

Individuals might also experience distress when talking about their diagnosis of incurable cancer, however, the aim of the research was to explore experiences and difficulties relating to general aspects of information giving, decision making and care, rather than to directly discuss issues surrounding death and dying. In a systematic review of patient, caregiver, health professional and researcher views and experiences of participating in research at the end of life, Gysels, Evans and Higginson (2012) found patients were generally willing to participate in research and most have a positive experience of doing so. A minority did experience distress, and this was higher when they were asked to discuss death. Although participants in the interviews carried out during this PhD were advised they did not have to talk about subjects they did not want to, there was no pressure to answer questions, and they could stop at any time, a small number did become upset during the course of the interview. When this occurred, I responded empathetically, allowing the participant time, and offering to take a break or stop the interview, as well as offering additional support through contact with the patient’s clinical team.

Gysels, Evans and Higginson (2012) also found patients preferred to have initial contact by health professionals known to them, and have face-to-face interviews in their own home. Initial contact with potential participants was therefore made by a member of the treating team in all cases and, as face-to-face contact was not possible due to COVID-19 restrictions, video interviews were encouraged over telephone interviews.

To reduce the chance of interviewing patients known to me, participants were not recruited from the clinic in which I continued to work during the PhD. Where necessary, participants with medical queries or concerns were directed to their clinical teams and confidentiality was maintained throughout.

University of Southampton Faculty Research Ethics Committee (ERGO number 60486) and NHS Health Research Authority (HRA) approval was obtained prior to commencement (REC reference 20/PR/0478).

Further detail on the methods used for the interview phase are given in Section 4.2, page 90.

2.3.3 Healthcare professional survey

Having established an understanding of the issues from the patient’s perspective, the third phase of this research involved a survey of healthcare professionals, to understand their views and experiences of SDM in the setting of incurable cancer, with a particular focus on HL, as well as barriers faced, and strategies used to support the process.

2.3.3.1 Aims and objectives

The overall aim of this survey was to understand healthcare professionals' views and approach to SDM in the context of incurable cancer, with a focus on HL.

The objectives were:

1. To understand the views and experiences of healthcare professionals towards SDM in the context of incurable cancer
2. To explore the barriers to SDM in the context of incurable cancer reported by healthcare professionals
3. To explore how perceived lower HL affects how healthcare professionals approach SDM with patients with incurable cancer
4. To identify what strategies might be useful to support SDM for patients with incurable cancer and lower HL.

2.3.3.2 Survey design

When exploring options for data collection, the possibility of collecting data through interviews with healthcare professionals was considered, however, some hospital COVID-19 restrictions remained in place, and it was unclear whether others might be reintroduced. In addition to this, and following recent experiences of a prolonged recruitment period for the patient interviews, recruitment of healthcare professionals to participate in interviews, whilst under this additional pressure conferred by the pandemic, may have been similarly challenging. Further, conducting interviews with colleagues, whether direct or indirect, may have produced more inhibited responses as participants may not have felt they could speak entirely freely. For these reasons, and with support from the literature for using online surveys as a means of collecting qualitative data (Braun *et al.*, 2021), an online survey design was therefore used. It was anticipated this more anonymous nature of data collection would allow participants to reflect on their practice and provide truthful responses. In addition to overcoming the practical issues above, the survey allowed for wider distribution, as the link could be shared via email through professional bodies and word of mouth, or through social media. It also offered participants greater convenience and flexibility, allowing them to complete the survey at a time to suit them, including outside usual working hours.

When designing the survey, care was taken to make it user friendly and encourage completion by using a combination of tick-box questions alongside free text responses. It was piloted with three oncology healthcare professionals who confirmed the time taken for completing the survey was acceptable, and following which minor changes were made.

2.3.3.3 Ethical considerations

Ethical approval for the survey was given by the University of Southampton's Faculty Research Ethics Committee (ERGO number 65382).

Further detail on the methods used for the survey is given in Section 5.2, page 124.

2.3.4 Expert panel meetings

The final phase of the study, and final step of the Intervention Planning stage, involved bringing together the findings from the three previous pieces of work, and presenting these to patient, carer, and healthcare professional experts to reflect on the issues and discuss how to move towards supporting SDM when cancer can't be cured.

2.3.4.1 Aims and objectives

The overarching aim of these meetings was to draw on the panels' experience and expertise, discuss the key issues and intervention components identified through this work, consider existing interventions, and determine which aspects were likely to be most useful and achievable in this setting.

The objectives for the two panel meetings were the same:

1. To review key summary findings from systematic review, qualitative interviews, and healthcare professional survey
2. To discuss possible components for an intervention based on these findings
3. To review existing interventions
4. To consider which intervention components are likely to be most useful, engaging, and achievable in this setting and which to prioritise for future interventions

2.3.4.2 Format

The two panel meetings were held virtually, one using Microsoft Teams software, and the other using the Zoom meeting platform. The virtual nature made the meetings more convenient for participants to attend and protected them from the potential reintroduction of COVID-19 restrictions. It also facilitated easy recording for later reference.

Both meetings were split into two parts, with each part comprising an initial short presentation of the findings using Microsoft PowerPoint, followed by discussion.

2.3.4.3 Ethical considerations

An application was made for review by the University of Southampton's Faculty Research Ethics Committee. However, as the proposed meetings did not seek to collect data in a formalised research approach, they were considered to constitute involvement activities with PPI and stakeholder representatives and therefore formal ethical approval was not deemed necessary.

Further detail on the panel meetings is given in Section 7.2, page 161.

2.4 Chosen definitions and theoretical frameworks

As outlined in Chapter 1, various definitions and models for both SDM and HL exist. Those chosen to frame this work, along with justification for their use, are detailed below.

2.4.1 Shared decision making

Elwyn's Three Talk Model of SDM (Elwyn *et al.*, 2012; Elwyn *et al.*, 2017) was chosen based on its grounding in the UK's health system and incorporation into relevant NHS clinical guidelines. As practices, resources and attitudes differ between healthcare systems, it is appropriate to choose a model that has been tried and tested in the context within which this project is being undertaken.

2.4.2 Health literacy

2.4.2.1 Definition of HL

> "Health literacy is the combination of personal competencies and situational resources needed for people to access, understand, appraise and use information and services to make decisions about health. It includes the capacity to communicate, assert and act upon these decisions." (International Union for Health Promotion and Education, 2018)

The above definition of HL was chosen to frame the work. It emphasises that HL depends upon not only the individual, but also the resources available and the situation they find themselves in. A very well-educated person who does not have access to appropriate and relevant information may still find themselves struggling to understand their situation and unable to make informed decisions as a result, thus both personal and situational elements must be considered. This also has implications when considering possible interventions to support the development of HL. The definition highlights the importance of being able to communicate and act upon decisions made, which again may not be possible if the situation does not allow, potentially leading to frustration and a more negative experience. It does not rely on a pre-existing level of knowledge, suggesting everyone, regardless of background, has the potential to develop their HL and ultimately take a more active role in their care.

2.4.2.2 Conceptualisations of HL

The above definition fits with Nutbeam's conceptualisation of HL as an 'asset', which is used to frame some aspects of this project. The patient interviews focus on deficits of the system rather than the individual and encourage consideration of how things might be improved to help support patient understanding and develop HL. The systematic review, however, approaches HL from the 'risk' perspective, and explores the often negative outcomes associated with lower HL in the oncology setting. By taking these different views it is possible to consider the role and impact of HL from a range of different angles, presenting the more tangible impacts that may have implications for policy and are important for service delivery, but also considering the experience from the patient perspective, with a view to developing interventions to achieve more person-centred care.

Two models of HL relevant to SDM are utilised: Nutbeam's three levels of HL (Nutbeam, 2000), and Edwards et al.'s Health Literacy Pathway Model (Edwards *et al.*, 2012). Both describe the development of HL as a process with greater understanding leading to greater involvement in SDM. Edwards et al. also consider positive and negative influences on this process, including emotions, which seem particularly relevant in oncology when patients are faced with what are often life-changing diagnoses.

2.4.2.3 HL assessment tools

As discussed in section 1.4.3, numerous HL assessment tools exist. HL can be a sensitive subject given its association with general literacy and earlier conceptualisations focusing solely on an individual's ability or skills. To avoid causing anxiety during the interviews, the three self-report questions (Chew *et al.*, 2008) were chosen to gauge HL by asking participants to consider real life situations and without imposing a test like measure. The ability to deliver the questions verbally was also important given the remote nature of the interviews, which would have ruled out other tools requiring visualisation, such as the NVS (Weiss *et al.*, 2005).

Several methods have been described to score the questions, and the cut points used to categorise HL can differ. Figure 8 demonstrates one way of numerically scoring, where a score of three would suggest the individual faced difficulties with each scenario and would therefore have lower HL, whilst a score of 15 would suggest high HL. This method appears to correspond to that used by Chrischilles *et al.* (2019), in one of the studies included in the systematic review (Section 3.3.1), where participants were categorised as having low HL if they scored 12 or below. The scoring may also be the reverse of this, however, and the threshold and direction of the cut point would be different, as in the study by Xia *et al.* (2019) also included in the review, where a score of 10 or higher was considered to represent low HL. These differences account for some of the variation in thresholds used and add to the challenge when comparing studies using the measure.

	Corresponding numerical scores				
	1	**2**	**3**	**4**	**5**
1. "How often do you have someone (like a family member, friend, hospital/clinic worker or caregiver) help you read hospital materials?" (Help Read)	All of the time	Most of the time	Some of the time	A little of the time	None of the time
2. "How often do you have problems learning about your medical condition because of difficulty understanding written information?" (Problems Reading)	All of the time	Most of the time	Some of the time	A little of the time	None of the time
3. "How confident are you filling out forms by yourself?" (Confident with Forms)	Not at all	A little bit	Somewhat	Quite a bit	Extremely

Figure 8 - Chew questions and responses with possible corresponding numerical scores

Chew *et al.* (2008) recommended a threshold of "somewhat" be used for the question "Confident with forms", as this optimised both sensitivity and specificity for detecting inadequate HL. Although combining the three questions in the validation study was no more effective than the single question "Confident with forms", this question alone may be less relevant to the UK setting as patients in the NHS are not often required to fill in forms as part of their routine medical care. This phase of the study sought to hear from those who may have experienced difficulties relating to HL during the course of their care, and included a sample already identified as potentially having low HL by their healthcare team. For these reasons, all three of the questions were included, using the recommended cut-point of "somewhat" and accepting a response at this level to any of the three questions might identify someone who acknowledges they struggle with certain aspects of HL.

Though not without limitations (discussed further in Chapter 4), these questions tied in well with the interview format and allowed participants to consider their own experiences as a basis for assessing their HL.

2.4.3 Identities of those with cancer

Various terms have been used to describe groups or individuals diagnosed with cancer, yet individuals do not always relate to these given identities. The following section aims to explore some of these different terms and provide a rationale for those used in this work.

2.4.3.1 (Cancer) 'Survivor'

Although perhaps not always associated with those with a diagnosis of incurable disease, the term survivor can be defined as *"One who remains alive and continues to function during and after overcoming a serious hardship or life-threatening disease. In cancer, a person is considered to be a survivor from the time of diagnosis until the end of life"* (National Cancer Institute, 2020). Though this definition comes from the National Cancer Institute in the USA, other groups, such as the Multinational Association of Supportive Care in Cancer (MASCC) also define survivorship from the time of diagnosis to end of life (Multinational Association of Supportive Care in Cancer, 2023), and a Macmillan funded study of cancer prevalence in the UK (Maddams, Utley and Møller, 2012) used the term to describe all people previously diagnosed with cancer.

Other organisations, such as the European Society for Medical Oncology (ESMO) suggest survivorship starts after completion of curative treatment (Jordan et al., 2018), with the UK National Cancer Research Institute's Living with and Beyond Cancer Group considering survivorship to be the phase of cancer care after active treatment (NCRI Living With & Beyond Cancer Group, 2021).

The term 'survivor' has been embraced by many but rejected by others. In one recent study, those who had completed treatment for colorectal cancer were four times more likely to relate to survivor identity (Wee et al., 2021), with those still undergoing treatment preferring an alternative term. Berry et al. (2019) similarly found those undergoing active treatment were less likely to identify with the term 'survivor' and felt less positive about the term. Individuals still experiencing cancer-related symptoms have been found less likely to identify as survivors (Cheung and Delfabbro, 2016), and those with advanced disease were also less likely to relate to the survivor identity (Berry et al., 2019).

In the UK, a qualitative study of 40 participants at least five years after an initial diagnosis of breast, colorectal and prostate cancer found most did not endorse the term cancer survivor, as it did not reflect their personal experience and suggested an association with personal characteristics, or expectation of cure despite the known possibility of recurrence (Khan et al., 2012).

2.4.3.2 ‘Person with…’

In a move away from the ‘survivor’ label, some call for the use of descriptive terms instead (Khan *et al.*, 2012). Using person-first language such as ‘person with cancer’ or ‘person diagnosed with cancer five years ago’, the aim is to put the emphasis on the person rather than the condition they have. This approach is endorsed in Cancer Research UK’s style guide for health and patient information in preference to referring to individuals as patients, a word on their list to be avoided. However, it is interesting to note this guidance is for the development of *patient* information (Cancer Research UK, 2020). Throughout their website, Macmillan Cancer Support similarly use terms such as ‘people with cancer’, ‘people living with cancer’ or ‘people affected by cancer’, yet this terminology changes when accessing information aimed at healthcare professionals, where the term ‘patient’ is more widely used.

In another setting, a positive language guide produced by the Alzheimer’s Society creates a distinction between the two, advising the term ‘patient’ should be used only if a person is in hospital, or in relation to seeing a healthcare professional (Alzheimer's Society, 2018). This is reflected in a report by The Patients Association, a UK patient advocacy group, which found 85% of respondents were happy to be called ‘patients’, and this was felt particularly appropriate when referring to someone in hospital or when they have been diagnosed with an illness (The Patients Association, 2020). When asked about being referred to as a ‘person’, ‘person living with (your condition)’ or ‘person with (your condition)’, around 40% responded that they would not be happy with the term. It is important to note, however, that this survey was not of individuals diagnosed with cancer and involved patient advocacy group members likely to be comfortable with the term ‘patient’.

2.4.3.3 ‘Patient’

According to the Cambridge English Dictionary, the term patient describes *“a person who is receiving medical care, or who is cared for by a particular doctor or dentist when necessary”* (Cambridge University Press, n.d.).

Patient advocate, Michael Scott, makes an important point about the use of the term ‘patient’. Associations with passivity and suffering have led to attempts to find another word to describe such individuals, yet he notes *“every patient is an individual who is entitled to the respect and full attention of health care professionals. Whether the patient is active or passive, the health care professional should act–first and foremost–in the best interests of that patient”*, and the term can therefore be a helpful reminder of the healthcare professional’s obligation to that individual under any circumstances (Scott, 2010). A further view comes from the late Kate Granger, a consultant geriatrician who founded the #hellomynameis campaign after being diagnosed with terminal cancer. She referred to herself as a cancer patient and rejected the battle terminology (Granger, 2014).

In my personal life, I might know friends and family who have been diagnosed with cancer, and though I may offer support, I do not have the same responsibility towards them as I would for the individuals or patients I see in clinic. And whilst in clinic I do endeavour to see the person in front of me, to involve them in their care, to understand their priorities, I have a professional responsibility towards them that is different to the people with cancer I may know outside work.

This work is aimed at supporting the interaction between healthcare professionals and patients whilst they are seeking care for incurable cancer. Rather than making it easier to separate oneself from this responsibility, as might be the case if referring to 'people with cancer', use of this term is important as a reminder of the professional obligation and relationship between the two parties, and a prompt for healthcare professionals to think of the patients to whom that duty exists. The term 'patient' is therefore primarily used throughout this work.

2.5 Summary and next steps

This chapter has outlined the approach taken, with justification for the concepts and definitions on which this work is based.

The next chapter will go on to describe the first phase of work undertaken as part of the 'Intervention Planning' stage – a mixed-studies systematic review of the literature relating to HL in the oncology setting.

Chapter 3 The role of health literacy in cancer care: a mixed studies systematic review

3.1 Introduction

The concepts of HL and SDM are closely linked, with higher HL leading to greater involvement in decision making, and good understanding needed for informed and shared decisions to be made. Given its position in person-centred care, particularly in relation to SDM, and the potential association with a range of health outcomes, it is important to understand the wider role of HL in the oncology setting.

Undertaken as part of the initial Intervention Planning Stage in the Person-Based Approach (Yardley *et al.*, 2015), this chapter aims to provide an up to date, systematic review of the literature, enabling us to understand the clinical relevance of HL in cancer care more broadly than existing reviews have allowed (Papadakos *et al.*, 2018; Fernández González and Bravo-Valenzuela, 2019; Kieffer Campbell, 2020). Papadakos *et al.* (2018)'s scoping review focussed on the association between HL and self-management behaviours, whilst the review conducted by Kieffer Campbell (2020) included only studies from the United States. Reviews of interventions to support HL in cancer care include that by Fernández González and Bravo-Valenzuela (2019), which included only interventions published up to 2017. The field has continued to expand since then, as evidenced by the inclusion of five intervention studies published after that date (from ten included in this PhD's review), justifying an updated search. A further review by Housten *et al.* (2020) was published during the course of this PhD, and included interventions across the cancer care continuum, with the majority (28/36) falling into the category of prevention and screening. None of these reviews brought together the combination of prevalence, outcomes, and interventions as in this mixed studies systematic review, which is therefore able to paint a more complete picture of the scale, clinical relevance, and possible solutions.

Given the concept's complexity and the personal preference-specific nature of decisions made in oncology, a mixed studies approach was chosen. This ensured the patient voice was heard alongside the quantitative findings and sought to bring together in one place the key issues of interest to healthcare professionals in the field.

The review addresses four objectives: 1) to identify the prevalence of limited/lower HL in patients with cancer; 2) to identify which outcomes relate to limited HL in patients with cancer; 3) to explore the role and consequences of HL, reported by qualitative studies, as patients with cancer access, understand, appraise and use information and services to make decisions about health and 4) to explore what interventions have been developed or tested to support patients with limited HL in this setting.

Findings for two of the objectives, addressing the outcomes associated with HL in cancer care and the patient perspective as reported through qualitative studies, have been published (Holden *et al.*, 2021). These, and the remaining two objectives, are presented below.

3.2 Methods

The review protocol was prospectively registered with the International Prospective Register for Systematic Reviews (PROSPERO), entry number CRD42020166454.

3.2.1 Search strategy

Searches were carried out on four electronic databases (MEDLINE, EMBASE, PsycINFO and CINAHL) on 15/01/2021. Publications addressing cancer and HL were sought using terms identified through review of the existing literature, including MeSH terms (neoplasms, health literacy) and keywords (cancer, malignancy, neoplasm, tumour, carcinoma, health literacy and health competence). Outcomes were not stipulated due to the anticipated varied nature of the studies. The search strategy was reviewed by an experienced librarian. Visual scanning of reference lists from included studies was undertaken. Citations were managed through Endnote X9 and Microsoft Excel.

Screening of titles and abstracts was undertaken by two independent reviewers, with one screening all papers (Chloe Holden (CH)) and the supervisory team screening a third of papers each (Amélie Harle (AH), Richard Wagland (RW), Sally Wheelwright (SW)), with a preference for inclusion if there were disagreements. Following the screening process, full texts were obtained and independently reviewed for eligibility by two authors (CH and AH, RW or SW) according to the following criteria:

Inclusion:

- Patients aged ≥18 years with malignancy of any site (if mixed group, data able to be separated)
- English language

AND

- HL assessed with validated tool (concerning general or cancer HL, used in its validated form in its entirety)
- Measured outcomes associated with HL OR stated prevalence of lower/limited HL

OR
- Qualitative studies exploring the role of HL as patients access, understand, appraise, and use information and services to make decisions about health
OR
- Studies describing the development of or testing an intervention to support patients with limited/lower HL

Exclusion:
Use of the term ‘health literacy’ but referring to disease specific knowledge only
Case reports, review papers, conference proceedings, opinion pieces, editorials, letters to the editor, dissertations/theses, book chapters, protocols

At all stages, disagreements were resolved through discussion.

3.2.2 Data extraction

One reviewer (CH) extracted data from all papers, with independent extraction from eight papers by a second reviewer (RW, SW) to check for accuracy. Data on study characteristics (author, year, country study undertaken, setting, design, aims/objectives, inclusion/exclusion, recruitment procedure, HL measure used and how limited HL defined), sample (age range, sex ratio, cancer site, stage, number of participants and number of eligible participants if mixed group, proportion limited HL according to measure used), outcomes (as reported in individual studies, measures used and association with HL), intervention (details of type, time to administer, effect on outcomes) and qualitative methods used, data analysis procedure, key themes and findings and participant quotes were collected.

3.2.3 Quality appraisal

Quality was assessed using the Mixed Methods Appraisal Tool (MMAT) (Hong *et al.*, 2018), allowing all study types to be appraised using a single tool for consistency. MMAT scores are given out of 5, with a point scored for each ‘Yes’ answer, and none for ‘No’ or ‘Can’t tell’ responses. Studies were considered higher quality if they scored 4/5 or 5/5. Quality assessment was carried out by two independent reviewers, with one assessing all papers (CH), and the supervisory team assessing a third of the papers each. Disagreements were resolved through discussion.

3.2.4 Data synthesis

Statistical pooling of data was not performed due to the varied study designs, outcomes, HL assessment tools and thresholds used to identify participants with lower HL. Drawing on guidance developed by Popay *et al.* (2006), a narrative synthesis was undertaken.

After data extraction, studies were grouped and tabulated based on the four review objectives. To address the third, qualitative objective, a thematic analysis was performed (Popay *et al.*, 2006).

The key themes, authors' descriptions, and interpretations, and supporting quotations were extracted from the results sections of the original qualitative papers, alongside relevant contextual data. Using an iterative process, similar themes were grouped and used to develop meta-themes through regular discussion amongst the authors, drawing on existing definitions and theoretical frameworks (Nutbeam, 2000; Edwards *et al.*, 2012; International Union for Health Promotion and Education, 2018). Finally, relationships between studies across the objectives were explored through concept mapping, again drawing on existing models (Edwards *et al.*, 2012; International Union for Health Promotion and Education, 2018), and findings integrated.

3.3 Results

4440 records were retrieved from the searches (Figure 9). After removal of duplicates, 2495 titles and abstracts were screened. Full texts of 404 papers were reviewed for eligibility, and one additional eligible study was identified through reference list scanning. Eighty-four papers relating to 76 studies were ultimately selected for inclusion.

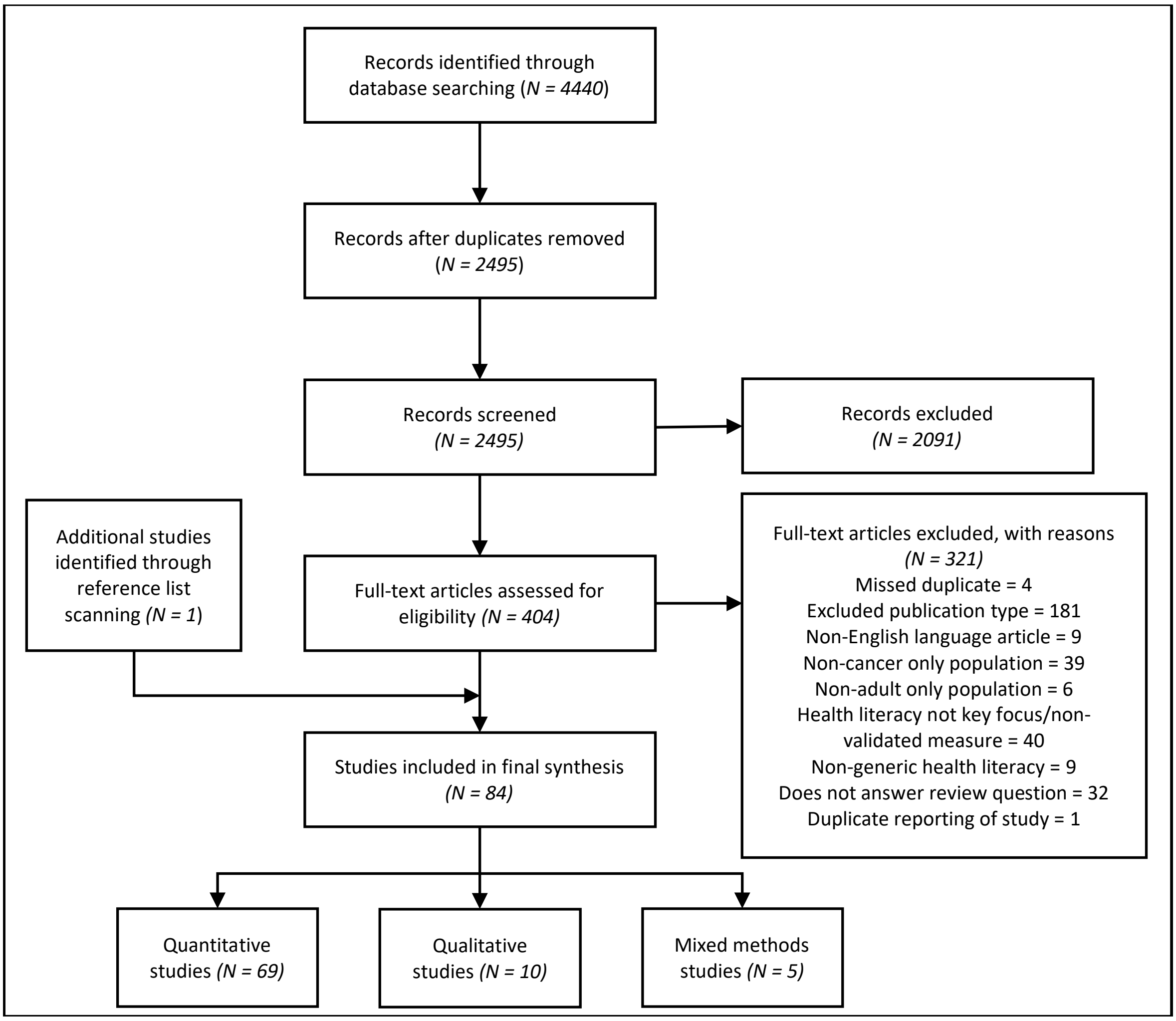


Figure 9 - PRISMA diagram showing records reviewed at each step of the process

3.3.1 Prevalence of limited/lower HL in patients with cancer

Fifty-one papers relating to 45 studies reported a prevalence of limited/lower HL (Table 2). Variations on 13 HL assessment tools were used, most commonly the REALM (N=13, prevalence 10-38%) and Chew screening questions (N=12, prevalence 3-65%). Sixty-nine percent of studies were carried out in the USA (N=31) and 27% included only patients with breast cancer (N=12).

Twenty-five studies were good quality (MMAT score 4-5/5, prevalence 3-86%). Where multiple papers referred to the same study, the paper with the largest sample size reporting prevalence was included, or, if the same size, the earliest paper was used.

Table 2 - Studies reporting prevalence of lower HL in cancer populations

Author (year)	**Location**	**Cancer site(s)***	**N ****	**HL measure**	**Categorisation of lower HL**	**% Lower HL**	**MMAT score**
Gunn *et al.* (2020)	USA	Breast	228	BRIEF	Score <u><</u>16	61%	3
Nilsen *et al.* (2020)	USA	Head and neck	218	Chew 3 questions	Score <u><</u>9	14%	5
Inglehart *et al.* (2016)	USA	Head and neck	372	Chew 3 questions	Dichotomised by mean score of 3.0	20%	5
Lim *et al.* (2019a)	Australia	Multiple	34	Chew 3 questions	"Using the cut-off recommended by Chew"	65%	5
Xia *et al.* (2019)	China	Multiple	4589	Chew 3 questions	Total score <u>></u>11	3%	4
Chrischilles *et al.* (2019)	USA	Breast	835	Chew 3 questions	Score <u><</u>12	24%	4
Scarpato *et al.* (2016)	USA	Bladder	368	Chew 3 questions	Score <u><</u>13	51%	3
Husson *et al.* (2015)	The Netherlands	Colorectal	1643	Chew single question	Response somewhat/a little/ not at all	14%	5
McDougall *et al.* (2019)	USA	Colorectal	301	Chew single question	Response a little/ none of the time	26%	4
Ousseine *et al.* (2020)	France	Multiple	4045	Chew single question	NR	37%	4
Clarke *et al.* (2021)	Ireland	Head and neck	395	Chew single question	Response somewhat or below	47%	4
Durand *et al.* (2021)	USA	Breast	615	Chew single question	Dichotomised by top response vs all others	45%	2
Post *et al.* (2020)	USA	Breast	298	CHLT-6	< 4 correct answers	31%	4
Dumenci *et al.* (2014)	USA	Multiple	1306	CHLT-6	No cut off specified	18%	3

Author (year)	**Location**	**Cancer site(s)***	**N ****	**HL measure**	**Categorisation of lower HL**	**% Lower HL**	**MMAT score**
Sundberg *et al.* (2020)	Sweden	Prostate	130	FHL CCHL	FHL: Scoring (3), (4) or (5) to >1 item CCHL: Scoring (1), (2) or (3) to >1 item	FHL: 45% CCHL: 61%	3
Polite *et al.* (2019)	USA	Lung, gastric and pancreatic	120	Health LiTT	Score <55	33%	4
Qaderi *et al.* (2021)	The Netherlands	Colorectal	118	HLS-EU-Q16	Score <12	8%	5
Halbach *et al.* (2016b)	Germany	Breast	1060	HLS-EU-Q16	Score <12	48%	2
Turkoglu *et al.* (2019)	Turkey	Bladder	126	HLS-EU-Q47	Score <33	67%	2
İlhan *et al.* (2020)	Turkey	Multiple	207	HLS-EU-Q-TR	Score <33	86%	4
Winton *et al.* (2016)	USA	Breast	336	NVS	Score <4	78%	5
Solowski *et al.* (2014)	USA	NR	40	NVS	Score <4	30%	1
Lillie *et al.* (2007)	USA	Breast	163	REALM	Score <63	23%	4
Kim *et al.* (2001)	USA	Prostate	30	REALM	Score <60	37%	3
Matsuyama *et al.* (2013)	USA	Not collected	32	REALM	Score <6th grade	19%	3
Song *et al.* (2012)	USA	Prostate	1581	REALM	Score <44	22%	3
Bickmore *et al.* (2016)	USA	Multiple	89	REALM	Score <9th grade	27%	2
Cox, Bowmer and Ring (2011)	UK	Breast	127	REALM Chew single question	REALM: Score <9th grade. Chew: Response at/beyond ‘somewhat’	REALM: 9% Chew: 19%	5
Hahn *et al.* (2010)	USA	Multiple	97	REALM S-TOFHLA	REALM: Score <45 S-TOFHLA: inadequate or marginal	REALM: 14% S-TOFHLA: 5%	5
Matsuyama *et al.* (2011)	USA	Multiple	138	REALM S-TOFHLA	REALM: Score <60. S-TOFHLA: Score <66	REALM: 38% STOFHLA: 14%	4
Mohan *et al.* (2009)	USA	Prostate	184	REALM-R	Cut off <9th grade	10%	4
Brewer *et al.* (2012)	USA	Breast	133	REALM-R	Score <8	21%	4
Mahal *et al.* (2015)	USA	Prostate	375	REALM-SF	Score <7	26%	4

Author (year)	**Location**	**Cancer site(s)***	**N ****	**HL measure**	**Categorisation of lower HL**	**% Lower HL**	**MMAT score**
Watson *et al.* (2020)	USA	Gynaecological	100	REALM-SF	NR	12%	3
Jewitt *et al.* (2016)	Canada	Multiple	37	REALM-SF	Score <7	19%	2
Wolpin *et al.* (2016)	USA	Prostate	26	SAHL-E	Score ≤14	19%	2
Burks *et al.* (2020)	USA	Breast	20	SBSQ	Marginal (6–7) and inadequate (8–15)	30%	5
Politi *et al.* (2019)	USA	Breast	120	SILS	Not defined	8%	4
Anderson *et al.* (2021)	USA	Multiple	183	SILS	Response some help needed	7%	3
Janz *et al.* (2017)	USA	Breast	1295	SILS	Response sometimes/often/ always	24%	2
Lee, Lee and Chang (2018)	South Korea	Lung	80	S-KHLT	Cut point of 6 dividing high and low HL	70%	4
Busch *et al.* (2015)	USA	Colorectal	347	S-TOFHLA	Score ≤22	30%	4
Beitler *et al.* (2010)	USA	Head and neck	8	S-TOFHLA	Score <53	38%	3
Gupta *et al.* (2020)	India	Multiple	224	S-TOFHLA	Score ≤16	48%	3
Koay *et al.* (2013)	Australia	Head and neck, lung	93	S-TOFHLA HeLMS	S-TOFHLA: NR HeLMS: Score ≤3	S-TOFHLA: 12% HeLMS: 17%	5

*Multiple refers to more than three tumour sites. **Includes number of review eligible participants (adults with cancer). Abbreviations: BRIEF, Brief Health Literacy Screening Tool; CCHL, Swedish Communicative and Critical Health Literacy Scale; CHLT-6, six-item Cancer Health Literacy Test; FHL, Swedish Functional Health Literacy Scale; Health LiTT, Health Literacy Assessment Using Talking Touchscreen Technology; HeLMS, Health Literacy Management Scale; HLS-EU-Q, European Health Literacy Survey Questionnaire; NVS, Newest Vital Sign; REALM, Rapid Estimate of Adult Literacy in Medicine; SAHL, Short Assessment of Health Literacy; SBSQ, Set of Brief Screening Questions, SILS, Single Item Literacy Screener; S-KHLT, Short form of the Korean Functional Health Literacy Test; S-TOFHLA, Short-Test of Functional Health Literacy in Adults

The reported prevalence across included studies ranged from 3-86%, but comparisons between studies are difficult due to the different measures and cut-offs used to determine HL. The study reporting a prevalence of 3% lower HL (Xia *et al.*, 2019) included individuals likely to have high HL, as being able to independently participate in a cancer rehabilitation club formed part of the inclusion criteria. In addition, the Chew questions were used, with a cut off of ≥11/15 to identify lower HL. This threshold is higher than used by other studies using the same screening questions, and these studies reported a higher prevalence (Chrischilles *et al.*, 2019; Nilsen *et al.*, 2020). Further explanation of the Chew question scoring can be found in Section 2.4.2.3.

At the other end of the range, İlhan *et al.* (2020) reported a prevalence of 86% inadequate HL using the Turkish HLS-EU-Q measure. This may relate in part to low levels of education within the sample, as two thirds of participants reported a level of middle school or lower. However, a comparative survey of eight European countries using the HLS-EU-Q reported a range in prevalence of limited HL (insufficient or problematic) from 29% in The Netherlands to 62% in Bulgaria (Sørensen *et al.*, 2015), suggesting this more comprehensive measure identifies a greater number of individuals who might be experiencing difficulties with HL.

3.3.2 Outcomes relating to HL in patients with cancer

Fifty-eight papers relating to 52 studies addressed this objective, of which 49 studies were of quantitative non-randomised design. The majority were conducted in the USA (31/52), and the most common HL assessment tools were variations on the Chew questions (16/52) and REALM (12/52). Breast (*N*=12) and prostate cancer (*N*=8) were the most studied individual tumour sites, and a further 21 studies included participants with a variety of cancer diagnoses. Thirty-two papers were considered higher quality (MMAT score 4/5 or 5/5). See Table 3 for details of included studies and Table 4 for a summary of reported associations between HL and outcomes.

Table 3 – Included papers reporting associations with HL

Author, year, location	**Study description**	**Cancer site(s) (no. participants*)**	**Outcomes**	**MMAT score**
Anderson, 2021, USA	Survey of female cancer survivors with at least one comorbidity from two cancer centres	Multiple (183)	Impact of cancer self-management on psychosocial functioning Perceived general health	3
Bol, 2018, The Netherlands	Cross sectional online survey of older (>65 years) cancer patients from two hospitals, an online panel, and a research panel.	Multiple (197)	Recall of information	3
Brewer, 2009, USA	Cross sectional self-administered questionnaire assessing risk communication formats with women post-surgery in single centre	Breast (163)	Estimating and interpreting recurrence risk Impact of risk results Ease of understanding formats.	5
Brewer, 2012, USA	Cross sectional randomised study testing risk communication formats with women eligible for genomic recurrence risk test in single centre	Breast (133)	Participant perception of how well results understood Trust in the accuracy of the test result	4
Busch, 2015, USA	Cohort study taking random sample (stratified according to self-reported years of education) from larger prospective, multi-site, observational study	Colorectal (347)	Receipt of adjuvant chemotherapy Survival	4
Cartwright, 2017, USA	Secondary analysis of data from cancer patients within five years of first cancer diagnosis, with valid medical record data, participating in cohort study	Multiple (752)	Number of admissions Days hospitalised 30-day readmission	5
Chan, 2020, Malaysia	Cohort survey of patients with cancer attending single cancer centre	Multiple (345)	Preference for patient centred care	4
Chang, 2019, Taiwan	Cross sectional descriptive study of patients with cancer attending single centre	Multiple (120)	Patient’s assessment of degree of SDM	4
Chrischilles, 2019, USA	Cross sectional questionnaire and linked cancer registry data from random sample of patients with breast cancer at eight centres	Breast (835)	Quality of life Upper extremity disability	4

Author, year, location	**Study description**	**Cancer site(s) (no. participants*)**	**Outcomes**	**MMAT score**
Clarke, 2021, Ireland	National postal survey of patients within 5 years of diagnosis	Head and neck (395)	Health related quality of life Use of self-management behaviours Fear of recurrence	4
Douma, 2012, The Netherlands	Longitudinal questionnaire study of radiotherapy outpatients at single centre	Multiple (104)	Information needs	3
Eton, 2019, USA	Survey and records review, part of larger prospective study, of cancer patients with at least one other chronic comorbid condition	Multiple (91)	Health related quality of life Treatment burden	2
Gonderen Cakmak, 2020, Turkey	Questionnaire study of medical oncology outpatients attending a single centre	Multiple (100)	Oral chemotherapy adherence	3
Goodwin, 2018, Australia	Cross sectional questionnaire study of members of prostate cancer support groups	Prostate (565)	Quality of life	3
Gunn, 2020, USA	Secondary analysis of data collected from randomised controlled trial at single centre	Breast (228)	Cancer related needs Patient self-efficacy	3
Gupta, 2020, India	Questionnaire study of patients receiving chemotherapy at single centre	Multiple (224)	Adverse drug reactions	3
Hahn, 2010, USA	Cross sectional survey, convenience sample of cancer patients in waiting rooms of two clinics providing care to uninsured populations	Multiple (97)	Health related quality of life Informed consent comprehension	5
Halbach, 2016, Germany	Part of prospective, longitudinal, multicentre cohort study, assessment during inpatient stay and subsequent postal survey	Breast (1060)	Unmet information needs	2
Halbach, 2016, Germany	Part of prospective, longitudinal, multicentre cohort study, assessment during inpatient stay and subsequent postal survey of older (>65 years) patients	Breast (413)	Fear of progression	3
Hendren, 2011, USA	Analysis of data prospectively collected for multi-site randomised study of patient navigation, used survey data from navigation arm	Breast and colorectal (103)	Patient navigation time	4

Author, year, location	Study description	Cancer site(s) (no. participants*)	Outcomes	MMAT score
Heß, 2020, Germany	Questionnaire study of patients admitted for inpatient cancer rehabilitation at single centre	Breast, prostate, colorectal (449)	Unexpressed needs	3
Heuser, 2019, Germany	Part of a prospective, longitudinal, multicentre cohort study, assessment during inpatient stay and subsequent postal survey	Breast (863)	Participation in multidisciplinary tumour conferences	3
Husson, 2015, The Netherlands	Longitudinal population-based survey from registry of patients	Colorectal (1643)	Health related quality of life Physical activity Mental distress	5
İlhan, 2020, Turkey	Cross sectional questionnaire of outpatients treated at single chemotherapy unit	Multiple (207)	Self-care management	4
Inglehart, 2016, USA	Sub-study of prospective cohort questionnaire study of patients at single cancer centre	Head and neck (372)	Human papilloma virus (HPV) related knowledge Information seeking behaviour	5
Janz, 2017, USA	Cross sectional survey and data from registry database of women with early stage breast cancer	Breast (1295)	Doctor-patient communication regarding risk	2
Jiang, 2019, USA	Longitudinal survey study of patients receiving capecitabine for gastrointestinal malignancy	Multiple (50)	Chemotherapy adherence	5
Joyce, 2020, USA	Cross sectional survey of men with prostate cancer attending two centres	Prostate (38)	Treatment regret	3
Kappa, 2017, USA	Retrospective notes review of patients who had undergone radical cystectomy at single centre	Bladder (504)	Use of post-operative discharge services	3
Kim, 2001, USA	Evaluation of CD-ROM shared decision-making aid by newly diagnosed patients at single centre	Prostate (30)	Prostate cancer knowledge	3
Koay, 2013, Australia	Cross sectional survey of patients recently diagnosed with lung or head and neck cancer at single centre	Head and neck, lung (93)	Distress	5

Author, year, location	**Study description**	**Cancer site(s) (no. participants*)**	**Outcomes**	**MMAT score**
Lee, 2018, South Korea	Cross sectional self-report questionnaire of older cancer patients (>60 years) who had undergone chemotherapy at single centre	Lung (80)	Quality of life Self-care behaviours	4
Lillie, 2007, USA	Cross sectional self-administered questionnaire study of women post treatment for early stage disease at single centre	Breast (163)	Preference for participation in decision making Retention of information Desire for additional information	4
Lim, 2019, Australia	Cross sectional survey of Chinese migrant cancer patients and carers from community support groups or identified through medical records	Multiple (68)	Cancer care coordination	4
Mahal, 2015, USA	Data from prospective, multi-site study of men with prostate cancer using records and questionnaires	Prostate (375)	Unproven use of early salvage androgen deprivation therapy (ADT)	4
Matsuyama, 2011, USA	Cross sectional questionnaire study of patients undergoing cancer treatment at two sites	Multiple (138)	Information needs	4
McDougall, 2018, USA	Cross sectional self-administered survey of patients identified through cancer registry, with oversampling of Hispanic and rural patients	Colorectal (277)	Cancer treatment related financial hardship Non-adherence to surveillance guidelines	4
McDougall, 2019, USA	Cross sectional self-administered survey of patients identified through cancer registry, with oversampling of Hispanic and rural patients	Colorectal (301)	Health related quality of life	4
Mohan, 2009, USA	Cross sectional self-administered survey of newly diagnosed men with localised prostate cancer from single centre	Prostate (184)	Perceived decrease in longevity with observation Perceived increase in longevity with treatment	4
Nakata, 2020, Germany	Part of a prospective, longitudinal, multicentre cohort study, assessment during inpatient stay and subsequent postal survey	Breast (927)	Need for psycho-oncological care	3
Nilsen, 2019, USA	Retrospective analysis of routine data from survivorship clinic questionnaire	Head and neck (218)	Quality of life	5

Author, year, location	**Study description**	**Cancer site(s) (no. participants*)**	**Outcomes**	**MMAT score**
Ousseine, 2020, France	Analysis of survey data from patients registered on disease database	Multiple (4045)	Medico-social follow up Cancer related fatigue Depression and anxiety Sequelae following treatment	4
Ozkaraman, 2019, Turkey	Cross sectional questionnaire study of patients attending medical oncology clinics at single centre	Multiple (111)	Quality of life Self-efficacy	4
Parker, 2020, USA	Cross sectional survey of women with early stage disease at single centre	Breast (46)	Chemotherapy knowledge	3
Plummer, 2017, Australia	Cross sectional telephone survey of women who had completed treatment for breast cancer at single centre	Breast (36)	Physical activity	4
Polite, 2019, USA	Single centre study testing effectiveness of a multimedia cancer clinical trials intervention	Lung, gastric and pancreatic (120)	Clinical trial attitudes, knowledge, and interest	4
Post, 2020, USA	Cross-sectional web-based self-report national survey of women with early stage breast cancer	Breast (298)	Knowing participation in change Patient activation	4
Rust, 2015, USA	Randomised controlled trial of medication adherence skills training, patients recruited from community support organisations	Breast (48)	Medication self-efficacy and adherence	2
Scarpato, 2016, USA	Retrospective database review of patients who had undergone radical cystectomy at single centre	Bladder (368)	Post-operative complications Readmission	3
Smith, 2020, Australia	Cross-sectional self-report questionnaire study	Multiple (150)	Knowledge and attitudes regarding clinical trials	3
Song, 2012, USA	Cross sectional multi-centre study using in-person structured questionnaires and records review	Prostate (1581)	Health related quality of life	3

Author, year, location	**Study description**	**Cancer site(s) (no. participants*)**	**Outcomes**	**MMAT score**
Tagai, 2020, USA	Cross sectional questionnaire study at four centres using baseline data from earlier randomised controlled trial	Prostate (431)	Self-efficacy for re-entry Perceptions of medical interactions Practical concerns	4
Turkoglu, 2019, Turkey	Cross sectional study of patients who had undergone surgery for bladder cancer at single centre	Bladder (126)	Compliance with cystoscopic follow up and treatment as per protocol	2
Watson, 2020, USA	Cross sectional questionnaire and selected interviews with women receiving oral anticancer treatment	Gynaecological (100)	Medication adherence	3
Winton, 2016, USA	Cross sectional study of women with breast cancer at single centre	Breast (336)	Type of initial operation for operable breast cancer	5
Wolpin, 2016, USA	Single centre observational study of eye-tracking data whilst participants used a web-based treatment decision intervention	Prostate (26)	Eye tracking patterns	2
Xia, 2019, China	Cross sectional survey of patients with cancer attending rehabilitation club	Multiple (4589)	Quality of life	4
Yen, 2020, USA	Secondary analysis of data from randomised controlled trial at four centres	Breast (311)	Observed SDM	3

* Includes adults with cancer only. Multiple refers to more than three tumour sites

Table 4 – Association of outcomes to HL reported by included studies

Category	Association	Outcomes
Information processing	Lower HL:	Lower understanding (Brewer *et al.*, 2009; Brewer *et al.*, 2012) Poorer estimation of recurrence risk (Brewer *et al.*, 2009) Greater information needs and greater decrease in needs over time (Matsuyama *et al.*, 2011; Douma *et al.*, 2012; Halbach *et al.*, 2016b) More time spent on prognostic information and infographic (Wolpin *et al.*, 2016)
	Higher HL:	Higher recall (Lillie *et al.*, 2007; Bol *et al.*, 2018) Greater knowledge (Kim *et al.*, 2001; Inglehart *et al.*, 2016; Parker *et al.*, 2020; Smith *et al.*, 2020)
Decision making	Higher HL:	Preference for more active participation (Lillie *et al.*, 2007) Higher perceived involvement (Chang, Li and Lin, 2019)
	No association:	Preference for more active participation (Polite *et al.*, 2019) Observed SDM (Yen *et al.*, 2020)
Quality of life	Lower HL:	Poorer quality of life (Song *et al.*, 2012; Husson *et al.*, 2015; Goodwin *et al.*, 2018; Lee, Lee and Chang, 2018; Chrischilles *et al.*, 2019; Eton *et al.*, 2019; McDougall *et al.*, 2019; Ozkaraman *et al.*, 2019; Xia *et al.*, 2019; Nilsen *et al.*, 2020; Anderson *et al.*, 2021; Clarke *et al.*, 2021)
	No association:	Quality of life (Hahn *et al.*, 2010)
Treatment and health service use	Lower HL:	Increased number and length of hospital admissions (Cartwright *et al.*, 2017) Increased likelihood of GP follow-up for cancer (Ousseine *et al.*, 2020) Increased use of post-operative discharge services (Kappa *et al.*, 2017) Increased likelihood of treatment complications (Scarpato *et al.*, 2016; Gupta *et al.*, 2020)
	Higher HL:	Increased odds of receiving chemotherapy (Busch *et al.*, 2015) Increased likelihood of breast reconstruction (Winton *et al.*, 2016) Lower likelihood of receiving unproven treatment (Mahal *et al.*, 2015) Greater treatment continuity (Turkoglu *et al.*, 2019)
	No association:	Hospital admissions and emergency department visits (Scarpato *et al.*, 2016) Adherence to recommended follow up (McDougall *et al.*, 2018)
Medication adherence	Higher HL:	Higher medication adherence (Rust, Davis and Moore, 2015; Jiang *et al.*, 2019; Gonderen Cakmak and Uncu, 2020)
	No association:	Medication adherence (Watson *et al.*, 2020)
Care coordination	Lower HL:	Poorer experience of care coordination (Lim *et al.*, 2019b) Greater requirement for patient navigation assistance (Hendren *et al.*, 2011) Lower likelihood of patient participation in multidisciplinary tumour conferences (Heuser *et al.*, 2019)

Category	**Association**	**Outcomes**
Other	Lower HL:	Lower levels of physical activity (Husson *et al.*, 2015; Plummer and Chalmers, 2017) Higher cancer related and unexpressed needs (Gunn *et al.*, 2020; Hes *et al.*, 2020) Greater need for psychological support (Nakata *et al.*, 2020) Increased financial hardship (McDougall *et al.*, 2018) Increased fear of progression or recurrence (Halbach *et al.*, 2016a; Clarke *et al.*, 2021) Greater treatment regret (Joyce *et al.*, 2020) Lower self-care management (İlhan *et al.*, 2020)
	Higher HL:	Greater self-efficacy (Gunn *et al.*, 2020; Tagai *et al.*, 2020) Preference for patient centred care (Chan *et al.*, 2020) Greater patient engagement (Post *et al.*, 2020)
	No association:	Mortality (Busch *et al.*, 2015) Distress (Koay *et al.*, 2013) Perception of doctors' communication of recurrence risk (Janz *et al.*, 2017) Perceived changes to longevity with treatment or observation (Mohan *et al.*, 2009)

3.3.2.1 Information processing

Five higher and seven lower quality studies considered outcomes relating to information processing. Lower HL was associated with lower ease of understanding, as well as higher and more variable estimates of risk relating to breast cancer recurrence in women with early-stage disease (Brewer *et al.*, 2009; Brewer *et al.*, 2012). Participants with lower HL had significantly higher unmet information needs in another large (*N*=1060) study of patients with newly diagnosed breast cancer, although confounding variables were not controlled for (Halbach *et al.*, 2016b). A smaller but higher quality study of patients with mixed tumour sites, which did consider confounders, reported a significant association between HL and information needs in bivariate analysis only (Matsuyama *et al.*, 2011). For radiotherapy outpatients with lower HL, the need for information about treatment at a single centre decreased significantly from pre-initial consultation to 3-5 weeks after the initial visit (Douma *et al.*, 2012), though again, confounders, including time between consultations and treatment course length, were not accounted for.

Higher HL was associated with higher information recall in patients with breast cancer and in older patients with mixed tumour sites (Lillie *et al.*, 2007; Bol *et al.*, 2018). It was also associated with greater disease specific knowledge about human papilloma virus (HPV) among patients with head and neck cancer (Inglehart *et al.*, 2016), greater prostate cancer knowledge in patients with the disease (Kim *et al.*, 2001), trials knowledge (Smith *et al.*, 2020) and, in a small single centre study, with chemotherapy knowledge (Parker *et al.*, 2020). A small study of patterns of eye tracking reported a difference between time spent on aspects of a web-based prostate cancer decision aid by those with higher and lower HL (Wolpin *et al.*, 2016). Those with lower HL appeared to spend longer on the prognostic text and infographic, but this was based on limited data from 12 participants.

3.3.2.2 Decision making

Four studies exploring HL and decision making (three of higher quality) found mixed results. Using self-report measures, an association between higher HL and preference for more active participation in decision making was reported in one study of women making decisions about breast cancer recurrence risk testing (Lillie *et al.*, 2007), and with higher perceived involvement in SDM in another cross-sectional study of cancer patients at a single centre (Chang, Li and Lin, 2019). Yet no association was found when assessing preference for involvement in decision making regarding participation in clinical trials (Polite *et al.*, 2019). A secondary analysis of data from a randomised controlled trial evaluating decision aids for breast cancer, the only study to measure observed SDM, did not find a difference according to HL (Yen *et al.*, 2020). The chosen cut point for the HL screening question was higher than is recommended (Wallace *et al.*, 2006; Chew *et al.*, 2008), with a higher sensitivity but lower specificity for detecting lower HL, which may account for the lack of difference seen (Type 2 error).

3.3.2.3 Quality of life

Twelve studies, of which eight were higher quality and five had over 500 participants, reported an association between lower HL and poorer quality of life. Studies included patients with colorectal (Husson *et al.*, 2015; McDougall *et al.*, 2019), breast (Chrischilles *et al.*, 2019), prostate (Song *et al.*, 2012; Goodwin *et al.*, 2018), lung (Lee, Lee and Chang, 2018), head and neck (Nilsen *et al.*, 2020; Clarke *et al.*, 2021) and mixed tumour sites (Eton *et al.*, 2019; Ozkaraman *et al.*, 2019; Xia *et al.*, 2019; Anderson *et al.*, 2021), and used a variety of HL and quality of life assessment tools. Only a single survey did not find a significant difference in quality of life between patients with low and higher HL (Hahn *et al.*, 2010), which may be due to its relatively small sample size compared with other large higher quality studies (Husson *et al.*, 2015; Chrischilles *et al.*, 2019; Xia *et al.*, 2019). The study included a convenience sample of 97 patients with mixed tumour sites recruited from the waiting rooms of two clinics and assessed HL using three tools. Lower HL ranged from 5%-46% using the different measures, though the authors found no association between any measure and quality of life.

3.3.2.4 Treatment and health service use

Eleven studies considered treatment and health service use, six of which were higher quality. Higher HL was significantly associated with increased odds of receiving adjuvant chemotherapy for stage III/IV colorectal cancer (Busch *et al.*, 2015). It was also associated with increased likelihood of reconstruction after mastectomy in a cross sectional study of 336 underinsured women with breast cancer attending a single centre (Winton *et al.*, 2016), though this did not reach significance in multivariate analysis (P=0.06) after adjusting for language, palpable mass, clinical stage, and surgeon (Winton *et al.*, 2016). No association between insurance status and reconstruction was found, though almost all participants were underinsured, and the overall rate of reconstruction was low. A further study of men with prostate cancer identified a trend for those with higher HL having a lower likelihood of undergoing unproven salvage androgen deprivation therapy for prostate specific antigen (PSA) recurrence (Mahal *et al.*, 2015), but this was again significant in univariable analysis only. In a single centre study of patients receiving chemotherapy, those with lower HL experienced more grade 3 and above adverse drug reactions (Gupta *et al.*, 2020).

Although no association was found in one retrospective study (Scarpato *et al.*, 2016), lower HL was significantly associated with increased number and length of hospital admissions in a cohort study of patients with mixed tumour sites (*N* = 752) (Cartwright *et al.*, 2017) after controlling for diagnosis, receipt of chemotherapy, comorbidities and other variables. In a national survey of 4045 French cancer survivors 5 years post diagnosis, those with lower HL were more likely to see their general practitioner for cancer follow up, which may suggest increased health service use, though data on frequency, reasons for visits, and contact with a specialist were not collected (Ousseine *et al.*, 2020).

Patients requiring post-cystectomy discharge services in one centre had lower HL scores; significant on bivariate analysis (Kappa *et al.*, 2017), however, a change in practice during the study period leading to increased numbers of patients receiving discharge services regardless of risk factors is likely to have affected outcomes. In the same centre, those with lower HL were significantly more likely to experience a minor post-operative complication (Scarpato *et al.*, 2016). Treatment continuity for patients with non-muscle invasive bladder cancer was significantly higher in those with adequate HL in another study (Turkoglu *et al.*, 2019), but it is not clear how this was assessed, and confounders were not controlled for. In another study, self-reported adherence to follow up after bowel cancer was not associated with HL (McDougall *et al.*, 2018).

3.3.2.5 Medication adherence

Four studies, of which one was higher quality (Jiang *et al.*, 2019), explored the association between HL and oral medication adherence. Adherence to general medications (Rust, Davis and Moore, 2015), specific oral chemotherapy (capecitabine) (Jiang *et al.*, 2019), and various anti-cancer medications, including hormonal and targeted treatments (Gonderen Cakmak and Uncu, 2020; Watson *et al.*, 2020) was assessed. Higher HL was associated with higher levels of adherence in three studies of up to 100 participants (Rust, Davis and Moore, 2015; Jiang *et al.*, 2019; Gonderen Cakmak and Uncu, 2020). One study of patients with gynaecological cancers (*N* = 100) did not report a significant association, though it was not powered to detect predictors of non-adherence (Watson *et al.*, 2020). All but one study (Jiang *et al.*, 2019) relied on self-report.

3.3.2.6 Care coordination

Three studies considered aspects of care coordination, of which two were small but higher quality (Hendren *et al.*, 2011; Lim *et al.*, 2019b). One survey of Chinese migrants with cancer in Australia found a positive correlation between higher HL and better experience of care coordination (Lim *et al.*, 2019b). Another, of patients with mixed tumour sites (Hendren *et al.*, 2011), found an association between lower HL and higher input required from a patient navigator, although this did not remain significant in multivariate analysis. The third study involving 863 women with breast cancer found those with 'inadequate' HL, as determined by the HLS-EU-Q16, were significantly less likely to participate in multidisciplinary tumour conferences than those with 'sufficient' HL (Heuser *et al.*, 2019).

3.3.2.7 Other outcomes

The remaining studies explored a range of other outcomes. Lower HL was associated with lower levels of physical activity, significant on bivariate analysis in a large study of patients with colorectal cancer (Husson *et al.*, 2015), and in stepwise regression analysis of patients with breast cancer (Plummer and Chalmers, 2017). It was also associated with higher cancer-related (Gunn *et al.*, 2020) and unexpressed needs (Hes *et al.*, 2020), increased likelihood of need for psychological support (Nakata *et al.*, 2020), increased fear of progression in a study of older patients with breast cancer (Halbach *et al.*, 2016a), higher fear of recurrence in patients with head and neck cancers (Clarke *et al.*, 2021), and greater treatment regret in a small study of men with prostate cancer (Joyce *et al.*, 2020). McDougall *et al.* (2018), found lower HL was independently associated with increased cancer treatment related financial hardship, as were rural residence, age, race/ethnicity, and marital status. It is important to note however, that income at the time of diagnosis and insurance status, which were likely to have also been associated, were not established. Self-care management scores were lower for patients with lower HL in another single centre study (İlhan *et al.*, 2020). Higher HL was associated with greater preference for patient centred care (Chan *et al.*, 2020), patient engagement (Post *et al.*, 2020), and self-efficacy in two studies (Gunn *et al.*, 2020; Tagai *et al.*, 2020), though no association was found in a third single-centre study (Ozkaraman *et al.*, 2019).

Mortality (Busch *et al.*, 2015), distress (Koay *et al.*, 2013), perception of doctors' communication of recurrence risk (Janz *et al.*, 2017) and perceived changes to longevity with treatment or observation (Mohan *et al.*, 2009) were not associated with HL.

3.3.3 The role and consequences of HL as patients with cancer access, understand, appraise, and use information and services to make decisions about health

Eight qualitative studies were identified and add the patient voice to the findings of this review (Table 5). Studies included patients with prostate (Zanchetta *et al.*, 2007; Oliffe *et al.*, 2011; Kayser *et al.*, 2015), breast (Rust and Davis, 2011; Burks *et al.*, 2020) and haematological malignancies (Cohen *et al.*, 2013). One included patients with different primary tumours (Martinez-Donate *et al.*, 2013) and one study did not report on tumour site (Treloar *et al.*, 2013). Only three studies used a HL assessment tool. Of these, one found none of the 30 participants who completed the measure had lower HL (Martinez-Donate *et al.*, 2013), another reported 6/20 participants had lower HL (Burks *et al.*, 2020), and the third study used the Health Literacy Questionnaire as a framework, comparing themes with scores, but did not report on the proportion with lower HL (Kayser *et al.*, 2015). The remaining studies explored the concept of HL in people with cancer without carrying out a formal assessment. Six studies were higher quality according to the MMAT, and one mixed methods study scored highly for the qualitative component but achieved a lower score overall.

Table 5 - Qualitative studies exploring role of HL in patients to access, understand, appraise, and use information and services to make decisions about health

Author (year) location	Aim/objectives	Study design, methods, analysis	Sample characteristics (number, tumour sites, age range, sex)	Themes	MMAT score
Burks *et al.* (2020) USA	To assess perceptions of risks, benefits, and informed consent process for patients enrolled in phase 2 clinical trial of intra-operative radiation therapy, nested study exploring how perceptions of risks/benefits of trial enrolment differed based on HL	Structured interviews with convenience sample of participants already recruited to phase 2 parent study and who had completed their three month follow up visit. HL measured using Set of Brief Screening Questions. Inductive open coding and constant comparative analysis.	20 participants, early stage breast cancer, 45-90 years, 100% female 6/20 lower HL according to screening questions	Weight of risks and benefits Pragmatic decision making Confidence in provider recommendation	5
Cohen *et al.* (2013) USA	To describe the meaning of patients' experiences with hematopoietic stem cell transplantation (HSCT), with a focus on HL.	Interviews using open ended questions conducted at five time points from pre-transplantation to 100 days post. Hermeneutic phenomenologic, descriptive, and interpretive research methods. Analysis of interviews and discussion until consensus reached by research team. Interviews continued until saturation and 20 participants from each ethnic group.	60 participants, haematological malignancies, undergoing stem cell transplant, 22-71 years, 50% female	They did not tell me Decision dilemmas Fears of dying Tough symptoms and side effects Relying on others	5
Kayser *et al.* (2015) Denmark	To explore whether scores and responses to the Health Literacy Questionnaire (HLQ) can identify individuals in need of information and support, reveal differences in perception and understanding in health-related situations within couples and explore whether the HL domains of the HLQ emerged as themes important to the men and their spouses.	Mixed methods approach. Patients and spouses interviewed separately using HLQ as framework. Transcripts analysed by one author. Key concepts and preliminary themes identified, then relationship between men and spouses analysed pairwise to create summary for couple. Summaries used inductively to identify further themes and confirm those from transcripts, and compared with HLQ scores to explore reported and actual differences within couples.	8 patient participants, early stage prostate cancer, 55-70 years, 100% male	Involvement of their spouses and people around them Their support from and interaction with healthcare professionals Their use of the Internet for information retrieval	3

Author (year) location	**Aim/objectives**	**Study design, methods, analysis**	**Sample characteristics (number, tumour sites, age range, sex)**	**Themes**	**MMAT score**
Martinez-Donate *et al.* (2013) USA	To identify the HL barriers and patient navigation needs of rural cancer patients in Wisconsin using the Chronic Care Model as a guiding and integrative framework.	Mixed methods approach. Face-to-face semi-structured interviews with patients from five centres. HL assessment performed (S-TOFHLA). Closed question survey completed by telephone. Focus groups and surveys with clinical staff. Transcripts coded inductively and deductively by trained researcher. Two research assistants reviewed coding and themes, and all met frequently to compare. Frequency and salience of themes analysed and integrated using Chronic Care Model Framework. Quantitative data integrated with qualitative analysis.	53 participants, multiple tumour sites (breast, lung, colorectal, prostate), 39-86 years, 63% female 0/30 lower HL according to S-TOFHLA (remaining participants did not complete)	Community Characteristics Self-management support Delivery System Design Decision Support	2
Oliffe *et al.* (2011) Canada	To describe how men who attend prostate cancer support groups (PCSGs) engage with HL and consumerism.	Part of larger ethnographic study. Participant observation at meetings of 16 participating groups. Field work and observations at provincial and national PCSG meetings and fundraising events. Individual interviews. Two researchers discussed and compared observations. Interview and observation data read by each author, and analyses developed during team meetings.	54 participants, prostate cancer, 53-87 years, 100% male	Numbers and measures as the foundation of prostate cancer literacy Group information processing Shopping around	5
Rust and Davis (2011) USA	To explore the issues of HL and medication adherence among underserved breast cancer survivors	Two focus groups of 12 participants each. Tapes transcribed and coded by one author; transcripts sent to other authors. Analysis based on grounded theory. Open coding, data compared for similarities/differences. Coding into categories, categories combined to form themes.	24 participants, breast cancer, age range not reported, 100% female	Inequality of access to health information Acquisition of medication information Medication usage and adherence Barriers to access to medications	5

Author (year) location	Aim/objectives	Study design, methods, analysis	Sample characteristics (number, tumour sites, age range, sex)	Themes	MMAT score
Treloar *et al.* (2013) Australia	To understand and integrate the perspectives of Aboriginal people, their carers and health workers regarding the HL required for engaging with cancer screening, diagnosis, care, and treatment.	Semi-structured in-depth interviews with patients, carers, and healthcare workers. Majority of interviews with patients and carers conducted by trained Aboriginal interviewers. Data coded for six major themes developed from the literature. Interpretive description used to inform analysis.	22 patient participants, tumour sites and age range not reported, 73% female	Recognising susceptibility to cancer Recognising opportunities to learn from each other Opportunities for practical services and programmes for HL in relation to cancer	5
Zanchetta *et al.* (2007) Canada	To describe, analyse, and understand the participants' ways of understanding and dealing with prostate cancer-related information as demonstrated by their informational strategies.	Open-ended, semi-structured interviews, journals, personal documents, genograms, ecomaps, observational notes. Transcripts divided into three levels of HL, patterns within groups identified. Genograms and ecomaps analysed to identify patterns among health-and-illness-related events. Understanding checked after each interview, six interviewees checked summary of interpretation.	15 participants, localised prostate cancer, 61-83 years, 100% male	Social and informational networks Overcoming professional medical language Spiritual and emotional influences Literacy levels Silence among men Deductive and hypothetical reasoning	4

Table 6 demonstrates how the original themes reported by the individual studies were grouped to form meta-themes. The meta-themes identified included situational influences (networks and system), personal influences, information processing, and consequences of HL. Situational influences refer to factors external to the person which influence their ability to process information. They include network influences, incorporating sources of information and support outside of the healthcare environment, and system influences, relating to professionals within the healthcare system and structural factors involved in care delivery. Personal influences refer to internal factors that might contribute to HL, such as prior experience, cultural values, and emotions. Information processing encompasses the strategies described by patients to help them process the information received. Consequences refer to the outcomes of these influences and processing, and include negative aspects, such as fear or uncertainty, as well as more positive outcomes, such as empowerment and better understanding.

Table 6 - Meta-themes and the contributory themes extracted from original papers

Meta-themes	**Themes from original papers**
Situational influences - Networks	Relying on others (Cohen *et al.*, 2013) Involvement of their spouses and the people around them (Kayser *et al.*, 2015) Group information processing (Oliffe *et al.*, 2011) Recognising opportunities to learn from each other (Treloar *et al.*, 2013) Social and informational networks (Zanchetta *et al.*, 2007) Their use of the internet for information retrieval (Kayser *et al.*, 2015) Pragmatic decision making(Burks *et al.*, 2020)
Situational influences - System	Overcoming professional medical language (Zanchetta *et al.*, 2007) Self-management support (Martinez-Donate *et al.*, 2013) Delivery system design (Martinez-Donate *et al.*, 2013) Support from and interaction with healthcare professionals (Kayser *et al.*, 2015) Opportunities for practical services and programmes for health literacy in relation to cancer (Treloar *et al.*, 2013) Inequality of access to health information (Rust and Davis, 2011) They did not tell me (Cohen *et al.*, 2013) Decision support (Martinez-Donate *et al.*, 2013) Confidence in provider recommendation (Burks *et al.*, 2020)
Personal influences	Recognising susceptibility to cancer (Treloar *et al.*, 2013) Community characteristics (Martinez-Donate *et al.*, 2013) Spiritual and emotional influences (Zanchetta *et al.*, 2007) Literacy levels (Zanchetta *et al.*, 2007) Silence among men (Zanchetta *et al.*, 2007)
Information processing	Numbers and measures as the foundation of prostate cancer literacy (Oliffe *et al.*, 2011) Deductive and hypothetical reasoning (Zanchetta *et al.*, 2007) Weight of risks and benefits (Burks *et al.*, 2020)

Meta-themes	Themes from original papers
Consequences	Shopping around (Oliffe *et al.*, 2011) Decision dilemmas (Cohen *et al.*, 2013) Fears of dying (Cohen *et al.*, 2013) Tough symptoms and side-effects (Cohen *et al.*, 2013) Medication usage and adherence (Rust and Davis, 2011) Acquisition of medication information (Rust and Davis, 2011)

3.3.3.1 Situational influences

All eight papers described themes relevant to the role of external situational influences on HL. Two key areas were identified: the importance of networks, which were largely supportive and facilitated understanding; and the system, which often acted as a barrier to HL development.

3.3.3.2 Situational influences - Networks

Social and informational networks played important roles as facilitators of HL and were among the situational resources available to patients enabling them to access, understand, appraise, and use information and services. Although some participants expressed a preference to deal with their diagnosis by themselves (Kayser *et al.*, 2015), many relied on friends and family for information and support (Zanchetta *et al.*, 2007; Oliffe *et al.*, 2011; Cohen *et al.*, 2013; Kayser *et al.*, 2015; Burks *et al.*, 2020). Learning from other patients about their experiences, often through support groups or organisations, allowed participants to develop a greater understanding of their diagnosis and treatment (Zanchetta *et al.*, 2007; Oliffe *et al.*, 2011; Cohen *et al.*, 2013). Support groups also offered participants the opportunity to hear from and talk to ‘experts’ outside the consultation setting, helping build confidence to ask questions:

> You find confidence and get encouraged to talk to health professionals, ask questions, and that will only come through building confidence. If you have any problem, try to seek the answer for it (73 year old attendee at prostate cancer support group for 14 years) (Oliffe et al., 2011).

Only occasionally, these social connections acted as barriers, such as when the knowledge imparted was inaccurate or led to increased fear (Treloar *et al.*, 2013). The internet was a valuable resource for many participants, who used it to find further information and additional support (Oliffe *et al.*, 2011; Cohen *et al.*, 2013; Kayser *et al.*, 2015; Burks *et al.*, 2020).

3.3.3.3 Situational influences - System

HL was also influenced by ‘system’ factors outside participants’ control. Professionals within the healthcare system played a vital role in imparting information, and, when done well, participants’ confidence in their clinicians made them feel more comfortable in their decision making (Burks *et al.*, 2020). Yet this information giving was not always done in a way participants could understand (Zanchetta *et al.*, 2007; Martinez-Donate *et al.*, 2013):

> They used too many big words… It is a complicated procedure. They explained everything, but you still don't get it. (35 year old postal carrier undergoing stem cell transplant) (Cohen et al., 2013).

The healthcare system itself placed high demands on participants' HL, through inconsistent access to resources and opportunities to further understanding (Rust and Davis, 2011) and over-complicated forms which some participants signed without fully understanding:

> I have signed a lot of papers without reading. I figure they ain't gonna give me nothing to sign if it's bad (rural cancer patient) (Martinez-Donate et al., 2013)

Participants in one study described cancer care as a "foreign" experience and didn't know what to ask about their treatment options (Martinez-Donate *et al.*, 2013), providing support more generally for the recommendations by Treloar *et al.* (2013) for improved community education to raise awareness and help prepare people for such a diagnosis.

3.3.3.4 Personal influences

Participants' HL was also affected by personal influences. These included cultural and community values such as stoicism, which led to patients 'suffering in silence' rather than 'bothering' healthcare professionals (Martinez-Donate *et al.*, 2013) and a "silence among men" impeding open discussion and thus understanding (Zanchetta *et al.*, 2007). Silence was exacerbated by limited prior experience of cancer (Treloar *et al.*, 2013). Participants' general literacy was influenced by social and cultural exposures over time, typically encouragement at school or home, and fed into their approach to learning about their condition (Zanchetta *et al.*, 2007).

3.3.3.5 Information processing

Some participants used strategies to help them process information, highlighted by two studies of male attendees at prostate cancer support groups. Focussing on numbers relating to pathological grading or biomarkers facilitated understanding of prostate cancer and allowed men to assess their options (Oliffe *et al.*, 2011). In another study, patients used a process of deductive and hypothetical reasoning, comparing information from different sources, or comparing themselves with others, to further their understanding, monitor response to treatment, and verify information given by healthcare professionals (Zanchetta *et al.*, 2007). A different study, assessing perceptions of the risks and benefits of participation in a trial of a novel radiotherapy technique for breast cancer, found many participants did not believe there were any risks, and most focussed instead on the positives, such as convenience of treatment, which were influential in their decision to take part (Burks *et al.*, 2020).

3.3.3.6 Consequences

The result of some of these influences and processes can be seen in the wider consequences of HL. Where there was conflicting advice or poor understanding, this led to decision dilemmas, and participants were prepared to accept treatment without full comprehension as a way of moving on and progressing their care (Cohen *et al.*, 2013). When the information patients needed was not given, or not in a way they could understand, they experienced greater fear:

> Many of the things you fear are those you don’t understand (42 year old industrial worker undergoing haematopoietic stem cell transplant) (Cohen et al., 2013).

Poorer prior understanding also led to more unanticipated side effects (Cohen *et al.*, 2013), which in turn influenced decisions about medication adherence (Rust and Davis, 2011).

Conversely, those who developed a good understanding and the confidence to do so were able to effectively navigate the healthcare system and exercise their rights to ensure they received ‘good care’ (Oliffe *et al.*, 2011). Patients accessed information in different ways, influenced by personal factors including the desire not to be a bother, and situational influences, such as time pressures on healthcare staff. When these influences were removed, if patients knew their clinicians well or they appeared to have time to talk, for example, or if patients had the confidence to overcome these influences, it was possible for them to seek and obtain the information they needed (Rust and Davis, 2011).

3.3.4 Interventions to support patients with limited HL in oncology

Addressing some of the issues and influences noted above, ten studies explored what interventions might be helpful in supporting patients with lower HL in this setting (Table 7). Five were conducted in the USA, two in Canada, and one in each of Australia, The Netherlands and Iran. Seven studies included participants with breast cancer, and three recruited participants with varying tumour types. Half were small pilot studies, using a variety of qualitative approaches and quantitative assessments to evaluate the interventions, and half were randomised controlled trials ranging in size from 48 to 615 participants. All studies aside from two (Smith *et al.*, 2019; Rastegar *et al.*, 2020) scored three or lower on the MMAT for methodological reasons.

Five studies involved development of informational tools or resources in conjunction with patient/public representatives (Hart *et al.*, 2015; Jewitt *et al.*, 2016; Iacobelli *et al.*, 2018; Smith *et al.*, 2019; van der Giessen *et al.*, 2020), of which all were well received and rated highly. All included small samples, and none looked for an effect of the intervention on outcomes. Hart *et al.* (2015) developed a set of six informational tools in varying formats to explain different aspects of treatment and care for breast cancer, whilst Iacobelli *et al.* (2018) created a mobile based application for women completing active treatment. Both evaluated the tool through focus groups of women with breast cancer. Smith *et al.* (2019) developed a 'talking book' (a written book with accompanying audio-recording) providing information for patients undergoing radiotherapy, which received positive feedback through semi-structured interviews. Jewitt *et al.* (2016) developed and evaluated an education pamphlet for older patients undergoing stereotactic body radiotherapy, which was reported by patients to be effective regardless of HL as assessed by REALM. The plain language tool developed by van der Giessen *et al.* (2020) in conjunction with patients and low literacy groups was aimed at supporting conversations around breast cancer genetic testing. A survey of healthcare professionals found over half intended to use the guide, and suggestions were made for further improvements.

Using a different approach, but also considering the influence of the system on HL, Bickmore *et al.* (2016) developed and tested a web-based search interface to help patients identify a relevant clinical trial. Although only a small number of participants had lower HL (n=23), more were able to find a correct trial using the intervention compared to those who did not, though this did not reach significance (5/14 intervention, 0/8 control, p=0.05).

Two randomised controlled trials focussed on decision making, both in the context of early stage breast cancer surgery. One tested an interactive decision aid designed to support patients with lower HL (Jibaja-Weiss *et al.*, 2011), and found those who used the aid had better knowledge scores and reported being better informed at the point of making a decision than those who did not. Interestingly, the intervention group demonstrated a preference for the more aggressive surgical option of mastectomy. The second study compared a single page text conversation aid and a four-page pictorial aid (again designed for a lower HL audience) with standard care prior to surgery (Durand *et al.*, 2021). Compared with standard care, the picture option grid improved knowledge, reduced decisional regret and increased SDM. In subgroup analysis, the difference in quality of life between higher and lower HL groups was smaller in the arm using the pictorial aid compared to usual care, but the same was not seen for SDM. There were baseline differences in HL between the three arms, and the option grid arm was smaller with just 69 participants compared to 276 and 271 in the pictorial and usual care arms.

Two small randomised controlled trials involved face to face educational sessions. One looked at a skills development programme for medication adherence (Rust et al., 2015). The two-hour workshop made no difference to HL, self-efficacy, or medication adherence in a pilot study of 48 participants with breast cancer randomised to intervention or control. The authors note, however, that the study was not adequately powered, and participants (many of whom were members of support groups) had high pre-test functional HL, self-efficacy, and adherence scores. The final study compared routine counselling after commencing chemotherapy with sessions tailored to support HL, and found both HL and self-care scores showed a greater increase in the intervention arm compared to control (Rastegar *et al.*, 2020).

Table 7 - Studies of interventions to support patients with lower HL in cancer care

Author (year), location	Study description	Description of intervention	Sample (number, site, stage, age range, % female)	Effect of intervention on outcomes	MMAT score
Hart *et al.* (2015), Canada	Development and focus group evaluation of informational tools involving breast cancer patients with suspected lower HL from single cancer centre	Six informational tools in varying formats (map, videos, timeline, description of staff roles, educational resources)	11 participants, breast cancer, stage not reported, age range not reported, 100% female	Tools all rated highly for addressing information needs and ease of use. Participants would recommend to other patients. The description of healthcare professional roles was rated most highly, and the video of survivor messages the lowest.	2
Iacobelli *et al.* (2018), USA	Development and focus group evaluation of mobile based application to improve HL involving breast cancer patients from single cancer centre	Mobile based app with information on breast cancer experience, medications, and list of resources such as support groups.	9 participants, breast cancer, stage not reported, 40-77 years, 100% female	Average response on the usability questionnaire 4.23/5 (SD = 0.9).	3
Smith *et al.* (2019), Australia	Development and evaluation of talking book by patients with self-reported low functional HL receiving radiotherapy at single centre	A4 sized talking book with sections on what cancer is, types of treatment, treating team, explanation of radiotherapy, planning, procedure, side effects, support, contact details, glossary.	16 review eligible participants (excluding carers), multiple tumour sites (breast, skin, brain, colorectal, gynaecological, lung), stage not reported, 33-74 years, 81% female	The intervention was well received. Feedback positive regarding the option to read and/or listen to the information, the use of photos and illustrations, the clear and easy to understand information. Perceived benefits were to facilitate communication, prompt questions and empower patients. Challenges included additional burden on healthcare staff, caregivers, and personal preferences regarding book design	5
Jewitt *et al.* (2016), Canada	Development and evaluation of education pamphlet involving elderly patients with early stage non-small cell lung cancer or oligometastases undergoing stereotactic radiotherapy (SBRT) at single centre	Pamphlet including description of SBRT, uses, what to expect during treatment simulation and treatment, and potential side effects.	37 participants, multiple tumour sites (lung, oligometastases from unreported primary), stage T1/T2 N0 or lung metastases, 56-93 years, 62% female	87% of participants rated the pamphlet effective. 73% reported it improved knowledge about SBRT. There was no statistically significant difference in the proportion of patients who found the pamphlet effective in the groups with high versus low HL (85.7% versus 86.7%, p=1.00)	2
van der Giessen *et al.* (2020), The Netherlands	Iterative development of plain-language guide to support conversations around genetic testing through feedback from focus groups and survey data	Plain language guide for discussing breast cancer genetic counselling.	11 patient participants, breast cancer, stage not reported, age not reported, 82% female	57% of 66 healthcare professionals intended to use the guide. Recommendations included further words be added, and some were unnecessary.	1

Author (year), location	**Study description**	**Description of intervention**	**Sample (number, site, stage, age range, % female)**	**Effect of intervention on outcomes**	**MMAT score**
Bickmore *et al.* (2016), USA	Between subjects randomised trial comparing conversational web-based clinical trials search interface with standard search engine in outpatient setting. Participants recruited from pool of cancer patients, all literacy levels	Web based search engine with explanation of difficult terms, read aloud option, simplified trial titles, education modules, confirmation of user search criteria, suggestions for changes if no trials found, option to save for later, summaries, differing level of detail	89 participants, multiple tumour sites (haematological, breast, GU, head and neck, lung), stage not reported, age range not reported, 54% female	When using a standardised task, 36% (5/14) of low HL participants found a correct clinical trial with the intervention vs none in the conventional interface group (p=0.05). For all participants, 43% (18/42) in the intervention group and 31% (14/45) in the control group found a correct trial (P=.28).	2
Jibaja-Weiss *et al.* (2011), USA	Randomised controlled trial comparing computerised interactive decision aid with standard educational materials for early stage breast cancer treatment in two centres	Computerized, multimedia, interactive patient decision aid utilizing edutainment. Soap opera episodes linked to interactive learning modules and values clarification exercise.	125 participants, breast cancer, stage I-IIIA, age range not reported, 100% female	Those in intervention group were less likely to prefer breast-conserving surgery (40.5% vs. 50.0%), more likely to prefer mastectomy (59.5% vs. 39.5%, P = 0.018), less unsure about preference, showed improved knowledge pre-surgery (P < 0.001), were more informed about options and risks (P=0.007) and clearer about personal values (trend, P=0.053).	3
Durand *et al.* (2021), USA	Multi-arm, multi-site cluster randomised controlled trial comparing two conversation aids (pictorial and text only) and standard of care, for women with early stage breast cancer prior to surgery	Option Grid: 1-page text-only conversation aid, tabular evidence-based summary of available options written in plain language. Picture Option Grid: 4-page pictorial conversation aid, same evidence but included images and simpler text	615 participants, breast cancer, stage not reported, age range not reported, 100% female	Patients in Picture Option Grid arm reported greater knowledge. Compared to usual care, those in the Picture Option Grid arm reported higher SDM (patient reported and observed). The difference in quality of life between patients with higher and lower HL was smaller in Picture Option Grid arm than usual-care arm.	2
Rust, Davis and Moore (2015), USA	Randomised controlled trial assessing impact of medication adherence skills training among African American women with breast cancer recruited from community support organisations	Medication adherence skills training workshop using cognitive-behavioural, problem-solving, and motivational interviewing, brochure to help communication with healthcare providers, medication record	48 participants, breast cancer, stage not reported, age range not reported, 100% female	There was no difference between intervention and control group on HL, medication adherence, and self-efficacy from pre-test to post-test. Univariate tests indicated the intervention had no effect on self-efficacy, medication adherence, or HL at the individual level.	2
Rastegar *et al.* (2020), Iran	Randomised controlled trial investigating effect of HL counselling versus control on self-care in women who have received chemotherapy for breast cancer at single site	Six x 1.5-hour sessions for both groups. Intervention topics included health-related concepts, personal health, self-care, managing sexual and mental health, treatment complications, effect of social support, and support services. Controls received routine counselling on mastectomy and chemotherapy.	72 participants, breast cancer, stage not reported, age range not reported, 100% female	HL and self-care scores showed a greater increase in intervention group compared to control group.	4

3.4 Combined synthesis and conceptual map

The concept map below (Figure 10) shows the relationships between the quantitative outcomes associated with HL (Objective 2) and the meta-themes identified from the qualitative synthesis (Objective 3). It also shows where interventions have been developed (Objective 4). It draws on the framework developed by Edwards *et al.* (2012) and the International Union for Health Promotion and Education (2018) definition of HL.

This combination of findings obtained using a mixed studies approach provide a more complete picture of the role of HL in oncology than would otherwise be possible. The quantitative data gives evidence for the measurable outcomes associated with HL, whilst the qualitative findings complement this by adding the patient voice, identifying influences of HL, and offering an insight into some of the associations seen. Findings relating to information processing and decision-making highlight some of the ‘Processes’ affected by these ‘Influences’ and demonstrate how HL may link to ‘Outcomes’.

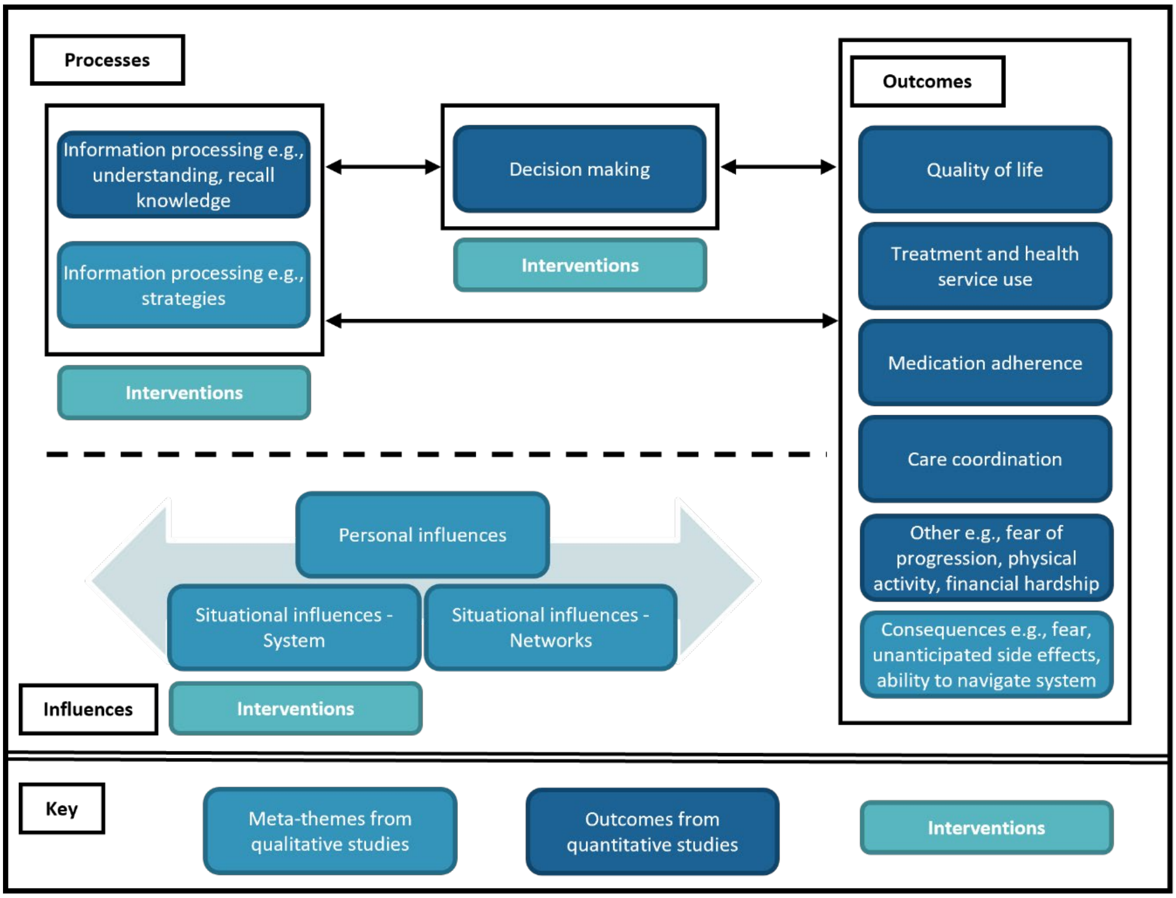


Figure 10 - Concept map demonstrating links between quantitative and qualitative findings as 'Processes', 'Outcomes’, and 'Influences' of HL, and targets of existing interventions

Patients with lower HL may have more difficulty understanding and recalling information, demonstrate lower knowledge and have higher unmet information needs (‘Processes’). The qualitative data suggest situational influences, including the way information is delivered, the complexity of the system, and the lack of resources available to patients make these tasks more challenging (‘Influences’). As such, patients are prepared to consent to treatments without fully understanding what they may entail, or the potential risks and benefits (‘Outcomes’). Fear and unanticipated side effects may arise as a consequence of lower HL through lack of understanding (‘Outcomes’) yet fear itself may influence and hinder comprehension (‘Influences’).

Those with higher HL are better able to process information (‘Processes’), engage more with health promoting activities such as exercise, and experience better quality of life (‘Outcomes’). They may be more likely to seek the additional information they need, perhaps learning to interpret numbers relating to their condition or finding opportunities to learn from others (‘Processes’). With greater understanding and knowledge of their disease and rights, they may take a more active role in making decisions and have greater confidence navigating the system (‘Outcomes’).

Existing interventions to improve understanding through development of accessible informational resources may improve some of the negative ‘Influences’, whilst education sessions and decision aids provide support for the required HL ‘Processes’.

3.5 Discussion

The findings from this mixed-studies systematic review demonstrate the scale, role, and consequences of HL in oncology, as well as identifying existing efforts to support HL. An overall prevalence of HL difficulties is difficult to determine due to the range of assessment tools used and populations studied, but according to the most frequently used measures, up to two thirds of individuals may find it difficult to access and use information to make decisions about health. The outcomes associated with HL are varied, with some having clear implications for care delivery, and others demonstrating the negative impact of HL difficulties on the experience of care as reported by patients themselves. Much of the work on developing interventions to support patients in this setting is in the relatively early stages, but ensuring the system is considerate of the burden it places on patients, taking steps to simplify information and processes, providing patients with opportunities to speak up, and making support available, will be important considerations when attempting to improve outcomes.

This review supports Edwards *et al.* (2012)’s Health Literacy Pathway Model, which draws on Nutbeam’s conceptualisation of HL as an asset that can be developed over time (Nutbeam, 2008).

The Model incorporates internal and external influences that may positively or negatively affect HL, factors also found to be important in patients with a cancer diagnosis. Such patients face many new challenges at a highly emotional time. It is therefore crucial that systems and networks are in place to support patients, making it easier for them to access, understand, appraise, and use the information they need by removing as many additional barriers as possible. In doing this, patients are afforded the best chance of being able to develop and use HL to take an active role in their health and make informed decisions based on what is important to them.

The decision-making preferences and degree to which patients with lower HL feel able to take on a more active role in the oncology setting require further study. The limited existing interventions to support SDM for patients with cancer and lower HL appear promising, but further, good quality studies are needed. Whether a patient wishes to be actively involved in decision making or prefers to be guided by their clinician, an understanding of the aims and potential risks of treatment are key to informed consent (General Medical Council, 2020). GMC guidance for doctors in the UK highlights the importance of taking steps to facilitate understanding, acknowledging patients have different information needs and may prefer to receive information in different formats (General Medical Council, 2020). These findings suggest this is not always achieved.

A further important finding is that lower HL is consistently associated with poorer quality of life. This may be linked with other outcomes identified in this review, such as increased fear, greater financial hardship, or a worse experience of treatment through higher levels of unanticipated side effects. Whether improving HL itself leads to better quality of life is as yet unknown (Stormacq *et al.*, 2020), and this is an important outcome for further study.

One limitation of this review is the exclusion of studies using measures relating to HL but referring only to literacy. This was to ensure *health* literacy remained the subject of interest, but other studies may have been missed. Secondly, to achieve consistency in a field with a range of measures, it was agreed that only those HL assessment tools used in their validated form would be included. Although this excluded some studies using non-validated adaptations, it was deemed necessary in order to draw any comparisons between studies. As found elsewhere, the range of HL measures and identification of participants with lower HL makes such comparisons difficult. Additionally, over half of the included studies were conducted in the USA, with only one carried out in the UK, which may limit the relevance of some results to other healthcare settings.

A major strength of the review is the use of a mixed studies approach, bringing together a more comprehensive picture of HL in cancer care, incorporating the patient voice and allowing us to better understand the experience from the patients' perspective. The broad inclusion criteria allowed identification of the scale of the issue and associations between HL and a wider range of outcomes than has previously been addressed, considering also existing work to support patients in this setting. Additionally, involvement of a multidisciplinary team of experienced researchers and clinicians at all stages of the review ensured consistency and rigour throughout.

3.6 Conclusion

HL plays a key role in cancer care, with important implications for patient experience and outcomes. Further research is required to understand decision making by those with lower HL receiving care for cancer. Future interventions aimed at supporting person-centred care in this setting should take account of HL and the factors influencing its development.

3.7 Summary and next steps

This review has highlighted several important associations between HL and the experiences of patients with cancer. Lower HL is associated with poorer outcomes in many areas of cancer care. Data from the qualitative papers appear to demonstrate more could be done to help patients feel fully informed and able to take a more active role in their care, but only a few interventions to support patients with lower HL in this setting were identified, and none specifically focus on incurable disease. Despite their close links, few studies have looked at the association between HL and decision making in this setting.

For the next phase of this PhD study, the following chapter describes qualitative work aiming to better understand the experiences, decision making, and challenges faced by patients receiving care for incurable cancer and suspected of having lower HL.

Chapter 4 A qualitative study of the experiences and decision making of patients with incurable cancer and suspected health literacy difficulties

4.1 Background

As found by the systematic review described in Chapter 3, HL is associated with a range of outcomes in cancer care, and those with lower HL tend to have greater difficulty understanding and processing cancer related information, experience poorer quality of life and have a poorer overall experience of care (Holden *et al.*, 2021). HL is also a prerequisite for SDM (Edwards *et al.*, 2012; Sørensen *et al.*, 2012; Bravo *et al.*, 2015), which is particularly relevant when decisions are preference sensitive, as in the palliative oncology setting, when treatments may offer marginal benefits at potentially significant risk. Existing studies exploring the relationship between HL and SDM in oncology have been quantitative evaluations (Lillie *et al.*, 2007; Chang, Li and Lin, 2019; Polite *et al.*, 2019; Shen *et al.*, 2019; Yen *et al.*, 2020) and little is known about the specific challenges faced by patients with incurable disease who might be unable to access and understand information through conventional routes.

The review identified a clear gap in our understanding of the experiences and challenges faced by those with lower HL and incurable cancer, the information giving and decision making process, and how we might be able to address these issues to improve SDM in this context. The next phase of this PhD study was developed to address this. Using a qualitative research design and considering HL from the 'asset' perspective, this phase, designed and undertaken during the COVID-19 pandemic, sought to learn more about the experiences of these patients. By gaining this deeper understanding and identifying where difficulties arise, whilst also acknowledging the implications COVID-19 would have for future care delivery, it was then possible to consider what changes might be needed to build HL and support patients to take a more active role in decisions about their care.

The objectives of this phase were: 1) to understand the experiences and decision making of patients with lower HL receiving care for incurable cancer in the NHS; 2) to identify particular challenges faced by patients with lower HL whilst receiving care for incurable cancer; and 3) to make recommendations about how best to support this patient group in clinical practice.

4.2 Methods

Semi-structured interviews were used to gather in-depth data on the experiences of patients with lower HL receiving care for incurable cancer. Participants were identified through the oncology departments of two NHS district general hospitals, both of which provide outpatient care, one also delivering inpatient care, to patients with a range of malignancies in the South of England. NHS Health Research Authority (HRA) approval was obtained prior to research activities being undertaken (REC reference 20/PR/0478) (see Appendix A.1 for additional feedback).

4.2.1 Participants

Potential participants were identified by clinical teams within the hospitals' oncology departments. Clinicians were made aware of the study during two departmental presentations and through informal communications, and were asked to consider patients they suspected might have HL difficulties. They were provided with a summary of the study and list of 'red flags' suggestive of possible difficulties (Weiss, 2003) (Figure 11) to aid identification of eligible participants. These behaviours/responses might align with the view of HL as a risk factor for poor health and behaviours which must be mitigated for, and are not in themselves fully in keeping with the ethos of a shared partnership between patient and healthcare professional. However, they were used as a guideline to help clinicians identify patients who might be finding it more difficult to access, understand and use health information and follow complex schedules, and therefore might be experiencing HL difficulties.

Behaviours
Patient registration forms that are incomplete or inaccurately completed
Frequently missed appointments
Non-compliance with medication regimens
Lack of follow-through with laboratory tests, imaging tests, or referrals to consultants
Patients say they are taking their medication, but laboratory tests or physiological parameters do not change in the expected fashion
Responses to receiving written information
"I forgot my glasses. I'll read this when I get home."
"I forgot my glasses. Can you read this to me?"
"Let me bring this home so I can discuss it with my children."
Responses to questions about medication regimens
Unable to name medications
Unable to explain a medication's purpose
Unable to explain timing of medication administration

Figure 11 - Red flag behaviours/responses that may indicate limited literacy (Weiss, 2003)

The inclusion criteria were:

- Diagnosis of incurable malignancy of any site
- Identified by a member of the healthcare team as potentially having difficulties with HL
- Age >18 years
- Capacity to provide informed consent
- English as a main language

Following identification, the patient's treating team introduced the study and obtained permission for CH to make contact.

4.2.2 Study procedure

Those who were interested and gave permission were contacted directly by telephone by CH. During this introductory call, a 'layered approach' was used to provide further detail about the study in line with Health Research Authority (2018) guidance on proportionate consent. An initial verbal explanation including the purpose and requirements of the study was given.

Further information according to the patient's preference (in the form of a standard participant information sheet (Appendix A.2), single page summary (Appendix A.3), or video recording (Appendix A.4)) was sent to interested individuals, and a time for a follow up call and interview was agreed. The study was described as seeking to explore how information is given to and understood by patients, how decisions about treatment are made and challenges faced by patients whilst receiving care for incurable cancer. The term health literacy was not used. Following PPI input obtained during development of the participant information materials, the use of posted pre-recorded video cards was identified as an option for those without internet access. Additional information was available and participants were given opportunities to ask questions, allowing them to control the amount of information they accessed (Health Research Authority, 2018).

Prior to commencing the interviews, the teach back technique was used to ensure understanding (Health Education England, 2017) and verbal consent was recorded (Appendix A.5). Participants were aware of the interviewer's medical background, but care was taken to ensure they had not met clinically.

In view of COVID-19 restrictions, interviews were conducted remotely by telephone or video call through Microsoft Teams and recorded using the same software. The interviews followed a topic guide agreed by the research team and framed around Nutbeam's levels of HL (Nutbeam, 2000) (Appendix A.6). Questions were piloted with two PPI members, one over telephone and the other over video call, whose comments and feedback were used to further refine the guide. The guide explored participants' experiences, involvement in decision making, and challenges faced. Reflexive notes were made after the interviews and the research team met regularly to discuss progress.

Towards the end of the interview, three screening questions were asked to establish participants' self-assessed HL (see 2.4.2.3), with responses "some of the time", "most of the time" or " all of the time" (questions 1 and 2), and "somewhat", "a little bit" or "not at all" (question 3) identifying those experiencing difficulties (Chew *et al.*, 2008).

Demographic data (age and sex), date and type of cancer diagnosis, date of diagnosis of incurable disease, stage, treatment received, and comorbidities were collected from participants' medical records after interview.

4.2.3 Data analysis

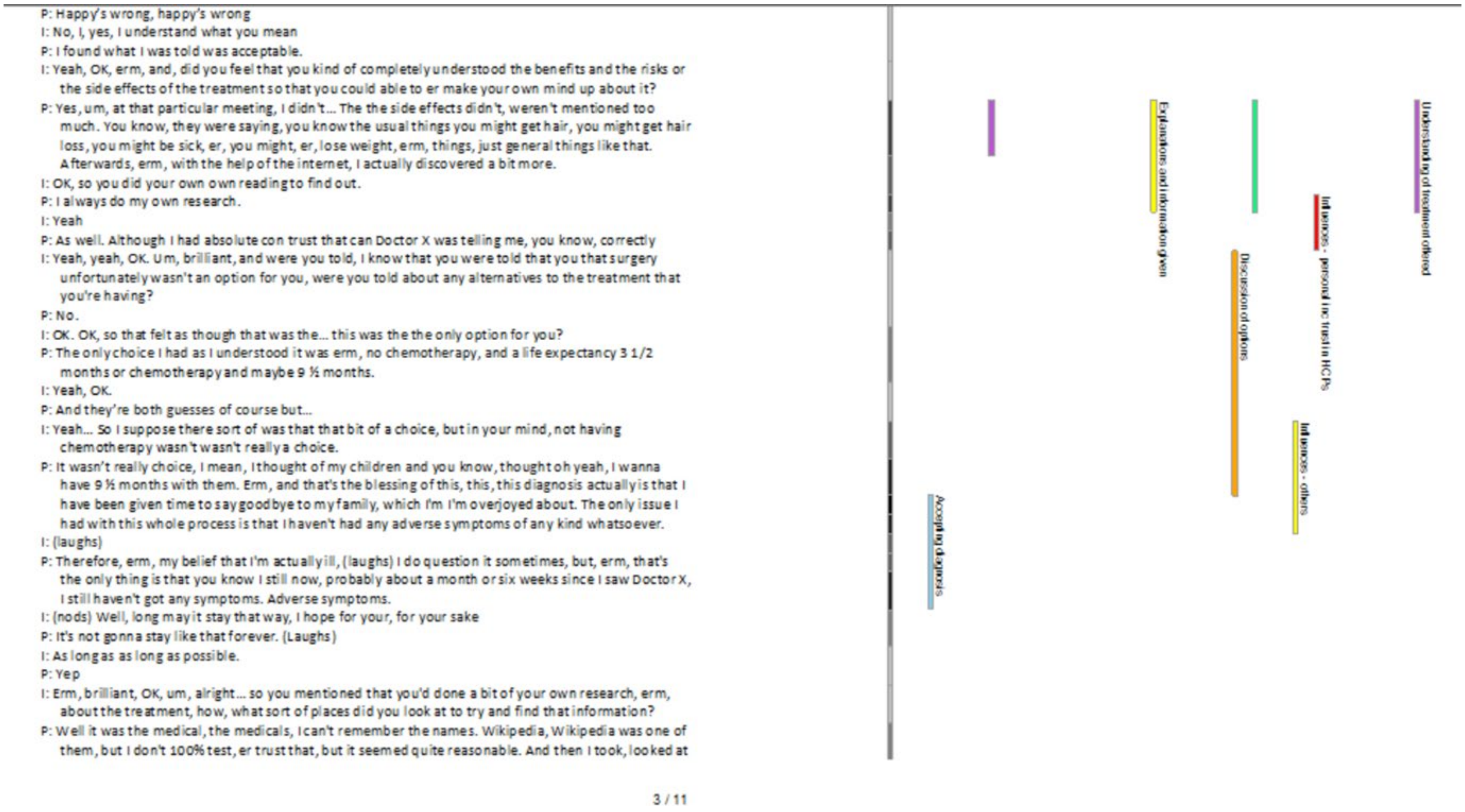
Data were analysed using the Framework Method, which provides a systematic approach to data analysis, drawing upon a priori issues informed by the original research questions, as well as those identified through analysis of interviewees' responses (Ritchie and Spencer, 2002; Ritchie and Lewis, 2003). The combination of deductive and inductive analysis seemed well suited for this analysis. Alongside findings from the systematic review, existing theory, including the Health Literacy Pathway Model (Edwards *et al.*, 2012) and Nutbeam's three levels of HL (Nutbeam, 2000), had informed the design of this phase of the study and interview questions (Appendix A.6). However, it was important to also identify as yet unknown issues, such as the role of emotions influencing participants' ability to process information and participate in SDM, and this was made possible through more inductive coding.

Interview recordings were transcribed verbatim by CH, allowing initial familiarisation with the data. CH and RW then independently read the first six transcripts, noting initial thoughts and themes. They met regularly to discuss codes to be used in constructing the initial framework, which was iteratively revised and agreed by the remainder of the supervisory team (AH and SW). The main a priori themes in the framework were based on the research objectives (e.g., experiences, decision making, challenges), whilst subthemes included those introduced through the interview questions and from existing frameworks (Nutbeam, 2000; Edwards *et al.*, 2012) (e.g., discussion of options, seeking information) as well as recurring themes identified in the data (e.g., accepting diagnosis, curveballs or changes to plan and uncertainty) (see Figure 12).

1) Experiences (Objective 1 - To understand the experiences and decision making of patients with lower health literacy receiving care for incurable cancer in the NHS)
    a) Diagnostic pathway
    b) Influence of Covid-19
    c) Navigating hospital, system, processes
    d) Other
    e) Overall care and support
    f) Acceptance
    g) Denial
    h) Feeling lucky or grateful
    i) Hope
    j) Need to be realistic
    k) Shock
    l) Uncertainty
    m) Receiving diagnosis
    n) Seeking information
    o) Symptoms
    p) Treatment
2) Communication with HCPs
    a) Contacting team
    b) Explanations and information given
    c) Speaking up and asking questions
3) Decision making (Objective 1 - To understand the experiences and decision making of patients with lower health literacy receiving care for incurable cancer in the NHS)
    a) Deliberation
    b) Discussion of options
    c) Efforts by patient to understand options
    d) Influences - HCPs
    e) Influences - others
    f) Influences - personal inc. trust in HCPs
    g) Involvement in decision making
    h) Other
    i) Provision of information
    j) Role of family, friends etc
    k) Understanding of treatment offered
    l) Understanding situation and disease
4) Challenges (Objective 2 - To identify particular challenges faced by patients with lower health literacy whilst receiving care for incurable cancer)
    a) Accepting diagnosis
    b) Curveballs or changes to plan
    c) Emotions affecting ability to process
    d) Information - amount
    e) Information - difficult to understand
    f) Information - type
    g) Lack of familiarity
    h) Let down
    i) Other
5) Recommendations and suggestions (Objective 3 - To make recommendations about how best to support this patient group in clinical practice)
    a) Changes to written information
    b) Including family
    c) More time
    d) Strategies
6) Other
    a) ...Cultural values
    b) Control over information
    c) Expectations
    d) Other
    e) Prior experience

Figure 12 - Framework for analysis of patient interviews

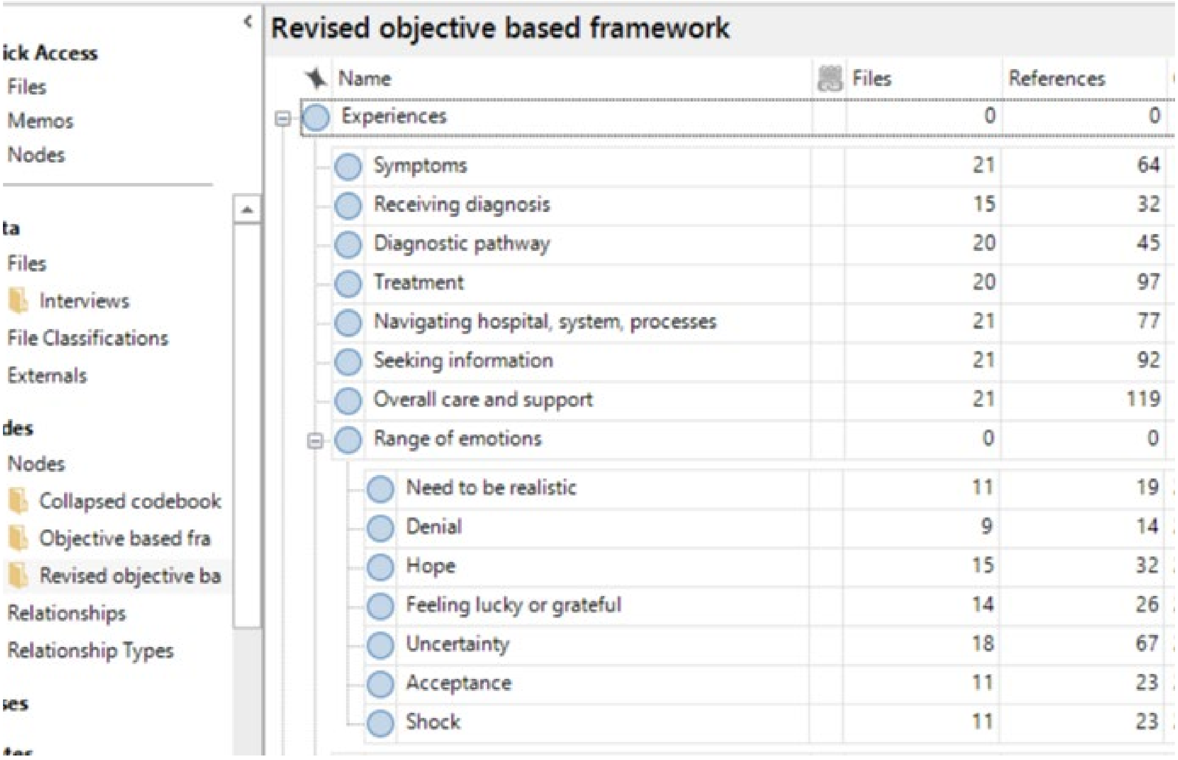
Each transcript was indexed according to this framework, using NVivo 12 software. An example of transcript labelling is shown in Figure 13, while Figure 14 demonstrates labelling assigned to framework themes, with the References column showing the number of extracts labelled to each subtheme.



P: Happy's wrong, happy's wrong
I: No, I, yes, I understand what you mean
P: I found what I was told was acceptable.
I: Yeah, OK, erm, and, did you feel that you kind of completely understood the benefits and the risks or the side effects of the treatment so that you could able to er make your own mind up about it?
P: Yes, um, at that particular meeting, I didn't… The the side effects didn't, weren't mentioned too much. You know, they were saying, you know the usual things you might get hair, you might get hair loss, you might be sick, er, you might, er, lose weight, erm, things, just general things like that. Afterwards, erm, with the help of the internet, I actually discovered a bit more.
I: OK, so you did your own own reading to find out.
P: I always do my own research.
I: Yeah
P: As well. Although I had absolute con trust that can Doctor X was telling me, you know, correctly
I: Yeah, yeah, OK. Um, brilliant, and were you told, I know that you were told that you that surgery unfortunately wasn't an option for you, were you told about any alternatives to the treatment that you're having?
P: No.
I: OK. OK, so that felt as though that was the… this was the the only option for you?
P: The only choice I had as I understood it was erm, no chemotherapy, and a life expectancy 3 1/2 months or chemotherapy and maybe 9 ½ months.
I: Yeah, OK.
P: And they're both guesses of course but…
I: Yeah… So I suppose there sort of was that that bit of a choice, but in your mind, not having chemotherapy wasn't wasn't really a choice.
P: It wasn't really choice, I mean, I thought of my children and you know, thought oh yeah, I wanna have 9 ½ months with them. Erm, and that's the blessing of this, this, this diagnosis actually is that I have been given time to say goodbye to my family, which I'm I'm overjoyed about. The only issue I had with this whole process is that I haven't had any adverse symptoms of any kind whatsoever.
I: (laughs)
P: Therefore, erm, my belief that I'm actually ill, (laughs) I do question it sometimes, but, erm, that's the only thing is that you know I still now, probably about a month or six weeks since I saw Doctor X, I still haven't got any symptoms. Adverse symptoms.
I: (nods) Well, long may it stay that way, I hope for your, for your sake
P: It's not gonna stay like that forever. (Laughs)
I: As long as as long as possible.
P: Yep
I: Erm, brilliant, OK, um, alright… so you mentioned that you'd done a bit of your own research, erm, about the treatment, how, what sort of places did you look at to try and find that information?
P: Well it was the medical, the medicals, I can't remember the names. Wikipedia, Wikipedia was one of them, but I don't 100% test, er trust that, but it seemed quite reasonable. And then I took, looked at

3 / 11

Figure 13 - Example of highlighted transcript labelling in NVivo



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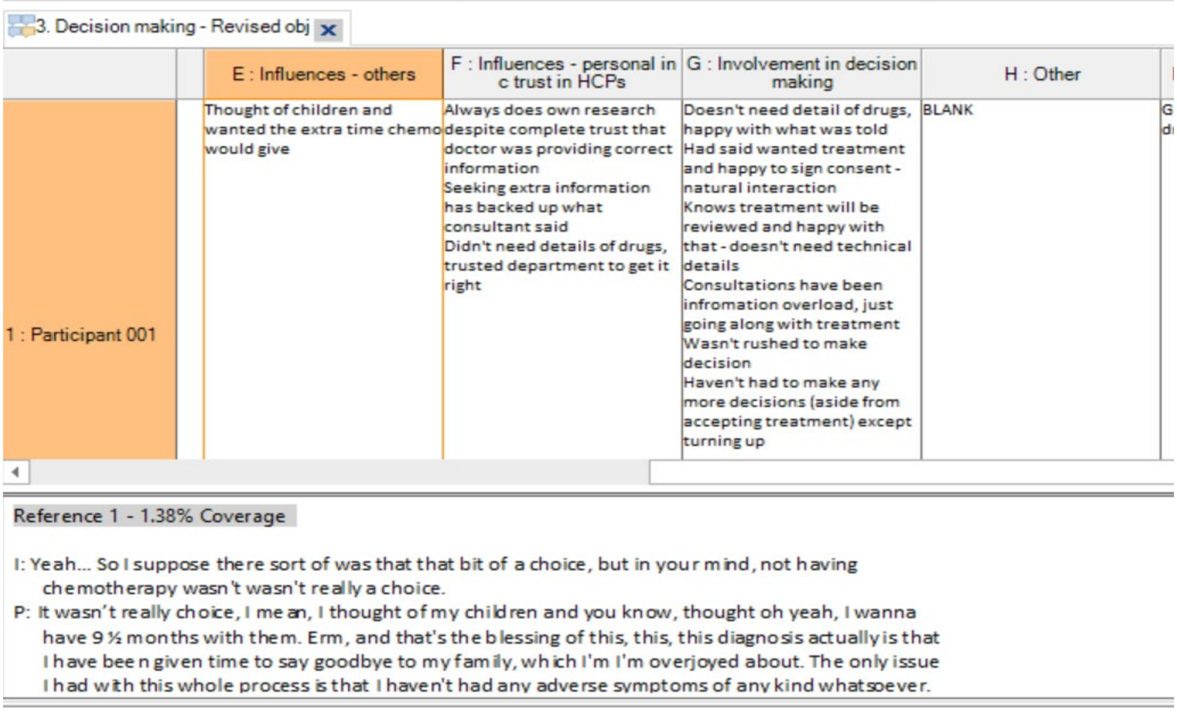
Relationships
Relationship Types

Revised objective based framework

Name	Files	References
Experiences	0	0
Symptoms	21	64
Receiving diagnosis	15	32
Diagnostic pathway	20	45
Treatment	20	97
Navigating hospital, system, processes	21	77
Seeking information	21	92
Overall care and support	21	119
Range of emotions	0	0
Need to be realistic	11	19
Denial	9	14
Hope	15	32
Feeling lucky or grateful	14	26
Uncertainty	18	67
Acceptance	11	23
Shock	11	23

Figure 14 - Example of labels assigned to themes in NVivo

From here, a set of thematic charts were created and the data within them summarised, retaining key terms, expressions and phrases (Ritchie and Lewis, 2003). Figure 15 is an example of a summarised excerpt, with the reference box below the table showing a partial transcript for the highlighted cell, whilst Figure 16 shows part of one of the six resulting thematic matrices.



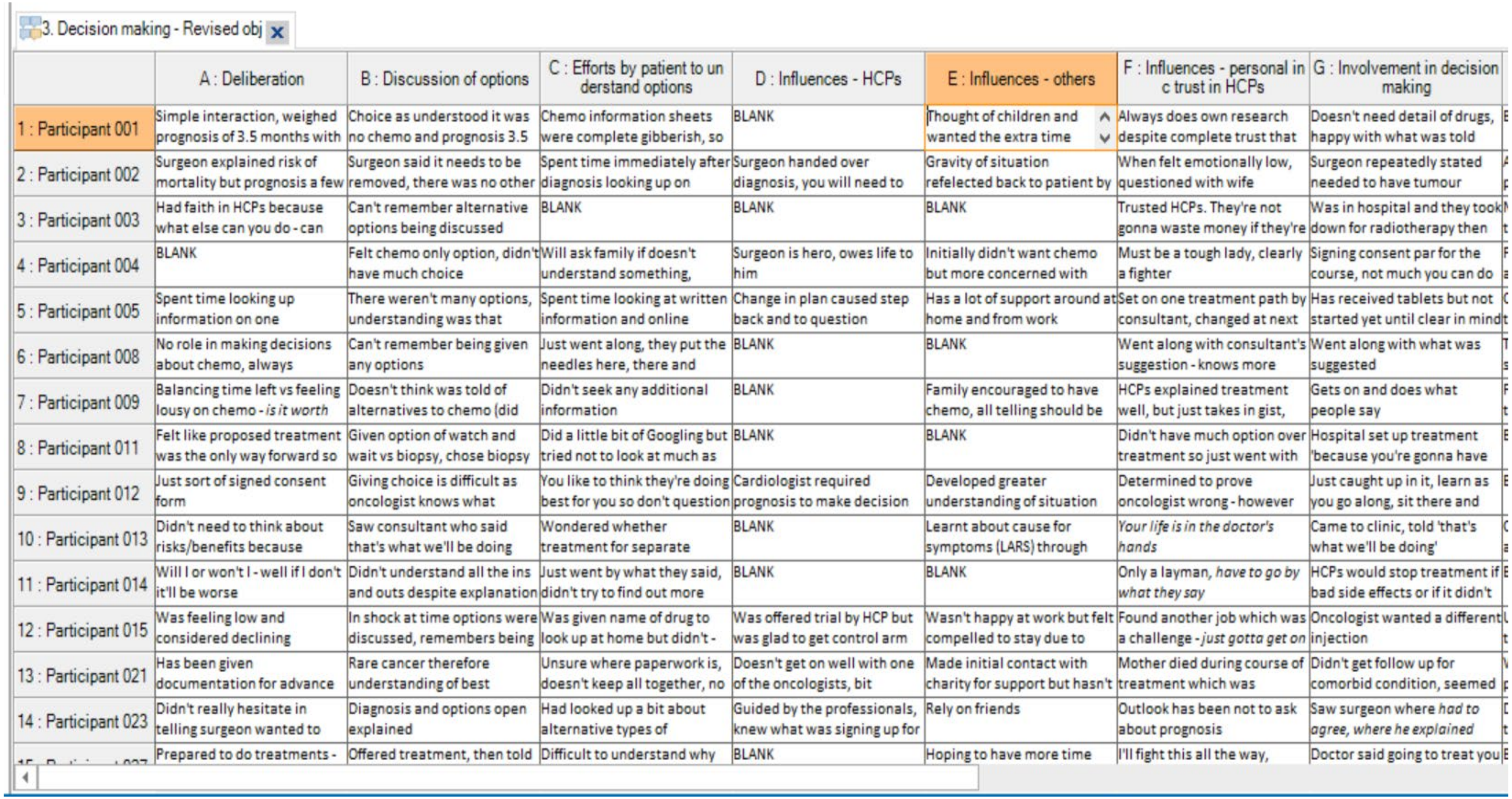
3. Decision making - Revised obj

	E : Influences - others	F : Influences - personal in c trust in HCPs	G : Involvement in decision making	H : Other
1 : Participant 001	Thought of children and wanted the extra time chemo would give	Always does own research despite complete trust that doctor was providing correct information Seeking extra information has backed up what consultant said Didn't need details of drugs, trusted department to get it right	Doesn't need detail of drugs, happy with what was told Had said wanted treatment and happy to sign consent - natural interaction Knows treatment will be reviewed and happy with that - doesn't need technical details Consultations have been infromation overload, just going along with treatment Wasn't rushed to make decision Haven't had to make any more decisions (aside from accepting treatment) except turning up	BLANK

Reference 1 - 1.38% Coverage

I: Yeah... So I suppose there sort of was that that bit of a choice, but in your mind, not having chemotherapy wasn't wasn't really a choice.
P: It wasn't really choice, I mean, I thought of my children and you know, thought oh yeah, I wanna have 9 ½ months with them. Erm, and that's the blessing of this, this, this diagnosis actually is that I have been given time to say goodbye to my family, which I'm I'm overjoyed about. The only issue I had with this whole process is that I haven't had any adverse symptoms of any kind whatsoever.

Figure 15 - Example of thematic charting in NVivo

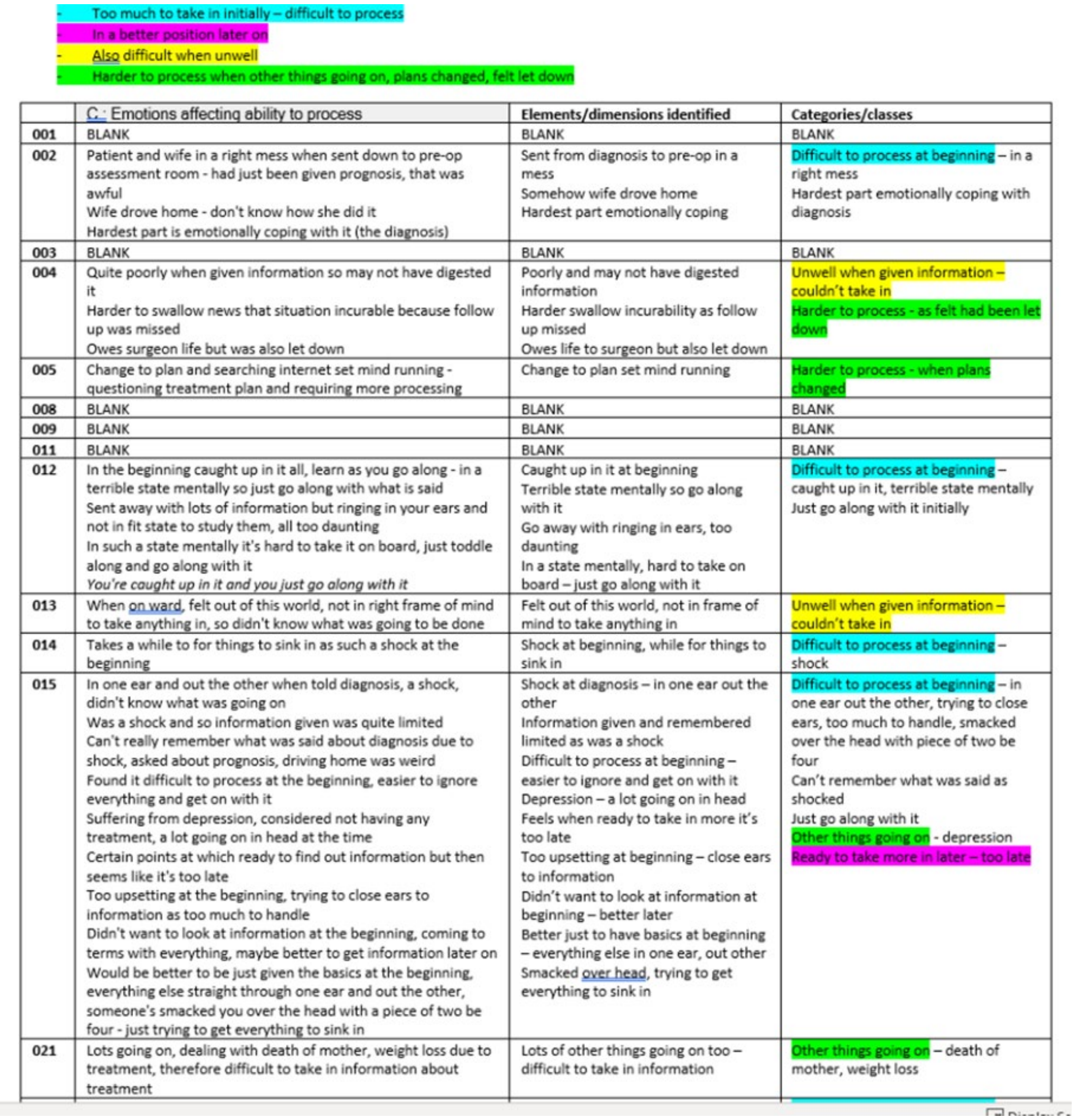


3. Decision making - Revised obj

	A : Deliberation	B : Discussion of options	C : Efforts by patient to understand options	D : Influences - HCPs	E : Influences - others	F : Influences - personal in c trust in HCPs	G : Involvement in decision making
1 : Participant 001	Simple interaction, weighed prognosis of 3.5 months with	Choice as understood it was no chemo and prognosis 3.5	Chemo information sheets were complete gibberish, so	BLANK	Thought of children and wanted the extra time	Always does own research despite complete trust that	Doesn't need detail of drugs, happy with what was told
2 : Participant 002	Surgeon explained risk of mortality but prognosis a few	Surgeon said it needs to be removed, there was no other	Spent time immediately after diagnosis looking up on	Surgeon handed over diagnosis, you will need to	Gravity of situation refelected back to patient by	When felt emotionally low, questioned with wife	Surgeon repeatedly stated needed to have tumour
3 : Participant 003	Had faith in HCPs because what else can you do - can	Can't remember alternative options being discussed	BLANK	BLANK	BLANK	Trusted HCPs. They're not gonna waste money if they're	Was in hospital and they took down for radiotherapy then
4 : Participant 004	BLANK	Felt chemo only option, didn't have much choice	Will ask family if doesn't understand something,	Surgeon is hero, owes life to him	Initially didn't want chemo but more concerned with	Must be a tough lady, clearly a fighter	Signing consent par for the course, not much you can do
5 : Participant 005	Spent time looking up information on one	There weren't many options, understanding was that	Spent time looking at written information and online	Change in plan caused step back and to question	Has a lot of support around at home and from work	Set on one treatment path by consultant, changed at next	Has received tablets but not started yet until clear in mind
6 : Participant 008	No role in making decisions about chemo, always	Can't remember being given any options	Just went along, they put the needles here, there and	BLANK	BLANK	Went along with consultant's suggestion - knows more	Went along with what was suggested
7 : Participant 009	Balancing time left vs feeling lousy on chemo - *is it worth*	Doesn't think was told of alternatives to chemo (did	Didn't seek any additional information	BLANK	Family encouraged to have chemo, all telling should be	HCPs explained treatment well, but just takes in gist,	Gets on and does what people say
8 : Participant 011	Felt like proposed treatment was the only way forward so	Given option of watch and wait vs biopsy, chose biopsy	Did a little bit of Googling but tried not to look at much as	BLANK	BLANK	Didn't have much option over treatment so just went with	Hospital set up treatment 'because you're gonna have
9 : Participant 012	Just sort of signed consent form	Giving choice is difficult as oncologist knows what	You like to think they're doing best for you so don't question	Cardiologist required prognosis to make decision	Developed greater understanding of situation	Determined to prove oncologist wrong - however	Just caught up in it, learn as you go along, sit there and
10 : Participant 013	Didn't need to think about risks/benefits because	Saw consultant who said that's what we'll be doing	Wondered whether treatment for separate	BLANK	Learnt about cause for symptoms (LARS) through	*Your life is in the doctor's hands*	Came to clinic, told 'that's what we'll be doing'
11 : Participant 014	Will I or won't I - well if I don't it'll be worse	Didn't understand all the ins and outs despite explanation	Just went by what they said, didn't try to find out more	BLANK	BLANK	Only a layman, *have to go by what they say*	HCPs would stop treatment if bad side effects or if it didn't
12 : Participant 015	Was feeling low and considered declining	In shock at time options were discussed, remembers being	Was given name of drug to look up at home but didn't -	Was offered trial by HCP but was glad to get control arm	Wasn't happy at work but felt compelled to stay due to	Found another job which was a challenge - *just gotta get on*	Oncologist wanted a different injection
13 : Participant 021	Has been given documentation for advance	Rare cancer therefore understanding of best	Unsure where paperwork is, doesn't keep all together, no	Doesn't get on well with one of the oncologists, bit	Made initial contact with charity for support but hasn't	Mother died during course of treatment which was	Didn't get follow up for comorbid condition, seemed
14 : Participant 023	Didn't really hesitate in telling surgeon wanted to	Diagnosis and options open explained	Had looked up a bit about alternative types of	Guided by the professionals, knew what was signing up for	Rely on friends	Outlook has been not to ask about prognosis	Saw surgeon where *had to agree, where he explained*
	Prepared to do treatments -	Offered treatment, then told	Difficult to understand why	BLANK	Hoping to have more time	I'll fight this all the way,	Doctor said going to treat you

Figure 16 - Example of one of six framework matrices in NVivo

Further interrogation of the data was then performed, looking within themes across cases. To do this, a table was created for each column of each matrix using the summaries taken from the original transcripts, identifying different elements, then assigning categories/classes (see Figure 17 for an example).



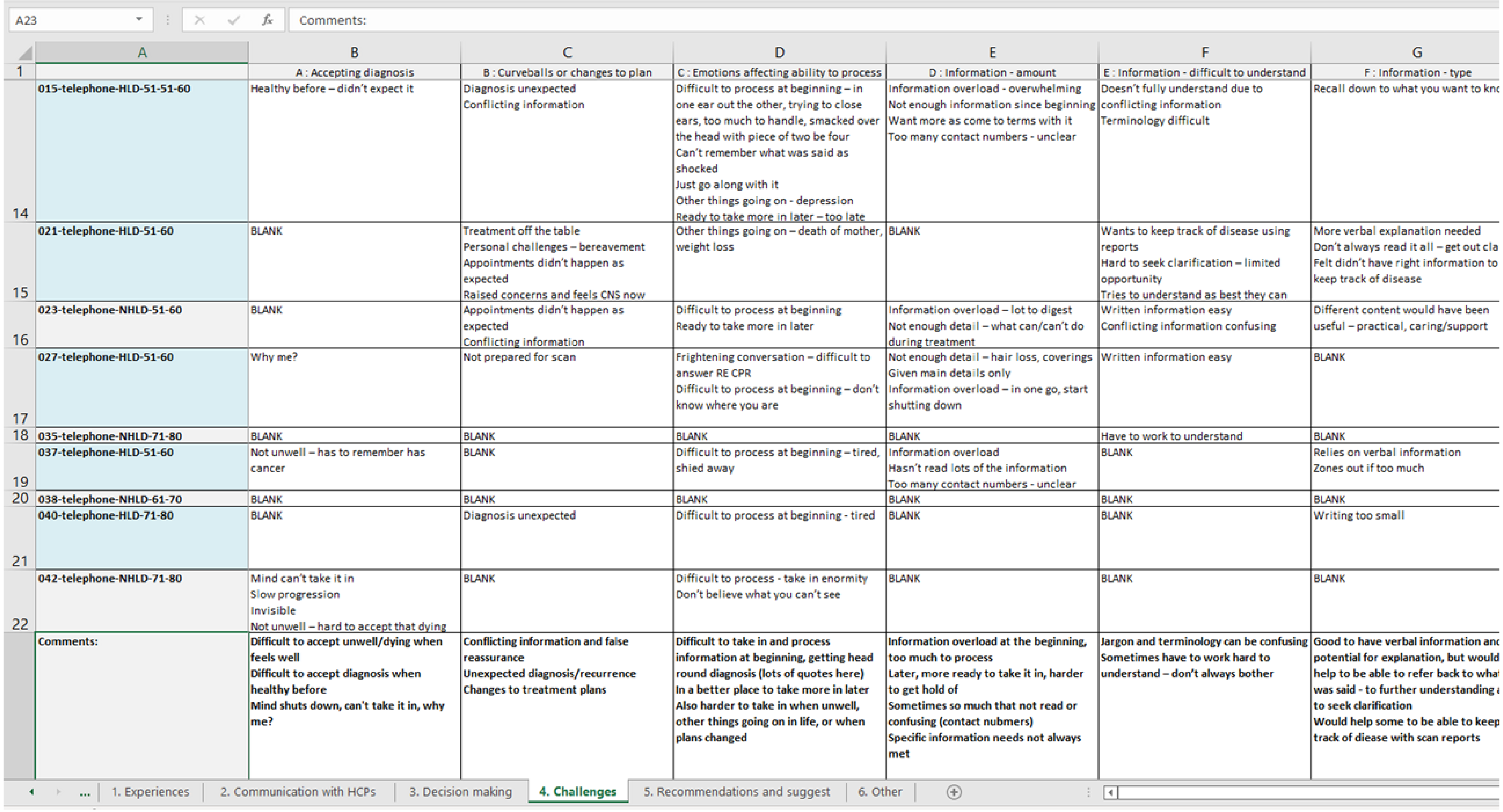
- Too much to take in initially – difficult to process
- In a better position later on
- Also difficult when unwell
- Harder to process when other things going on, plans changed, felt let down

	C: Emotions affecting ability to process	Elements/dimensions identified	Categories/classes
001	BLANK	BLANK	BLANK
002	Patient and wife in a right mess when sent down to pre-op assessment room - had just been given prognosis, that was awful Wife drove home - don't know how she did it Hardest part is emotionally coping with it (the diagnosis)	Sent from diagnosis to pre-op in a mess Somehow wife drove home Hardest part emotionally coping	Difficult to process at beginning – in a right mess Hardest part emotionally coping with diagnosis
003	BLANK	BLANK	BLANK
004	Quite poorly when given information so may not have digested it Harder to swallow news that situation incurable because follow up was missed Owes surgeon life but was also let down	Poorly and may not have digested information Harder swallow incurability as follow up missed Owes life to surgeon but also let down	Unwell when given information – couldn't take in Harder to process - as felt had been let down
005	Change to plan and searching internet set mind running - questioning treatment plan and requiring more processing	Change to plan set mind running	Harder to process - when plans changed
008	BLANK	BLANK	BLANK
009	BLANK	BLANK	BLANK
011	BLANK	BLANK	BLANK
012	In the beginning caught up in it all, learn as you go along - in a terrible state mentally so just go along with what is said Sent away with lots of information but ringing in your ears and not in fit state to study them, all too daunting In such a state mentally it's hard to take it on board, just toddle along and go along with it *You're caught up in it and you just go along with it*	Caught up in it at beginning Terrible state mentally so go along with it Go away with ringing in ears, too daunting In a state mentally, hard to take on board – just go along with it	Difficult to process at beginning – caught up in it, terrible state mentally Just go along with it initially
013	When on ward, felt out of this world, not in right frame of mind to take anything in, so didn't know what was going to be done	Felt out of this world, not in frame of mind to take anything in	Unwell when given information – couldn't take in
014	Takes a while to for things to sink in as such a shock at the beginning	Shock at beginning, while for things to sink in	Difficult to process at beginning – shock
015	In one ear and out the other when told diagnosis, a shock, didn't know what was going on Was a shock and so information given was quite limited Can't really remember what was said about diagnosis due to shock, asked about prognosis, driving home was weird Found it difficult to process at the beginning, easier to ignore everything and get on with it Suffering from depression, considered not having any treatment, a lot going on in head at the time Certain points at which ready to find out information but then seems like it's too late Too upsetting at the beginning, trying to close ears to information as too much to handle Didn't want to look at information at the beginning, coming to terms with everything, maybe better to get information later on Would be better to be just given the basics at the beginning, everything else straight through one ear and out the other, someone's smacked you over the head with a piece of two be four - just trying to get everything to sink in	Shock at diagnosis – in one ear out the other Information given and remembered limited as was a shock Difficult to process at beginning – easier to ignore and get on with it Depression – a lot going on in head Feels when ready to take in more it's too late Too upsetting at beginning – close ears to information Didn't want to look at information at beginning – better later Better just to have basics at beginning – everything else in one ear, out other Smacked over head, trying to get everything to sink in	Difficult to process at beginning – in one ear out the other, trying to close ears, too much to handle, smacked over the head with piece of two be four Can't remember what was said as shocked Just go along with it Other things going on - depression Ready to take more in later – too late
021	Lots going on, dealing with death of mother, weight loss due to treatment, therefore difficult to take in information about treatment	Lots of other things going on too – difficult to take in information	Other things going on – death of mother, weight loss

Figure 17 - Example of further interrogation of matrix columns

Taken from Matrix 4, column C) Emotions affecting ability to process. Colour coding highlights recurrence of categories within the subtopic/column.

Forty-nine tables were created from the six matrices. The resulting categories were copied into a blank copy of the original matrix and further scrutinised, with comments below each column describing the contents (Figure 18). Categories were then grouped under overarching broader classifications (Appendix A.7), forming the basis of the final themes.



	A	B	C	D	E	F	G
1		A : Accepting diagnosis	B : Curveballs or changes to plan	C : Emotions affecting ability to process	D : Information - amount	E : Information - difficult to understand	F : Information - type
14	**015-telephone-HLD-51-51-60**	Healthy before – didn't expect it	Diagnosis unexpected Conflicting information	Difficult to process at beginning – in one ear out the other, trying to close ears, too much to handle, smacked over the head with piece of two be four Can't remember what was said as shocked Just go along with it Other things going on - depression Ready to take more in later – too late	Information overload - overwhelming Not enough information since beginning Want more as come to terms with it Too many contact numbers - unclear	Doesn't fully understand due to conflicting information Terminology difficult	Recall down to what you want to knc
15	**021-telephone-HLD-51-60**	BLANK	Treatment off the table Personal challenges – bereavement Appointments didn't happen as expected Raised concerns and feels CNS now	Other things going on – death of mother, weight loss	BLANK	Wants to keep track of disease using reports Hard to seek clarification – limited opportunity Tries to understand as best they can	More verbal explanation needed Don't always read it all – get out cla Felt didn't have right information to keep track of disease
16	**023-telephone-NHLD-51-60**	BLANK	Appointments didn't happen as expected Conflicting information	Difficult to process at beginning Ready to take more in later	Information overload – lot to digest Not enough detail – what can/can't do during treatment	Written information easy Conflicting information confusing	Different content would have been useful – practical, caring/support
17	**027-telephone-HLD-51-60**	Why me?	Not prepared for scan	Frightening conversation – difficult to answer RE CPR Difficult to process at beginning – don't know where you are	Not enough detail – hair loss, coverings Given main details only Information overload – in one go, start shutting down	Written information easy	BLANK
18	**035-telephone-NHLD-71-80**	BLANK	BLANK	BLANK	BLANK	Have to work to understand	BLANK
19	**037-telephone-HLD-51-60**	Not unwell – has to remember has cancer	BLANK	Difficult to process at beginning – tired, shied away	Information overload Hasn't read lots of the information Too many contact numbers - unclear	BLANK	Relies on verbal information Zones out if too much
20	**038-telephone-NHLD-61-70**	BLANK	BLANK	BLANK	BLANK	BLANK	BLANK
21	**040-telephone-HLD-71-80**	BLANK	Diagnosis unexpected	Difficult to process at beginning - tired	BLANK	BLANK	Writing too small
22	**042-telephone-NHLD-71-80**	Mind can't take it in Slow progression Invisible Not unwell – hard to accept that dying	BLANK	Difficult to process - take in enormity Don't believe what you can't see	BLANK	BLANK	BLANK
	Comments:	**Difficult to accept unwell/dying when feels well** **Difficult to accept diagnosis when healthy before** **Mind shuts down, can't take it in, why me?**	**Conflicting information and false reassurance** **Unexpected diagnosis/recurrence** **Changes to treatment plans**	**Difficult to take in and process information at beginning, getting head round diagnosis (lots of quotes here)** **In a better place to take more in later** **Also harder to take in when unwell, other things going on in life, or when plans changed**	**Information overload at the beginning, too much to process** **Later, more ready to take it in, harder to get hold of** **Sometimes so much that not read or confusing (contact nubmers)** **Specific information needs not always met**	**Jargon and terminology can be confusing** **Sometimes have to work hard to understand – don't always bother**	**Good to have verbal information anc potential for explanation, but would help to be able to refer back to wha was said - to further understanding a to seek clarification** **Would help some to be able to keep track of disease with scan reports**

Figure 18 - Screenshot of categorised matrix for theme 'Challenges'

Drawing on the challenges identified, and suggestions made by participants during the interviews, recommendations addressing the third research objective were developed by CH, in discussion with the supervisory team.

Participants were not invited to provide feedback on the findings, but those still alive after the final interview was completed were offered a summary of preliminary findings (Appendix A.8).

4.3 Findings

Forty-two potential participants were contacted by CH, and 21 interviews conducted between November 2020 and October 2021. Of those who did not participate, seven declined at the point of initial contact, and a further fifteen declined after receiving the study information and arranging a provisional interview date. Reasons for non-participation are shown in Figure 19. One participant was identified after interview to have been receiving adjuvant treatment and therefore did not meet the eligibility criteria. Their responses were not analysed with the rest of the data as the nature of conversations and decisions made were different, but points relevant to their general experience of the system and recommendations for improvement were considered alongside the completed analysis.

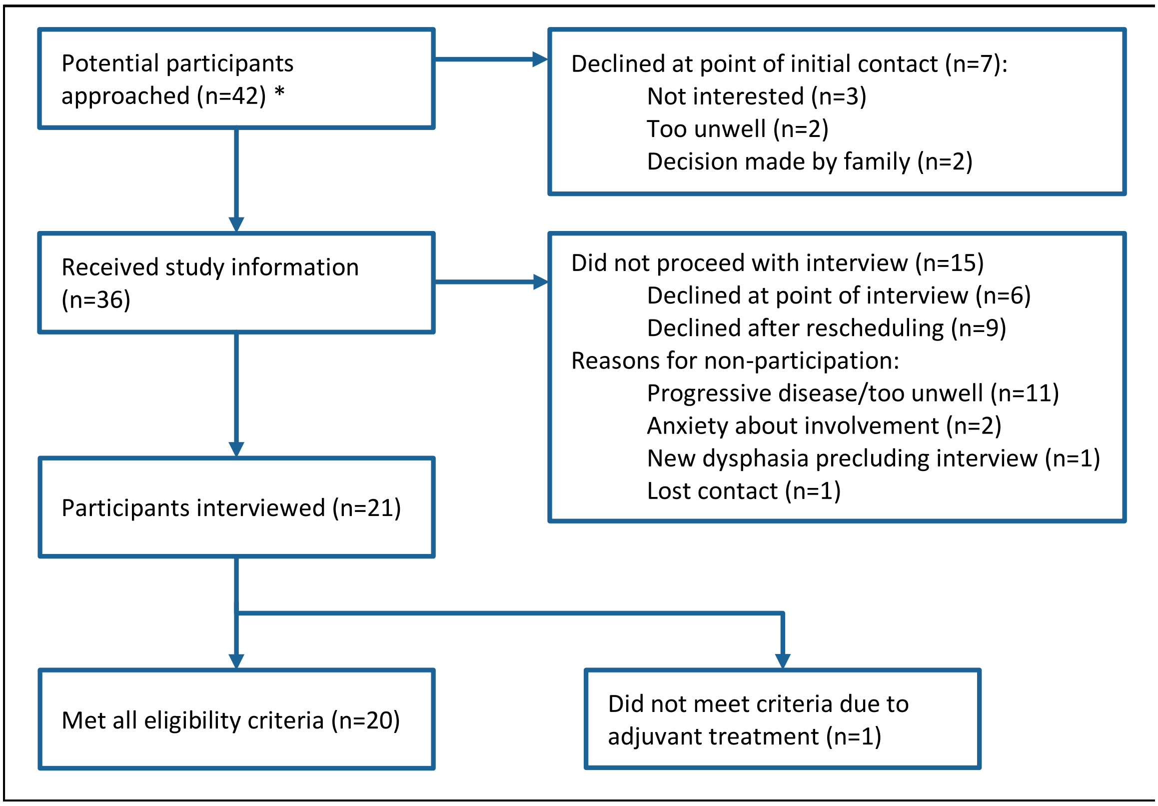


Figure 19 - Participant recruitment and reasons for non-participation

* One potential participant was approached twice, therefore 43 approaches were made in total. This individual initially declined after the first contact and subsequently received study information but later decided not to participate

Twelve participants met criteria for HL difficulties (HLD) using the screening questions, and eight reported no HL difficulties (NHLD). HL difficulties are classified throughout the findings based on these questions. The original protocol included a plan for separate analyses to be conducted for participants with and without HL difficulties if there were sufficient numbers in each group. However, some responses given during the interviews suggested the Chew questions may not discriminate between people with and without HL difficulties and the decision was therefore made to analyse the entire data set together.

4.3.1 Participant characteristics

Nineteen of the 20 included participants were aged 51 years or over, and two thirds were male (Table 8). Participants had a variety of cancer diagnoses and had received various treatments. Most had received anti-cancer treatment within the preceding three months.

Table 8 – Participant characteristics

Characteristic	No. participants (N=20)
Age range	
18-30	0
31-40	1
41-50	0
51-60	5
61-70	6
71-80	8
Sex	
Female	7
Male	13
Primary tumour site	
Breast	1
CNS	3
Upper GI	2
Lower GI	3
Ovarian	2
Lung	4
Head and neck	2
Prostate	2
Renal	1
Treatments received *	
Surgery	7
Chemotherapy	13
Radiotherapy	13
Immunotherapy	4
Hormone therapy	3
Targeted agents	3
Anticancer treatment <3 months	

Yes	16
No	4
HL according to Chew	
HLD	12
NHLD	8

* Total greater than 20 as some participants received more than one treatment modality

Participants received study information in a variety of ways (Table 9). Just six requested the standard full-length participant information sheet alone, whilst others took this alongside a summary version, or preferred just to receive a summary in either a one-page written or video format. Video cards were sent to six potential participants, two of whom were subsequently interviewed and included in this analysis, and both screened as experiencing HL difficulties. The majority were telephone interviews, and the median duration was 52 minutes (range 33-109).

Table 9 - Study information preferences and interview type according to HL

HL according to Chew	Study information preferences						Interview type	
	One-page summary	Full PIS	Video summary	One-page + full PIS	Video summary + full PIS	All three	Telephone interview	Video interview
HLD	2	3	1	3	3*		10	2
NHLD	2	3	1		1	1	5	3

*Includes two video cards

The seven themes below are presented according to the first two research objectives:

- The experiences and decision making of patients suspected of having HL difficulties whilst receiving care for incurable cancer in the NHS
    - Supportive staff in an imperfect system
    - Additional pressure from COVID-19
    - In the expert's hands
    - Treatment not so bad
- Challenges faced by patients suspected of having HL difficulties whilst receiving care for incurable cancer
    - Emotional hurdles
    - Accessing and understanding information
    - Wanting to be a good patient

Finally, a series of recommendations about how best to support this patient group in clinical practice are made, addressing the third objective.

4.3.2 The experiences and decision making of patients suspected of having HL difficulties whilst receiving care for incurable cancer in the NHS

The majority of participants presented with symptoms, either to their GP or through emergency admission to hospital. Two were originally diagnosed through cancer screening pathways, and one was referred after an incidental abnormal finding on a routine blood test. For many, the diagnosis was initially unclear, and they were treated for a non-malignant cause in the first instance. Many participants had prior experience of the healthcare system through management of comorbidities or work, but for others who had been previously fit and healthy, the experience was entirely new. Most reported developing greater familiarity with the system, processes, and language over time.

4.3.2.1 Supportive staff in an imperfect system

Participants valued the care shown by individuals within the healthcare system but were also aware of its weaknesses. Standardised processes and administration could seem impersonal at times, particularly during the diagnostic pathway, and this made an often-unfamiliar experience even more challenging. One participant described confusion caused by the terminology used in an appointment letter, when he didn't see who he was expecting in clinic. Whilst the letter stated he would be seeing the registrar, he was instead seen by the pharmacist. This led him to question his knowledge of healthcare professional roles, added to his unease, and highlighted the sometimes impersonal nature of care processes in a large healthcare organisation:

> It says for instance, you've got a meeting with the registrar. I'm there thinking, I don't understand that, but that's the pharmacist, so for the hospital, the registrar's probably a registrar pharmacist, but I have no idea… so I'm trying to work out who that would be and what that's for, and I think well it probably is the pharmacist, but that seems strange to call them a registrar (Participant 005, 61-70, male, HLD)

Particularly in the early stages, when participants were still undergoing investigation or had not yet been established under a team, it wasn't always easy to know who to contact or where to turn for help. The emotional support some participants needed to come to terms with this life-changing news was not always readily available, creating additional anxiety and making the diagnosis even harder to deal with:

> When we were sent away from the hospital, we were given nothing in terms of support, or how to get support. All the support that we do have, we've had to get, find ourselves. I mean in the first, few weeks, after coming out of there, I was throwing out rubber rings everywhere, trying to find someone to talk to (Participant 002, 61-70, male, NHLD)

Doubt crept in when participants perceived failures in their care, were given conflicting information or plans changed, and this took time to process:

> And the sad part is that they were well aware in 2018 that I had shadows on the lung, which is on my record somewhere, and sadly it was not followed up… This is why I find

> it… harder, harder to accept… Although erm, I know the cancer is slow growing (Participant 004, 61-70, female, HLD)

Such occurrences could cause people to take a step back, requiring them to process this new information before they could move forwards and participate fully in decision making.

Despite these issues, most participants reported a good overall experience of care. Healthcare teams were highly regarded and perceived to be contactable and supportive in the majority of cases. Participants knew there was someone they could call with questions or concerns, and those who had done so found this a positive experience. Explanations given by clinicians were reported to have been clear, rarely included jargon, and efforts were made to explain things in a way participants could understand.

> I cannot fault the NHS, well Hospital A, they've been brilliant. The staff have been brilliant, they're friendly, they're always, always there trying to help, whatever, erm, yeah, can't knock them. (Participant 013, 71-80, male, HLD)

4.3.2.2 Additional pressure from COVID-19

Many participants described an awareness that the NHS was under additional pressure due to the COVID-19 pandemic, and this affected the care they received. One described feeling as though he had been put 'on the backburner' when two telephone consultations he was expecting didn't happen. The impression he had from the media was that the NHS was prioritising new patients and, as his disease was stable at the time, he was therefore of a lower priority. Others felt they had missed out because of reduced face-to-face contact with healthcare professionals, making it harder for some to ask questions or seek information:

> I think when you go face to face you, I don't know, you seem to be able to come out with more questions and that don't you? You come, which you should be able to do on a video, but erm, I don't know it's just… perhaps it's just a mental thing talking to somebody face to face, sort of in person (Participant 013, 71-80, male, HLD)

When participants did attend hospital, there was less opportunity for family to be present, and several reported being alone when receiving their diagnosis. One felt well supported after the consultant offered to invite his family in to explain the diagnosis, ultimately helping them accept it:

> There was no visiting, the ward was closed, and the consultant actually offered for my boys, my sons to come, to the ward, and she would explain what they'd found. Which I

> thought was brilliant… So that was some of the best communication I have ever experienced. (Participant 001, 71-80, male, NHLD)

Another described being left alone, feeling unsupported and without hope in a side room, her family having heard only some of what was said over a video call:

> I was having an erm… video call with my partner and my kids at the time, and I screamed I said I don't want to die, I don't want to die, and she didn't even say, no you're not going to or, you know, there's things we can do, nothing was said to me just, what I had, how sorry she was, and she walked out of the room… And I was left to deal with it. And all I wanted to do then was just go home. Get out of there because I didn't feel right, I wanted to go… Horrible way to tell somebody (Participant 027, 51-60, female, HLD)

The diagnosis came as a shock for both participants, but the clinician's handling of the situation significantly impacted the participants' experience of receiving the news.

The restrictions to social contact, risk of catching COVID during anticancer treatment and vaccine side effects placed an additional burden on participants during an already difficult time. Whilst one noted remote consultations had saved money on taxi fares to the hospital, they felt on balance that both they and their doctor had missed out by not having face-to-face contact.

4.3.2.3 In the expert's hands

Participants described putting their trust in the team looking after them to act in their best interests. Doctors as the experts were there to do a job and were expected to get it right:

> Interviewer: And, in general when it comes to, sort of thinking about your health, do you tend to like to be involved and have a say in what happens?
>
> Participant: Yeah, a little bit but not very much. I mean you, you, effectively employ somebody who's supposed to know what they're doing, let them get on with it (Participant 035, 71-80, male, NHLD)

There was a general feeling the decision regarding treatment had already been made by the clinician or wider multidisciplinary team, and most described going along with this recommendation. This was true regardless of HL according to the screening questions. Some took comfort from knowing set care pathways were being followed, and a team approach taken to determining and delivering care. Several also felt treatments wouldn't be offered if not worthwhile or cost effective:

> I’m one of the sorts of people that, when I look at something like the oncologist, you know the, the erm, Dr X, he knows a hell of a lot more than I do. So, if he’s recommending, then I’ll go with it… because he wouldn’t be recommending if he didn’t think it would do me any good (Participant 040, 71-80, male, HLD)

When asked whether she had been involved in decision making, one participant didn’t feel it was her place, and wrongly assumed each time a change was suggested, it was to try something ‘better’:

> Interviewer: Do you feel you’ve been involved in those decisions about your care and your treatment?
>
> Participant: Er, yes, I think so, yeah, obviously not when they changed the chemo, because they’ve always changed it for a, for a better one I suppose, to try to kill off the cancer cells… (Participant 008, 71-80, female, HLD)

Although it is indeed better to switch treatments when a regime doesn’t work or stops being effective (providing the patient wishes to continue active anticancer therapy), this does not mean the chance of response is higher, and often the efficacy of a treatment is lower in later lines of therapy.

Turning down a recommendation in favour of ‘doing nothing’ was often seen as foolish, or as though giving in to death. Whether participants described themselves as tough, a fighter, or as someone who goes along with things and does as they’re told, all ultimately accepted treatment.

> I know possibly you could just turn round and say I don’t want that and I’m not having chemo or I’m not having an operation or something but, faced with what you’re faced with, to me, that would be rather silly. So, you tend to just go along feeling that they know best and they’re doing their best for you… (Participant 012, 61-70, female, HLD)

The few who considered declining treatment felt they were too old, had been through too much, or were feeling low emotionally, and friends and family factored in all of their decisions to proceed:

> The other thing is the fact that, if you’ve got so, like so many months, and you can get on with your life as it is, then you’ve got to put it against if you’re doing all, you’re doing these chemos, and you feel lousy all the time… is it, you know, is it worth doing it? So I’d, I would have preferred not to but like I say you’ve got the kids, the grandkids all saying why you should do it, and it puts you in an awkward position really… (Participant 009, 61-70, male, HLD)

Signing consent was seen as a necessity to cover those delivering the treatment and an expected step in agreeing to a plan. One participant, however, described having a ‘get out clause’ by not reading the information he had been given, almost abdicating responsibility for his part in the decision to commence treatment:

> Yeah I think it was given to me in a way I understand but what I would say is… all the written information that I was given, I didn’t always read it. … So there’s a, there’s a kind of, there’s a kind of get out clause there (Participant 021, 51-60, male, HLD)

Another remarked that whilst the doctor knows about the disease, the patient knows their body best, suggesting a more balanced partnership between two experts. However, she also commented that patients shouldn’t be too involved in decisions as they were likely to make *‘wrong choices for themselves’* and should instead be guided by the medical professionals who know what has to be done, indicating a more deferential role (Participant 027, 51-60, female, HLD). Many participants reported being content with their involvement in the decision-making process.

4.3.2.4 Treatment not so bad

Participants had undergone various treatments, and some had received multiple lines of systemic anti-cancer therapies during the course of their disease. Some had had pre-formed ideas of what treatments such as chemotherapy would be like from the media or through reading about side effects, and were surprised and grateful when their own experiences were not so bad.

> He said we’ll look into what kind of chemo is best for you. And I immediately panicked and like I say, was envisaging erm, lots of, injections every five minutes, but then they said something about it could be just a tablet we give you, it could be something else, it could be a drip, or it could be both. And I thought well OK, that’s OK, it doesn’t sound too invasive really… The most invasive thing was the drip and that’s no real problem, I’m happy to say there weren’t any side effects from that either (Participant 037, 51-60, male, HLD)

Most reported side effects from the treatments they had received, in some cases life threatening. Several attended hospital or had to stop because of toxicity, but this was generally downplayed, and treatment was perceived to be tolerable:

> But on my first week of having it, I ended up getting septicaemia? I was rushed in… And they didn’t think I was going to make it… I was absolutely OK really with the chemo apart from, the odd infection I kept picking up I had to go in hospital and get, and have

> antibiotics through a drip, apart from that, no I, I, I… swam through the chemo, it was the radiotherapy that caused me the trouble. Chemotherapy was fine I, I was sick once (Participant 027, 51-60, female, HLD)

Participants appeared prepared to put up with side effects, accepting they were part of the recommended treatment pathway deemed in their best interests to follow.

> I don't really do a lot because it, it really drains me. If I'm not doing too much, if I'm just sort of like lazing around… it's not too bad, it's if you try to do things… It's like it, it drains all the energy out of you… My legs, joints and that, ache all the time… That, that bit's annoying (Participant 009, 61-70, male, HLD)

Evidence of treatment success in the form of physical changes, investigation results and continuing survival were encouraging, as was being in a position to receive treatment, with participants generally hopeful assessments would be conducive to ongoing therapy.

4.3.3 Challenges faced by patients suspected of having HL difficulties whilst receiving care for incurable cancer

4.3.3.1 Emotional hurdles

Understandably, for individuals facing a life changing illness such as incurable cancer, there were important emotional factors to consider alongside the physical experience of the disease. For most participants, the diagnosis came as a great shock:

> I've been dropped down a hole and I'm trying to get out of it, and I'm scrambling up the ladder like mad, and it's, you know, I've been going 100 miles an hour with the whole shock of it really (Participant 002, 61-70, male, NHLD)

Some described finding it particularly difficult to accept their illness when they were feeling so well, or when they had been fit and healthy before. Despite many presenting with symptoms, the possibility of cancer as the cause did not come to mind. Even whilst investigations were underway and there was likely a suspicion of malignancy, participants were not always aware of this, and the diagnosis often came out of the blue:

> I just didn't have any idea because I was a bit confused as to why they were expecting me to behave in a certain way or, you know, taking someone along with me for, moral support or to drive me, home… but I wasn't expecting that kind of news (Participant 015, 51-60, male, HLD)

Many described finding it difficult to take in much of what was said after hearing their diagnosis, which was often a time when important information was imparted and decisions about management plans were made:

> In the very beginning you're just caught up in it all because you learn as you go along which is unfortunate because, they just say, what you're going to do, what's going to happen and you just sit there and go yes, yes, yes, because you don't know any different. And the, there isn't any sort of, obviously you're in a terrible state mentally as well, there isn't sort of anyone to, to sort of try to explain everything for you and what is the best and that… (Participant 012, 61-70, female, HLD)

Several participants spoke of being frightened or worried, faced with their mortality. One described her fear when advised a Do Not Attempt Cardiopulmonary Resuscitation (DNACPR) decision would be appropriate:

> You've just been told what you've got, and then they come out with, and I'm going to put non-resuscitation. Well, when you hear those words it, it frightens you to death. I looked up and said you're going to do what? We'll put in none, we, we feel it's no, resuscitation, I said you are! What, what gives you the right to tell me I, I can't be resuscitated? If something was to happen? Well, we feel you wouldn't benefit from it, I said well, I want to be resuscitated. I don't care if I come back, a vegetable or this or that, I said no, I said I want to come back. I didn't like that, you know, it's, they sort of say we think it's, we'll put down no resuscitation, that's so frightening to hear all this! (Participant 027, 51-60, female, HLD)

The participant had just been given the diagnosis of incurable disease, and before coming to terms with this news, she then had to face her mortality, by being told rather than by discussing what would happen in the event of her heart stopping. The timing of this conversation so soon after receiving the diagnosis may have suggested to the patient death was even more imminent than previously imagined, creating additional fear. Despite being otherwise happy to follow professionals' recommendations, the participant was terrified by these conversations, making it more difficult for her to fully comprehend the situation.

Some participants were grateful their diagnosis offered them more time than other acute life-threatening conditions might have allowed, giving them an opportunity to spend time with family. However, one described worrying his prognosis might be so short he wouldn't have time to put his affairs in order, a fear only allayed when he was given a cycle of treatment longer than he had been expecting to survive:

> Once I knew I was on a course of pills, it suddenly hits you, you know your brain sparks and you think well, they think I’ve got enough time left on this planet to take all this course of pills, it’s not as though it’s, as urgent as I might have thought. (Participant 037, 51-60, male, HLD)

Uncertainty about the future featured in most participants’ accounts. Having agreed to a management strategy, participants reported being unsure about what would follow once their current treatment ended, or how they would feel, and this made it difficult to think or plan ahead:

> I'm, sitting here now and I've got no symptoms. I've had two sets of or two cycles. Is it two cycles? Of treatment, erm, and I've taken those quite well. I’ve had no adverse effects from them, but I've got no idea… I want to know how I'm going to deteriorate and, you know, I'm not going to say how I'm going to die but I want to know how I'm going to deteriorate, so I can manage my life and get on with it (Participant 001, 71-80, male, NHLD)

4.3.3.2 Accessing information to further understanding

Participants trusted information provided by healthcare professionals, and often relied on this as their primary source of reference. Several reported being given too much information at once, particularly at the beginning, some of which seemed irrelevant at the time and was put aside, and some wanted to know more as time went on. Many felt they had to be selective, picking out the details most important to them:

> I was definitely told, and they explained it well. But I’m the sort of person, I don’t really take a lot of notice, I get, I take in like the gist of it, I take the erm, like the common-sense side of it, and then I just get on with it and just do what people say (Participant 008, 71-80, female, HLD)

Though most recalled being told some side effects of treatment, written information was often given by healthcare professionals to back this up and provide further detail. Some participants didn’t feel the need to read and understand it, relying instead on what they had been told. Most reported the written information was generally easy to understand, though some did find the language used too difficult:

> She told me… that she was going to give me two types of drugs, I don’t know whether that’s right, you know, two, yeah, two drugs. Two basic drugs, which I've never heard of and never remember the names of. And then she gave me two very technical sheets on

> those… which quite honestly was complete gibberish to me (Participant 001, 71-80, male, NHLD)

Participants generally appeared to have a good understanding of the incurable nature of their illness and broad aims of treatment. Some were aware they had spread disease, knew the locations of their tumours and understood how this impacted their treatment options, whilst others were less clear. While some were happy just to know the basics, others didn't get the specific information they wanted, such as details of support services and where to seek help with hair loss. Few appeared to have sufficient understanding about valid alternatives including what was seen as 'doing nothing', or the trajectory of their disease, to help them make fully informed and balanced decisions.

> In the meeting I had with the doctor, he said well you can basically just do nothing, you don't want people playing around with you, and you, you're possibly going to live, he didn't actually give a date but I think reading between the lines, probably, I don't know, maybe four weeks if I was lucky. Or he said, I'm quite happy, if you want to take the proactive route, it'll mean messing around with you, but it might, we might be able to extend it, he said I don't think we'll ever cure it, but we can certainly hopefully give you a lot more time, or some more time, again he didn't specify he said he really didn't know I don't think to be honest (Participant 038, 61-70, male, NHLD)

Several participants reported not wanting to know important details such as prognosis at the time of diagnosis, as it was too much to take in initially. Whilst some described being in a better place later, this was often after key information had been imparted and decisions about treatment made. One participant specifically asked about prognosis but did not get a satisfactory answer, and an opportunity to improve her understanding was missed:

> They just said they didn't know, they couldn't tell me, so… I left it, I didn't ask anymore… I thought no I've asked once, I'm not going to ask, I'm not asking that one anymore… what I don't know now won't hurt me (Participant 008, 71-80, female, HLD)

Some participants suggested it would help to have more time to process this news and consider what else they would like to know, before meeting again a few days or weeks later to discuss further.

Several expressed an interest in keeping up to date with the state of their disease by reading scan reports or accessing their notes, though this sometimes required them to look up medical words to understand the content. One suggested a document summarising their health and updated over time might help them keep track of what was happening with their cancer.

Most participants reported they could contact the oncology department with questions or concerns, though some described confusion over the roles different professionals played, and who to call in which circumstance. Many sought additional information from sources such as the internet to find facts and further their understanding, noting however, that as well as not always being reliable, it was also possible to stumble across unwanted and unwelcome information online. Some set out to hear about others' experiences through support groups or online forums, whilst others didn't feel this would suit them. Of those who did not seek additional information, all but one reported HL difficulties according to the screening questions.

Many participants relied on support from friends and family to help them navigate the healthcare system, seek, and understand information, and make decisions about care, and most had someone to fill these roles. One without close family described how a friend acted as her advocate, asking questions when she felt unable to, or reminding her if she forgot. Another had limited social support to help with the day-to-day practicalities of living with cancer. He felt having someone to read out the paperwork he had been given, point out which telephone number to use when, and field the many calls he wasn't used to dealing with would help him navigate this challenging time.

4.3.3.3 Wanting to be a good patient

Despite most participants reporting being able to speak up and ask questions, many described a hesitancy to do so. Some were conscious they did not want to be a burden by bothering busy healthcare professionals. Others worried their questions would be seen as trivial:

> Participant: Sometimes I'm a little bit hesitant to phone up asking about those sorts of things? You know, but to me it's quite important? To have things to look forward to and, I think, whether I would perhaps be, like I say a bit reluctant to ask, about that?
>
> Interviewer: And may I ask what, what makes you feel reluctant? Or it might not be something you can put your finger on
>
> Participant: No, maybe, I feel, am I wasting somebody's time, just asking that? But it is important to me? (Participant 023, 51-60, female, NHLD)

Most were mindful clinicians were busy and didn't want to take valuable time away from other patients in need. They instead relied on planned contacts, which could be a 'lifeline', especially when not receiving active treatment. Some participants described a pressure to remember to ask everything they wanted to know during the appointment, feeling they would otherwise miss their chance to get answers.

One described a hesitancy stemming from his childhood when he was told off by the doctor for wasting his time. Following this encounter, he had always tried to figure out his health issues himself. Despite being encouraged to call, and staff being pleased if he did, he put off contacting the acute oncology team when he experienced significant toxicity from his anti-cancer treatment, only doing so later after being persuaded by his wife (Participant 040, 71-80, male, HLD).

Other participants were concerned their healthcare team might think badly of them for speaking up or requesting access to their notes. The one participant who initially declined treatment believed the relationship with her consultant was damaged after she 'refused' treatment:

> I got the imp, the wave off of him that he was really angry with me that I'd refused treatment… six months previously. I really think he was annoyed with me because I refused treatment, that's the vibe I was getting off of him (Participant 042, 71-80, female, NHLD)

This was a rare example but led to the participant feeling she was in the wrong for not accepting treatment and unable to communicate with her consultant as a result. She 'begrudgingly' gave consent, not wanting to waste the doctor's time but without fully understanding the possible side effects, subsequently reporting she regretted her decision to proceed with treatment, and would have made a different decision if she'd had all the information up front.

4.3.4 Recommendations

Having identified the challenges for people with HL difficulties facing decisions when cancer can't be cured, the next step was to consider potential improvements to support this patient group in clinical practice. Drawing on specific suggestions made by participants, the literature, and in discussion with the supervisory team, a series of recommendations to support SDM were subsequently developed, and are presented in Table 10 alongside additional supporting participant quotations.

Table 10 - Summary of recommendations to support SDM

Considerations	**Participant quotes**	**Recommendations for improvement**
Address peoples' emotional needs	*It'd be better if you just had your main doctor's appointment that day, then the lung nurse say to probably ring you, a few days after, let you digest that first, and then you could probably ask, answer her questions… But all together on one day, you just start shutting down, I did, it was too much (Participant 027, 51-60, female, HLD)* *She could have maybe suggested… I can appreciate what you're going through, or you've had some dreadful news, this is the number, I can email you some details about a counsellor? I had to wait a long time before I heard from (Hospital A), so, in that period, there was no communication and it would have been helpful … it may have been a time when I could have perhaps picked up the phone, I didn't know who to turn to… I've heard of all these organisations or charities, but I'm unaware how they fit in, what they offer... At some stage it would have been really helpful, to have been given that information? These support groups are there if you need them… This is a list of organisations, just ping it out to patients. (Participant 023, 51-60, female, NHLD)*	Give people time and space to process information (including longer or multiple appointments) Ensure easy access and signposting to support services (both within and outside the hospital) from the outset
Facilitate control over information	*All I'll say, I've just said it, if it were written in plain English… If they'd really thought that the audience was the patient, they should have been written in plain English. (Participant 001, 71-80, male, NHLD)* *You know that DVD that you sent to me? I think, one of those, specifically for each patient, I reckon that would carry a lot more weight and more understanding for people than, any piece of paper would. Because you're listening to it and you're taking it in aren't you? You're learning. Piece of paper you can sort of skim that when you're reading it and miss pieces that you're supposed to be reading (Participant 027, 51-60, female, HLD)* *In the beginning it's all just too daunting to be honest and I mean, the booklets are quite good… but obviously they cover all sorts of cancers, and then you get recipe books and things, well when you've just been told that you've got cancer… the last thing you need is a recipe book. It's later on you learn how important it is to eat well and keep well and exercise and all that sort of stuff… (Participant 012, 61-70, female, HLD)* *I do forget and think oh, I must ask them this… you might write it down, but then you lose your, piece of paper that you wrote it down on… So it would be nice to get, maybe an update? Every year? With just the relevant information that you require and then, if you wanted to see, the prognosis, how many years, to have that on it. Some people may not want that, so don't add it. So you ask the patient (Participant 015, 51-60, male, HLD)* *If you've been to see your oncologist, it would be nice, the following week, to get a copy of what was said… we met on, whenever and I explained this and discussed that, because then when you go back the next time you can think, well did you explain that? You might have thought you explained it but, because I didn't understand it, I don't think you did explain it… (Participant 012, 61-70, female, HLD)*	Ensure information is written in plain English Offer personalised information to reduce confusion and information overload Offer information according to patient preferences whilst bearing in mind implications for informed consent Offer alternatives to written information and consider access e.g., video cards Revisit conversations and make information easily accessible beyond the first consultation Provide summaries or easy access to records for reference and allow people to monitor progress Encourage people to prepare questions and ensure these are reviewed

Considerations	**Participant quotes**	**Recommendations for improvement**
Develop a partnership	*They explained it as best they could, but I mean, I'm only a layman, I don't understand all the ins and outs, but I had to carry, get on with the treatment anyway because there's nothing else to do is there? You have to go by what they say, you know? (Participant 014, 71-80, male, HLD)* *Our meeting was quite short… so in terms of talking to them at length about what I want out of it, I expect we, it was more of they just told me what was going to happen… And I said OK. We never talked in detail about the response to treatment and what happens, and that… They did say about the quality of life… That was their priority (Participant 002, 61-70, male, NHLD)*	Break down the expert-layman barrier to create a more equal footing Place greater emphasis on the patient as the expert in themselves Ensure greater transparency of options and discussion of priorities
Involve others to enhance understanding	*They sort of give you all the information at the beginning of a half hour appointment type of thing, and, at the end of it you're then expected to make a decision. You don't have a chance to go away and, sort of, think about what you've been told, you don't have a chance if you wanted to, to discuss it with, anybody (Participant 034, 51-60, male, HLD)* *I think meeting with other people, who've had similar experiences, you can all help one another… there was sort of just people, with cancer issues. Ranging from recently diagnosed people to very poorly people and things. And I think sometimes in that situation, you can actually help each other a lot, which lessens the burden then on the professionals. (Participant 012, 61-70, female, HLD)*	Encourage support from friends/family, offer advocate if not available Ensure patients have the opportunity to discuss decisions with others if wanted Offer opportunities to hear from other patients through charities/support groups Be aware of other information sources e.g., media, and signpost to reliable resources
Organisational considerations	*The letter writing is very generalistic… perhaps it just does need someone who can simplify that as they're going along, and, sort of use some common sense and say we need to try and make this really straightforward for the patients, so they fully understand… who they're seeing, and what it's about I think that's, a little bit of clarity on that would be really helpful (Participant 005, 61-70, male, HLD)* *Somebody like myself, if they could ever have, access to some kind of appointed, for want of a better expression PA… To be there with them and say I'll read this form out to you, this is what this means… just somebody to read out the stuff they've given you if you're not up to doing it... Maybe somebody that can look up the right phone numbers, because I've got so many phone numbers I wouldn't know which to ring for whatever emergency (Participant 037, 51-60, male, HLD)* *If you get a problem, they're all pleased for you to ring up… But it's just something you don't do readily… And I mean they said often enough, anything goes wrong, phone the hotline. I've got a card in my pocket with the hotline number on… but you still don't do it…. Interviewer: Do you think if somebody had happened to phone you, would you have told them what was going on? P: Oh yeah. (Participant 040, 71-80, male, NHLD)*	Ensure correspondence (including appointment letters) is clear and easy to understand to avoid confusion Provide flexibility in scheduling e.g. multiple short appointments, face-to-face if wanted Offer support to manage treatment schedules, paperwork etc. Where possible, offer additional contact enabling people to raise issues if they may be hesitant to call Provide clear contact details for people to seek additional information/help

4.4 Discussion

The experiences of participants in this study highlight a number of challenges for SDM in this setting, and several areas for improvement. Though some findings are specific to those who reported HL difficulties, many issues are likely to be relevant to all patients regardless of HL and will have implications for SDM in incurable cancer more generally.

One of the first considerations is to address patients' emotional needs, ensuring they have the time and support necessary to process the information given and take on an informed role in decision making. Existing literature suggests anxiety and distress associated with such a diagnosis may negatively impact individuals' ability to recall and process information (Kessels, 2003; Derry, Reid and Prigerson, 2019). Many participants in our study reported finding it hard to take in information immediately after being told difficult news. This was often when they were given complex details of treatments, schedules, and toxicities, were involved in resuscitation discussions, and had important decisions to make. Several described feeling able to take in more information over time, but some topics, such as prognosis, were difficult for patients to raise. Several participants described uncertainty about what to expect for the future in terms of the disease trajectory and treatment options. It is therefore important to ensure patients are given time, both during and between appointments, and are supported to process and come to terms with the information they have been given. It could also be helpful for a member of the team to check back at a later point, either at a subsequent consultation or with a follow up phone call, to establish understanding, re-explore these issues and address any outstanding queries. By supporting these discussions over multiple appointments, patients may become more informed, prepared, and able to fully participate in making the decisions that are right for them. Some participants were keen to receive additional emotional support, but information on how to access this was not always readily available. The degree to which patients might draw on different sources of support, such as counselling or support groups, will vary according to their needs and preferences, but as one participant suggested, it might help to clearly set out the services available, and the roles different organisations play. This may make it easier for people to access these services, feel more supported and better able to face the challenges in front of them. The Implement-SDM model (Joseph-Williams *et al.*, 2019), developed from observed SDM in clinical practice, similarly identified the importance of these social and emotional factors. It draws attention to the importance of providing comprehensive emotional and practical support, suggesting that in certain contexts this may be of greater importance than the decision itself (Joseph-Williams *et al.*, 2019).

Although participants generally found the written resources easy to understand, some would have found them more helpful if simpler language was used, and several described being overloaded with information early on. Ensuring resources are easily available, written in line with HL principles and offered beyond the first contact might allow people to take on more information when in a better mindset to do so. Several participants accepted the offer of receiving information about this study in video format, either sent electronically or played through a physical video card. One in particular found the card extremely valuable. She felt it would have helped her explain her diagnosis to her family, allowing them to process and accept the information in their own time at home, and leaving her with something tangible to refer back to, a ‘safety net’ once her contact with healthcare professionals became less frequent after completing treatment. Greater availability of video or audio recordings would give patients more choice and control over the information they can access and could facilitate better understanding for those who don’t find written resources helpful. Some participants relied on the verbal information they were given by healthcare professionals and shied away from paperwork, whilst others sought information from external sources, including the internet. In their study of patient involvement in decision making, Smith *et al.* (2009) found greater differences between participants with higher and lower levels of education rather than HL levels, noting participants with a lower level of education relied more on practitioners as their main source of information. However, this was one of the main areas in the participants’ responses where differences in HL according to the screening questions were noted, as those who did not seek additional information tended to screen as having HL difficulties.

One further way participants attempted to keep informed about their disease was by requesting access to their medical record, though this is not generally written with the patient as the intended audience. As suggested by one participant, having an easily understandable, personalised record to refer back to may provide clarity for some patients, allowing them to keep track of changes to their disease and treatment and better informing any decisions they may have to make. Similar resources already exist to record treatments and side effects, such as the Cancer Research UK ‘Your cancer treatment record’ (Cancer Research UK, 2022), however, this is a relatively lengthy document (84 pages), and may be overwhelming, particularly for those who find it more difficult to use and understand written information. A clearly written, updateable summary over just a few pages, or perhaps a brief video or audio recording, might be more accessible.

The experiences described by participants in this study suggest an ongoing power imbalance between clinicians and patients, and whilst most reported they could ask questions, or call up after the consultation, many were hesitant to do so. Several participants described negative interactions with healthcare professionals which left them feeling they had done something wrong, including after declining an offer of treatment, seeking help ‘inappropriately’, requesting records or raising concerns. Such experiences reinforce the idea shared by many of the need to be a ‘good patient’ and of not wanting to be a burden. In addition, as the less powerful actors in the partnership, patients may not have the capacity or ability to mobilise the necessary affective, cognitive, informational and relational resources to fully participate in the process, further lessening their sense of control (Hunt and May, 2017). However, whilst clinicians are experts in the disease and treatments, patients should be equal in this partnership, and their priorities need to be actively explored to ensure any proposed management plan is in line with what is important to them. Acknowledging patients may be hesitant to speak up for a variety of reasons and offering encouragement to voice their priorities and questions may ultimately allow them to gain a better understanding and take a more active role in decisions about their own health.

Follow up calls to patients may provide additional opportunities for people to seek clarification and consolidate understanding, and raise concerns they might not otherwise have felt able to. Ensuring priorities are routinely discussed and documented, highlighting to patients the value of their own expertise in themselves, and providing encouragement and permission to actively contribute to the decision making process may also help foster a more balanced partnership. Posters or videos in waiting rooms, a simple leaflet, or a brief line in a clinic letter may help prepare patients for this.

These information seeking practices and hesitance to speak up tie in to findings from a meta-synthesis of the literature carried out by Edwards, Davies and Edwards (2009), who identified HL as a mediator of external influences and empowerment in decision making consultations. Their proposed model demonstrates how patients may become informed and subsequently empowered through engagement with information, provided they are supported to do so. HL plays an important part in this, and those with higher HL appear more likely to become empowered as a result of their engagement with information. However, patients may become disempowered if the healthcare professional does not support and indeed limits the patient’s involvement. Alternatively, patients may be wary of using the information, or not want to be seen as questioning medical authority. Despite becoming well informed as a result of their own information seeking, such patients make a more active choice not to act as empowered patients, and ultimately defer the decision to their clinician. Relevant also to the findings from these interviews, patients may become non-empowered as a result of not seeking information, and again, may prefer their healthcare provider to make decisions on their behalf (Edwards, Davies and Edwards, 2009).

As was found in another study of patients undergoing radiotherapy for a variety of cancers, participants described following recommendations made by clinicians they felt would be acting in their best interests (Smith *et al.*, 2017), and agreed to treatments in the belief they wouldn't be offered if they weren't going to work. Unfortunately, however, there are never any guarantees a treatment will work, particularly in later lines of systemic therapy, and there is often a trade off in quality of life when pursuing life-extending treatments. As an offer of treatment might be hard to turn down, clinicians must seek to understand the patient's perspective to be able to counsel them through these difficult conversations, and be mindful of presenting full and clear information to support decision making. Additionally, individuals with lower HL and in the palliative phase of their illness are likely to be particularly susceptible to explicit or implicit persuasion (Geurts *et al.*, 2022). In one qualitative study of recorded consultations between clinicians and patients with end-stage COPD and/or cancer, and a lower level of education or HL, persuasive communication behaviours were used in every one of the 28 recorded encounters, averaging three per consultation (Geurts *et al.*, 2022). Behaviours such as authoritative framing, which include giving a recommendation and presenting the options as a decision based on expert consensus, the illusion of decisional control, including presenting an option as having no other choice, and biased presentation of information, with emphasis on the benefits and downplaying or limited discussion of side effects, are some examples which appear to have been described by participants in this study. Whilst there may not always be true equipoise between two options, and therefore a clinician may make a recommendation based on likely benefit in terms of clinical outcomes, such as survival, the value placed on these outcomes may differ according to the individual patient, and the less favoured option may therefore be more appropriate depending on their priorities, preferences, and life aside from their cancer diagnosis. Ensuring discussions are balanced, take account of what matters most to the patient and keep this conscious or subconscious persuasive power in mind is therefore essential. Whilst signposting to other sources of reliable, unbiased information may also help inform these decisions, many participants in this study relied primarily on information given by their healthcare professionals, and this may therefore have a limited impact in this patient group.

It is also important to engage with family, friends, and advocates, and identify those individuals who might benefit from additional social support to navigate the complex processes associated with their diagnoses. Additionally, although they do not suit everyone, some participants found it helpful to learn from other peoples' experiences through support groups or online forums, with one noting the importance of re-establishing groups lost during the COVID-19 pandemic. Such groups can be a valuable resource for patients to support each other and potentially lessen the burden on healthcare professionals, and signposting to relevant groups may make it easier for some to access.

The COVID-19 pandemic brought many additional challenges and led to rapid changes in the way healthcare is delivered. Some, including restrictions to visiting, which resulted in many people facing difficult conversations on their own, have been lifted, and patients are encouraged to have someone with them at such times, as they were before the pandemic, to provide support. Other changes, such as the increased use of remote consultations, are likely to continue, as part of the NHS Long Term Plan to redesign outpatient care and make digitally enabled care mainstream (NHS England, 2019a). Whilst remote consultations can allow greater flexibility for both patients and staff, our findings suggest the reduction in face-to-face contact may make it even harder for patients with HL difficulties to speak up and further their understanding of their situation. Furthermore, video interviews (and therefore consultations) were not possible for some participants, with others preferring to be interviewed over telephone, potentially restricting communication through the loss of non-verbal cues. Although our qualitative sample was small, those with HL difficulties tended to proceed with telephone rather than video interviews. This is in keeping with a recent cross-sectional study of 18130 telehealth visits scheduled during the pandemic, which found an independent association between lower HL and audio rather than video consultations (Brown *et al.*, 2022). These issues are further explored in a large body of work carried out prior to and during the pandemic by Greenhalgh *et al.* (2021), who identified significant political, organisational, economical, technical, relational and clinical challenges in the successful implementation of remote consultations, and highlighted the need for digital inclusion to reduce the risk of worsening inequality, including those with lower HL.

Participants' self-reported HL was assessed using a validated screening tool. However, several issues limiting the tool's ability to distinguish between those who experienced HL difficulties and those with no HL difficulties were encountered. The screening questions did not always appear to reflect the individuals' HL as reported through their own experiences in response to the other interview questions. One participant (001), described the information sheets as *'gibberish'*, yet responded *'none of the time'* when asked the question "How often do you have problems learning about your medical condition because of difficulty understanding written information?" This could have been because he perceived the information sheets to be written for a clinical audience rather than for him as a patient, but also highlights an issue with the use of subjective assessments rather than objective measures which directly assess an individual's skills. Other participants appeared to misinterpret the questions: Participant 005, for example, reported he needed help and had problems reading 'most of the time', implying HL difficulties, yet when asked during the interview whether the written information he had been given was clear and easy to understand, he replied it was. He went on to explain how he used this information as a *'base document'* when searching online to do *'a little bit of extra research'*, which subsequently helped inform his decision making, suggesting he was in fact able to access, understand, appraise, and use information to make decisions. One reason for this discrepancy could be that the questions and five possible responses may have been hard for participants to follow when heard just once or twice. Initially, the questions and responses were only repeated if requested by the participant, but later in the study when this issue became more apparent, they were repeated if the participant appeared to have misunderstood. The verbal delivery of questions, used in the validation study of the tool, was chosen to avoid the need for participants to read the questions themselves, but some may have misheard or misinterpreted them as a result. Finally, some participants struggled to choose an answer to fit their personal situation. In this scenario, the question and possible responses were repeated, and participants supported to make a selection. In the small number of instances where this was not achieved, a judgement was made based on the answer given as to whether this met the threshold identifying HL difficulties. For example, the response from one participant of *'no I'm fine filling forms out, that's not a problem'*, was not suggestive of HL difficulties, whilst the response *'I always have difficulty with forms'* suggested the individual did face difficulties with HL. Whilst the sample therefore includes those with and without HLD according to the screening questions, it reflects a group of patients identified as experiencing challenges accessing, understanding, and using information or following complex schedules, which is in keeping with current HL definitions (Section 1.4.1).

4.4.1 Study limitations

Despite its strengths, including recruitment of a relatively large number of individuals with HL difficulties during the COVID-19 pandemic, this study did have limitations. Due to the recruitment, consent process, and nature of the study topic, it was not possible to confirm participants' medical history until after the interview. This led to the erroneous recruitment of one individual in receipt of adjuvant treatment. As specific decisions are fundamentally quite different in this setting, this participant's responses could not therefore be included in the main analysis, though elements relevant to general aspects of care were considered alongside the study findings. Additionally, further demographic details including ethnicity, education and socioeconomic status were not collected. This limits our understanding of the participants' backgrounds and the other important factors which may have had a bearing on their HL, navigation of the healthcare system and involvement in decision making.

4.4.2 Clinical implications

This study has important implications for clinical practice. By hearing from those who have experienced difficulties getting the information they wanted or needed, or not being as involved in their care as they might have liked, it has been possible to identify a number of barriers to SDM in the palliative oncology setting, many of which will be relevant to others regardless of HL.

The findings from this study should therefore be considered when developing interventions to support SDM in this setting, and many of the recommendations can be easily incorporated into routine clinical practice with potential to improve the patient experience. Though unlikely to change behaviour on its own, ensuring information and processes are developed using simple language, avoiding jargon and available in a range of formats to suit individuals' preferences will make navigating this unfamiliar environment easier for all patients. However, our findings suggest that in addition to addressing informational needs, including ensuring the amount of information provided is in keeping with how much the patient can and wishes to take in, interventions aimed at increasing SDM will also need to overcome the psychological and social barriers affecting patients' involvement.

4.5 Conclusion

These findings demonstrate why it can be challenging for patients with HL difficulties to access the information needed to make truly informed decisions about their health and feel able to speak up and take a more active role in their care. The significant emotional burden placed on patients when they receive a diagnosis of incurable cancer may limit the information they can process, and when this information is not easily accessible, patients may be left with an incomplete understanding of their disease and available options. Power imbalance in the partnership can make it difficult for patients to turn down an expert's recommendation and the patient's own expertise may go unrecognised. As such, SDM can be difficult to achieve, and patients and clinicians risk reaching decisions that are out of keeping with the patient's priorities. To succeed in supporting SDM in this setting, it is therefore important to consider the challenges faced by patients and address this combination of psychological, social, and informational needs.

4.6 Summary and next steps

The work contained within this chapter offers a greater understanding of the experiences and challenges faced by those reporting HL difficulties whilst receiving care for incurable cancer. In addition to the emotional challenges associated with such a diagnosis, patients face barriers to accessing and understanding information, as well as system related and social constraints which contribute to power imbalances and can make it difficult for people to take a more active role in decision making.

Having achieved this greater understanding of the challenges faced by patients, it is important to also consider the process from the perspective of healthcare professionals, to learn about their experiences and views and consider how these barriers might be overcome. The following chapter describes the next phase of work in this PhD study, a survey of healthcare professionals who care for those with incurable cancer, which seeks to further this understanding and explore the issues from this alternative perspective.

Chapter 5 NHS healthcare professionals' views and experiences of shared decision making in the setting of incurable cancer

5.1 Background

The study described in Chapter 4 identified barriers to SDM from the perspective of patients with incurable cancer who have experienced difficulty getting information and/or have not been as involved in decision making as they would like. Participants faced a number of challenges whilst receiving care for incurable cancer, including overcoming the emotional hurdles associated with their diagnosis, and difficulty accessing and understanding information about their disease and treatments. They described following recommendations put forward by healthcare professionals – trusting the experts to get things right for them. Most patients still appear to expect a more traditional paternalistic approach to healthcare decision making, and may find it hard to speak up or be reluctant to do so for fear of being labelled difficult. Faced with these emotional challenges, along with difficulty accessing the information needed to evaluate the options for themselves, patients perceived their role to be to agree to treatments offered, deeming it foolish not to.

These findings from the patient perspective are vital to further our understanding of why SDM is not always achieved, and provide a starting point when considering how to implement change. However, SDM requires input from at least two parties, and it is important to learn from the healthcare professionals on the other side of this partnership to gain a different perspective of the challenges faced. Existing work by De Snoo-Trimp *et al.* (2015) identified several barriers to SDM in the palliative oncology setting, resulting from clinicians' positive attitudes towards treatment, particularly in the first line setting, the perceived imbalance in the partnership as a result of their expert knowledge, and their assumptions about patients' preferences. However, little is known about how clinicians' views and approaches to SDM in incurable cancer may differ when a patient is perceived to have lower HL.

5.1.1 Aim and objectives

This survey aimed to understand healthcare professionals' views and approach to SDM in the context of incurable cancer, with a focus on HL.

The objectives were:

1. To understand the views and experiences of healthcare professionals towards SDM in the context of incurable cancer
2. To explore the barriers to SDM in the context of incurable cancer reported by healthcare professionals
3. To explore how perceived lower HL affects how healthcare professionals approach SDM with patients with incurable cancer
4. To identify what strategies might be useful to support SDM for patients with incurable cancer and lower HL.

5.2 Methods

5.2.1 Data collection

Following guidance on developing online surveys (Braun *et al.*, 2021), an anonymised online survey (Appendix B.3) on Microsoft Forms was devised to address the objectives. Tick-box and multiple-choice questions were included at the beginning to capture demographic data, and for ease of completion where more complex responses were not required. The response options for these items were chosen based on clinical experience within the team and drawing on the literature, and an 'other' option was included to allow participants to add alternatives. Several free text questions followed, which required completion before participants could continue with the survey. Brief descriptions of the terms health literacy (adapted from the International Union for Health Promotion and Education (2018) definition) and shared decision making (adapted from Coulter and Collins (2011)) were provided ahead of the questions referring to these concepts. Several iterations of the survey were produced and reviewed by the supervisory team resulting in improvements to the initial survey design. Once no further changes were suggested, the survey was piloted with three oncology healthcare professionals (one clinical oncology registrar and two cancer clinical nurse specialists (CNS)) to determine the time taken to complete the survey and ease of completion. All felt the survey was easy to complete and did not take too long (up to 20 minutes). A small number of minor changes to wording were made as a result of feedback given.

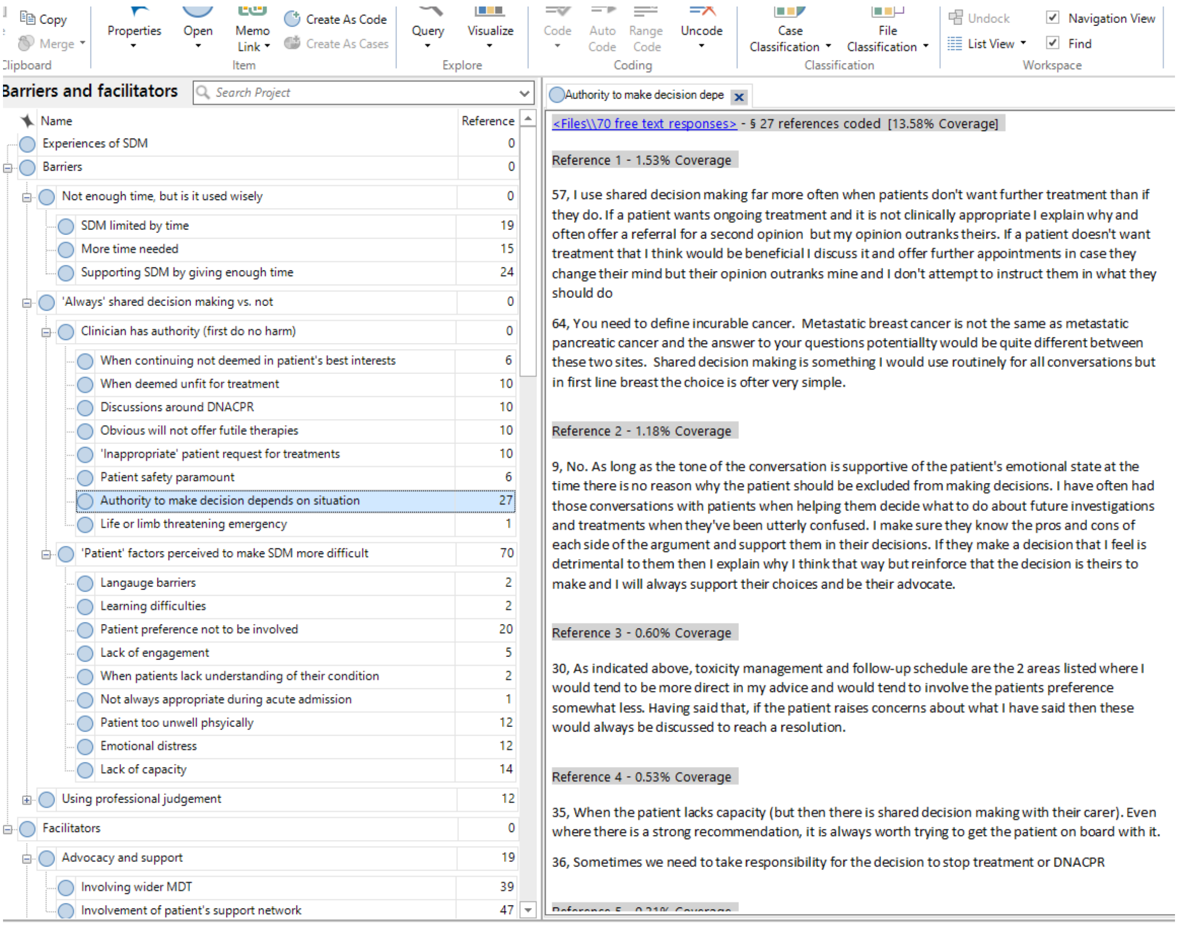
The primary goal of the survey was to collect free text qualitative responses, and whilst the quantitative data were used to support and provide context for the findings, the intention was not to generate generalisable quantitative data. In line with guidance on using online surveys to conduct qualitative research (Braun *et al.*, 2021) and other online qualitative surveys using thematic analysis (Grogan, Turley and Cole, 2018), a target sample size of 30 responses was set using convenience sampling.

The survey was accessed using an online link and was distributed to members of the UK Oncology Nursing Society (UKONS) via their electronic newsletter and social media; members of the Association of Cancer Physicians (ACP) via email; and members of the newly established board of the UK Association of Supportive Care in Cancer (UKASCC) via email. These UK based organisations were chosen to reach a variety of oncology healthcare professionals within the NHS setting, and recipients were encouraged to share the link with colleagues. Eligible participants included healthcare professionals working with adults in the NHS diagnosed with incurable cancer. On accessing the link, participants were presented with a brief introduction to the study and eligibility criteria, as well as a link to the participant information sheet and contact details for further information. Participants were required to check a box to confirm they had read the participant information sheet and agreed to take part before they could continue with the survey. The study was approved by the Faculty Research Ethics Committee (FREC) at the University of Southampton (ERGO No: 65382) and was open to responses between 23/08/2021-30/09/2021.

5.2.2 Analytic method

At closure of the survey, data were downloaded, and free text responses collated according to question and participant number. Qualitative data analysis was carried out using NVivo 12 software and was guided by the approach to thematic analysis outlined by Braun and Clarke (Braun and Clarke, 2006;2019). After reading and re-reading the data and noting initial ideas, the data were coded across all survey questions (see Figure 20 for an example, with corresponding references to right). Initial coding was largely semantic and included codes such as “SDM limited by time”, but subsequently more latent codes such as “not enough time, but is it used wisely?” were used. Codes were then grouped, and these groupings refined to form themes addressing the research objectives (see Figure 21 for an example of provisional categories, with descriptions and supporting quotations).

The quantitative data were considered alongside the qualitative findings. No statistical analysis was planned given the anticipated small sample size and focus on generating primarily qualitative data. Instead, a descriptive analysis was performed.



Barriers and facilitators

Name	Reference
Experiences of SDM	0
Barriers	0
Not enough time, but is it used wisely	0
SDM limited by time	19
More time needed	15
Supporting SDM by giving enough time	24
'Always' shared decision making vs. not	0
Clinician has authority (first do no harm)	0
When continuing not deemed in patient's best interests	6
When deemed unfit for treatment	10
Discussions around DNACPR	10
Obvious will not offer futile therapies	10
'Inappropriate' patient request for treatments	10
Patient safety paramount	6
Authority to make decision depends on situation	27
Life or limb threatening emergency	1
'Patient' factors perceived to make SDM more difficult	70
Langauge barriers	2
Learning difficulties	2
Patient preference not to be involved	20
Lack of engagement	5
When patients lack understanding of their condition	2
Not always appropriate during acute admission	1
Patient too unwell physically	12
Emotional distress	12
Lack of capacity	14
Using professional judgement	12
Facilitators	0
Advocacy and support	19
Involving wider MDT	39
Involvement of patient's support network	47

<Files\\70 free text responses> - § 27 references coded [13.58% Coverage]

Reference 1 - 1.53% Coverage

57, I use shared decision making far more often when patients don't want further treatment than if they do. If a patient wants ongoing treatment and it is not clinically appropriate I explain why and often offer a referral for a second opinion but my opinion outranks theirs. If a patient doesn't want treatment that I think would be beneficial I discuss it and offer further appointments in case they change their mind but their opinion outranks mine and I don't attempt to instruct them in what they should do

64, You need to define incurable cancer. Metastatic breast cancer is not the same as metastatic pancreatic cancer and the answer to your questions potentiallty would be quite different between these two sites. Shared decision making is something I would use routinely for all conversations but in first line breast the choice is ofter very simple.

Reference 2 - 1.18% Coverage

9, No. As long as the tone of the conversation is supportive of the patient's emotional state at the time there is no reason why the patient should be excluded from making decisions. I have often had those conversations with patients when helping them decide what to do about future investigations and treatments when they've been utterly confused. I make sure they know the pros and cons of each side of the argument and support them in their decisions. If they make a decision that I feel is detrimental to them then I explain why I think that way but reinforce that the decision is theirs to make and I will always support their choices and be their advocate.

Reference 3 - 0.60% Coverage

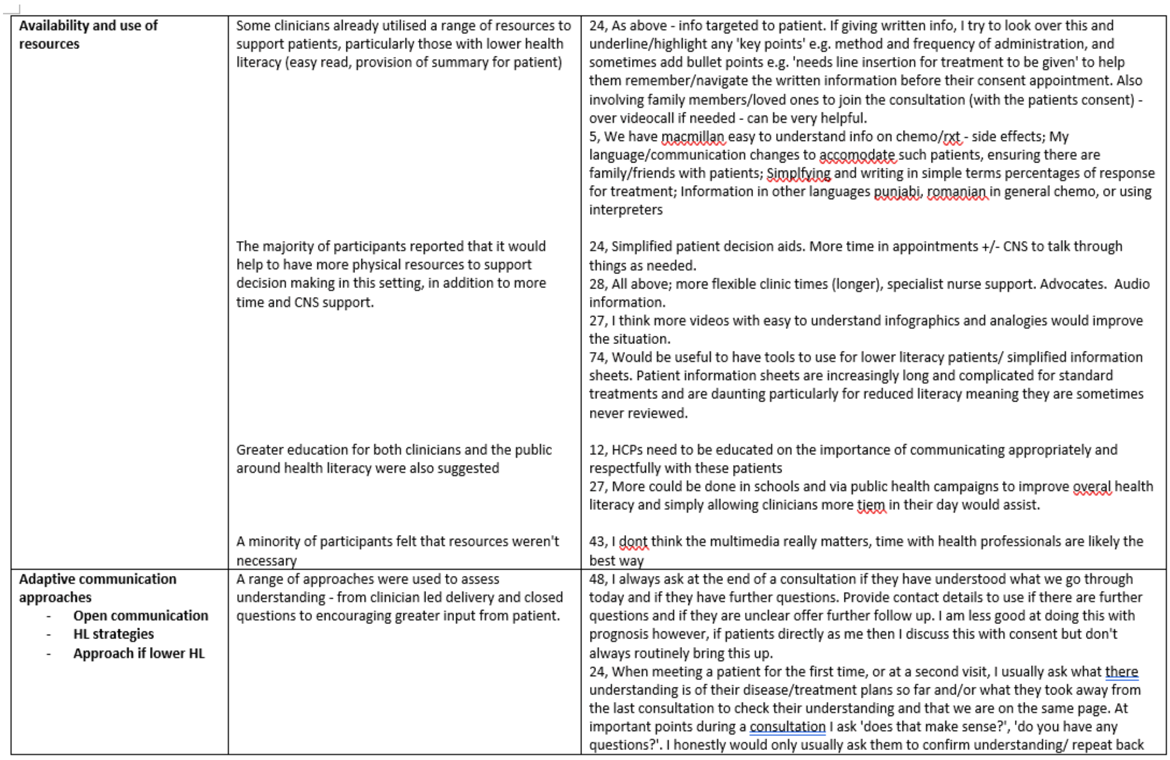
30, As indicated above, toxicity management and follow-up schedule are the 2 areas listed where I would tend to be more direct in my advice and would tend to involve the patients preference somewhat less. Having said that, if the patient raises concerns about what I have said then these would always be discussed to reach a resolution.

Reference 4 - 0.53% Coverage

35, When the patient lacks capacity (but then there is shared decision making with their carer). Even where there is a strong recommendation, it is always worth trying to get the patient on board with it.

36, Sometimes we need to take responsibility for the decision to stop treatment or DNACPR

Figure 20 - Screenshot of partial codebook in NVivo



Availability and use of resources	Some clinicians already utilised a range of resources to support patients, particularly those with lower health literacy (easy read, provision of summary for patient)	24, As above - info targeted to patient. If giving written info, I try to look over this and underline/highlight any 'key points' e.g. method and frequency of administration, and sometimes add bullet points e.g. 'needs line insertion for treatment to be given' to help them remember/navigate the written information before their consent appointment. Also involving family members/loved ones to join the consultation (with the patients consent) - over videocall if needed - can be very helpful. 5, We have macmillan easy to understand info on chemo/rxt - side effects; My language/communication changes to accomodate such patients, ensuring there are family/friends with patients; Simplfying and writing in simple terms percentages of response for treatment; Information in other languages punjabi, romanian in general chemo, or using interpreters
	The majority of participants reported that it would help to have more physical resources to support decision making in this setting, in addition to more time and CNS support.	24, Simplified patient decision aids. More time in appointments +/- CNS to talk through things as needed. 28, All above; more flexible clinic times (longer), specialist nurse support. Advocates. Audio information. 27, I think more videos with easy to understand infographics and analogies would improve the situation. 74, Would be useful to have tools to use for lower literacy patients/ simplified information sheets. Patient information sheets are increasingly long and complicated for standard treatments and are daunting particularly for reduced literacy meaning they are sometimes never reviewed.
	Greater education for both clinicians and the public around health literacy were also suggested	12, HCPs need to be educated on the importance of communicating appropriately and respectfully with these patients 27, More could be done in schools and via public health campaigns to improve overal health literacy and simply allowing clinicians more tiem in their day would assist.
	A minority of participants felt that resources weren't necessary	43, I dont think the multimedia really matters, time with health professionals are likely the best way
Adaptive communication approaches - **Open communication** - **HL strategies** - **Approach if lower HL**	A range of approaches were used to assess understanding - from clinician led delivery and closed questions to encouraging greater input from patient.	48, I always ask at the end of a consultation if they have understood what we go through today and if they have further questions. Provide contact details to use if there are further questions and if they are unclear offer further follow up. I am less good at doing this with prognosis however, if patients directly as me then I discuss this with consent but don't always routinely bring this up. 24, When meeting a patient for the first time, or at a second visit, I usually ask what there understanding is of their disease/treatment plans so far and/or what they took away from the last consultation to check their understanding and that we are on the same page. At important points during a consultation I ask 'does that make sense?', 'do you have any questions?'. I honestly would only usually ask them to confirm understanding/ repeat back

Figure 21 - Example of category grouping in Microsoft Word

5.3 Results

5.3.1 Participant demographics

Seventy responses were received, of which 26 were completed outside standard working hours of 9am-5pm. The majority of participants were doctors, either consultants (n=33) or middle grade (n=17) (see Table 11), and the commonest specialty was medical oncology (n=48). Over half of participants were awarded their professional qualification at least ten years ago (n=41) and only six reported less than five years' experience. The commonest tumour sites were lower gastrointestinal (n=21), upper gastrointestinal (n=17), urological (n=14), and breast (n=13), and 26 participants worked across all tumour sites such as in acute oncology or rotational training roles. No participants worked with haematological or central nervous system malignancies. Most (n=66) had contact with patients with incurable cancer at least three times per week.

Table 11 - Participant data

	No. participants (N=70)
Role	
Consultant	33
Advanced nurse practitioner (ANP)/CNS/consultant nurse	19
Middle grade doctor	17
Pharmacist	1
Specialty	
Medical oncology	48
Multiple e.g., CNS roles	7
Palliative care	6
Acute oncology	5
Clinical oncology	4
Time since awarded professional qualification	
Less than one year	1
1-5 years	5
5-10 years	23
10-20 years	15
Over 20 years	26
Tumour sites covered	
All tumour sites e.g., acute oncology, rotational trainees	26
Upper gastrointestinal	17
Urological	14
Breast	13
Lung	10
Skin/melanoma	8
Neuroendocrine	5
Gynaecological	4
Cancer of unknown primary	3
Head and neck	2
Sarcoma	1
Teenage and young adult	1
Frequency of contact with patients with incurable cancer	
Daily	54
Two to three times per week	12
Once a week	1
Less than once a week	3

5.3.2 Quantitative findings

Situations when participants less commonly reported using SDM included: discussing cardiopulmonary resuscitation, making follow up plans, adjusting treatment doses, considering the need for hospital admission, and managing toxicities (Figure 22). More participants usually or always used SDM when offering first or subsequent lines of treatment, discussing the need for further invasive investigations, discussing symptom control and end of life, and offering referral to palliative care.

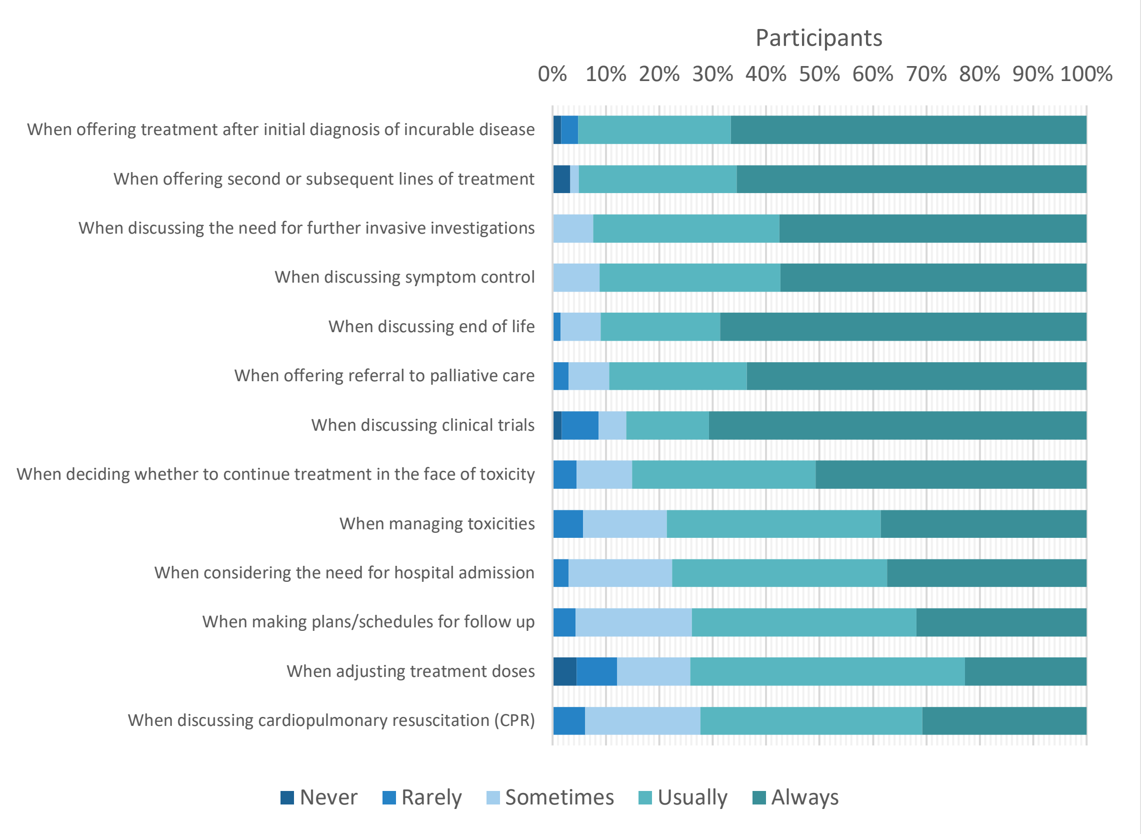


Figure 22 - Responses to question "How often do you use shared decision making with patients with incurable cancer in the following situations?”
(Shown as percentage of respondents as not all scenarios applied to all participants)

When SDM is carried out, most healthcare professionals reported ‘usually’ or ‘always’ following the main steps recommended in the NICE guidance on SDM (National Institute for Health and Care Excellence (NICE), 2021) (Figure 23).

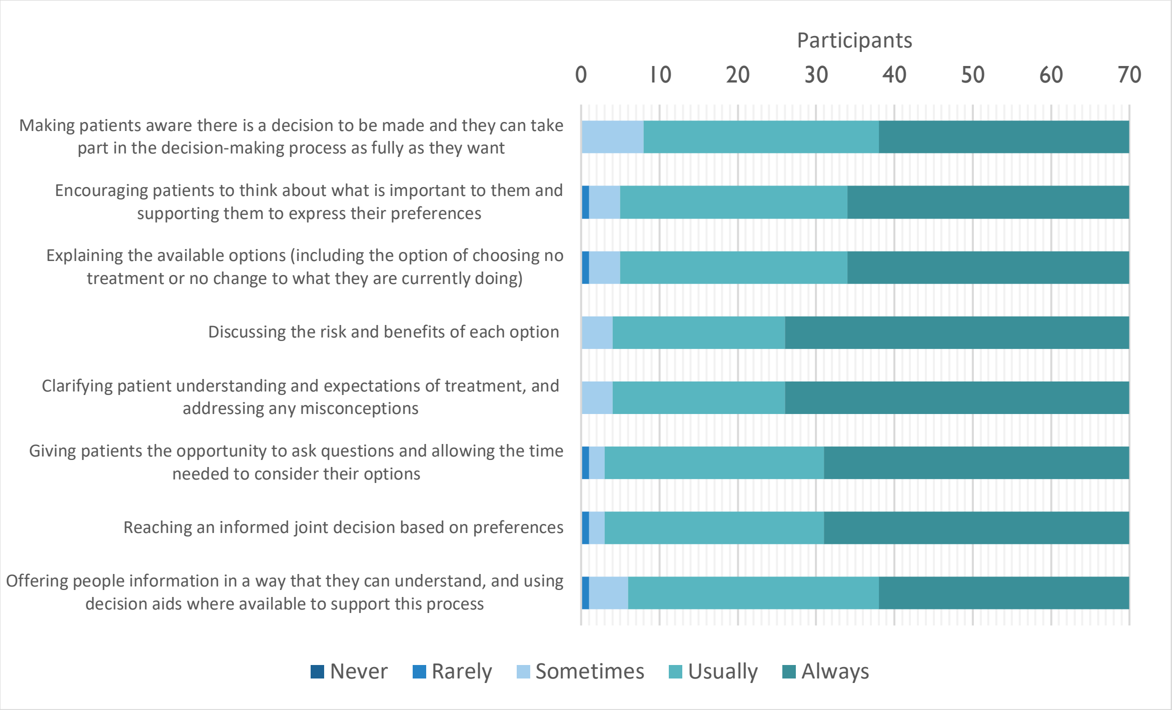


Figure 23 - Self-reported frequency with which steps of SDM are followed when talking to patients with incurable cancer about decisions

Participants least commonly reported checking patients' understanding of their disease status, the aims of treatment and prognosis with the results of tests/investigations and when starting a new treatment, and were most likely to do so when specifically asked by the patient (Figure 24).

Just over half of participants reported checking understanding of prognosis when starting a new treatment, and only around half would check understanding of prognosis or the aims of treatment with the results of tests or investigations. Overall, participants reported checking understanding of disease status and the aims of treatment more commonly than prognosis, with a few participants selecting the 'other' option commenting that checking understanding of prognosis was more nuanced and needed to be guided by the patient.

Outside the given time points, other opportunities at which participants check understanding include when reviewing patients after presenting acutely to hospital, when disease is progressing and discussing future care, and when following up after a discussion by another clinician.

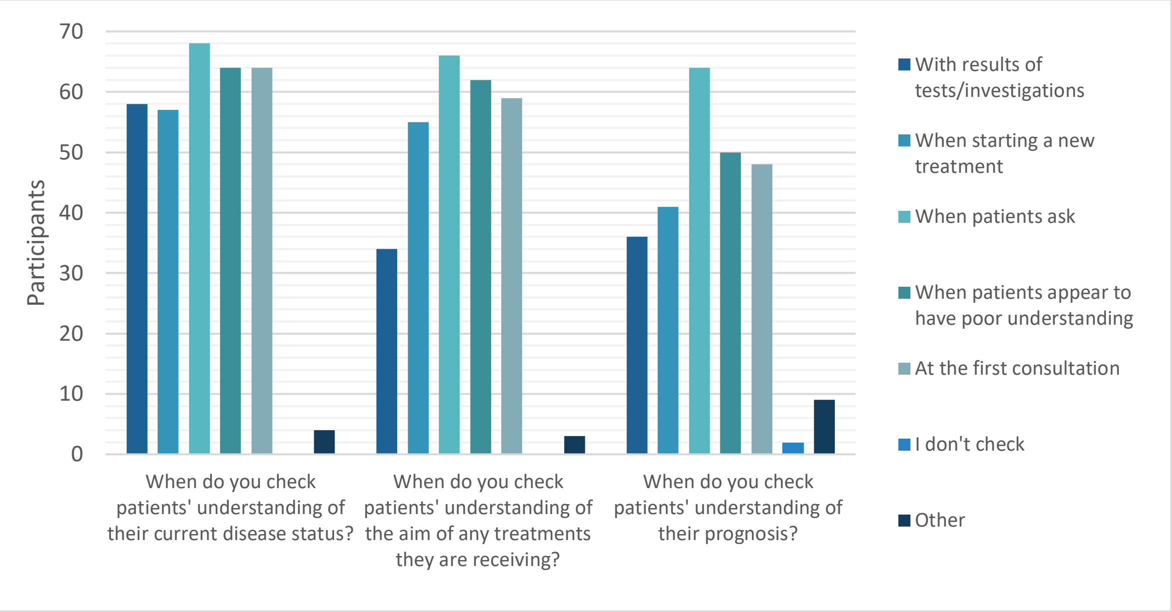


Figure 24 - Participant’s self-report of when they check patients' understanding of their disease status, the aim of treatment and prognosis

The most common reasons for healthcare professionals’ reluctance to use SDM in the setting of incurable cancer included factors relating to the ‘system’, the patient, and the clinician. The commonest ‘system’ related factors included lack of time, reported by over half of respondents, and lack of resources to support SDM. Patient factors included the impression the patient is too unwell to participate in SDM, when the patient has made an explicit request that a decision is made on their behalf, or when the patient is perceived to be unable to understand information relating to decision making. The most common clinician factor was when there was a preference for one option over another because other options may be less effective. Only a small number of participants reported that their own personal preference for one option or concern that the patient would make an unwise choice would make them reluctant to use SDM (Figure 25).

Participants were asked to select all relevant options from a list of factors and provide other examples where applicable. Other examples included unrealistic family expectations, colleagues not being open to or unable to have such discussions, and a lack of good data to support one option over another.

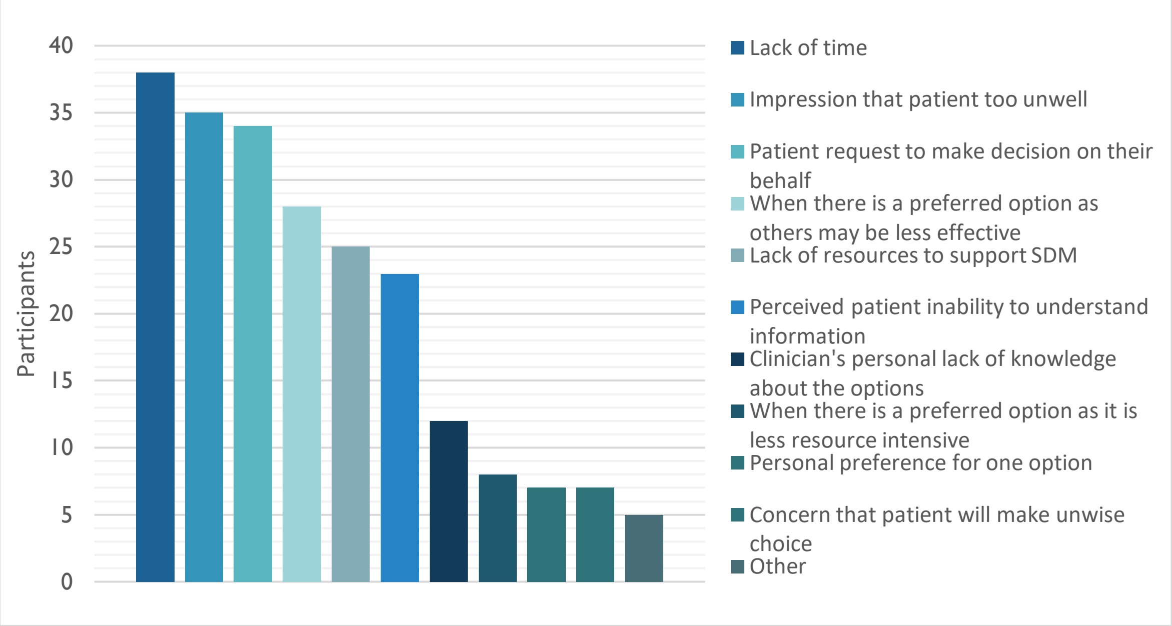


Figure 25 – Factors leading to clinicians' reluctance to use SDM in incurable cancer

Most participants (51/70) reported there were no patients with whom they would not attempt SDM. Just over half (36/70) reported their approach to SDM changed when they suspected a patient may have lower HL, and many (40/70) described strategies they had found useful in this situation. The majority (60/70) felt more could be done to make SDM easier for people with lower HL facing decisions about management for incurable cancer.

5.3.3 Qualitative findings

Seven themes were generated from the qualitative data to address the objectives. They were:

- SDM is not always appropriate vs 'Always' SDM
- Not enough time, but for what?
- SDM isn't for everyone
- Clinical experience rather than a tick-box process
- Adaptive communication approaches
- Use of resources to aid understanding
- Involving others

5.3.3.1 Views and experiences of healthcare professionals towards SDM in the context of incurable cancer

Most participants reported usually or always using SDM in most situations, but views towards its utility and applicability in the context of incurable cancer appeared to fall on a spectrum. At one end were those who felt SDM was not always appropriate and had clear ideas about when it could or should not be used. At the other end of the spectrum were those who held the view that SDM ought to "always" be possible, and made an effort to overcome any challenges to facilitate this. In between were those who felt SDM should be used where possible, but admitted this was not always done for a variety of reasons.

5.3.3.1.1 SDM is not always appropriate vs 'Always' SDM

In situations relating to safety, such as in the face of toxicity, over which the clinician is perceived to have the authority and a duty to 'do no harm', clinicians reported needing to be more directive, explaining the situation, and making the decision rather than offering a choice.

> Sometimes patients wish to continue chemo despite unacceptable toxicities and the shared decision making needs to be more one sided. (Participant 50, consultant medical oncologist, 5-10 years' experience)

Some participants also described situations when patients or their families wanted to 'push on' inappropriately or 'demanded' treatments the clinician perceived to be futile or not in the patient's best interests. This made SDM more challenging, as the desired treatment was not available to the patient and therefore not an option:

> It is very difficult to do when patients want treatment which cannot be offered. For example, surgical intervention in bowel obstruction if surgical team do not agree. (Participant 15, advanced nurse practitioner, 5-10 years' experience)

Cardiopulmonary resuscitation (CPR) was a particular area where SDM was considered to be less appropriate. Some clinicians saw it as their responsibility to make the decision, taking on the burden themselves and not opening it up for discussion with the patient:

> Sometimes we need to take responsibility for the decision to stop treatment or DNACPR (Participant 36, medical oncology consultant, 5-10 years' experience)

One participant described a tendency to exert their authority when they consider a treatment not clinically appropriate, and use SDM when patients decline treatment against their clinical recommendation:

> I use shared decision making far more often when patients don't want further treatment than if they do. If a patient wants ongoing treatment and it is not clinically appropriate I explain why and often offer a referral for a second opinion but my opinion outranks theirs. If a patient doesn't want treatment that I think would be beneficial I discuss it and offer further appointments in case they change their mind but their opinion

> outranks mine and I don't attempt to instruct them in what they should do (Participant 57, medical oncology consultant, 10-20 years' experience)

Despite the challenges of the situations described above, many felt SDM, as the gold standard, should always be possible for every decision, and should be supported even when patients make choices which may be seen as unwise:

> As long as the tone of the conversation is supportive of the patient's emotional state at the time there is no reason why the patient should be excluded from making decisions… If they make a decision that I feel is detrimental to them then I explain why I think that way but reinforce that the decision is theirs to make and I will always support their choices and be their advocate. (Participant 9, clinical nurse specialist in palliative care, over 20 years' experience)

5.3.3.2 Barriers to SDM in the context of incurable cancer reported by healthcare professionals

5.3.3.2.1 Not enough time, but for what?

The most commonly reported barrier to the use of SDM in incurable cancer was lack of time, and many participants suggested that more time allocated for appointments would allow for more SDM to take place. When time is limited, the clinician's agenda appears to take precedence over discussion of the patient's priorities or addressing their questions, immediately creating an imbalance between the two experts in the partnership:

> Time can limit how long I can explore a patient's preferences and what is important to them but if that is the case I encourage them to think about it and then come back with their decision (Participant 57, medical oncology consultant, 10-20 years' experience)

One participant who advocated for SDM described their efforts to overcome this barrier, ensuring patients are given the time they need during their appointment and staying late to catch up:

> In the list of potential barriers to shared decision making I ticked very few options as I believe it's important to ensure those barriers are overcome. This often comes at the expense of spending more time in clinic than we have technically got with patients and spending a lot of time out of hours catching up with clinic admin and jobs to compensate for taking longer with patients than allocated. (Participant 47, medical oncology consultant, 10-20 years' experience)

5.3.3.2.2 SDM isn't for everyone

Several patient factors also contributed to clinicians' reluctance to use SDM. When patients are considered to be too unwell, either physically or emotionally, they may be deemed unable to participate in decision making, and clinicians may not attempt to involve them as fully in the process. Likewise, those perceived to be unable to understand the information pertaining to the decision or who appear less engaged may be involved less in decision making. Several healthcare professionals noted that, though it was uncommon, they would not use SDM when patients requested not to be involved.

> When patients choose not to be involved in that discussion, although it is rare for them to not want to engage at all (Participant 14, palliative care CNS, over 20 years' experience).

Other patient groups with whom clinicians reported they might find SDM challenging included those with learning difficulties, where there are language barriers, and those who lack capacity.

5.3.3.2.3 Clinical experience rather than a tick box process

Several clinicians reported preferring to rely on clinical judgement, building relationships with patients and getting a feel for their wishes and preferences over time, rather than following the recommended steps of SDM as a 'tick box' exercise. Some also made assumptions about patients' priorities, their wishes to discuss prognosis, and their awareness not only that there are decisions to be made, but that they can take an active part in making. These assumptions about patients' understanding and preferences potentially limit opportunities to promote involvement in the SDM process:

> I often wouldn't specifically signpost that there is a decision to be made and that they can be involved - I feel that this is normally implied and obvious in the context of the conversation that we are already having. The fact that the patient is sat in front of me in a consultation room suggests that we both want to help reach a decision that is in their best interests (Participant 30, medical oncology consultant, 1-5 years' experience)

Others were more aware of their ability, given their position of authority, to guide patients in their decision making. Whilst some were mindful they could do more to explore the decision from the patient's perspective and incorporate this into the discussion, others made a conscious choice to omit certain aspects of the process:

> I regularly miss out the option of doing nothing. I do regularly explain to my patients the consequence of doing nothing (death within 12 months). It is probably due to the

> 'beacon of hope' idea/premise. (Participant 68, trust grade doctor in medical oncology, 5-10 years' experience)

As noted above, a few participants acknowledged their ability to meet all steps of SDM was hindered by a personal lack of skills, resources, or a lack of accurate data to support discussions.

5.3.3.3 Healthcare professionals' approaches to SDM with patients with incurable cancer and perceived lower HL

Many participants reported their approach to SDM changed if they suspected the patient had lower HL, with descriptions suggesting discussions become more patient centred by allowing more time, greater exploration of priorities, and through giving clearer explanations. Examples of specific strategies and approaches used by healthcare professionals are shown in Table 12.

Table 12 - Healthcare professionals' approaches to SDM with patients with incurable cancer and perceived lower HL

Adaptive communication approaches	Delivering information and ensuring understanding - Using simple explanations, basic terminology, ensuring no jargon, de-medicalising - Reducing the options discussed - Explaining repeatedly or in different ways - Summarising often - Using examples and stories - Checking understanding regularly, following up and revisiting
	Encouraging patient involvement - Asking about priorities and using this to guide discussions - Reinforcing impact on what is important to them - Establishing patients' information needs and adapting to this - Encouraging patient to write/ask questions - Specific techniques e.g., neurolinguistic programming
	Developing relationship - Building up therapeutic relationship - Being less doctor and more human, kind, empathetic - Listening carefully
	Taking time - Giving more time to think - during consultation, repeat visit, follow up call
Use of resources to aid understanding	Offering written notes/tailored written summary/copying into clinic letters Offering recorded summary Using pictures Providing easy to understand written resources Highlighting relevant parts of written information, adding notes
Involving others	Signposting to patient groups Offering contact details Involving family/friends Involving GP Involving CNS – to support during consultation, follow up and check understanding Involving other allied health professionals e.g., learning difficulties coordinator Discussing in MDT

5.3.3.3.1 Adaptive communication approaches

When patients are perceived to have lower HL, healthcare professionals described using simpler language, as well as presenting and discussing fewer options in an attempt to simplify the decision.

> I try to target the information I give and I present it at the right level for the patient in front of me. In some cases, too much information can be overwhelming so I may limit the options to those that I feel are in the best interests and select key pros/cons to highlight. (Participant 24, clinical fellow in medical oncology, 5-10 years' experience)

Participants also reported making a greater effort to explore patients' priorities, and allowing more time during appointments, offering additional appointments and follow up contacts, to ensure understanding.

> Listen. Try to give them time. Two stage consent process where feasible. See people back & check explicitly if they seem overwhelmed. Mix of chat with other members of the team. Listen to my CNS team. (Participant 51, medical oncology consultant, 10-20 years' experience)

Many participants described using closed questions to assess patients' understanding or find out whether they had any questions, however, lots reported using HL appropriate strategies including teach back (asking people to explain what they have understood, perhaps asking how they would re-tell this to their family). A small number also described using 'chunk and check', giving smaller amounts of information, and checking understanding before moving on.

5.3.3.3.2 Use of resources to aid understanding

Participants reported making greater use of a variety of physical resources to support discussions, such as offering written notes or drawings, and providing written or recorded summaries for patients as well as easier to read resources.

> [I use] Diagrams; More understandable analogies that they can understand once I have an understanding of their view of the world; Simple notes reflecting words that they have used (Participant 44, consultant medical oncologist, over 20 years' experience)

5.3.3.3.3 Involving others

Participants reported involving others to help provide support to the patient, from formal sources including other healthcare professionals, peer support through support groups, and by involving family and friends.

> More likely to recommend that they discuss the information with friends/relatives/GP to help them improve their ability to engage in the decision-making process. (Participant 30, consultant medical oncologist, 1-5 years' experience)

Doctors relied heavily upon their cancer clinical nurse specialist (CNS) colleagues to help aid understanding, following up after consultations and acting as a point of contact for outstanding questions and queries.

> Ask/clarify what they understand/ask them to repeat, offer opportunity to discuss at next clinic/or give/check that they have a valid contact number of secretary or CNS if any issues arise after clinic. Have CNS or relative during consults. Give them enough time to digest or reflect on info during consults (Participant 41, specialty doctor in medical oncology, 10-20 years' experience)

5.3.3.4 Strategies to support SDM for patients with incurable cancer and lower HL

Participants were asked what they thought would be useful to support SDM for people with lower HL facing decisions about management for incurable cancer. They were provided with examples including provision of patient information in alternative formats such as audio or video recordings, increased use or availability of patient advocates, and routine use of prompts encouraging patients to ask questions. Strategies suggested by participants fell into four main categories: advocacy and support, communication skills, patient information and tools and logistical/system level changes (see Table 13).

Table 13 - Suggested strategies to support SDM for patients with incurable cancer and lower HL

Advocacy and support	Communication skills
– Better access to advocates, support workers, cancer coordinators (opt out) – More CNS support – during consultation, to support understanding and follow up – Greater involvement of wider team - palliative care, interpreters, learning difficulty support – More opportunities for patients to talk to other patients – Closer linking with GP – Greater involvement of advocates including family	– Better communication skills training – Resources/strategies to support clinician with deferential/demanding patients – Greater use of HL friendly approaches e.g., teach back techniques – Starting conversations early – Being honest – Permission to tailor approach – not all want or need in depth SDM

Patient information and tools	Logistical/system level changes
– Easy read/simpler/easily digestible information – More pictorial resources – Videos – of cancer centre, easy infographics – Audio/video recordings – Apps/interactive patient information system with audio-visual resources – Information sheets in different languages – Question prompts and tools used to form questions pre-appointment – Simplified patient decision aids – Documentation from previous conversations about preferences of care	– More time – Multiple appointments – Identification of people who may have lower HL before appointment to adapt communication, ensure CNS present – School education/public health campaigns

Many participants agreed advocacy was important. Advocates may include friends or family, but members of the clinical team or independent advocates in more formal roles may also be needed to fulfil this role, and access to such support was noted to be limited. Greater teamworking, involvement of the wider multidisciplinary team and links with colleagues in other specialities and in the community were suggested, whilst some also felt having the opportunity for patients to talk to other patients in a similar situation would be beneficial.

Good communication is fundamental to successful SDM, and several participants felt greater training for clinicians on how to approach SDM conversations in these circumstances would be useful, as well as education on HL specific techniques. One participant identified the need for specific information and strategies to support clinicians with the more challenging situations for SDM, such as when a patient is deferential or demanding.

Various physical patient information resources and tools were suggested to support SDM conversations for those with lower HL, including more accessible patient information in a range of formats, and greater use of audio-visual resources and apps. There was also support for simplified patient decision aids and tools to prompt patients to ask or help them formulate questions. One participant also felt documentation from previous conversations regarding the patient’s preferences of care would be useful.

Finally, participants suggested several bigger picture logistical or system level changes. More time and greater availability and flexibility of appointments were common suggestions, though some participants acknowledged this was difficult to achieve in reality. One suggestion to ensure time is spent with those most in need was to identify those with lower HL before the appointment, to allow preparation and ensure the necessary support and resources were available. As well as these more immediate approaches to help on an individual level, three participants suggested longer term public health approaches, such as increased health education provided in schools or through public health campaigns, could be beneficial to improve HL and therefore enable people to take a more active role in their care.

A small number of participants did not feel more could be done to support decision making for those with incurable cancer and lower HL and were unsure of the benefit of additional tools or resources, placing the emphasis instead on clinicians' communication skills and styles.

5.3.3.5 Summary of themes/findings

A summary of the main themes and findings presented in this section can be found in Figure 26.

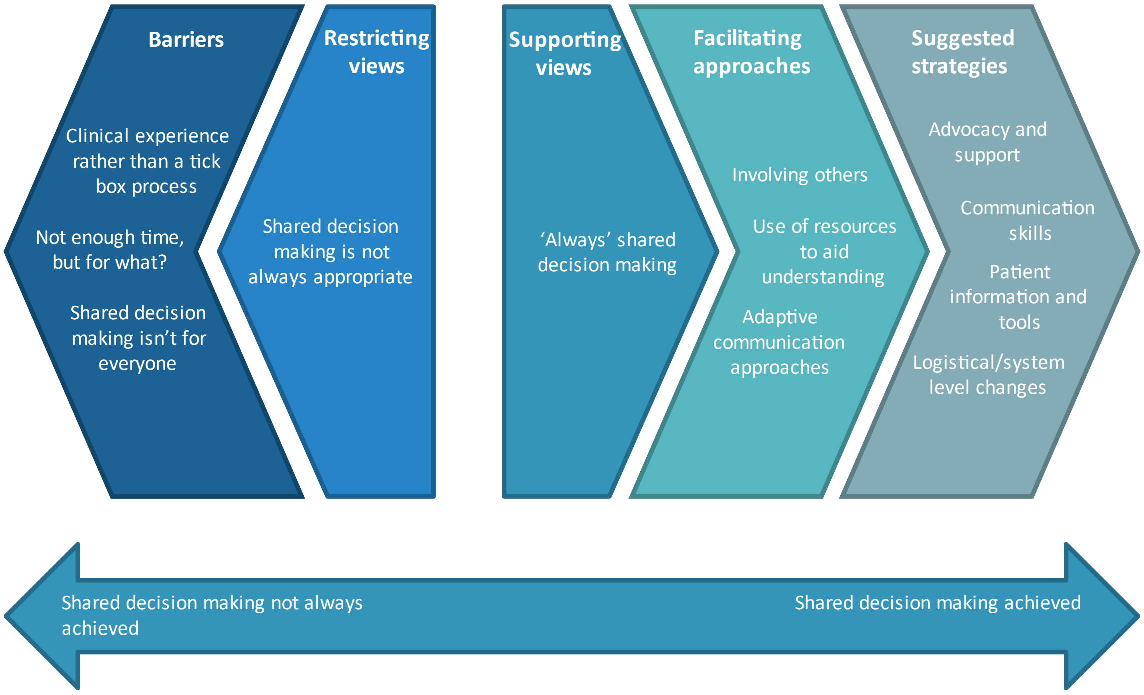


Figure 26 – Views, barriers, facilitating approaches and suggested strategies to support SDM in the context of HL difficulties and incurable cancer

5.4 Discussion

This survey sought the views and experiences of healthcare professionals caring for patients with incurable cancer in the NHS. It was successful in recruiting a mixed sample of experienced clinicians across a variety of roles, whose different perspectives offered a more rounded understanding of the process than might have been achieved by surveying a single professional group.

The recently published NICE and GMC guidance on SDM advocate for its use in all encounters, except when a person lacks capacity or in unexpected emergencies when immediate lifesaving care is needed (General Medical Council, 2020; National Institute for Health and Care Excellence (NICE), 2021). The healthcare professionals responding to this survey, however, demonstrated a range of views towards SDM in incurable cancer. Whilst some felt SDM should always be possible and sought to overcome barriers for this to happen, others were very clear about situations in which they would be reluctant to use it, or patients with whom they would find SDM more challenging and therefore might not attempt it.

SDM has been described as an ethical imperative, essential for respecting autonomy, but also important for beneficence (balancing the benefits of treatment against the risks and costs) and non-maleficence (avoiding harm) (Stiggelbout *et al.*, 2012). Some participants in this survey felt that, as the 'gold standard', SDM should always be the goal, providing examples of how they overcome barriers, staying late in order to give patients enough time, or using tailored communication approaches to facilitate understanding.

Other respondents identified circumstances in which they might be reluctant to use SDM, or would find it more difficult. These included situations where the clinician might perceive themselves to have the authority – primarily when decisions concerned safety, or when patients 'demanded' treatments the clinician believed to be dangerous or futile. In addition to their ethical duties and acting in the best interests of the patient, healthcare professionals play a key role in protecting valuable NHS resources by not offering futile treatments. Further, the perceived burden to the patient of making such decisions could be high and clinicians may fear causing distress. These findings are similar to those from a systematic review of the appropriateness of SDM by van der Horst *et al.* (2023). Whilst there was some disagreement amongst the included papers, situations where SDM was deemed not appropriate included when the patient's request for treatment was in conflict with the clinician's judgement, options were restricted by institutional policies or there is a potential threat for the patient's safety. Navigating these difficult conversations can be extremely challenging, and some healthcare professionals were mindful of the need to avoid giving the illusion of choice when one didn't exist, reflecting also on their duty to take responsibility for certain decisions. Some decisions appeared to be considered safer and more amenable to sharing or even deferring to the patient, for example when discussing symptom control or planning for end of life, in which case the patient is considered to have greater authority and their preferences are given greater weight.

Elwyn *et al.* (2022) also note certain situations impose limits on the potential for SDM, and suggest alternative strategies need to be considered in these circumstances. Such situations include when wider interests override individual wishes (perhaps when patients wish to continue treatment in the face of significant toxicity), when evidence of benefit is insufficient or absent (in the case of patients 'demanding' treatments for which there is no evidence) and when lowered decisional capacity is present. The authors also suggest SDM should not be used when profound existential uncertainty exists, giving the example of treatment decision making in incurable cancer. SDM is certainly challenging in this context, as illustrated by the work undertaken during this PhD study. However, these are also the types of decisions where a SDM process can be particularly valuable, as individuals' priorities in the same situation may differ, with some prioritising longevity at any cost and others preferring to minimise toxicity and avoid medicalisation, for example. Ensuring patients are given time, receive the emotional support they need to come to terms with their diagnosis, and establishing their priorities and goals ('team talk'), are provided with clear and easily understandable information about the options available to them ('option talk'), and considering the options in the context of these priorities, in order to ultimately reach an informed, preference-based decision ('decision talk'), is crucial (Elwyn *et al.*, 2017).

Conversations around cardiopulmonary resuscitation (CPR) can be particularly challenging for both healthcare professionals, as highlighted in this survey, and patients (Chapter 4). Whilst acknowledging the complexities of individual clinical situations, joint guidance from the British Medical Association, Resuscitation Council (UK) and the Royal College of Nursing sets out the key ethical and legal principles of CPR decision making and seeks to provide clarity for healthcare professionals. Whether SDM is appropriate in the context of CPR is nuanced, and depends on careful assessment of the likelihood of success (British Medical Association, 2016). The guidance states *"if the healthcare team is as certain as it can be that a person is dying as an inevitable result of underlying disease or a catastrophic health event, and CPR would not re-start the heart and breathing for a sustained period, CPR should not be attempted".* It goes on to note *"when a person is in the final stages of an incurable illness and death is expected within a few hours or days, in almost all cases CPR will not be successful"*. Thus, when a person is clearly at the end of their life, this assessment of the likelihood of success may be relatively straightforward, and a clinical decision not to attempt CPR may be made. Whilst it is important to involve the patient and those close to them, they do not have a right to demand treatment that is not clinically appropriate, and healthcare professionals have no obligation to offer or deliver such treatment (British Medical Association, 2016). The decision and rationale should be clearly and sensitively explained, with efforts made to establish understanding, and should there be disagreement, a second opinion should be offered. Though it may not be possible or appropriate for this decision to be shared, other opportunities for SDM at this time may include decisions around preferred place of care, involvement of palliative care teams, and may include discussion of priorities with family/relatives.

The likelihood of success of CPR is not always so clear cut, however, and the approach differs where CPR is a treatment option with a poor or uncertain outcome. In this instance, the decision is not solely clinical. Instead, patient wishes are paramount, and unless the patient declines, SDM should take place. Discussion of the risks and adverse effects, such as the need for transfer to an acute hospital, the need for intensive care, or potentially poor neurological outcomes should be discussed, and balanced against the chance of success. It is also important to address any misconceptions. However, the guidance notes some patients may have specific reasons for wanting to try to delay death, even despite these risks and even if just for a short time, and these factors should be considered when attempting to reach an agreed decision (British Medical Association, 2016). If there is a reasonable chance CPR will successfully restart the heart and breathing for a sustained period, and the likely quality of life is acceptable to the patient, then the patient's wish for CPR should be respected, even if the healthcare team do not feel the risks are justified by the very small chance of success. It is important to note, however, that the definition of 'sustained' is not given. Given the sensitive nature of the subject, the emphasis throughout the guidance is on careful and skilled communication, and professionals are encouraged to support conversations using information in formats people can understand. Whilst the guidance does also cover instances where adults lack capacity, this discussion assumes an individual has capacity.

Besides these specific decisions, participants gave several reasons for their reluctance to use SDM, most commonly due to lack of time. Both the time allocated during appointments and opportunities to bring patients back to clinic at a later date are limited. This can result in clinicians feeling a need to prioritise their own agenda, ensuring their knowledge about the disease and treatments has been imparted, sometimes at the expense of seeking the expert knowledge from the patient about their priorities and preferences. Time spent addressing patients' questions, informational needs and encouraging involvement may also depend on the clinician's attitude towards SDM, and whether it is prioritised in their practice. Time is a commonly given barrier to SDM (Légaré *et al.*, 2008), however, in a Cochrane review of 105 studies exploring the use of decision aids for people facing screening or treatment decisions, eight of ten studies looking at consultation length reported no difference, while in two studies, consultations involving a decision aid took a median of just 2.6 minutes longer than those without (Stacey *et al.*, 2017). Seeking to keep consultation time down by choosing less patient-centred approaches may be a false economy, as the time saved during this appointment may be lost at a later date if the patient has not had the opportunity to fully understand their situation and the available options and contribute to making the decisions that are right for them. Patients who do not have a full understanding of the possible toxicities from treatment, for example, might experience greater fear and unanticipated side effects (Cohen *et al.*, 2013), which in turn might necessitate increased involvement of healthcare professionals. In the same systematic review, Stacey *et al.* (2017) found those exposed to decision aids tended to choose more conservative options, which, in the oncology setting, may ultimately reduce workload in the longer term.

Certain patient related factors also contributed to healthcare professionals' reluctance to use SDM, including when the patient appeared too unwell, or unable to understand and therefore not in a position to engage in SDM. In some cases, such patients may lack capacity, and the decision making process is necessarily different. Yet it is also important to acknowledge that clinicians may make judgements about a patient's competence (based on their appearance, manner or accents as signals of their social class), which could in turn influence their interactions and alter how they approach information giving and decision making within the consultation (Durante and Fiske, 2017). Healthcare professionals also reported being reluctant to use SDM when it appeared the patient did not want to be involved in the decision. Whilst it is true that not all patients will want to take an active role in decision making, it is important this is explored and discussed rather than assumed, and efforts are made to ensure barriers to involvement are overcome, information needs are met, and support is provided to facilitate such discussions. In such instances, family members or those close to the patient may take a more prominent role in contributing to the decision making process, helping them understand the information they have been given, supporting deliberation, or providing more of an insight into the patient's wishes and priorities if the patient does not want or feel able to engage. Some of the participants in this survey reported making assumptions about patients' preferences for involvement and understanding of their role. However, as seen in the interviews described in Chapter 4, patients may also be unaware there is a decision to be made or there are valid options available to them, and may not feel able to speak up to voice their priorities or go against a recommendation. Previous studies have shown physicians' perceptions of patients' preferences for involvement in decision making are often inaccurate (Elkin *et al.*, 2007), even when the prediction is made by those with advanced communication skills training and after a lengthy consultation (Bruera *et al.*, 2001). Compounding this, some healthcare professionals reported favouring a more clinician-led approach without attempting to involve the patient. Returning to the model of external influences on information use in shared decision-making and patient empowerment proposed by Edwards, Davies and Edwards (2009), such attitudes and practices are likely to dissuade patients from engaging with information and support services, or may result in disempowerment of those who have become informed.

Frameworks designed to support SDM can be valuable in making the process and roles explicit to both parties. The framework used in this PhD, the Three Talk Model, sets out the main stages of SDM as 'team talk', 'option talk' and 'decision talk' (Elwyn *et al.*, 2017). In 'team talk', clinicians are encouraged to work with patients, describe the choices and make clear there is a decision to be made, offer support, and ask about goals. This stage emphasises the need to work together and draws on the patient's own expertise. 'Option talk' prompts discussion and comparison of the alternatives, rather than presenting a single recommendation, whilst ‘decision talk’ seeks to establish informed preference-based decisions taking account of the patient’s priorities. Some participants in the survey did express a preference for getting to know patients and using clinical judgement rather than following a set process for SDM. As shown above, however, these judgements and assumptions are not always accurate, and whilst establishing relationships and trust are extremely important, significant decisions may need to be made before such relationships have had a chance to fully develop. Following a more structured approach may empower and give patients permission to become more involved and speak up, as well as protecting healthcare professionals from making incorrect assumptions.

Clinicians reported offering simpler explanations using easily understandable language, giving more time and support, and making greater efforts to ensure family are present and priorities explored when patients are suspected to have lower HL. However, studies have shown that clinicians are not aways able to accurately identify those who are experiencing difficulties with HL (Voigt-Barbarowicz and Brütt, 2020), and patients may take steps to conceal such difficulties from healthcare professionals and those around them (Parikh *et al.*, 1996). One way to address this is by using ‘HL universal precautions’, in which clinicians are encouraged to assume all patients might have difficulty understanding medical information, and make efforts to simplify communication, check understanding, make systems easier to navigate, and support people to improve their health (Brega *et al.*, 2015). Nutbeam and Lloyd (2021) take this further, suggesting an approach of proportionate universalism, ensuring health services and resources are accessible, clear, understandable and usable to all, but focusing particularly on engaging those most affected by lower HL and thus improving HL differentially across the social gradient (Nutbeam and Lloyd, 2021). Whilst this approach could be beneficial for all, it does reintroduce the need to make an assessment of individuals’ HL in order to prioritise resources, and there is as yet no established tool able to do this comprehensively and effectively in the clinical setting. In addition, some clinicians may worry about offending or appearing to patronise patients, or be concerned their own professional status and knowledge could be questioned as a result of offering simplified information, and may therefore be reluctant to use such an approach (Brooks *et al.*, 2020).

Participants identified many strategies to support SDM for patients with incurable cancer and lower HL. These ranged from more targeted interventions, such as simplified decision aids and question prompt lists, to much wider reaching strategies including public health and school education campaigns. These different types of strategies reflect existing work and thinking around the concept of HL. This includes viewing HL as a risk factor for poorer health and outcomes, typically leading to more context specific interventions such as decision aids, or as an asset to be developed and resulting in wider health outcomes, through public health education and education of healthcare professionals to support development of generalisable skills (Nutbeam, 2008; Nutbeam and Lloyd, 2021). Suggestions given by participants also reflect the growing appreciation of the need for good team working to support SDM amongst healthcare professionals in and outside the hospital setting, also involving those close to the patient, such as friends, family, and advocates, and offering additional support where it does not exist.

5.4.1 Study limitations

The use of an online survey was effective for collecting a large number of responses and allowed flexibility and ease of completion for busy clinicians - around a third of survey responses (27/70) were completed outside normal working hours. However, this phase of the study did have a number of limitations. Recruitment was primarily achieved through sharing of the survey link via a small number of professional bodies, and this is reflected in the sample, with a much higher number of medical oncologists than any other specialty or profession. Though it was not designed for this purpose, the quantitative data are therefore descriptive of a convenience sample and not representative, so the findings may not be generalisable. Data on participants' location was not collected, and the responses may represent views from a limited number of centres based on word-of-mouth sharing. There is also potential for bias, as those with an interest in the topic will have completed the survey and are likely to be more aware of their practice and the role of SDM. Finally, the nature of data collection through a survey was reliant on participants' self-report of their own practice, and clinicians may have been more likely to overemphasise their use of SDM compared with their actual day-to-day practice.

5.5 Conclusion

Whilst some healthcare professionals working with patients with incurable cancer endeavour to use SDM at every opportunity, others reported a number of barriers to its use. Lack of time is commonly given as a reason not to undertake SDM, but it is unclear whether more time would facilitate this, or whether the patient agenda would continue to come second to that of the clinician. Approaches used by participants to support SDM for those perceived as having lower HL are likely to be beneficial for all. Strategies including system level changes, communication skills training, better access to advocacy and support and a wider range of easily accessible resources to support the information giving and decision making process have been suggested. Given the range of views towards SDM and barriers identified, it is likely a combination of these strategies will be needed to facilitate SDM for patients with incurable cancer and suspected lower HL.

5.6 Summary and next steps

The findings from this chapter highlight a number of barriers to SDM in incurable cancer from the perspective of healthcare professionals, and, when combined with the challenges identified by patients (Chapter 4), paint a much clearer picture of why SDM can be difficult to achieve in this setting. Healthcare professionals report that they already use a range of approaches and strategies when they suspect an individual may be experiencing HL difficulties, but most of the respondents felt more could be done to help support SDM in this setting and offered a variety of suggestions as to how this could be achieved.

In order to begin to address these challenges, it is necessary to explore these possible strategies in greater detail and in the context of what might be achievable, then prioritise areas for future development. To this end, the next chapter will consider how the barriers and strategies identified to date fit with the Three Talk Model of SDM (Elwyn *et al.*, 2017), in preparation for further discussion with expert panels of patients, carers and healthcare professionals.

Chapter 6 Synthesis of findings

6.1 Introduction

The findings from the study phases detailed in the preceding chapters provide evidence for the many challenges for SDM in the context of lower HL and incurable cancer, as well as numerous possible strategies to support the process. They take into account views of both patients and healthcare professionals and consider individual challenges as well as wider issues. In this chapter, these findings are brought together as part of the intervention planning stage of the Person Based Approach (Yardley *et al.*, 2015) in preparation for further discussion at two expert panel meetings.

A key activity to be undertaken as part of the PBA is the development of an Intervention Planning Table, in which all available evidence about what elements are needed in the intervention, and why, is brought together (Yardley *et al.*, 2022). The table combines target behaviours, barriers, and facilitators to these, with supporting evidence, and possible intervention ingredients. Evidence may include relevant empirical literature, theories and models, primary qualitative research, and discussions with PPI representatives and other stakeholders. The authors of the PBA suggest collating these sources of evidence in this way can provide a structure to support co-creation with stakeholders, record the rationale and evidence base for the intervention elements, and capture unresolved questions or issues to be followed up (Yardley *et al.*, 2022). The table may also include behaviour mapping, as in Band *et al.* (2017)'s paper on intervention planning for a digital intervention for self-management of hypertension, or may include ranking criteria to guide decisions about inclusion of different intervention elements.

In this chapter, the themes and findings from three sources (a systematic review of the role of HL in cancer care (Chapter 3), a qualitative interview study of the experiences of patients with incurable cancer suspected of having lower HL (Chapter 4), and a survey of healthcare professionals' views and experiences of SDM (Chapter 5)) are combined in an Intervention Planning Table. The target behaviours of SDM in the Three Talk Model (Elwyn *et al.*, 2017), were used as a basis for this process.

The Three Talk Model was developed in and has been applied to an NHS context (Joseph-Williams *et al.*, 2017), and is recommended by UK healthcare guidelines (National Institute for Health and Care Excellence (NICE), 2021). It considers three main 'talks' or stages of SDM (team talk, option talk and decision talk), alongside active listening and promoting deliberation. It encourages clinicians to set the scene for SDM, emphasising the need for healthcare professionals and patients to work together to achieve an outcome that best suits the patient. It includes prompts such as asking the patient about their goals, making them aware choices exist, and providing support to reach a decision. Whilst some aspects are done well, it is clear from this PhD study that others are not always performed. The model therefore provides a useful framework for considering the barriers and facilitators to each of these stages/behaviours, and possible intervention ingredients that might help address some of the issues.

6.2 Methods

Development of the Intervention Planning Table drew on the PBA (Yardley *et al.*, 2015), and used the Three Talk Model of SDM (Elwyn *et al.*, 2017) to guide the behaviours to be targeted. Earlier analyses in this project drew on frameworks with a greater focus on the concept of HL itself, including the Health Literacy Pathway Model (Edwards *et al.*, 2012) and Nutbeam's three levels of health literacy (Nutbeam, 2000), in order to seek a more in depth understanding of the challenges faced by patients with lower HL. For this part of the project, however, given the PhD's overall aim of developing an intervention to support SDM (as opposed to developing HL per se) it was important to consider in detail the specific target behaviours required for SDM. The Three Talk Model, with its grounding in the NHS, was chosen to provide the structure for this synthesis, and the different components of the Model (team talk, option talk, decision talk, active listening and promoting deliberation) were broken down to form a set of target behaviours required for SDM to take place.

Having set out the target behaviours, the key themes and findings from each phase of work were considered in turn, to establish at which point of the SDM process they posed a barrier or acted to facilitate SDM. Different components of the themes related to different target behaviours, and some themes appeared multiple times, in part acting as a barrier, and at other times as a facilitator. As an example, the theme 'In the expert's hands' from the patient interviews was considered a barrier to 'working together', (doctor's job to get it right), but was a facilitator to 'providing support' (team approach, set care pathways followed). Possible intervention components identified from the systematic review, patient interviews and healthcare professional survey were also evidenced, and additional components were generated based on the barriers identified and background knowledge of the existing literature.

Reviewing and presenting the data in this way provided a clear outline of the evidence, allowing further review and consideration of possible intervention elements, as well as setting out the key issues for discussion with expert stakeholders (described in Chapter 7).

6.3 Findings

The table presented within this section (Table 14) brings together these key themes and findings. It is arranged in sections covering different aspects of the Three Talk Model, and draws on each source of evidence to provide an in-depth understanding of the different users' perspectives, and demonstrate how different intervention ingredients may address some of the challenges faced.

Table 14 - Barriers, facilitators, and possible intervention ingredients for SDM, with sources of evidence (patient interviews (PI), systematic review (SR), healthcare professional survey (HS))

Target behaviours	**Barriers to target behaviour (source of evidence)**	**Facilitators to target behaviour (source of evidence)**	**Possible intervention ingredients**
Team talk – work together, describe choices, offer support, and ask about goals. ***"Let's work as a team to make a decision that suits you best"***			
Working together	In the expert's hands – doctor's job to get it right (PI) Being a good patient – hesitance to speak up (PI) Personal influences – stoicism, suffering in silence, limited experience of cancer (SR) SDM not always appropriate – patient factors including preference not to be involved, lack of capacity, too unwell (HS)	Accessing information to further understanding – support from friends and family acting as advocates (PI) Consequences – confidence to navigate system and exercise rights (SR) Always SDM – SDM should always be possible, working around difficulties (HS) Advocacy and support – working with family when lack of capacity, low HL (HS)	• Involvement of advocates including family (HS) • Identifying in advance those who might have lower HL to ensure CNS support, adapt communication (HS) • School education/public health campaigns (HS) • Create environment where patients feel their input/expertise is valued • Emphasising team approach at all encounters • Encouraging and providing patients opportunity to speak up • Responding positively if patient forthcoming
Making patient aware that choices exist	Accessing information to further understanding – limited discussion and understanding of alternatives including 'doing nothing' (PI) SDM not always appropriate – clinician has authority, safety first, not offering futile treatments (HS) Clinical experience rather than tick box process – making assumptions about patients (HS) Clinical experience rather than tick box process – more direct recommendations, using authority to guide towards right decision (HS)	Always SDM – patient has authority, stakes lower (HS)	• Explicitly stating that decision to be made, there is a choice including doing nothing

Target behaviours	**Barriers to target behaviour (source of evidence)**	**Facilitators to target behaviour (source of evidence)**	**Possible intervention ingredients**
Providing support	Imperfect system – standardised processes, unclear where to go for support (PI) Accessing information to further understanding – unmet information/support needs (PI) Being a good patient – limit to planned contact (PI) Care coordination – poorer experience and greater need for help (SR) Greater need for psychological support (SR)	In the expert's hands – team approach, set care pathways followed (PI) Supportive staff – contactable and supportive, someone to call with questions (PI) Situational influences (networks) – friends, family, support groups sources of support (SR) Situational influences (system) – confidence in clinician and comfort in decision making (SR) Advocacy and support – working with wider team, fundamental role of CNS (HS)	• Simpler, more useful appointment letters (PI) • Routine contact by CNS/support worker – check in call after first consultation (PI) • Routine signposting to support services (PI) • Support to manage schedule etc. (PI) • Greater access to advocacy services (HS) • Follow up after discussion - calls by CNS/further appointments (HS) • Linking with GP (HS)
Discussing goals	Emotional hurdles – uncertainty about what comes next, the future (PI) Being a good patient – hesitance to speak up (PI) Not enough time – limited appointment slots (HS)	Adaptive communication approaches – greater exploration of priorities (HS)	• Explicit enquiry regarding patient goals - working with support worker in advance of appointment • Goals/value clarification exercises
Option talk – discuss alternatives using risk communication principles. *"Let's compare the possible options"*			
Discussing alternatives	Emotional hurdles – hard to take in after bad news (PI) Accessing information to further understanding – too much information at beginning, written information not always easy to understand/not always read (PI) In the expert's hands – doing nothing is foolish (PI) Information processing – lower understanding, greater unmet information needs (SR) Situational influences (system) – information not always understandable, complicated paperwork, inconsistent access to resources (SR) Information processing – focus on benefits influencing decisions (SR) Clinical experience rather than tick box process – direct recommendation, using authority to guide decision (HS) Adaptive communication approaches – whittled down options in attempt to simplify if low HL (HS)	Supportive staff – explanations clear with no jargon (PI) Accessing information to further understanding – patients trust information given by HCPs (PI) Situational influences (networks) – facilitators of HL, supporting understanding (SR) Consequences – confidence to ask/supportive staff encourage information seeking (SR) Advocacy and support – role of CNS and others to follow up and facilitate understanding (HS) Availability and use of resources – easy read information, patient summaries etc. (HS)	• Range of information formats available at multiple time points – video, pictures (PI) • Use of easy to understand, lay language (PI) • Access to details of diagnosis/prognosis/options to refer back to (PI) • Decision aids (HS) • Encourage presence of family/friend/advocate (HS) • Availability and use of resources - greater availability of wider range of resources (HS) • Availability and use of resources - greater education about HL (staff and public) (HS) • Spacing out information giving – separating bad news/prognostic info from technical details of treatment etc

Target behaviours	Barriers to target behaviour (source of evidence)	Facilitators to target behaviour (source of evidence)	Possible intervention ingredients
Decision talk – get to informed preferences, make preference based decisions. *"Tell me what matters most to you for this decision"*			
Reaching informed preferences	Treatment not too bad – influences from media, others' experiences etc. (PI) Fear of progression or recurrence, greater distress (SR) Situational influences (networks) – inaccurate information or causing increased fear (SR) Situational influences (system) – unfamiliar environment/experience, unsure what to ask (SR) Consequences – greater fear arising from lack of understanding (SR) Clinical experience rather than tick-box exercise – lack of personal skills and data to support SDM (HS)	Accessing information to further understanding – use of internet, support groups to supplement information (PI) Information processing – strategies including comparing information from different sources (SR) Adaptive communication approaches – checking understanding, using HL strategies (HS)	• Opportunity to hear from/discuss with other patients (PI, HS) • Opportunity to discuss options with relevant teams e.g., supportive care with palliative care team (HS) • Question prompt lists (HS) • Clinician training • Signposting to reliable sources of information e.g., Macmillan Cancer Support
Making preference based decisions	In the expert's hands – feel decision already made (PI) In the expert's hands – following recommendation, foolish to turn down, influence of family (PI) Being a good patient – not wanting to waste clinicians' time, will be negatively perceived (PI) Consequences – conflicting advice/poor understanding, accepting treatment without full understanding (SR) SDM not always appropriate – when clinician has authority, safety first, not offering futile treatment (HS)		• Emphasising importance of patient preferences – values clarification • Helping patients to align preferences with options • Giving permission to turn down offered treatments
Additional elements – active listening (paying close attention and responding accurately) and deliberation (thinking carefully about options when facing a decision)			
Actively listening	Additional pressure from COVID-19 – video calls potentially limiting communication (PI) Accessing information to further understanding – not always easy to get information at later date (PI) Not enough time –limited by appointment slots (HS) Clinical experience rather than tick box process – making assumptions about patients (not asking) (HS) Adaptive communication approaches – assessing understanding with closed questioning (HS)	Adaptive communication approaches – assessing understanding by being open and encouraging (HS)	• Availability of face to face appointments (PI) • Communication skills/SDM training (HS) • Flexibility in appointment scheduling (HS) • Eliciting preferences prior to consultation RE involvement, documentation of previous conversations about preferences (HS) • Question prompt lists (HS)

Target behaviours	Barriers to target behaviour (source of evidence)	Facilitators to target behaviour (source of evidence)	Possible intervention ingredients
Promoting deliberation	Imperfect system – conflicting information, changing plans (PI) In the expert's hands – not my place to decide on treatment (PI) Emotional hurdles – shock of diagnosis, difficult to accept (PI) Accessing information to further understanding – need more time to process and consider what more information needed (PI)	Adaptive communication approaches – given more time if lower HL (HS)	• Offering multiple appointments (PI, HS) • Separating delivery of bad news from decision making (PI) • More time (HS)

6.3.1 Team talk

In ‘team talk’, the focus is on working together, making the patient aware choices exist and describing these, providing support, and discussing their goals. Several barriers to these behaviours were identified. When thinking about working together, patients may be stoic, hesitant to speak up, and trust their care is in expert hands, conforming to the more traditional patient role and deferring to the clinician. Healthcare professionals may feel SDM is not appropriate, and take a more paternalistic role, fitting with these patient expectations. Patients may not be made aware choices exist if there has been limited discussion of the options, which may result from clinicians’ assumptions about patients, their preference for one option over another, or a need to exert their authority in the context of safety related decisions. The constraints of the system may limit the support available to patients, who may not know how to seek the additional help they need and may not feel they can bother healthcare professionals between planned appointments as they do not want to be a burden. Discussion of goals can also prove challenging when patients are faced with uncertainty and are hesitant to speak up, and when there is limited time available to explore this further during appointments.

Healthcare professionals’ attitudes can facilitate these processes, when SDM is considered to be ‘always’ possible, or in cases where the patient is perceived to have the authority. Clinicians who work with friends and family and the wider team, who are contactable and supportive and who actively explore patients’ priorities may help develop HL, further building confidence to become more involved, and nurture more SDM.

Interventions might include school/public health education about HL and SDM, to try and reset expectations and create a more balanced partnership between patient and clinician. Creating an environment where people feel their expertise is welcome and valid, where their input is needed to inform good decision making, and where they are encouraged and supported to speak up may also help. Interventions might also include taking measures to ensure the steps of SDM are made explicit, including that there is a decision to be made, and establishing goals. These may take the form of simple prompts or decision aids to support clinicians with this process. Particularly important in the context of incurable cancer, clearly and routinely signposting to support services, linking with other teams, including the GP, and checking in after consultations to establish understanding and fill in any gaps would put people in a better position for processing and using information to be able to reach a decision.

In some cases, particularly when resources are limited, it might help to identify in advance those who face difficulties with HL, in order to offer additional support or ensure access to an advocate if wanted or needed, and to encourage patients to think about their priorities and preferences for discussion at their appointment.

Some of these ingredients could be incorporated into more easily understood and clearer routine communications, perhaps by including a sentence in an appointment letter setting expectations about patients' involvement in consultations, encouraging people to prepare questions in advance, or think about their priorities.

6.3.2 Option talk

In 'option talk', alternatives are compared and discussed according to risk communication principles. The evidence suggests, however, that a range of barriers can prevent this from happening. Patients face a significant emotional burden, which can make it hard to take in complex information about different options. Further, the alternative to active treatment may not be seen as a viable option, and patients may focus on the potential benefits of treatment, downplaying any risks. Clinicians might make direct recommendations, with limited explanation of alternative options, particularly if they perceive there to be a superior choice, and may whittle down or offer fewer options in an attempt to make things easier for those with HL difficulties. Information resources to support these conversations are not always easy to access, read or understand, whilst too much may be given at the beginning and not be readily available later on. This might result in poorer understanding, and greater reliance on the potentially limited and skewed information given by healthcare professionals.

Patients trust what they are told by healthcare professionals and tend to rely on this even if they do seek additional information elsewhere. This can therefore facilitate open discussion of the options. Clear explanations without jargon and written information that is easy to read and understand, including simple summaries, provide people with something to refer back to after the consultation. Additional support through the patient's networks or support groups, and through opportunities to speak again with the healthcare team after the appointment can help address gaps, foster understanding, and facilitate comparison of the options.

Possible intervention ingredients to support option talk might include offering a range of easily understandable resources in a variety of formats, giving patients choice according to their preferences and providing them with reliable information to support deliberation once outside the consultation room. Summary details of the patient's disease and simple decision aids providing clear comparisons of the options may also facilitate this. Separating delivery of bad news from complex details about management options, and encouraging the presence of friends, family and advocates may allow patients to consider the options more clearly. Finally, educating patients and healthcare professionals with the aim of supporting the development of HL might raise awareness of its importance, and generate long term benefits for patients' future interactions with healthcare professionals.

6.3.3 Decision talk

'Decision talk' involves getting to informed preferences, and reaching preference based decisions. Reaching informed preferences can be challenging however, particularly when the healthcare environment and illness are unfamiliar. Patients' expectations may be based on portrayals in the media or from hearing others' stories, and fear or distress may arise from the unknown, from inaccurate information, or from a lack of understanding. Patients may again feel pressure to conform to the traditional patient role, feeling the decision has already been made by the experts, not wanting to waste their time, and not wanting to turn an offer of treatment down, as doing so would be considered by them to be foolish. Further, a lack of real life patient data may hinder healthcare professionals' attempts to ensure preferences are accurately informed, and lead to further uncertainty. Conflicting advice or a negative clinician attitude towards SDM pose further barriers to reaching informed preference based decisions.

Strategies such as comparing information from different sources, using support groups or the internet to further understanding may help some patients gather the information they need, though many patients are mindful the internet is not always a reliable source of information. Use of HL strategies such as teach back and chunk and check, to check understanding and address misconceptions may facilitate this further.

Interventions may include opportunities to hear from other specialist healthcare professionals, such as the palliative care team, or discuss the realities of treatment with other patients, to provide people with a more accurate portrayal of what to expect. Signposting to reliable sources of information on the internet may also help with this. Question prompt lists might highlight important aspects patients hadn't considered and help them identify gaps in their knowledge. Interventions might also include clinician training to support such conversations, emphasising the importance of patient preferences and helping patients align their preferences with available options. A reminder for healthcare professionals to give patients permission to turn down offered treatments could also be considered.

6.3.4 Active listening

'Active listening' involves paying close attention and responding accurately, which may be made more difficult in time pressured consultations, or when video consultations mean the additional cues perceptible when in the same room are lost. Coupled with limited time, clinicians may use closed questions to check understanding, and make assumptions about patients rather than explicitly enquiring. Despite some patients feeling more able to take on information at a later date, this is not always easy to ask for and obtain.

Healthcare professionals may adapt their communication when they suspect a person has HL difficulties, perhaps assessing understanding with open questioning, or encouraging patients to explain what they have been told, enabling identification of gaps and unmet information needs.

When considering how to promote active listening, interventions might include communication skills or training on SDM, tools such as question prompt lists, or opportunities to elicit and document preferences prior the consultation. Flexible appointment scheduling and opportunities for face-to-face contact according to patient and clinician preference are also important.

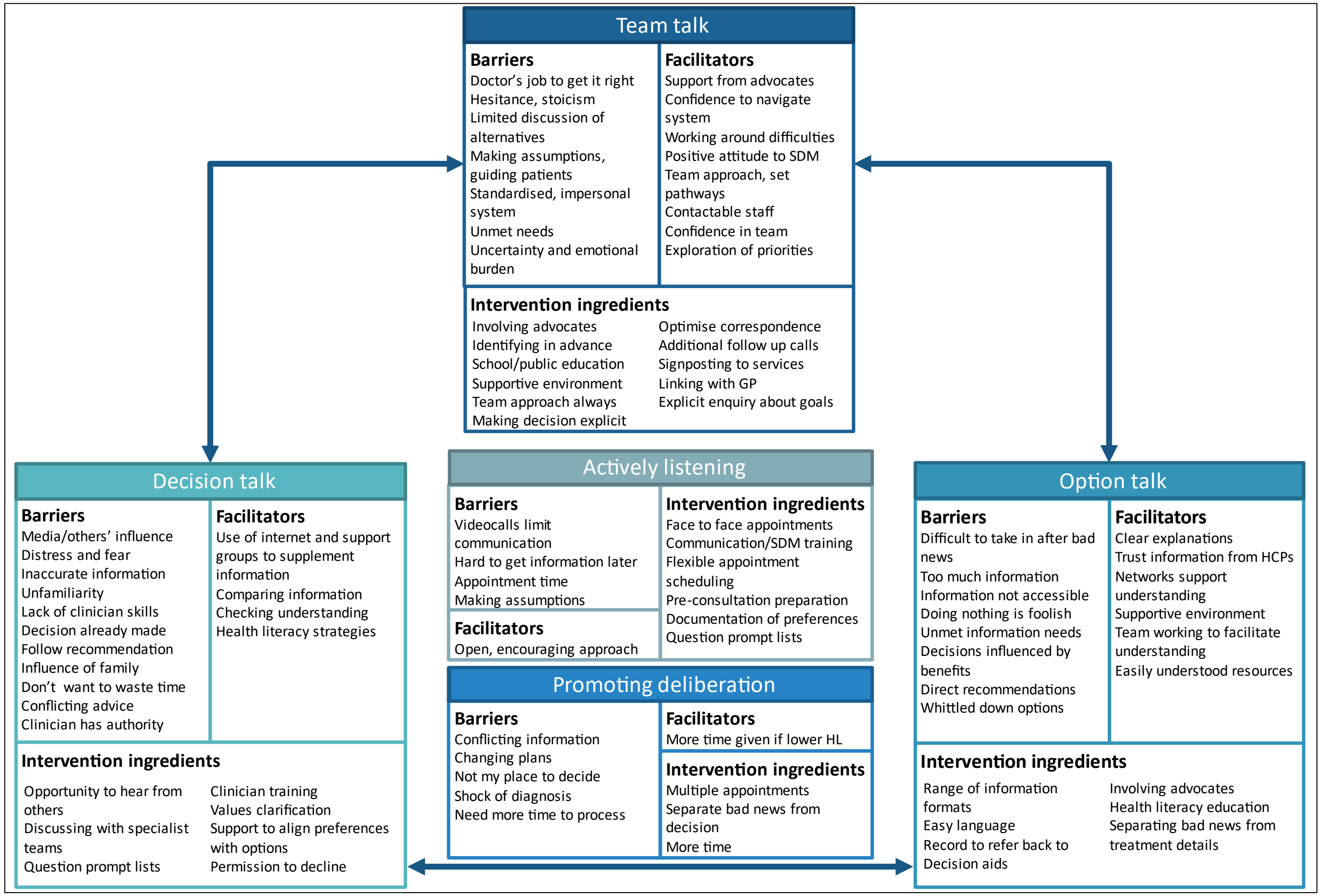
6.3.5 Promoting deliberation

Finally, ‘deliberation’ involves thinking carefully about the options when facing a decision. This can be hindered by emotional factors, such as shock or difficulty accepting the diagnosis, and uncertainty when conflicting information is given, or plans change. These factors may necessitate more time to process the information and consider what further details are required. Further, if patients believe it is not their place to decide on treatment, as this is the expert clinician’s job, deliberation might not take place.

An important facilitator of deliberation is time, and particularly when clinicians suspect a patient might have lower HL, they make more time for patients in order to facilitate SDM.

Strategies that support offering multiple appointments, separating delivery of bad news from decision making, and allowing more time to have these conversations and for people to deliberate, perhaps away from the hospital environment, could be beneficial.

These findings are further represented in Figure 27, which depicts the barriers, facilitators and possible intervention ingredients according to the Three Talk Model (Elwyn *et al.*, 2017). As set out in the Model, there is a dynamic interaction moving back and forth between the three ‘talks’, whilst ‘actively listening’ and ‘promoting deliberation’ are constant considerations throughout.



Team talk

Barriers
Doctor's job to get it right
Hesitance, stoicism
Limited discussion of alternatives
Making assumptions, guiding patients
Standardised, impersonal system
Unmet needs
Uncertainty and emotional burden

Facilitators
Support from advocates
Confidence to navigate system
Working around difficulties
Positive attitude to SDM
Team approach, set pathways
Contactable staff
Confidence in team
Exploration of priorities

Intervention ingredients
Involving advocates
Identifying in advance
School/public education
Supportive environment
Team approach always
Making decision explicit
Optimise correspondence
Additional follow up calls
Signposting to services
Linking with GP
Explicit enquiry about goals

Decision talk

Barriers
Media/others' influence
Distress and fear
Inaccurate information
Unfamiliarity
Lack of clinician skills
Decision already made
Follow recommendation
Influence of family
Don't want to waste time
Conflicting advice
Clinician has authority

Facilitators
Use of internet and support groups to supplement information
Comparing information
Checking understanding
Health literacy strategies

Intervention ingredients
Opportunity to hear from others
Discussing with specialist teams
Question prompt lists
Clinician training
Values clarification
Support to align preferences with options
Permission to decline

Actively listening

Barriers
Videocalls limit communication
Hard to get information later
Appointment time
Making assumptions

Facilitators
Open, encouraging approach

Intervention ingredients
Face to face appointments
Communication/SDM training
Flexible appointment scheduling
Pre-consultation preparation
Documentation of preferences
Question prompt lists

Promoting deliberation

Barriers
Conflicting information
Changing plans
Not my place to decide
Shock of diagnosis
Need more time to process

Facilitators
More time given if lower HL

Intervention ingredients
Multiple appointments
Separate bad news from decision
More time

Option talk

Barriers
Difficult to take in after bad news
Too much information
Information not accessible
Doing nothing is foolish
Unmet information needs
Decisions influenced by benefits
Direct recommendations
Whittled down options

Facilitators
Clear explanations
Trust information from HCPs
Networks support understanding
Supportive environment
Team working to facilitate understanding
Easily understood resources

Intervention ingredients
Range of information formats
Easy language
Record to refer back to
Decision aids
Involving advocates
Health literacy education
Separating bad news from treatment details

Figure 27 - Barriers, facilitators and possible intervention ingredients based on Three Talk Model of SDM (Elwyn *et al.*, 2017)

6.4 Discussion

The findings set out in this chapter demonstrate the need for a more complex approach to supporting SDM in the setting of incurable cancer and lower HL. They offer an explanation for why a single, simple intervention may improve one aspect of SDM but is unlikely to address all identified barriers, and provide support for addressing different elements of the process and tailoring to the individual. As an example, a question prompt list may encourage patients to think about and ask for the information they need, helping them reach informed preferences. However, for people to feel able to speak up, this requires a supportive environment and an engaged clinician who has the skills to actively listen and respond, and is able to provide the desired information in an appropriate and understandable format to suit the patient. Similarly, communication skills training for clinicians may provide them with strategies to support SDM discussions, but the addition of easy to use tools such as decision aids will enhance these conversations further, by clearly outlining the decision to be made and providing a balanced comparison of the options. Such a tool may also act as a resource for patients to take away and refer back to, which, when given sufficient time to do so, will allow people to deliberate and consider their decision away from the hospital environment, perhaps also discussing the implications with those around them.

In addition to identifying barriers to all stages of SDM, the findings also point to their different origins. Some stem from socio-cultural influences and expectations of clinician-patient roles, with patients leaving decisions to the experts, and healthcare professionals seeing it as their responsibility to make decisions on behalf of patients, at times making assumptions about their preferences. Other barriers relate to the additional emotional challenge of decision making in the context of incurable disease, and the influence this can have on processing information in order to reach informed preference based decisions. Barriers also arise from the inflexible and at times impersonal system, which limits the time and resources available to patients. When considering how to intervene to address these barriers and improve SDM, it is therefore important to take these different aspects into account, and the intervention ingredients presented demonstrate some of the ways this might be achieved.

6.5 Summary and next steps

This chapter has brought together the evidence for the barriers, facilitators, and possible intervention ingredients, highlighting the complexities of SDM in the context of HL difficulties when cancer can't be cured. Many possible intervention ingredients have been proposed, addressing the multitude of barriers identified.

The next phase of the project was to present these findings to expert panels of patients and healthcare professionals, to seek their feedback and further explore what steps could be taken to facilitate greater SDM in the palliative oncology setting. Given the complexity of the Intervention Planning Table presented in this chapter (Table 14), the findings were summarised for the first panel meeting involving healthcare professionals, and further refined to incorporate feedback from this meeting for discussion with the patient and carer group.

Chapter 7 Expert panel meetings

7.1 Background

In the previous chapter, findings from the preceding PhD study phases were combined to demonstrate the barriers and issues an intervention to support SDM must address to be effective. Having synthesised this work, a key activity to undertake as part of the Intervention Planning stage of the PBA was consultation with experts and other stakeholders (Yardley *et al.*, 2015). This chapter therefore describes two meetings, one with patients/carers and one with healthcare professionals, and presents an overview of the feedback obtained. This feedback informed the development of overarching headings outlining the key issues for SDM when cancer can't be cured, in the context of HL difficulties.

Having gathered evidence for the barriers and possible strategies to support SDM in this setting, it became clear that SDM in this context is complex, with several different challenges and possible solutions. The purpose of the stakeholder meetings was therefore to discuss the key issues and intervention components identified through this work and consider how these might apply in a real world NHS setting. It was important to consider existing interventions, and draw on the panels' experience and expertise to determine which aspects were likely to be most useful and achievable in this setting. Feedback from the meetings could then be used to help inform recommendations for future interventions.

7.1.1 Objectives

The objectives for the two patient/carer and healthcare professional meetings were the same:

1. To review key summary findings from systematic review, qualitative interviews, and healthcare professional survey
2. To discuss possible components for an intervention based on these findings
3. To review existing interventions
4. To consider which intervention components are likely to be most useful, engaging, and achievable in this setting and which to prioritise for future interventions

7.2 Methods

A combined meeting could have proven intimidating for some patient and carer members who might not have felt comfortable to speak up. Likewise, healthcare professionals may not have felt they could talk so openly. For these reasons, separate meetings were planned to maximise the contribution of all members.

An application was submitted to the University of Southampton for institutional ethical approval. However, such approval was deemed unnecessary as the planned work was not considered to constitute research: the meetings did not seek to generate new research material for formal qualitative analysis, and there was no plan to use direct participant quotes. Instead, summaries and notes of the discussion points were made. The same study procedures for a formal focus group covered by ethical approval were followed, including agreement to record the meeting for later reference.

7.2.1 Healthcare professional meeting

7.2.1.1 Recruitment and eligibility

A list of potential attendees was discussed and agreed with AH, to ensure representation of healthcare professionals from across the region using knowledge of colleagues to identify those with an interest in the subject and relevant experience to contribute to the discussion. Potential attendees were approached, in some cases after email introduction by AH, and the purpose of the meetings explained. All expressed interest in participating, and were asked about their availability in order to identify a possible date for the meeting able to accommodate most members. All who had been approached agreed and were able to attend. RW was also in attendance to provide support by recording the meeting, taking notes, and summing up at the end.

7.2.1.2 Attendees

Eleven healthcare professionals joined the meeting, including:

- 1 cancer support worker
- 1 project support officer on SDM transformation team
- 2 cancer clinical nurse specialist (one with community linking role)
- 1 specialist palliative care nurse
- 1 community oncology matron
- 1 head of cancer nursing
- 2 consultant clinical oncologists
- 2 consultant medical oncologists

Healthcare professionals worked in various locations across the Wessex region, including three district general hospitals, one tertiary centre, and community settings.

7.2.1.3 Format

The meeting was scheduled to last two hours and all of this time was used. It was held virtually over Microsoft Teams for convenience to participants who worked at different hospital sites and was recorded for reference purposes. The research findings were presented to participants in a PowerPoint presentation split into two sections (Appendix C.1), and discussion was initiated following each section. Participants were offered no incentives for taking part.

Notes were taken during the meeting by RW, who subsequently typed and summarised them. After the meeting, these were reviewed alongside the video recording, further comments added, and the main findings identified from the discussion were refined, after which the recording was deleted. Summarised findings were incorporated into the slides for the patient and carer meeting.

7.2.2 Patient and carer meeting

7.2.2.1 Recruitment

Several channels of recruitment were pursued with the goal of recruiting patients or carers with experience of incurable cancer who had faced difficulties accessing or understanding the information they have been given, or not been as involved in decision making as they would like. Due to the nature of the subject and specific group sought, this proved challenging. Contact was first made with one of the local hospital Trusts, however they had few patient experts following COVID and did not know of any who would be suitable. Recruitment was then attempted through the regional Cancer Alliance patient and public involvement network, who shared an advert for the meeting among organisations they were in contact with as well as directly with their volunteers and via social media. Unfortunately, none of these approaches generated any interest. A further local cancer patient and carer panel were approached, but again, no members were considered to meet the criteria. Following on from this, direct contact with two cancer clinical nurse specialists led to the identification of one possible patient who may have been able to assist. However, in the absence of other potential contributors and uncertainty about the patient’s confidence and comfort participating in such a meeting, an alternative approach was sought.

Ultimately, the Patient and Public Involvement group at University Hospital Southampton were able to assist with identifying and recruiting members for the meeting. The same group had been approached when seeking PPI contributors for the patient interviews, and as a result, the engagement team and some members were already familiar with the project. One of the engagement officers, Barney Jones (BJ), shared an advertisement (Appendix C.2) via the UHS R&D

PPI Opportunities email contact list, and asked members of the local Public Involvement Network to publicise the opportunity. One contributor was contacted directly due to an awareness of their eligibility from previous conversations. Following the successful recruitment of six patients/carers, BJ coordinated a time for the virtual meeting, reviewed the presentation slides, and sent an invite to all participants.

7.2.2.2 Contributing attendees

The meeting began with six patient and carer attendees, and was opened by BJ. One attendee experienced connection difficulty and had to leave the meeting before having a chance to contribute. The presentation materials were sent on to this attendee after the meeting by BJ, but no additional feedback was received. One attendee made a single typed contribution in the chat box. The remaining four attendees were visible on camera and contributed to discussions throughout. They included:

- A carer for his wife who died of cancer some years ago
- The spouse of a person treated for cancer with curative intent, and whose brother-in-law died of cancer in his 30s
- One attendee whose sister had recently died of a rare cancer at an early age (in her 30s), and whose mother had died of metastatic cancer after a short period of illness (6 months)
- A person living with incurable cancer, who was an active contributor to PPI and research groups

7.2.2.3 Format

The one and a half hour meeting was held virtually over Zoom and recorded by BJ for reference purposes. Project findings including key points from the healthcare professional meeting were summarised and presented in a PowerPoint presentation (Appendix C.3). The meeting was split into two sections with time for discussion following each and a short comfort break in between. Participants were offered payment for their time in line with recommendations made by the supporting Patient and Public Involvement team.

Notes were taken contemporaneously by AH, who observed the meeting, and key recurring themes identified. These were again reviewed and revised whilst watching the recording, which was subsequently deleted.

7.3 Findings

After reviewing and revising the key themes identified by RW and AH, the themes and supporting comments were compiled into two separate documents. This allowed comparison between feedback from the two meetings (healthcare professionals and patients/carers) to identify similarities and differences from the different perspectives. Informed by the findings presented in Chapter 6, and considering the socio-cultural, emotional, and system-related sources of these barriers, the themes were then combined, where possible, under overarching headings. These headings were:

- Changing mindsets
- Communication skills and balanced discussion of options
- Teamworking and prior preparation to ensure people are well supported
- Inflexible system and logistical challenges
- Resources to support SDM

Under each of these headings and following a summary description, feedback from the meetings is presented in a series of tables.

7.3.1 Changing mindsets

A key discussion point in both meetings was the need to change the culture around clinician and patient roles and patient involvement in decision making (Table 15). This was true for both the healthcare setting and in society as a whole. Within the NHS, the view that SDM has a role only in limited circumstances must be shifted towards one of wanting to support and facilitate SDM ‘always’. Whilst in wider society, greater public education about health-related issues and perceptions of diseases, including cancer, may provide a means of empowering people and ultimately preparing them for a more active role in future health related encounters.

Table 15 – Key themes and feedback supporting 'Changing mindsets'

Clinician knows best (HCPs)	Clinicians making assumptions about patients e.g., that they want to be told what to do, but in reality patients are not being given opportunity Need sea change and to change perspective. Patients are experts in themselves, need to shift our views and theirs
Power imbalance (HCPs)	Imbalance of knowledge – clinicians do have the power When seeing people in their own homes, the agenda can be set by them, they have more control
Facilitating SDM (patients/carers)	Responsive system providing what a patient needs when they need it Recognising value of SDM in even smaller/simpler decisions that affect the patient directly
Education of patients and wider population (patients/carers)	Need culture shift to facilitate SDM within health system

	Education of school-aged children/university students - preparing them for SDM and decisions they are likely to have to make at some stage for themselves and others Changing public perceptions of cancer

7.3.2 Communication skills and balanced discussion of options

Members of both panels also agreed on the importance of communication skills as a basis for good SDM and an overall positive experience of care (Table 16). There was some discussion about individual clinicians' ability to successfully engage in such conversations despite additional skills training, and a suggestion that peer review for clinicians to observe and be observed, learning from colleagues, might be beneficial. Additional focus in the patient and carer group included communication with specific groups, such as those for whom English is not their first language, or where an individual's culture might affect the topics people feel comfortable discussing.

Table 16 - Key themes and feedback supporting 'Communication skills'

Communication skills (HCPs)	Need advanced communication skills training Some clinicians don't appear able to communicate in a way to facilitate SDM Clinicians sometimes think they are 'doing' SDM but may not be or not doing it well. Peer review/observation of consultations as way to develop/improve practice Being able to select the right approach for patient based on personality/preferences Need to engage patient at beginning and explore priorities
Communication skills (patients/carers)	Need for greater communication skills amongst clinicians Language skills – overcoming culture/language differences between patients and clinicians – role of speech and language Need to use lay language – not always done Different levels of detail needed in written information Interprofessional communication is key Need good communication early on Discussing changes in plans, need "meaningful" explanations Need to ensure understanding

As well as overall communication skills, both groups talked about some of the challenges associated with trying to have a balanced discussion of the options (Table 17). Healthcare professionals acknowledged their own shortcomings in discussing the 'time toxicity' impact of pursuing active anticancer treatment approaches, whereby the true benefit in terms of quality time gained is limited as patients may spend more time in hospital attending appointments, receiving treatment, or as a result of side effects. There was also a feeling, however, that the alternative option of supportive care with no active anticancer treatment was becoming less acceptable to patients. Attendees noted it could be harder for people to say no to treatment than to agree to it, which is even more challenging when the alternative option is not presented as a legitimate choice. In addition, clinicians may be overly optimistic about treatment options, contributing to some patients' unrealistic expectations of what might be achievable. The patient and carer group discussed how the pressures of an aggressive disease or rapidly changing trajectory may make the choices appear even more limited in terms of options available and decisions to be made, and this is further compounded by the complexity of some healthcare pathways or when plans have to be changed.

Table 17 - Key themes and feedback supporting 'Balanced discussion of options'

Treatment and no treatment options - the 'no treatment' option should be presented as a legitimate choice (HCPs)	Harder to say no than yes, 'no treatment' option not always presented Becoming harder to sell 'no treatment' – media, expectations Need to set expectations, include palliative care early, balanced discussion including time toxicity, asking 'what do you want from time left?'
Barriers to SDM (patients/carers)	Late presentation limiting options Rapid catastrophic patient decline Symptoms - pain making conversations difficult The number of decisions that need to be made Complex pathway and changing plans

7.3.3 Teamworking and prior preparation to ensure people are well supported

Both groups talked about the need for good team working to enable joined up care and effective SDM (Table 18). This was important not just within cancer teams, ensuring the expertise of all members was utilised to its fullest potential and allowing patients to benefit from their different knowledge, communication approaches and styles, but also through closer working with other services, including palliative care, GPs, and community teams. Healthcare professionals noted, however, that it could be hard to keep track of what services were available in the community in order to signpost patients. The cancer clinical nurse specialist (CNS) role was highlighted by both groups as particularly valuable, and CNSs were seen by patients and carers as having more time to spend providing support. However, the patient/carer group did reiterate the need for support at the beginning of the journey, before relationships with healthcare professionals become established.

Table 18 - Key themes and feedback supporting 'Teamworking to ensure people are well supported'

SDM needs a team approach (HCPs)	Working in teams key – benefit from having multi-professionalism in clinic CNS follow up calls, community support Combined clinics and input from palliative care would be valuable from the start
Community (HCPs)	Supportive services exist but there is a need for more community specialist palliative care support

	GPs/community teams can sometimes help with literacy, someone to attend appointments (social prescribers) but hard to know what/where and postcode lottery Hard to keep up with resources
Facilitating SDM (patients/carers)	Interprofessional collaboration - teamworking Established relationships – fortunate, two HCPs providing support and explanation – different styles, continuity Time (CNS has more time)
Barriers to SDM (patients/carers)	Lack of cohesion at the start of the journey before relationships with HCPs established

There was also some discussion in the healthcare professional group of the benefits of pre-consultation preparation to facilitate discussions in the clinic (Table 19). Some members described work to identify patient priorities in advance, making the appointment more useful and efficient, or explaining the options (including that of no active cancer treatment) during an information clinic before any decision making has taken place, to make patients aware of this option from the outset. The point was also made of the link between HL and deprivation, and the need to be aware of additional factors which may influence a patient's decision making, such as practicalities of getting to hospital for treatment, or the support needed in such situations to allow people to accept treatment. Finally, the need to be mindful of not contributing to distress was raised, by preparing people that there is no right or wrong answer, and ensuring discussions are supportive and options given are not overwhelming.

Table 19 – Key themes and feedback supporting 'Pre consultation preparation'

Patient preparation for consultations regarding what patients want to know and their priorities – more efficient consultations (HCPs)	Unpicking priorities before clinic makes time more useful, patient feels more listened to, encourages questions Identifying who might benefit from information beforehand and target to those who might struggle HL and social deprivation – linked to other issues and things that make life difficult e.g., paying for travel, support Information clinic for new patients – explaining options including no treatment/palliative care from outset Fear of doing the 'wrong' thing – prepare patients that there is no right or wrong People almost disabled by information – options can be distressing

7.3.4 Inflexible system and logistical challenges

As throughout this project, the limited time available for patients and clinicians to have meaningful conversations and address all information needs to support SDM was highlighted by both groups (Table 20). From the healthcare professionals' discussion came the view that clinicians may collude with patients by not asking questions, as they do not have enough time to deal with the consequences of the answers given. Compounding the often rigid appointment scheduling, both groups discussed how the pace of disease and need to avoid missing a window of opportunity for treatment may also add time pressure, and may limit opportunities to build relationships and have lengthy and open discussions. The patient and carer group also noted the inflexibility of the system which requires patients to fit in, even when this is difficult for them, and doesn't make it easy for people to raise challenges to this. Finally, despite these issues, the healthcare panel group made the point that good SDM may actually lead to less work, and this may therefore act as an incentive for busy clinicians.

Table 20 - Key themes and feedback supporting 'Inflexible system and logistical challenges'

System Design (patients/carers)	The "cup of coffee with Macmillan" model not always realistic – when timescale months not years, or it appears there is not enough time Patients have to fit the mould even if they can't (i.e., no transport to attend the appointment that has been made) Difficult to challenge the system to suit the individual's needs (appointments, language) – perceived negatively
Barriers to SDM (patients/carers)	Complex pathway and changing plans
Limited time (HCPs)	Avoid asking questions – don't want to hear answers, lack of time Momentum of treatment – no time to process diagnosis before commencing treatment, already on pathway Good SDM may lead to less work

7.3.5 Resources to support SDM

The final area discussed by the panels was the role of additional resources to support SDM (Table 21). Both groups discussed the recording of consultations, which, from the patient and carers' perspective was seen as a useful resource to refer back to. However, healthcare professionals acknowledged individual clinicians may have different preferences and not all would feel comfortable with this. The recommended practice of writing clinic letters to patients rather than colleagues, as was previously the norm, was also raised. Healthcare professionals found it difficult to strike the right tone and such letters took longer to get right. Both groups mentioned the benefits of having an additional person (friend, relative, advocate) present to support the patient, dialling them in if unable to attend in person, and the need to identify good quality reliable sources of information for patients to be signposted to, acknowledging information found on the internet may not always be of good quality.

Table 21 - Key themes and feedback supporting 'Resources to support SDM'

Practicalities (HCPs)	Recording consultations – clinicians have different personal preferences Dialling in if someone can't be there Signposting to resources Difficult to write good letters to patients
Barriers to SDM (patients/carers)	Poor information on the internet
Facilitating SDM (patients/carers)	Patient and advocate/relative attending consultations together – helps to take in information Recording consultations to refer back to – so much detail

7.4 Discussion

The panel meetings provided a valuable opportunity to consolidate findings from the project and promoted further conversation around the key issues for SDM when cancer cannot be cured.

Rather than generating new qualitative data, the meetings sought to consider how the previous findings fit within the NHS context, and discuss the applicability of the proposed intervention ingredients in this setting. As such, recruitment did not seek to be fully representative, though a range of stakeholders with relevant experience was invited, and the meetings did not include formal data generating procedures. Discussion of the barriers and strategies to support SDM during the two meetings reinforced findings from the earlier studies, whilst also providing a different perspective and lens through which to view them. Whereas the patient interviews and healthcare professional survey drew on individuals' experiences, these meetings encouraged attendees to reflect on and discuss those responses, to consider the findings in the context of their own experiences, and generated discussion about possible solutions in the NHS setting. Participants were able to relate to the findings, and none appeared to be discordant with their experiences.

However, whilst findings from the meetings were informative, it was not possible to fully address all of the intended objectives. The research findings from the systematic review, qualitative interviews, and healthcare professional survey, as well as existing interventions from the literature, were reviewed (objectives 1 and 3). However, in depth discussion of specific intervention components was not achieved (objectives 2 and 4). It had been hoped it would be possible to identify one or a small number of key issues to prioritise, or interventions to further develop. However, what became clear, as throughout this project, was that the factors influencing SDM for people with lower HL and incurable cancer were complex. Whilst a single targeted intervention may support some areas of SDM, a more comprehensive approach is likely to be needed to address the full range of challenges identified. As such, a variety of different considerations must be made, and efforts must address as many barriers as possible in order to progress towards better SDM in this setting.

7.5 Summary and next steps

This chapter brings to a close the data generating elements of this PhD. It describes the process by which the barriers and facilitators of SDM identified throughout this study were considered in the context of the NHS clinical setting, through discussion with expert stakeholders. It highlights the complexities of SDM in the setting of incurable cancer and lower HL, and gives a clear rationale for a multi-targeted approach to supporting SDM, ranging from widespread cultural shifts in perceptions of clinician and patient roles in the healthcare setting, to much more specific and simple changes.

The following chapter will discuss the development of guiding principles and the components of a complex intervention addressing the main barriers to SDM in this setting.

Chapter 8 Combined findings and intervention

8.1 Introduction

The previous chapters in this thesis have described the phases undertaken during this PhD study seeking to understand how best to support SDM in incurable cancer, with a focus on HL. Findings have been interpreted incorporating knowledge gained throughout the process, and in each phase, it has been possible to identify several important influences which have gone on to inform the next phase of the study.

The systematic literature review described in Chapter 3 demonstrated the disadvantage faced by those with lower HL, who experience poorer quality of life and an overall poorer experience of care. Few studies specifically looked at SDM in this patient group, though the review identified several factors which may make SDM more challenging for patients, including difficulties accessing and processing information. A range of personal and situational factors appeared to influence these experiences. Findings from this phase confirmed the importance of ensuring efforts to promote SDM are inclusive and consider the needs of patients who may experience difficulties with lower HL, who may have much to gain from the additional support.

The next phase of the study aimed to gain a deeper insight into these patient experiences, by hearing directly from those diagnosed with incurable cancer and who appeared to have experienced difficulties with HL (Chapter 4). This phase sought to learn more about decision making from the patient’s perspective and explore the personal and situational factors which may influence these experiences, considering also how these challenges might be addressed. The emotional burden associated with a diagnosis of incurable cancer negatively impacted participants’ ability to take on and process information, and the desired information wasn’t always easily available. Involvement in decision making was influenced by the social pressure of wanting to be a good patient, alongside an expectation that decisions would be made for patients in their best interests by the experts, and that their own role in this process was limited.

As SDM is (at least) a two sided process, it was also important to better understand the views of clinicians towards SDM. The next phase therefore sought to explore when healthcare professionals might be reluctant to use SDM, instead presenting patients with a direct recommendation, and whether their practice changed when faced with patients they suspected of having lower HL. In this third phase, described in Chapter 5, a spectrum of views towards SDM was identified. Some healthcare professionals reported SDM should always be the goal and described efforts to overcome barriers, whilst others described the limits of this approach in certain situational, personal, patient and decision related circumstances. Healthcare professionals described various ways in which their approach to SDM changed if they suspected a patient had lower HL, and made suggestions for how the process could be improved to support these patients. These suggestions ranged from simple, smaller interventions such as video patient information, to larger policy changes, and a further phase of work was therefore planned to prioritise and rationalise these, to inform the development of a complex intervention to support SDM in this setting.

In the final phase of work (Chapter 6 and Chapter 7), findings from the previous three phases were integrated and considered alongside the stages of SDM set out in the Three Talk Model (Elwyn *et al.*, 2017). This process made it possible to clearly visualise the barriers and facilitators to the different stages of SDM, the sources of evidence contributing to them, and how they might be overcome. Following this, the findings were further summarised for presentation at two expert panel meetings, and feedback from the ensuing discussions was combined to identify a number of key priorities. These included cultural issues relating to clinician and patient roles, communication skills training and teamworking, logistical challenges and practical resources.

In this next chapter, and again drawing on the Person Based Approach to Intervention Development (Yardley *et al.*, 2015), findings from each of these phases will be combined to 1) identify the overarching issues and challenges for SDM when cancer can’t be cured, with a focus on lower HL, 2) develop guiding principles highlighting how an intervention could address these issues, and 3) identify the components of a team based intervention to support SDM in the palliative oncology setting.

8.2 Methods

The final activity in the Intervention Planning stage of the PBA is the creation of guiding principles, the aim of which is to highlight how the intervention will address key issues crucial to engagement in the specific context of the target users (Yardley *et al.*, 2022). This involves initially describing the intervention objective (to support SDM), and subsequently drawing on a range of sources to identify the psychosocial characteristics of the population (those with a diagnosis of incurable cancer who face difficulties with HL), and the key issues, needs and challenges the intervention must address in order to achieve the intervention objective (described in Chapter 6 and Chapter 7). It became apparent during the course of this project that no single simple intervention would address all of the identified issues for SDM, however, a combination of measures, informed by these guiding principles and incorporated into a complex intervention, could be used. Development of guiding principles entails identifying the design objectives that address these issues as well as key intervention features that will address each of the design objectives. To achieve this, the five main discussion points resulting from the panel meetings were incorporated into the existing findings to identify three overarching issues or barriers for SDM in incurable cancer and HL difficulties, providing the user context for the guiding principles. A number of design objectives were then outlined for each of these. Finally, drawing on the existing literature as well as suggestions made by patients and healthcare professionals throughout the study, key intervention features addressing each of these considerations were identified.

8.3 Overarching issues and challenges for SDM when cancer can't be cured, with a focus on lower HL

Building on the findings from discussions held with expert stakeholders described in Chapter 7, which were themselves informed by the combined evidence presented in Chapter 6, it has been possible to identify three overarching barriers and provide accompanying recommendations to support SDM in the setting of incurable cancer and lower HL. The three main barriers include:

- Persistence of traditional paternalistic clinician-patient roles
- Dealing with the emotional hurdles
- Practical issues – the system isn't perfect

None of these are specific to the palliative oncology setting, nor to individuals who experience HL difficulties, but each has particular relevance in these situations and featured prominently in the accounts given by the patients and healthcare professionals in this study.

The first, concerning traditional views towards paternalistic clinician-patient roles, is a socio-cultural barrier, relevant to all healthcare settings and decisions. It reflects the perceptions of wider society towards medicine and healthcare, healthcare professionals' attitudes towards their own roles and that of their patients, and encompasses issues relating to power and authority.

The second barrier, dealing with the emotional hurdles, highlights the particular emotional challenges faced by patients diagnosed with an incurable cancer. Whilst people may share a common tumour site, with similar symptoms and sometimes even similar treatments, the emotional challenges faced and decision making differ between those receiving treatment with curative intent and those facing incurable disease. This barrier is also likely to have relevance to other life-limiting conditions where decisions must balance quality with quantity of life.

The final barrier relates to more practical issues and the additional burden conferred by the structure of the health care system. This includes the use of standardised processes, lengthy patient information written in language that is not always easy to understand, and limitations to appointment scheduling and opportunities for contact between healthcare professionals and patients, hindering open conversation and understanding.

Although these barriers are applicable to all faced with a diagnosis of incurable cancer, each presents additional challenges for those with HL difficulties, who may be disproportionately disadvantaged as a result. The three barriers will now be discussed in greater detail, with consideration given to how each might be overcome in order to better support SDM when cancer can’t be cured, particularly in the face of lower HL.

8.3.1 Persistence of traditional paternalistic clinician-patient roles

Key points:

- Patients expect to be given recommendations in their best interests and perceive choice as saying yes/no to this
- Patients do not feel they have the knowledge or expertise to make an equal contribution and play a balanced part in the discussion
- Clinicians want to do their best by patients and may limit options or steer patients towards the decision they feel is correct
- Clinicians feel responsibility to keep patients safe
- Time may limit exploration of a patient’s goals or preferences, and patients may be hesitant to volunteer this information
- There are entrenched cultural views towards these roles and relationships, which can be hard for both clinicians and patients to overcome

Both clinicians and patients appear accepting of and expect a traditional approach to healthcare decision making, whereby the clinician presents a recommendation, and the patient agrees to this, or more rarely, chooses to go against it. Whilst healthcare professionals may understand the rationale for involving patients to a greater extent in decisions about their care and be keen to support it, the current model is well entrenched, and it can be difficult for clinicians to align a more shared approach to care with their professional responsibilities. On the other side of the partnership, patients may feel they lack sufficient knowledge, be unaware they can have a say or consider their contributions are not a valuable addition to the decision making process, and may therefore default to assuming a more passive role. This may be particularly true for those who experience difficulties with HL and find it hard to obtain the information they need to feel sufficiently well informed.

Problems may also arise from faulty assumptions made by either party based on these views. Patients may assume treatment wouldn’t be offered if it wasn’t going to be worthwhile, or may perceive that rejecting the clinician’s ‘recommendation’ would be foolish, and speaking up may create the reputation of being a time waster. Meanwhile, healthcare professionals may wrongly assume it is obvious to the patient there is a decision to be made and the invitation to take part in this decision making is implicit, or may make assumptions about peoples’ preferences for involvement.

To create a more balanced partnership, wider cultural change is needed, highlighting the benefits of SDM to both healthcare professionals and patients. In addition to this, targeted efforts supporting clinicians to engage with SDM and providing opportunity, encouragement, and permission for patients to speak up and get involved will be needed.

8.3.2 Dealing with the emotional hurdles

Key points:

- Diagnosis comes as a shock making it difficult to take in information immediately afterwards
- It is important for people to be able to come to terms with this before attempting to make decisions and launching into treatment (but note the pressure of disease trajectory and organisational time pressures)
- Fear of doing the wrong thing – options presented by clinician seen as right and best to follow recommendation, whilst ‘doing nothing’ is seen as foolish
- Greater fear and distress results from poorer understanding/lower HL
- There may be a lack of familiarity with diagnosis, processes, healthcare systems
- People may feel uncertainty about the future – the disease trajectory, treatment timescales, what comes after
- Changing plans can set people back in terms of their acceptance and understanding

For some people, the diagnosis and processes leading to it may be their first significant experience of illness and the healthcare environment. For almost all, a diagnosis of incurable cancer will come as a significant shock, and it will take time to process this news before a person is able to take on board the complex information needed to actively engage in discussions about treatment and their priorities. Patients may experience greater fear and distress if they do not have a good understanding of their situation, perhaps as a result of lower HL. They will be keen not to make a wrong choice, and may therefore be inclined to follow the recommendations made by healthcare professionals even if these do not align with their priorities. Once a route has been chosen, changes to this plan can set people back, requiring them to reassess and process information relating to their situation before they can come to terms with it once again. People may experience uncertainty about short term practicalities relating to the treatment schedule and how they might feel, as well as longer term considerations and planning for the future.

Some of these experiences are shared with those receiving treatment with the aim of cure, though the considerations differ. In an adjuvant setting, the person may already have been cured, but may discuss the possibility of treatment to reduce a hypothetical risk of recurrence and consider the potential impact of short and long term side effects of treatment now and in the future. In the incurable setting however, the discussion is around anticipated benefits of treatment on quality or length of life, balanced against potential toxicities which may significantly impact quality of life in the short term and the person's ability to enjoy and make the most of their remaining time. Both carry a significant but different emotional burden, and people may need more support and help to process than is available in a time-limited consultation. Close teamworking within and between hospital and community teams, drawing on different members' respective expertise and skills, is key to providing patients with well-rounded support and continuity of care. It is also important to allow people time and space without feeling rushed or pressured, and to arm them with the information they need. In the context of incurable disease, this may mean opening up discussions about the future, the disease trajectory and what to expect during and after treatment. And for those who experience difficulties with HL, it is important to ensure the information given, if wanted, is accessible and useful, not buried in a lengthy document which may be too daunting to read.

8.3.3 Practical issues – the system isn't perfect

Key points:

- Limited time during appointments – pressure to impart necessary information
- Not always easy for patients to seek further information/ask questions despite encouragement
- Written information not always easy to understand and alternatives not readily available
- Letters and communications sometimes unnecessarily complicated

The final barrier to SDM relates to the organisational or practical issues which make it more difficult to effectively navigate and engage with the healthcare system. These issues can be challenging for all, regardless of HL, and whilst some can be overcome with time and greater familiarity, simple steps could be taken to make things easier for all involved.

Time pressures have been reported throughout this project, and both healthcare users and providers are acutely aware of this. Coupled with the perceived inflexibility of the system to which patients must conform, this does not portray a culture in which the patient is firmly in the centre, their priorities listened to and always taken into account when making decisions.

In terms of resources, written information is often more easily available than other formats that may be preferred by patients, and there is often a mismatch between patients' information needs and the resources they are given.

8.4 Guiding principles

The overarching issues described in section 8.3 provide the user context for the intervention, highlighting the characteristics of both patients and healthcare professionals likely to affect engagement. Following the PBA, it is important to next identify what the intervention must achieve to address these issues and thus improve engagement (the key design objectives) and subsequently consider the key features of the intervention that will achieve those objectives (Yardley *et al.*, 2022). These elements are set out in Table 22, which outlines the guiding principles for an intervention to support SDM when cancer can't be cured, taking into account the specific challenges faced by those with lower HL.

Table 22 - Guiding principles for an intervention to support SDM when cancer can't be cured, with a focus on HL

User context	**Key design objectives**	**Intervention features**
Persistence of traditional clinician-patient roles Clinicians and patients still expect and conform to traditional paternalistic roles	Encourage clinicians to proactively explore patients' preferences for care and involvement (rather than making assumptions) and engage with SDM	• Make it easy by providing useful, user-friendly resources to support decision making conversations • Communication skills training to support SDM • Emphasis on what can be gained from good SDM
	Encourage patients to want to engage with SDM	• Create supportive environment for SDM • Provide patients with resources to support SDM • Emphasis on importance of patient's priorities and preferences
	Ensure there is opportunity for people to process their diagnosis, or come to terms with changing plans, and offer support to do so	• Early signposting to sources of support • Emphasis and encouragement to bring support person • Allow time to process information
Dealing with the emotional hurdles A diagnosis of incurable cancer brings significant emotional challenges which can impede understanding and decision making	Ensure good, joined up teamworking in and out of hospital	• Ensure good interprofessional communication • Encourage teamworking • Offer follow up contacts after difficult/decision making conversations
	Provide clear information, as and when needed by the patient, to facilitate understanding and reduce uncertainty	• Offer patients the opportunity for conversations about possible disease trajectories and treatment timescales, and provide resources to refer back to

User context	Key design objectives	Intervention features
	Ensure resources are written with HL principles in mind and have a wide scope to increase uptake and reduce waste	• Generic templates/resources where possible but allowing tailoring to individual (e.g., patient summaries, decision aids) • Simplified information using lay language • Short resources focusing on key information • Easy access to alternative formats e.g., videos
Practical issues – the system isn't perfect The system and resources are often not set up to be easy for patients to use and understand	Make the system easier to navigate and more conducive to patient involvement	• Clearer and better utilised communications • Facilitate flexibility in appointment scheduling to suit patient and circumstances • Make use of community services where available to provide additional support • Where more widespread changes are not possible, consider identifying early on those who may struggle, to ensure appropriate support and resources available

8.5 An intervention to support SDM when cancer can't be cured

Based on the guiding principles described above, the following section outlines a team based, complex intervention for supporting SDM when cancer can't be cured, which seeks to overcome the specific challenges faced by those with lower HL. As has been previously demonstrated, a combined approach is needed to address the variety of issues described, and buy in from clinical teams will be necessary to achieve success. In line with NHS England's SDM Implementation Framework (NHS England, 2019b), this complex intervention involves elements aimed at preparing patients, training clinical teams, and making the system more supportive of SDM (Figure 28). This section therefore seeks to provide clinical teams with a range of options addressing the identified issues, from which they might select those most feasible according to local need and available resources. Teams are encouraged to use existing evidence-based resources where possible, and ensure development of any new materials is carried out with health literacy principles in mind.

Figure 28 - An intervention to support SDM when cancer can't be cured

8.5.1 Prepared patients

It is clear from this study's findings that patients are not always aware of their role in SDM, do not always feel empowered to speak up, and often face significant emotional hurdles to overcome before they can take in the complex information they are given and process this effectively. It is therefore important to help patients become better prepared for engaging in SDM by providing early emotional support, making them aware of their own role in making decisions about their care and encouraging them to actively participate, and providing opportunities to seek the information they need to inform their decisions. Figure 29 outlines changes that could be implemented to prepare patients with lower HL and incurable cancer for SDM.

Prepared patients

At diagnosis:

- ☐ Signpost to support services (charities, counselling, information centres) and peer support opportunities
- ☐ Provide clear details of contact person and their role at diagnosis

Prior to appointment:

- ☐ Simple leaflet on SDM included with new patient appointment letter
- ☐ Include a line in appointment letter encouraging patients to engage, speak up, ask questions
- ☐ Encourage patients (in appointment letters/telephone contacts) to bring relative/friend

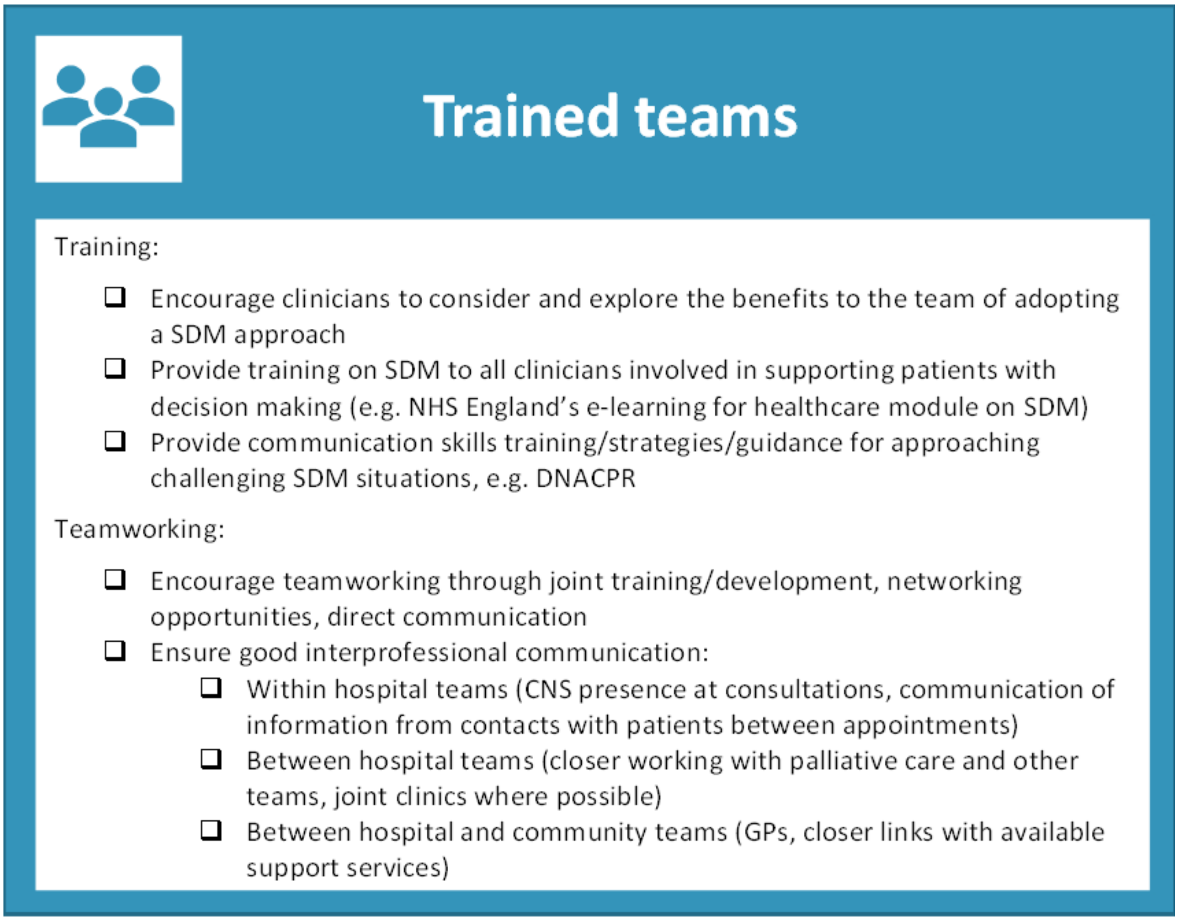
At appointment:

- ☐ Video/posters in waiting room explaining SDM
- ☐ Promote use of question prompts e.g. Ask 3 questions/BRAN
- ☐ Make clear to patients when there is a decision to be made, and their role in reaching this decision
- ☐ Offer opportunities for conversations about disease trajectories/treatment timescales and support with resources to refer back to e.g. brief summary of consultation, brief treatment /cancer record

Figure 29 - Preparing patients for SDM

8.5.2 Trained teams

Effective SDM also relies on the engagement and skills of clinicians involved in decision making, and it is therefore important that teams receiving training in SDM, with demonstration of its relevance to their clinical practice, and strategies to support situations where SDM may be more difficult, such as those identified by healthcare professionals in Chapter 5. As well as highlighting the need for specific training on SDM, Figure 30 also emphasises the importance of good team working, drawing on all members of the wider team involved in caring for the patient in order to benefit from the different expertise offered through multi-disciplinary team working.



Trained teams

Training:

- ☐ Encourage clinicians to consider and explore the benefits to the team of adopting a SDM approach
- ☐ Provide training on SDM to all clinicians involved in supporting patients with decision making (e.g. NHS England's e-learning for healthcare module on SDM)
- ☐ Provide communication skills training/strategies/guidance for approaching challenging SDM situations, e.g. DNACPR

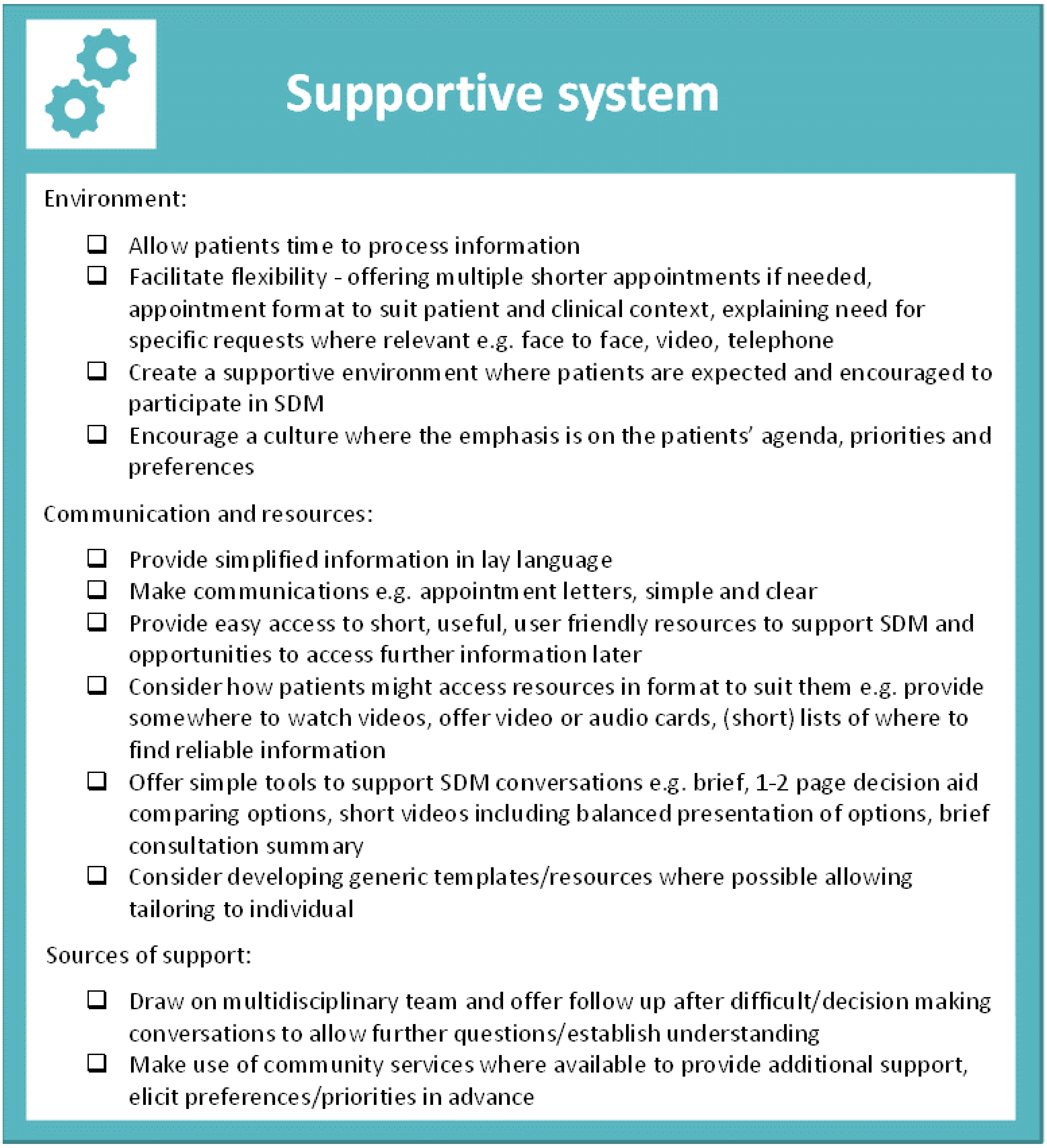
Teamworking:

- ☐ Encourage teamworking through joint training/development, networking opportunities, direct communication
- ☐ Ensure good interprofessional communication:
    - ☐ Within hospital teams (CNS presence at consultations, communication of information from contacts with patients between appointments)
    - ☐ Between hospital teams (closer working with palliative care and other teams, joint clinics where possible)
    - ☐ Between hospital and community teams (GPs, closer links with available support services)

Figure 30 - Training teams in SDM

8.5.3 Supportive system

The third component of this complex intervention (Figure 31) addresses changes to the system to increase flexibility and create a more supportive and conducive environment for SDM to take place. Though there is necessarily rigidity in appointment scheduling, facilitating flexibility where possible, particularly to allow patients time to process information about their diagnosis and management options is crucial. It is also important to create an environment where patients are encouraged and supported to speak up, and where their priorities and preferences are taken into account. Care should be taken with communications and resources to provide information in a simple and clear manner to avoid confusion, using lay terminology, and offering information in a variety of formats to suit the individual and support their understanding away from the consultation setting. Few relevant decision aids were identified during this project, and teams may wish to develop brief tools with a balanced presentation of the available options to support decision making, and consider recording video/audio alternatives for those who prefer to receive information in this way. Finally, patients should be offered support following decision making conversations, and signposted to external and local support services where available.



Supportive system

Environment:

- ☐ Allow patients time to process information
- ☐ Facilitate flexibility - offering multiple shorter appointments if needed, appointment format to suit patient and clinical context, explaining need for specific requests where relevant e.g. face to face, video, telephone
- ☐ Create a supportive environment where patients are expected and encouraged to participate in SDM
- ☐ Encourage a culture where the emphasis is on the patients' agenda, priorities and preferences

Communication and resources:

- ☐ Provide simplified information in lay language
- ☐ Make communications e.g. appointment letters, simple and clear
- ☐ Provide easy access to short, useful, user friendly resources to support SDM and opportunities to access further information later
- ☐ Consider how patients might access resources in format to suit them e.g. provide somewhere to watch videos, offer video or audio cards, (short) lists of where to find reliable information
- ☐ Offer simple tools to support SDM conversations e.g. brief, 1-2 page decision aid comparing options, short videos including balanced presentation of options, brief consultation summary
- ☐ Consider developing generic templates/resources where possible allowing tailoring to individual

Sources of support:

- ☐ Draw on multidisciplinary team and offer follow up after difficult/decision making conversations to allow further questions/establish understanding
- ☐ Make use of community services where available to provide additional support, elicit preferences/priorities in advance

Figure 31 - Creating a supportive system for SDM

8.5.4 Implementation and evaluation

Whilst implementation of each of the components is recommended to address the issues identified throughout this study, it is important to acknowledge the constraints on doing so as a result of teams' competing priorities and workload, funding, and resources. Where implementation of the full intervention is not possible, teams are encouraged to consider which smaller scale changes might be possible (e.g. distributing or publicising the Ask 3 Questions, including a line in appointment letters to promote SDM, encouraging clinicians to undertake brief training on SDM, considering how to make alternatives to written information easily accessible to patients) and incorporate these into routine care. For teams wishing to implement and more formally evaluate these changes, measurement of SDM using the SDM Q-9 or CollaboRATE scales prior to and after implementation is recommended (NHS England, 2019b).

8.6 Discussion

The barriers presented in this chapter represent a range of patient and healthcare professional views and experiences, and the subsequent guiding principles and proposed intervention for supporting SDM in the context of incurable cancer and lower HL have been developed with the NHS clinical setting in mind. Whilst the challenges described here reflect the experiences of patients with HL difficulties and a diagnosis of incurable cancer, they may also resonate with others who have a serious illness and are facing decisions about their care. The guiding principles and resulting intervention, meanwhile, may make things easier and improve the experience of all patients, regardless of HL. By approaching the challenges for SDM from the perspective of those who may find it harder to access and use information to make decisions, this ensures those who may already face disadvantage are not left further behind.

A key area highlighted by both expert panels included the need for large scale cultural changes and a shift in how we as a society view the relationships between patients and healthcare professionals, and peoples’ roles in their own health. Whilst changing policy and public health education is beyond the scope of what might be achievable for clinical teams in a healthcare setting, the different components of the proposed intervention describe changes that could be implemented to improve attitudes towards and engagement with SDM in day to day clinical practice. They also include smaller changes to documentation and resources, which may be more achievable at a departmental or individual level. Whilst the intervention does not specifically address other markers of disadvantage, simplifying processes, offering easily accessible information in a format to suit the individual, promoting involvement in line with patient preferences and ensuring excellent support will make things easier for all patients.

Though adoption of any of the individual intervention components may lead to a more positive experience for those seen during day to day clinical practice, a combination of measures using different approaches will likely be needed in order to bring about significant and lasting improvements to how decision making is carried out.

8.7 Summary and next steps

In this chapter, findings from the evidence gathered during the different PhD phases have been combined and distilled to form three overarching barriers that influence SDM in the setting of incurable cancer and HL difficulties. These barriers incorporate socio-cultural influences, personal emotional influences, and practical, system related barriers which work against the process of SDM. Guiding principles addressing these issues have subsequently informed the development of a complex intervention to support SDM in this setting.

The final chapter in this thesis will discuss the study’s findings and novel contributions, with reference to the literature and existing guidelines, offer further reflection on the research process, methods used, and limitations of the study, and discuss future work to advance the field.

Chapter 9 General discussion and conclusion

9.1 Discussion of findings and practical implications

The previous chapters in this thesis have outlined the different phases of the PhD study, which sought to explore how best to support SDM when cancer can’t be cured, with a focus on HL. In this chapter, the study’s research questions and aims will be revisited, findings from the different study phases brought together, and the contributions made demonstrated, with consideration of the practical implications of the work.

A number of specific aspects and limitations of the project will be discussed, as well as the influence of the COVID-19 pandemic and a reflection on my role as researcher and clinician.

Finally, the potential for future work will be considered, and the study will be brought to its conclusion.

9.1.1 Overview of study phases

The table presented on the next two pages (Table 23) provides an overview of the different study phases. The first part repeats that presented in Chapter 2 and includes a reminder of the aims and objectives of each phase, with an update to show when each was carried out.

The second part outlines the key findings for each phase, the novel contributions made, and demonstrates the progression of the project as the findings and gaps identified during each phase went on to inform the next. These are then discussed in greater detail.

Table 23 – Summary table showing study phases

	Mixed studies systematic review	**Patient interviews**	**Survey of healthcare professionals**	**Expert panel meetings**
	Chapter 3	**Chapter 4**	**Chapter 5**	**Chapter 7**
Timing	Initial search performed October 2019, updated January 2021	Interviews carried out between November 2020 - October 2021	Survey open to responses from August – September 2021	Panel meetings held November 2022 (Maternity leave Dec 2021 – July 2022)
Aim	To bring together the literature relating to HL in cancer care, to improve understanding of the challenges associated with HL in this context, and efforts already made to address them, and provide an overview of the subject that would inform the intervention development process.	To explore the experiences of and challenges faced by patients lower HL receiving care for incurable cancer, acknowledging the implications COVID-19 will have for future care delivery, and consider how best to support decision making for this patient group.	To understand healthcare professionals' views and approach to SDM in the context of incurable cancer, with a focus on HL	To discuss the key issues and intervention components identified through this work, consider existing interventions, and determine which aspects are likely to be most useful and achievable in this setting
Objectives	1. To identify which outcomes relate to limited HL in patients with cancer 2. To identify the prevalence of limited HL in patients with cancer 3. To identify what qualitative studies have explored the role of HL in patients to access, understand, appraise, and use information and services to make decisions about health 4. To explore what interventions have been developed or tested to support patients with limited HL in this setting	1. To understand the experiences and decision making of patients with lower HL receiving care for incurable cancer in the NHS 2. To identify particular challenges faced by patients with lower HL whilst receiving care for incurable cancer 3. To make recommendations about how best to support this patient group in clinical practice.	1. To understand the views and experiences of healthcare professionals towards SDM in the context of incurable cancer 2. To explore the barriers to SDM in the context of incurable cancer reported by healthcare professionals 3. To explore how perceived lower HL affects how healthcare professionals approach SDM with patients with incurable cancer 4. To identify what strategies might be useful to support SDM for patients with incurable cancer and lower HL	1. To review key summary findings from systematic review, qualitative interviews, and healthcare professional survey 2. To discuss possible components for an intervention based on these findings 3. To review existing interventions 4. To consider which intervention components are likely to be most useful, engaging, and achievable in this setting and which to prioritise for future interventions

	Mixed studies systematic review	**Patient interviews**	**Survey of healthcare professionals**	**Expert panel meetings**
Key findings	• Lower HL is associated with poorer outcomes in cancer care, including poorer quality of life and overall experience of care • Few studies have looked at the association between HL and decision making in this setting • Data from the qualitative papers suggest more could be done to help patients feel fully informed and able to take a more active role in their care • Few interventions to support patients with lower HL exist in this setting, and none focus on the specific issues surrounding incurable disease	• Participants were well supported by their cancer teams and felt their care was in expert hands • Priorities were not always discussed, and many seemed unaware of the potential for greater involvement in decision making beyond agreeing to or declining the clinician's recommendation • Patients described difficulties accessing and understanding information, the emotional hurdles they faced, and a desire to be a good patient • Several recommendations for overcoming these challenges were made	• Views towards SDM differ, with some reporting it should always be possible, and others identifying situations where it can be more challenging • Barriers include lack of time, patient and decision related factors, and clinician attitudes and assumptions • Healthcare professionals adapt their approach to SDM if they suspect HL difficulties • Strategies identified by professionals include advocacy and support; communication skills; patient resources; and logistical/system level changes	• Discussion of findings from the previous three phases led to the development of five overarching issues that should be considered to support SDM when cancer can't be cured, with a focus on HL • They include: - Changing mindsets - Communication skills and balanced discussion of options - Teamworking to ensure people are well supported - Inflexible system and logistical challenges - Resources to support SDM
Novel contribution	This review presents a comprehensive picture of the association of lower HL with a range of poorer outcomes in cancer care, and provides justification for ensuring efforts to improve care consider the needs of those who face HL difficulties.	This is the first study specifically seeking to learn more about the experiences of those facing HL difficulties with incurable cancer. It provides an insight into the challenges for SDM and suggests why some measures for increasing SDM may not succeed.	These findings demonstrate the specific challenges for SDM in the setting of incurable cancer from the perspective of healthcare professionals, and help explain some of the experiences of decision making described by the patients interviewed.	Feedback from the panel discussions led to the identification of overarching issues for SDM in this setting. No single area was prioritised for future development, though both panels highlighted the need for a cultural shift to enable greater patient involvement in decision making.
Gaps and further work	Further work is needed to understand the challenges faced by those with incurable cancer and HL difficulties, and how this affects SDM	Further work is needed to understand the barriers to involving people with incurable cancer and HL in decision making from the clinicians' perspective	Many strategies to support SDM in this setting have been suggested. Further work is needed to identify the priority areas for future development	Strategies capable of addressing the combination of personal, socio-cultural and system related factors influencing SDM must now be developed and tested.

9.1.2 Discussion of findings and contributions

The summary presented in Table 23 provides an overview of the findings and contributions of each study phase. It also demonstrates the progression of the PhD based on gaps identified by the preceding work. This section will discuss these findings and contributions in greater detail.

The mixed studies systematic review described in Chapter 3 provides a comprehensive overview of the wider role of HL in cancer care not otherwise available in the published literature. Other related reviews exist but are limited to studies undertaken only in the United States (Kieffer Campbell, 2020), or include only self-management related outcomes (Papadakos *et al.*, 2018). Two further reviews have looked at interventions to improve HL in cancer patients. One included those aimed at cancer prevention and screening in addition to supporting those with a diagnosis of cancer (Housten *et al.*, 2020), whilst the other included articles published up to 2017 (Fernández González and Bravo-Valenzuela, 2019). Given the increasing interest in the field of HL, an update as part of this combined review was therefore felt to be warranted. This decision was justified by the inclusion of 43 papers (out of the total 84) published during or after 2018, including five of the ten intervention papers. The systematic review undertaken during this study, part of which has been published (Holden *et al.*, 2021), allows a more complete view of the wider role of HL in cancer care by considering prevalence, outcomes and interventions, as well as the specific association of HL with SDM. It also provides a compelling argument for ensuring the needs of those who experience HL difficulties are addressed when developing interventions in order to improve outcomes.

The next phase involved the recruitment of individuals suspected by healthcare professionals of experiencing HL difficulties receiving care for incurable cancer, in order to understand their unique experiences and involvement in decision making. In work exploring a similar aim carried out by a group in The Netherlands during the course of this PhD study, focus groups were held with patients with limited HL to learn about their experiences of SDM and identify the support necessary to enable increased participation (Noordman, Oosterveld-Vlug and Rademakers, 2022). A screening tool, based on the same Chew questions as were used in this study, was used to identify lower HL, though participants were included if they had visited a healthcare provider in the last 12 months rather than having a specific medical diagnosis. The authors similarly found patients tended to follow healthcare professionals' recommendations and felt they were in expert hands. They did note, however, that participants' preferences were generally discussed and taken into account, which did not appear to be the case for the patients interviewed in this PhD study. The need for more time and support to participate in SDM, including using additional resources, were also common findings. As participants in the focus groups did not share a common illness, however, the exploration of these issues in the specific context of incurable cancer, as in this PhD study, has allowed identification of additional barriers relevant to SDM in this setting.

As was found during this PhD, another recent ethnographic study of decision making in head and neck cancer similarly observed that patients may unquestioningly delegate decision making to the doctor, having been presented with a recommendation of the ‘best’ treatment based on discussion with a multidisciplinary team (Hamilton *et al.*, 2022). The authors suggest this can create a ‘cycle of paternalism’, whereby patients are grateful to accept clear recommendations made by clinicians, and clinicians are reassured to know they are acting in the patients’ best interests. Presenting the MDT recommendation in this way was shown to act as a barrier to SDM, limiting more open discussion of the options, and resulting in some patients making decisions that were not in line with their priorities. An example is given where a patient and clinician made a decision to proceed with a less radical treatment option, which was at odds with the patient’s priority of survival. The patient’s priorities were not fully explored, and his misconception that surgery would cause further spread, when it would in fact give him the best chance of cure, was not addressed, and strongly influenced his decision. The study was not limited to those with incurable disease, but in the palliative setting, should a patient’s priorities not be fully explored, the patient may go on to choose a more aggressive and intensive treatment option, which may be out of keeping with their preference to maintain independence, quality of life, or minimise time in hospital. Though not a focus of the study, these findings further emphasise the importance of HL, alongside the need for effective communication, to establish good understanding and facilitate informed decision making.

In another study, Nelson *et al.* (2020) explored chemotherapy decision making amongst patients with advanced lung cancer and identified a number of the same challenges found during this PhD study’s interviews. Patients were unaware there was a decision to be made, there was a perceived lack of a positive alternative supportive care option, treatment decisions were influenced by patients’ trust in the healthcare professionals and opting out of a proposed treatment was challenging. Ziebland, Chapple and Evans (2015) explored barriers to SDM in pancreatic cancer and similarly found patients didn’t consider there to be a real choice, described pressure from others to proceed with treatment, and experienced confusion as a result of conflicting information. However, these studies did not seek to explore the additional barriers faced by those who experience HL difficulties. This is important as interventions aimed at supporting SDM may rely on written or complex information, and the specific recruitment of such individuals in this PhD study provided this valuable perspective.

It is also important to acknowledge the significant emotional burden associated with a diagnosis of incurable disease. Derry, Reid and Prigerson (2019) attribute the limited success of some decision aids in advanced cancer to a lack of emphasis on mitigating the psychological barriers faced by patients in this setting. Findings from these interviews provide further evidence for the need to consider these wider social, cultural, and emotional influences when developing interventions to support SDM.

In the third phase of work, it was important to learn about the issues from the perspective of healthcare professionals. Clinicians involved in caring for patients with advanced cancer are experienced in dealing with the uncertainty of such a diagnosis, and have expertise in handling the conversations and situations in which SDM might be used, often having completed additional advanced communication skills training. Despite this, the healthcare professionals surveyed identified several barriers to SDM in this context. Alongside the often cited barrier of a lack of time, decision and patient related factors were commonly encountered in this setting. These included the challenge of conversations around DNACPR when this might be considered futile, stopping treatments when they risk causing patients harm, and a reluctance to engage in SDM when a patient is distressed.

A study in which many similar barriers and strategies were identified was again carried out in The Netherlands. In that study, 17 healthcare professionals who regularly discussed treatment and palliative care options for patients with cancer and chronic obstructive pulmonary disease (COPD), were interviewed about their views and approaches to SDM and HL, the barriers faced and strategies for overcoming them (Roodbeen *et al.*, 2020). Whilst this study and the PhD shared similar findings, including the importance of time as a barrier and potential strategy, the use of resources and adaptive communication, need for greater collaboration and education, and patient and decision characteristics, differences were also identified. One difference lies in the reasons given by healthcare professionals for why SDM is not always possible. Rather than assuming patients won't have the necessary knowledge to participate, as in Roodbeen *et al.* (2020)'s study, clinicians in the survey described their overarching responsibility for patients' safety, and deemed it necessary to take responsibility for certain decisions themselves. A further finding in this PhD study was the preference of some clinicians to rely on their clinical judgement, develop relationships and get to know their patients, rather than following a tick-box process for SDM. One flaw with this approach, however, is the timescale with which decisions sometimes need to be made as a result of the clinical situation, making it difficult to rely on these established relationships. This issue can be compounded by inaccurate clinician assumptions about patients' preferences for involvement and patients' lack of awareness of the opportunities available to them if not fully informed about the decision making process. In these circumstances, ensuring the presence of an advocate can support patient understanding, help the clinician gain a greater insight into the patient’s perspective and promote a SDM approach. An additional strategy identified by the survey for overcoming the barriers included wider efforts to raise awareness of and seek to improve HL and understanding of health, disease and SDM, including through public health and school education initiatives. The use of a survey within this PhD allowed data collection from a larger number of respondents, and as they were professionals working in the NHS, findings have greater relevance to UK healthcare practice.

Finally, the panel meetings brought together patients, carers, and healthcare professionals with an interest in SDM in incurable cancer, and experience of the challenges posed by HL difficulties, to discuss these issues and consider how best to move forwards to improve care. The clear need for a change in culture and attitudes, both within the healthcare setting and wider population, was highlighted by both panels. Shifting society’s views regarding the patient’s role in healthcare and decision making will play an important part in moving away from a more paternalistic model of care delivery towards one where the patient is seen as an equal contributor and true partner in the decision making process. Within the healthcare setting, it will be important to consider how to redress the power imbalance to facilitate a team approach to decision making. Galasiński, Ziółkowska and Elwyn (2023) consider the social and cultural influences on SDM, and discuss its role in overcoming epistemic injustice. Epistemic injustices include testimonial (judging some narratives less worthy than others because they are given in a local dialect, or from certain social groups), hermeneutical (silencing a person’s account because their experience is unusual and impossible to contextualise), the effect of evidence-based medicine (which prioritises evidence from quantitative controlled trials and overlooks the individual patient story) and the power imbalance between clinicians and patients including the clinician’s control over healthcare encounters (Galasiński, Ziółkowska and Elwyn, 2023). These socio-cultural influences and the imbalance of power have been notable throughout this PhD study, and the injustices described may be particularly likely to be experienced by those who face difficulties with HL. To overcome this, the authors advocate viewing SDM as a process occurring within these existing power structures. They suggest that whilst clinicians must give up the communicative advantage they possess for SDM to occur, SDM must *‘leverage the dominant power of the clinician to introduce a more equal communication process. SDM explicitly suspends power in order to get started’ (Galasiński, Ziółkowska and Elwyn, 2023).* In this way it may be possible to make room for another expert, the patient, to participate.

An extensive programme of work has already been carried out to understand the challenges for SDM in the NHS, and consider how these barriers might be overcome to embed SDM into routine practice (Joseph-Williams *et al.*, 2017). However, this PhD study has highlighted additional important issues that must be considered in the context of advanced, incurable cancer, and the particular challenges posed by HL difficulties in this setting.

9.1.3 Relevance to existing SDM guidance

Good SDM, in the context of person-centred care, remains an important goal for the delivery of good healthcare, yet it continues to be difficult to achieve in practice. In the NHS, the recent GMC and NICE guidance (General Medical Council, 2020; National Institute for Health and Care Excellence (NICE), 2021) seek to instil a culture where SDM is the norm and set out recommendations for its use. Whilst this is a great step towards integrating SDM into routine clinical practice, the guidelines do not fully take into account or address the many nuanced situations where SDM can be more difficult, including where there are significant emotional barriers preventing an individual from being able to fully process the information they are given.

The NICE guidance contains little specific information to support the situations identified by healthcare professionals as particularly challenging in the survey, such as when a patient requests a treatment that is unavailable or is considered futile or unsafe. The GMC guidance does provide further detail on this, although perhaps not to the degree required by those faced with such situations. Whilst stating *'all patients have the right to be involved in decisions about their treatment and care and be supported to make informed decisions if they are able',* it also outlines steps to take in the event of a disagreement with the patient's choice of option. It promotes discussion with the patient to explore their reasons, understanding and expectations, but ultimately allows the clinician to override the patient's request for a treatment if deemed inappropriate: *'if after discussion you still consider that the treatment or care would not serve the patient's needs, then you should not provide it'* (General Medical Council, 2020). On the other hand, a patient's decision to take no action must be respected, even if this is considered unwise. If this appears to be out of keeping with their beliefs or values, steps may be taken to check the patient has understood the relevant information, alternatives, and consequences of their decision and if it is not clear they have understood, further support should be offered. Such scenarios are always likely to be difficult, and further emphasise the need for excellent resources, communication skills and support to facilitate good understanding and improve the chance of an agreeable outcome for all. As discussed in Chapter 5, decision making around DNACPR can pose particular challenges for patients and healthcare professionals, and separate, specific guidance on this seeks to differentiate when SDM may or may not be appropriate (British Medical Association, 2016).

An important point highlighted by the NICE guidance is the need to discuss alternatives, which, in the case of incurable cancer, includes not having anticancer treatment. It recommends clinicians '*openly discuss the risks, benefits and consequences of each option, making sure the person knows this includes choosing no treatment, or no change to what they are currently doing'*, and advises training in SDM for healthcare professionals should include *'sharing and discussing the information people need to make informed decisions, and making sure they understand the choices available to them (including the choice of doing nothing or not changing the current plan' (National Institute for Health and Care Excellence (NICE), 2021)*. Whilst discussion of options is key to SDM, the term 'doing nothing' can cause confusion. It was used by patients to negatively describe what they perceived as the only alternative to systemic treatment (4.3.2.3) and was deemed particularly unhelpful by healthcare professionals in the panel meeting, who were clear the alternative to anticancer treatment, which involves addressing an individual's symptoms and needs as they arise, is much more than this, and can result in better outcomes for some patients. However, whilst the lay understanding of this alternative can sometimes be inaccurate, formal terminology describing such care can also be unclear. NICE guidance suggests a distinction between supportive care, given alongside disease-modifying therapies, and palliative care, which is described as primarily conservative and aimed at giving comfort in the last months of life (National Institute for Health and Care Excellence (NICE), 2019a). Others, such as the Marie Curie end of life charity, use the terms interchangeably to describe holistic care given at any stage after a terminal diagnosis, including alongside treatments, and aimed at making people feel supported and comfortable, rather than curing the illness (Marie Curie, 2022). Taking care to avoid the term 'doing nothing' and framing alternatives in a more neutral way may help all parties to approach decision making from a more balanced perspective.

Finally, there is a reliance in both guidelines on the use of quality assured patient decision aids and high-quality resources, offered in the person's preferred format, to support SDM discussions. Many of the healthcare professionals surveyed felt it would be helpful to have more resources to facilitate SDM conversations. Unfortunately, and as reflected by many of the survey responses, such resources are not always readily available in the palliative oncology setting. Some hospitals are more easily able to offer a range of information resources to patients, through dedicated centres such as those run by Macmillan. Not all cancer hospitals have such a centre, however, and the format and number of available resources is much more limited, meaning there may not be appropriate and understandable resources available for those who struggle with standard written information, such as those with HLD. Equitable, easy access to resources and alternatives to standard written information are needed to increase uptake in order for them to be routinely incorporated in decision making conversations as per the guidance. In addition to this, very few relevant decision aids exist. However, whereas it would be useful to have a wider array of information in different formats to offer patients according to their preference, development of a small number of simple, easily accessible, generic aids could be more practical. Given the regular emergence of new data and treatments, it would be difficult to maintain accurate and up-to-date decision aids for these changing clinical scenarios. A limited number of generic aids may involve less work to produce than a large range of specific ones, could be used in a variety of contexts, and may be easier for clinicians to implement if they are able to become familiar with them and do not have to select from a vast number of more specific aids each time. One example of such an aid may include a simple, broad comparison of palliative chemotherapy versus best supportive care in an Option Grid style design (Yen *et al.*, 2020), which could be tailored during the consultation to a specific regime or patient, presenting the two options in a more balanced and equal way and stimulating further discussion.

9.1.4 Practical implications

Current guidance applicable to the NHS (General Medical Council, 2020; National Institute for Health and Care Excellence (NICE), 2021) provides an excellent basis for establishing SDM as the norm, but additional work and resources are needed to support the full implementation of the process in the palliative oncology setting. Findings from this PhD study provide an important insight into the particular challenges for SDM when cancer can’t be cured, identifying the additional barriers faced by those with HL difficulties, and emphasising the need for a comprehensive approach addressing the socio-cultural, personal, and logistical issues to achieve SDM.

As outlined in Section 8.3, this work sets out the components of a complex intervention for clinical teams, including a number of practical suggestions for overcoming these barriers to improve SDM.

These intervention components include smaller changes made on an individual level, to team based and structural changes. Whilst large scale shifts in the way clinicians and patients interact and see themselves as partners in decision making will take time and require more substantial policy and public health intervention incorporation of some of the smaller scale intervention components into clinical practice, alongside the existing recently published guidance, will help facilitate SDM conversations. Preparing patients, training teams and creating an environment conducive to SDM through supportive systems is key.

Making sure people are given the time and support they need to come to terms with their diagnosis will allow them to take in subsequent information and begin to develop a better understanding of their situation. Ensuring the resources provided are relevant, easy to understand and in an accessible format will make it easier, for those who choose, to learn about their disease and the options open to them. Coupled with good communication and encouragement to speak up, this may create an environment where patients and clinicians are on more of an even footing, where patients are informed and feel more able to participate in decisions about their care, ultimately contributing to improved patient experience.

9.2 Limitations

9.2.1 The concept, definition, and measure of HL

The concept of HL is surrounded by its own controversies, and though many of the general principles are similar, there remains a lack of consensus on how exactly it should be defined, conceptualised, or measured. This can make it challenging to identify whether the same concept is being studied, and to compare findings from research based on different understandings of HL and using different measures. The definition chosen to frame this study acknowledges the role of external influences on HL rather than relying on an individuals' skills and knowledge. This seemed a more helpful way of approaching the issue than judging a person's understanding based solely on their own competence, when they may be faced with a complex and unfamiliar system, a new language of confusing terminology, and reams of information which may not have been clearly written with the end user in mind. Considering these additional influences allows us to identify areas within the system which may be amenable to change.

For the second phase of the study, the patient interviews, an assessment of HL was included, but in line with the above understanding of HL, it was important to avoid objectively testing participants or focusing on their individual skills. The Chew HL screening questions were therefore chosen (Chew *et al.*, 2008), which ask patients to consider their own experience and also reflect the availability of resources and support to facilitate understanding. Some limitations of the measure noted during the course of this study have been discussed elsewhere, and include the inconsistent methods of scoring to categorise HL, and concerns about the questions' ability to accurately distinguish between those with and without HL difficulties (see section 4.4). Further, the questions do not address the second part of the chosen HL definition: *'It includes the capacity to communicate, assert and act upon these decisions'* (International Union for Health Promotion and Education, 2018). This is an important point to note, as findings from the interviews identified that some patients were hesitant to speak up and felt they should go along with the healthcare professionals' recommendations, which would not have been captured by the assessment tool. Such hesitance or passivity reflects the power imbalance that exists between clinicians and patients, and has potential to hinder SDM, regardless of an individual's knowledge and understanding (Joseph-Williams, Elwyn and Edwards, 2014). One HL measure which does explore this issue in greater detail is the Health Literacy Questionnaire (Osborne *et al.*, 2013), particularly subscale six 'Ability to actively engage with healthcare providers'. According to the scale, those with a high level of HL will be proactive about health and in control of relationships with healthcare providers, able to seek advice when necessary, and empowered. Though the nine scales of this measure were considered too lengthy to use as a screener for the interviews, it would have been interesting to compare participants' responses to this more comprehensive measure with the descriptions they gave during the interviews.

9.2.2 Scope of exploration of wider socio-political influences

An important point highlighted at the Second (Confirmation) Review, was the need to consider the wider social and political aspects of the work, including associations between HL and other markers of disadvantage, such as deprivation, socio-economic status, education, housing, and ethnicity. These issues are clearly inextricably linked and were touched upon in the healthcare expert panel meeting, where the influence of other barriers to healthcare such as affording and arranging travel to appointments, availability of childcare and impact on work were discussed. Additional factors such as non-English language communication and the influence of different cultures on peoples' approach to healthcare and communication were also raised in the patient and carer panel meeting.

Whilst the relationships between HL, SDM and these wider influences have been discussed throughout this Thesis, data specifically pertaining to these additional demographic variables were not collected as part of the patient interview phase of the study, nor was this specifically addressed during the healthcare professional survey. Recruitment of participants meeting the eligibility criteria proved challenging in itself, and it would not have been possible to stratify sampling to achieve adequate diversity of ethnic groups, income or even age within the scope of this project.

9.3 Influence of COVID-19

This study started in August 2019, and the first phase of participant data collection was being planned in early March 2020, around the time of the start of the COVID-19 pandemic. In some ways this was fortunate timing, as it meant the interviews, survey, and panel meetings could be designed with COVID-19 restrictions in mind, resulting in successful applications for ethical approval without the need for subsequent major amendments to comply with social distancing rules. It did, however, restrict the opportunities available for data collection and influenced the methods used for the different phases. In early discussions regarding recruitment of participants for interview, for example, the use of clinic lists to identify eligible patients, before approaching and possibly screening them in the waiting room was considered. As this was no longer going to be possible, recruitment instead relied on healthcare professionals identifying potential participants and making a subjective judgement of HL based on their knowledge of the patient. The interviews were carried out remotely, either by video, or, more commonly, by telephone, in order to comply with COVID-19 restrictions. Although this did allow greater flexibility and convenience, the option to carry out in person face to face interviews would have been preferred, particularly given the nature of the participants' illnesses and the potential for upset arising from discussing issues relating to this. Alternative methods of data collection involving in-person contact, such as through observation of consultations, were also discounted.

The influence of COVID-19 was also present when planning the healthcare professional survey and panel meetings, and contributed to the decision to proceed with an online survey and virtual rather than in-person meetings. By this time, people were more familiar with the technology and were used to undertaking different personal and professional activities in this way. For the survey in particular, this was a less burdensome means of collecting data, and allowed participants the flexibility to respond at a time to suit them, including outside of normal working hours. The ease with which participants could commit to a virtual rather than in-person panel meeting, with the associated need to travel, is also likely to have contributed to the high attendance. The virtual nature of the meetings did require additional consideration to determine how to best share and explain the supporting information, and generate orderly and constructive discussion, with all voices heard. Again, the communication and interactions between members of the panels may have been different had we all met in person, but the unpredictable nature of the pandemic and changing restrictions meant it was safer to make plans in this way rather than risk having to alter them should the situation change.

Aside from the practical implications of conducting a study during the pandemic, there were also wider implications in terms of both patient and healthcare professionals' behaviours, responses, and the experiences they described. Although the study was not designed to look specifically at the effect of the pandemic and associated restrictions on these experiences, it was important to be aware of and acknowledge their impact in the findings and consider their relevance to future practice. Given the additional pressure associated with working during the pandemic, care was taken when approaching healthcare professionals to be mindful of the extra burden associated with identifying participants for the interviews. Recruitment was likely to have been impacted by the additional workload and changes to in-person contact, which may have limited opportunities for healthcare professionals to discuss the study with patients, and meant all patient contact after initial introduction of the study was carried out remotely. The offer of a video summary of the study and video interviews allowed some participants to put a face to the name, but the lack of face-to-face contact may have affected my ability to build a good rapport with some participants.

Finally, there was understandably a huge degree of uncertainty at the start of the pandemic about its impact on my research and the timeframe for the PhD. It was initially unclear whether I would need to return to work clinically, and for how long. Early in the pandemic, and after discussion with my supervisors, I submitted an application to suspend the PhD, briefly returning to full time clinical work. Fortunately, the caseload locally was low, and I was soon able to resume my studies. I have since been able to secure a short extension to make up for this lost time, before ultimately returning to clinical training.

9.4 Applicability of the Person Based Approach to this PhD study

In the earlier phases of this study, it was anticipated that a single intervention, perhaps in the form of a patient decision aid or user-friendly patient held record, might resolve the issues for SDM in the context of lower HL when cancer can’t be cured. As such, the Person Based Approach (Yardley *et al.*, 2015) was used to guide the gathering of relevant information from a range of different sources, and create a clear profile of the target populations and issues faced to inform guiding principles for said intervention. This approach led to the development of the main phases of work undertaken as part of this PhD study, shown in Table 23 and described in Chapters 3-8.

It became apparent as the study progressed, however, that the issues for SDM were more complex and varied than could be entirely encompassed by a single, simple intervention, and guiding principles for a complex intervention were instead developed. The PBA provided a framework for thinking about the specific user characteristics and barriers likely to affect engagement, the intervention design objectives to improve engagement, and the key intervention features to achieve the objectives, and it therefore remains an appropriate approach to have used.

9.5 Reflexivity

Prior to commencing this PhD, I was working as a medical oncology registrar in training, with eight years of medical experience, of which three and a half years were spent working in oncology. Throughout this time, I had had experience of caring for those with both curable and incurable disease in a wide range of different tumour sites, and I continued to work in a colorectal oncology clinic one afternoon a week during the PhD. I also have personal experience of cancer in my family, and a number of loved ones have died of their disease after varying durations of illness and at different stages in my career, including during this PhD.

The idea for the study was conceived after thinking about some of the more difficult encounters I have had as a clinician and considering how things could have been done differently, and reflects my own personal interest to try and improve the experiences of those diagnosed with incurable cancer. Taking this into account, it would have been impossible to entirely remove myself and my experiences from the study, and they are therefore likely to have had some influence over the conduct and analysis of the different phases. This influence has been positive and beneficial, enabling me to conduct the patient interviews with a greater degree of understanding and empathy, for example, and meaning the healthcare professional survey and panel meetings were developed with an insider perspective of the clinicians' workload and competing priorities in mind. However, although I have been careful to be aware of this influence and try to remain objective, it will not have been possible to entirely remove this experience from my analysis and interpretation of findings.

The learning I have gained during this PhD has already begun to influence my own practice, and I have a much greater appreciation of the different factors at play when consulting with patients with incurable disease in the clinic. I feel privileged to have been able to carry out this work, and to have had the opportunity to spend time talking to and learning from patients in a non-clinical capacity. Many of the experiences described by the patients who kindly participated in the interviews have stuck with me, and I now try to take nothing for granted when sharing information and offering treatments. However, despite the knowledge I have gained during this study, my own attempts at SDM are still not perfect. I consciously try to spell out to patients that there is a decision to be made, we will work as a team to try and find the right option for them, and emphasise that they do not have to accept treatment and will be supported either way. However, I still struggle at times to clearly elicit patients' priorities, fully establish understanding, and do not often have suitable alternatives to standard written information to hand. I continue to reflect on these encounters and seek to understand what could have been done differently.

When considering individuals' HL, I have been uncomfortable with some of the terminology used to label patients. Throughout this study, I have tried to avoid using the term 'inadequate health literacy' in my own work, and have changed the term used, from initially referring more to 'lower' health literacy, and latterly preferring 'difficulty with health literacy', or 'health literacy difficulties'. Whilst these do not sit entirely comfortably either, I feel they better reflect the external or situational influences on HL, and take some of the pressure away from the individual themselves.

9.6 Future work

This study has highlighted some important issues influencing shared decision making in the context of incurable cancer from the perspective of those who face difficulties with HL. There is inevitably overlap with work carried out in other fields and, as one healthcare professional remarked in the survey, it is important not to *"reinvent the wheel but learn from other specialties rather than make it a cancer specific issue" (Participant 21).* Having said this, whilst there are commonalities in the overall approach to SDM, there is scope for the development of cancer specific resources to support conversations about SDM in the incurable setting. There are specific details about anticancer treatments, scheduling, risks, and benefits, which differ in the palliative setting, and which it is important to understand when considering whether or not to receive such treatments. There is also a need to offer a more balanced view of the alternatives to anticancer treatment, and present sufficient relevant information about what this might entail to support equal discussion of the options. Such resources may be adapted from those developed for other patient groups, but, as recommended in the existing SDM guidance, good quality, easily understandable and relevant decision aids and patient information, are needed (General Medical Council, 2020; National Institute for Health and Care Excellence (NICE), 2021), and these should be specific to the particular needs of those with incurable cancer.

Considering publicly accessible tools, several inventories of decision aids exist, yet few include aids relevant to decision making in incurable cancer. There are eight NHS Decision Support Tools, none of which are aimed at cancer decision making (NHS England, 2023). The Ottawa Decision Aid Inventory A-Z includes 41 decision aids for cancer, of which none are for advanced disease (Ottawa Hospital Research Institute, 2019), and the more comprehensive and recently updated Ottawa Decision Aid Library Inventory includes 160 cancer directed decision aids from a total 775, of which five are for advanced disease, but none are publicly available (Ottawa Hospital Research Institute, 2022). Another database, the MED-DECS International database for support in medical choices, does list a few aids for the palliative setting (MED-DECS, No date). These include the American Society of Clinical Oncology decision aid set for chemotherapy decisions in stage IV lung cancer developed in 2009 (American Society of Clinical Oncology (ASCO), 2009), a set of aids in Dutch for second line palliative chemotherapy in breast and colon cancer (Tummers *et al.*, 2012), and an aid to support the decision between supportive care +/- anticancer treatment for metastatic disease from the University of Sydney (Leighl *et al.*, 2002). The first of these, the ASCO decision set, is now long out of date. The Dutch decision aids are not available in English, though they were shown to increase knowledge and were associated with stronger treatment preferences without adversely impacting wellbeing in a randomised controlled trial carried out across 17 hospitals in the Netherlands (Leighl *et al.*, 2011). The third aid, for metastatic colorectal cancer, is a 32 page booklet with accompanying narration, and was shown in a randomised controlled trial to significantly increase understanding of prognosis, options and benefits, though decisional conflict, treatment decisions and anxiety were similar across intervention and control groups (Leighl *et al.*, 2011). However, none of these limited selection of available aids for use in advanced cancer appear to have been specifically developed with HL in mind, and further work is therefore needed to develop relevant resources.

One example of such a resource might be the adaptation of a tabular text based or pictorial conversation aid such as the Option Grid or Picture Option Grid (Durand *et al.*, 2021) comparing palliative intent systemic anticancer treatment with best supportive care. This could include generic information relating to the aims, possible benefits, risks and pathways or trajectories of the options, and allow personalisation in terms of individual prognosis or specific relevant toxicities if desired. However, rather than focusing solely on the specific details relating to anticancer treatment and reinforcing the commonly held view that the decision is between treatment or ‘doing nothing’, this could facilitate further and more detailed communication about the alternative(s) (Kinsey *et al.*, 2017). Presenting the options side by side in this way may also make it easier for patients to compare them, highlight the choice to be made (Kinsey *et al.*, 2017), and encourage a more balanced discussion of the options (Elwyn *et al.*, 2018).

Another example to support patients’ understanding of their disease might be a short paper-based patient held record, giving patients something to refer back to and share with loved ones when they come away from their appointment and are potentially overwhelmed with information. Work is needed to determine whether such a resource could help improve understanding, and if so, whether this might facilitate involvement and allow greater contribution to decision making. A variety of patient information resources already exist, but continued efforts are needed to build on this, paying careful attention to how best to support people to access these. This may mean considering alternatives such as portable video cards or video displays in waiting rooms, and avoiding reliance on internet or app-based resources which risk increasing disadvantage when not all have means of accessing them.

Further resources might also be useful to help elicit patients’ concerns and encourage them to think about the questions they might like the answers to, tools known as question prompt lists. The Patient Concerns Inventory (PCI) is one example of a tool to identify the concerns patients would like to discuss in clinic (Rogers, El-Sheikha and Lowe, 2009). It has primarily been developed for use in the setting of head and neck cancer, although work is ongoing to create Inventories applicable to different tumour sites. The ‘at diagnosis’ tool consists of a list of 56 items or issues the patient would like to discuss, and includes topics such as causes of cancer, treatment related queries including chance of cure, prognosis, future treatment options available, issues relating to follow up, social, emotional, and physical wellbeing. The ‘post treatment’ version lists issues under the same domains, and also gives patients the opportunity to highlight people they may wish to talk to, such as a dietician, a financial advisor, or an emotional support therapist. The tools can be completed electronically or on paper, and have been shown to be generally acceptable and felt by patients to be helpful in an evaluation across one cancer network (Rogers and Lowe, 2014). From a HL perspective, however, almost a fifth of patients encountered problems completing the touch screen in the initial development study, with several giving the reason as not having brought their reading glasses, which may suggest difficulties (Rogers, El-Sheikha and Lowe, 2009). A volunteer was on hand to support patients with this, but the two-page list of tick boxes may nonetheless be overwhelming for some. One recent review of questions prompt lists for the cancer setting found the number of questions included ranged from 11-189 (Miller and Rogers, 2018), and whilst some studies showed positive outcomes, including reduced anxiety and increased questions asked, this was not consistent across all included papers. An earlier review looking in greater detail at the characteristics of the tools found that question prompt lists were generally combined with other intervention components, such as patient/provider communication, or coaching, and included one delivered via video on an educational DVD (Brandes *et al.*, 2015). Additional work is needed to assess the benefit of such tools more comprehensively in the oncology setting, to determine the optimum number and type of questions to ask, and to establish how the delivery of the questions could be further adapted to make them more accessible to those who experience difficulties with HL. Shorter, generic question prompts available and supported for use in the NHS include the four BRAN questions (Choosing Wisely UK, 2020) and ‘Ask 3 questions’, adapted from the MAGIC programme in the UK and based on work by Shepherd *et al.* (2011), which have been shown to improve information given by health professionals and increase patient involvement.

Beyond the accessibility of resources to support understanding and decision making, further work is also needed to better understand the influence of culture on the roles patients and clinicians assume in the setting of incurable cancer, and to explore how these roles might be developed to facilitate more balanced discussions about care.

It is also important to learn what more can be done to prepare people emotionally for the decisions they face, to allow them to feel able to participate in decision making, and manage the uncertainty associated with these difficult decisions and the disease trajectory itself. When the system works well, patients are supported from diagnosis through treatment, often by a clinical nurse specialist. If patients have the contact details for the team and feel able to call, this can provide them with an opportunity to ask questions, seek clarification, and access additional services such as counselling. The important role of the wider healthcare team in providing support to patients, through their presence at consultations, assisting understanding, being on the end of the telephone to answer questions, and helping people navigate the system was clearly highlighted throughout the study. However, this support is not always available or accessible, such as in those early days before the patient is under an established team, when care is transferred between hospitals, when patients present acutely to hospital as a result of their as yet undiagnosed disease, or when the diagnosis is made incidentally during investigations for another condition. In some cases, acute oncology and cancer of unknown primary teams play an important part in filling this gap, providing the emotional support which is particularly necessary at these times of uncertainty. At other times, however, there are gaps in the support available. With increasing pressures in the NHS, the time available to spend with patients and develop these important relationships is under threat, and capacity to keep professionals in these vital positions, to provide this essential contact and support, must be built upon and maintained in order for progress to be made in improving SDM.

Finally, it is important to explore ways of increasing flexibility in the system to better tailor it to individual patients' needs. Some may prefer video or telephone appointments, reducing the need to travel, whilst others will prefer face to face contact and feel more comfortable asking questions in this setting. Offering patients two shorter appointments rather than a single long appointment may give them more time to come to terms with the information they have been given, search for additional information and involve their support person in the decision making process (Herrmann *et al.*, 2021). However, personal preference and concerns such as the logistics of travelling to and from the hospital must be considered, and, where possible, plans tailored to suit the individual.

The intervention described in Chapter 8 has been developed with the NHS clinical context in mind, and has the potential for broad uptake across clinical teams who may wish to implement any number of the individual components. Evaluation of the changes brought about through implementing the intervention may take the form of quality improvement or service evaluation, allowing more rapid integration of changes, or a more formal research approach could be considered. Such an approach might involve close working with a clinical team, identifying the components considered by them to be of particular importance and feasible within their clinical context. It would be helpful to first evaluate the existing service with a range of patient reported measures, including satisfaction with care and SDM, and analysis of the current SDM process e.g., from receipt of appointment letter to the point at which a decision is reached. The intervention, comprising elements of each of ‘prepared patients’, ‘trained teams’ and ‘supportive systems’ could then be implemented by the team, and a repeat analysis undertaken. Brief interviews with patients and carers, as well as focus groups with healthcare professionals, could be used to seek feedback from those involved in the SDM process, allowing an assessment of any improvements brought by the intervention, and highlighting to the team those components considered particularly useful, or not. Intervention components could then be more fully embedded or discarded as appropriate, or other components added if gaps were identified. In this way, the intervention can be tailored to meet the clinical need, whilst also gathering evidence to justify changes made.

Many of the recommendations made in this Thesis and the proposed intervention components may already be known and accepted by those who support SDM, yet there may be concerns over the cost implications of such measures in an already underfunded and overstretched system. The guidance is clear that SDM should be embedded across the board (National Institute for Health and Care Excellence (NICE), 2021), however, it can be challenging to find the financial resources to make such changes. Whilst an increase in funding would facilitate the provision of additional resources, support and flexibility, further longitudinal work may be useful to establish the practical and economic implications of delivering SDM at a departmental or Trust level, adding weight to the argument and providing further justification for allocating scarce funds to the cause.

9.7 Conclusion

This study has advanced our understanding of the challenges for SDM when cancer can’t be cured, from the perspective of those who face difficulties with HL. It has identified a number of social, cultural, systemic, and personal factors which influence the decision making process and must be overcome to increase SDM in this setting. To achieve this, it will be necessary to increase the quality and availability of resources to support SDM; ensure patients are well supported and given enough time, with their emotional needs are addressed; ensure clinicians are provided with adequate training to facilitate such conversations; and continue to work towards shifting patient and clinician views from the current paternalistic model of healthcare delivery to a more person-centred approach to decision making.

Future work to support SDM in palliative oncology must take account of the particular challenges faced by those who experience difficulties with HL, and ensure this disadvantaged group, who already experience poorer outcomes and care, do not get left even further behind.

Appendix A Materials and supporting information for patient interviews

A.1 Email containing feedback from REC committee

RE: IRAS 286618. HRA & HCRW Approval issued

Mon 28/09/2020 09:49

Dear Dr Holden,

Further to the email below the committee wished to make a few comments about this application. These do not form part of the formal opinion but I wanted to pass them on to you.

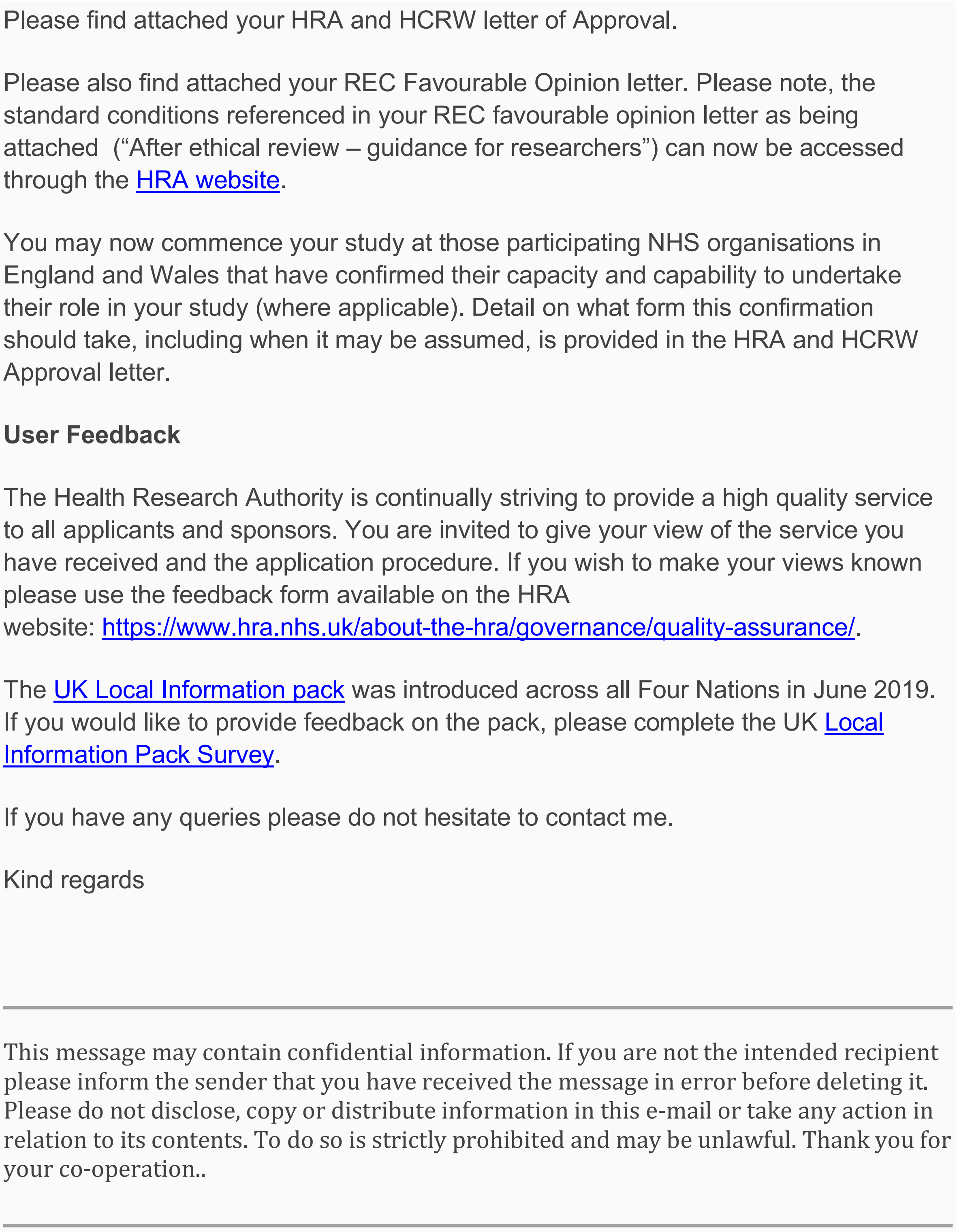
1. The committee wished to compliment the researchers noting that they had taken considerable trouble in designing the study taking careful account of the views of patients and making the research "Covid friendly".
2. The committee highlighted that they liked the summary document that will be sent to participants.
3. The committee wished to remind the researchers that some patients may wish to talk at length and therefore these interviews may last longer than one hour. Noting that it was unclear who would undertake the interviews (40 proposed) the committee highlighted that this would be a considerable undertaking for the researcher to do alone.

Many kind regards

From: riverside.rec@hra.nhs.uk <riverside.rec@hra.nhs.uk>
Sent: 28 September 2020 09:33
To:
Cc:
Subject: IRAS 286618. HRA & HCRW Approval issued

Dear Dr Holden

RE: IRAS 286618 Cancer information your way: get what you need to make your decisions. HRA & HCRW Approval issued



Please find attached your HRA and HCRW letter of Approval.

Please also find attached your REC Favourable Opinion letter. Please note, the standard conditions referenced in your REC favourable opinion letter as being attached (“After ethical review – guidance for researchers”) can now be accessed through the HRA website.

You may now commence your study at those participating NHS organisations in England and Wales that have confirmed their capacity and capability to undertake their role in your study (where applicable). Detail on what form this confirmation should take, including when it may be assumed, is provided in the HRA and HCRW Approval letter.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: https://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

The UK Local Information pack was introduced across all Four Nations in June 2019. If you would like to provide feedback on the pack, please complete the UK Local Information Pack Survey.

If you have any queries please do not hesitate to contact me.

Kind regards

A.2 Participant information sheet (long version)

Study Title: Cancer information your way: get what you need to make your decisions

Researcher: Chloe Holden

ERGO number: 60486

You are being invited to take part in the above research study.

To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve.

Please read the information below carefully. Ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part.

If you are happy to take part you will be asked to give verbal consent.

What is the research about?

I am a cancer doctor and am carrying out this research as part of my PhD at the University of Southampton. My research is looking at how to support patients with cancer that cannot be cured to make decisions about their care. This study is part of my research.

Patients diagnosed with cancer that cannot be cured are given lots of information about their diagnosis and treatment. This can be a very daunting time. Patients may have to find their way around the different areas of the hospital. They often have to try to remember all of the instructions and information given to them by their healthcare team. They might be faced with some difficult decisions.

We are doing this study because we want to understand more about what this is like for patients, and find out how we can make things easier.

The research is being funded by the Robert White Legacy Fund and the University of Southampton is the research sponsor. This means that they will take responsibility for starting, managing and making sure that there is funding for the study.

Why have I been asked to take part?

We want to hear from people who have had problems getting the information they need or making decisions about their care. We asked cancer teams to think about whether any of their patients could help us.

Your cancer team have suggested you might be able to help us with this study. They think that your experiences might help us to learn more.

What will happen to me if I take part?

- We will ask you to take part in 1 interview.
- The interview will take about 1 hour.
- We want to do this with a video call if we can, or by telephone.
- You can be in your own home, or wherever you feel comfortable, so you won't need to travel anywhere.
- We will use some set questions but want to hear about your experiences in your own words. It is your personal experience

that is important to us and will help us to learn how to make things better.

- We will record the interview so that we can listen back to what you have said. Afterwards, we will listen to the recording and write down your words. We will then read it very carefully to better understand things from your point of view.
- After the interview, you won't need to do anything else. If you would like to hear about the results of the study, we can send you a summary of the results once the study has finished.

Are there any benefits in my taking part?

You will not benefit directly from taking part in this study.

We hope to help other patients in the future by learning from your experiences.

Are there any risks involved?

- Some people might feel uncomfortable talking about their experiences during the interview. We will not ask you to talk about any topics which you do not want to talk about.
- This study is about finding out how to make the system better and making things easier for all patients. It is about learning how cancer teams can improve the quality of the care they provide.
- If you feel uncomfortable during the interview, you can ask the interviewer to stop at any time. There is no pressure to carry on if you do not want to.
- If you appear upset by what has been discussed, the interviewer may ask if they can tell your doctor or nurse so that they can help to support you.

- Some members of the research team work at the hospital, but are not part the main team looking after you.
- Your care and treatment will not be affected by you taking part in the study.

What data will be collected?

- We will need to collect some personal data so that we can contact you about the study. We will ask for:
    - Your name
    - Your telephone number
    - Your address
    - Your email address (if you have one)
- During the interview, we will ask you for some 'special category' data too. This means that we will ask:
    - Your age
    - Your occupation
    - Some information about your diagnosis and treatment (but don't worry if you don't know the details).
- We will record what you tell us during the interview in response to our questions.
- We would also like to look at your medical records to collect some data about your cancer diagnosis and treatment.

Will my participation be confidential?

Your participation and the information we collect about you during the research will be kept strictly confidential.

Who will be able to access my data?

- Members of the research team and responsible members of the University of Southampton may be given access to data about you. This would be:
  - For monitoring purposes
    and/or
  - To carry out an audit of the study to make sure that the research is being done according to the regulations.
- Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may need access to your data.
- The research team (myself and my three supervisors) will have access to the data for the purpose of doing this research.

All these people have a duty to keep your information, as someone taking part in research, strictly confidential.

How will my data be kept safe?

We will keep your data safe using password protected computer files on the University of Southampton's secure system.

We will keep your name and contact details separate from the answers you give in the interview and the data from your medical records. We will use a number to identify you instead to keep your information private.

Once we have written down what you said from the interview recording, we will delete the recording. The written copy will be kept securely in a password protected electronic file.

We will keep your contact details until the end of the study. If you would like to hear about the results of the study we will let you know. After that, your contact details will be securely destroyed.

If, during the interview, we become aware of any serious risk of harm to yourself or others, then we may need to break confidentiality to talk to the research team for advice. This is very unlikely to happen, and if needed then we will talk to you first.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to give verbal consent to show you have agreed to take part.

If you have said that it is OK for your nurse or doctor to give us your contact details, we will telephone you to see if you would like to take part in the study.

What happens if I change my mind?

You have the right to change your mind and withdraw (leave the study) at any time. You do not have to give a reason and your participant rights or routine care will not be affected.

You can ask the interviewer to stop the interview at any time.

If you withdraw from the study, we will only keep the information about you that we have already collected for the purposes of achieving the objectives of the study. This means that we will keep your answers to the interview questions but will remove your name and contact details.

What will happen to the results of the research?

- Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent. This means that we might use some of your words (quotes) in our reports, but people will not know that they were from you.
- The findings from the research will be written up as part of my studies with the University.
- We hope to send the results to an academic journal, so that we can share what we have learnt with other people who look after patients with cancer.
- We will send you a summary of the findings if you are interested.

Where can I get more information?

If you would like to know more, please contact the research team:

Name:	Dr Chloe Holden
Professional title:	PhD Student (Health Sciences)
Email:	c.e.holden@soton.ac.uk.
Address:	School of Health Sciences Building 67 University of Southampton University Road Highfield

SO17 1BJ

Telephone: 0300 019 8263

What happens if there is a problem?

If you have a concern about any part of this study, you should speak to the researchers who will do their best to answer your questions.

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

The University of Southampton is the research sponsor. They will take responsibility for starting, managing and making sure that there is funding for the study.

If you would like to make a formal complaint about the study to the hospital, you can contact the Patient Experience Centre at Poole Hospital (Tel: 0300 019 8499, Mobile: 07758 272495, Email: patientexperienceteam@uhd.nhs.uk)

Thank you for taking the time to read this information sheet and for thinking about taking part in the study.

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity.

As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project.

Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

Poole Hospital will keep identifiable information about you from this study for 10 years.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

A.3 Participant information sheet (summary version)

UNIVERSITY OF Southampton

NHS
University Hospitals Dorset
NHS Foundation Trust
Poole Hospital

Participant Information Summary

Cancer information your way: get what you need to make your decisions

What is the research about?

- Making information about cancer and its treatments easier for everyone to understand
- Helping people to get more involved in their care

Why have I been invited to take part?

- Your cancer team have put you forward as they think that you might be able to help us
- You might have experience of:
  - Being given information that was not easy to understand
  - Wanting to be more involved in decisions but not knowing how or not feeling able to
- You do not have to take part, it is your choice

What will happen to me if I take part?

- We will ask you to do 1 interview lasting about 1 hour
- We will do the interview by video or phone call, when and wherever you feel comfortable
- We will ask you questions about:
  - How you were given information
  - How decisions about treatment were made
  - Any difficulties that you may have faced
- We will need to record the interview
- We will ask to look at your medical records for details about your diagnosis and treatment

What are the benefits of taking part?

- We will learn from your experiences so that we can make things easier for all patients

What might be the downsides/risks of taking part?

- You might feel uncomfortable talking about your experiences. If so, we can stop, there's no pressure

How can I find out more?

Talk to your medical team or the research team (Chloe): c.e.holden@soton.ac.uk 01202 448263. Supervisors: Dr Richard Wagland, Dr Sally Wheelwright, Dr Amélie Harle

07/08/2020 version 2

ERGO 60486/IRAS 286618

A.4 Example video card summary

Front cover:

NHS University Hospitals Dorset NHS Foundation Trust

NHS University Hospitals Dorset NHS Foundation Trust Poole Hospital

UNIVERSITY OF Southampton

Cancer information your way: get what you need to make your decisions

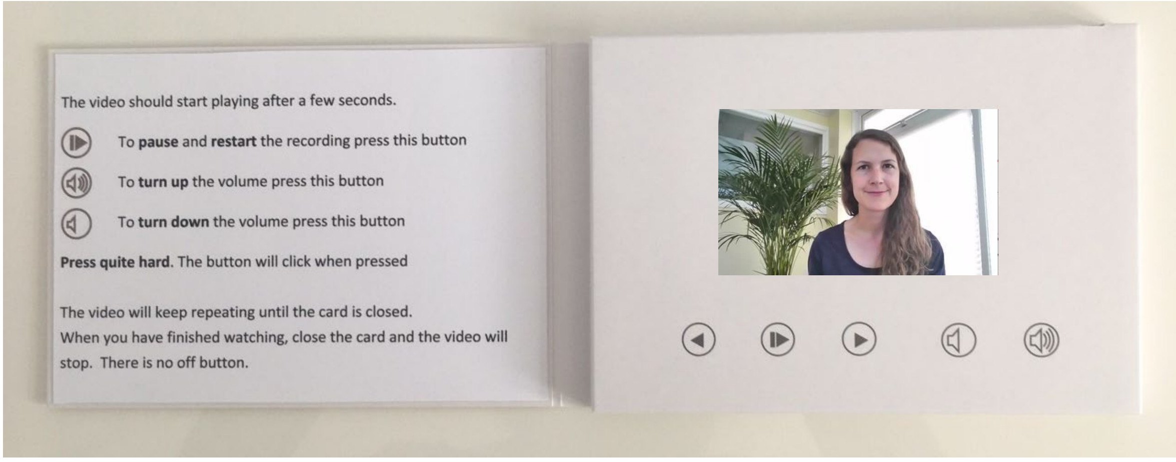
Video participant information summary

To find out more, speak to your medical team, or contact Chloe:
c.e.holden@soton.ac.uk 0300 019 8263

Open here →

26/08/20 Video summary v1.1 IRAS number 286618
Supervisors: Dr Richard Wagland, Dr Sally Wheelwright, Dr Amélie Harle

Inside of card with instructions and still image from summary video



The video should start playing after a few seconds.

⏯ To **pause** and **restart** the recording press this button

🔊 To **turn up** the volume press this button

🔈 To **turn down** the volume press this button

Press quite hard. The button will click when pressed

The video will keep repeating until the card is closed.
When you have finished watching, close the card and the video will stop. There is no off button.

A.5 Verbal consent procedure

Verbal consent procedure

Study title:	Cancer information your way: get what you need to make your decisions
Researcher name:	Chloe Holden
ERGO number:	60486

To be read out to participant:

Thank you for agreeing to take part in the study. We now need to make a formal recording to say that you have agreed to take part. Is that OK with you?

I will tell you when I am starting and stopping the recording.

I will start the recording now.

<start recording>

Please can you start my telling me your name?

Thank you. For our records, your participant number is:

I hope that you have had a chance to look at or listen to the information about the study. In a minute, I would like to check that I have explained things clearly to you by asking you to tell me a bit about the study. Before I do, would you like me to explain anything more about the study to you?

Is there anything you would like to ask me about the study?

So that I can check that I have explained things clearly, please could you tell me a bit about the study and what I am asking you to do?

(Further explanation if required)

This study is part of my research to learn how we can help patients to be involved in their care. We want to find out how to make the information we give people easier to understand. We want to learn how people make decisions about their care. We hope that we will find a way to make things easier for all patients.

We want to hear from people who may have had problems getting the information they need or making decisions about their care. Your cancer team have put you forward for this study because they think that your experiences might help us to learn more.

I would like to have a conversation with you to hear about your experiences. If you take part, I will ask you questions about your cancer and treatment, and the information you have been given about it. I will ask about how you have been involved in decisions about your care. I also want to know if you have any ideas about how to make things better. This should take about 1 hour, and we will do the interview over the phone or by video call.

(Clarification about risks/benefits if needed)

You might not get anything out of taking part. We hope that the research will help other patients in the future.

You might feel uncomfortable talking about your experiences. We do not have to talk about anything that you do not want to talk about. If want to stop at any time then we will. If you appear distressed then I might ask for your permission to tell your cancer team, so that they can give you additional support.

I will need to record the interview so that I can write down what you say and look back at what you have told me. Once I have written it down and checked it, I will delete the recording. I will keep the written copy securely on the University’s computer system.

Is that OK with you?

We will keep your answers from the interview confidential. Only myself and my supervisors will be able to see them unless officially needed by the University or the law. The University will keep the written copy of your answers safely for 10 years, then destroy it.

I will write up the results of the study for my university assessment. We also want to share the results with other people who look after patients with cancer. This is so that other teams can learn from it and improve the way that they give information. We might do this by writing about the study in a scientific journal. We might quote you, which means using your words, but will not use your name, so people will not know that it was you.

Is that OK with you?

During the interview, I would like to ask some questions about your diagnosis and treatment, but don’t worry if you don’t know the details. After the interview, I would like to check your medical records to get some details about your cancer, treatments you have had and any other illnesses.

Would that be OK with you?

We can stop the interview at any time if you would like, and you do not have to talk about anything that you don’t want to.

It is completely up to you whether you take part in the study. If you agree to take part, you may leave the study at any time without giving a reason. This will not affect your care or treatment. If we have started or finished the interview, then the answers you have already given may still be used. They will only be used for this research project.

Do you understand that you do not have to take part in this study and you may leave it at any time?

Do you understand that if you leave the study then the information you have already given me may still be used to answer the study questions?

We have talked about lots of things. Is there anything else you would like to ask me about the study?

Finally, do you give permission for me to interview you?

Thank you very much

Please stay on the line. I will now stop this recording and we will start a new recording for the interview.

<stop recording>

A.6 Topic guide

Thank you for agreeing to take part in this interview today. Please answer questions freely and let me know if you want to stop at any point. I will be recording the interview.

I will start the recording now

<start recording>

We know that people diagnosed with cancer are often given lots of complicated information and are sometimes faced with some very difficult decisions. We want to find out about how people are given information about their diagnosis and treatment, and whether it is easy to understand. We want to know if there are things that are particularly difficult to understand, so that we can look at how to make them clearer. We also want to find out how we can help patients to speak up and be more involved in decisions about their care, if they want to.

Our goal is to make sure that we give people the information they need, in a way that they can understand, so that they can be involved in decisions about their health.

(Background)

Before we start talking a bit more about that, I'd like to find out a bit about your background if that's OK?

Would you mind telling me a bit about yourself, like how old you are, whether you are currently working and what sort of work you do?

And if you feel able to, please could you tell me a little bit about your cancer and what treatments you have had? Don't worry at all if you don't know all the details.

How much of the day are you able to be up and about? What sort of things are you able/not able to do? (Assessment of ECOG performance status)

(Questions relating more to functional health literacy - refers to the ability to understand health information to improve knowledge and be able to navigate the health system)

1. I'd like you to try and think back to a time when you started a new treatment for your cancer. This may have been surgery, chemotherapy, radiotherapy or something else. Can you tell me a bit about that experience?
    a. How were you given information about this treatment?
    b. Was the information given to you in a way that you could understand?

   c. Did you feel that you completely understood the benefits and risks or side effects of the treatment so that you could make up your own mind about it?
   d. What were you told about any alternatives to this treatment?
   e. Did you try to find out any more about the treatment or alternatives other than what your doctor or nurse told or gave you?
      i. How did you try to do this?
   f. Did you have to sign a consent form for treatment?
      i. How did you feel about doing this?
   g. How did you feel about this whole process of deciding whether to have this treatment?
2. We know that there can be a lot to get your head around when diagnosed with cancer. Especially when people use medical words, it can feel like there is a whole new language to learn.

Lots of people tell us that they sometimes need help understanding this new medical information or filling out forms. We think that more could be done to help make it easier for people understand.

   a. What are the types of information or forms that you have found or think might be the most difficult to understand?
   b. Has it ever been difficult to know where to go for your appointments, how to get there or what they are for?
      i. Can you tell me a bit about what happened?
   c. How do you deal with things like this when they are difficult?
   d. When things like this aren’t easy to understand, how does that make you feel?

(Questions relating more to critical health literacy - refers to the critical appraisal of information and ability to engage in shared decision making)

3. Have you ever found it difficult to make a decision about your care or treatment because you didn’t feel you had enough information or things hadn’t been explained clearly?
   a. Could you tell me more about this?
   b. Do you feel that you understand enough about your cancer and how it affects your health to be able to make these decisions?
   c. How much have you felt able to ask questions about your care or treatment?
      i. Please could you tell me more about this?
   d. How confident have you felt telling your doctor or nurse what is important to you when thinking about treatment decisions?
   e. Do you feel that you have been involved in decisions about your care?

        - i. Can you tell me how?
    - f. Have you been as involved in decisions about your care or treatment as you would like?
        - i. If not, then can you tell me why you think this is?

(Questions relating more to interactive health literacy - refers to an individual's ability to act independently on this information, with increased self-confidence and successful interaction with healthcare services)

4. We sometimes have to make decisions about what to do between hospital appointments if we feel unwell or aren't sure about something. How do you go about this?
    - a. Do you feel able to contact your medical team if you have any worries or questions?
    - b. How would you do this?

(Chew questions)

5. I'd now like to ask you three short questions about how easy or hard you find it to be involved in your care
    - a. How often do you have someone (like a family member, friend, hospital/clinic worker or caregiver) help you read hospital materials?

        None of the time, a little of the time, some of the time, most of the time, all of the time
    - b. How often do you have problems learning about your medical condition because of difficulty understanding written information?"

        None of the time, a little of the time, some of the time, most of the time, all of the time
    - c. How confident are you filling out forms by yourself?

        Not at all, a little bit, somewhat, quite a bit, extremely
6. If you did find it difficult to do things like filling in forms and reading medical information, would you want your doctor or nurse to know?
    - a. Why/why not?

(Questions about how to help support)

7. What more do you think could be done to help make it easier for people to receive information about their cancer and treatments?
    - a. Do you have any ideas about how things could be done differently?
    - b. Would it have helped if you had been given information in a different way or the forms were made easier to understand?
        - i. What could have been different?

c. Some people find that they can understand and remember things better if they see them in pictures or a video, or can listen back to what was said.
    i. Have you ever been given information in this way?
    ii. Do you think this would help? Why?
    iii. Would you like to be given information in this way?

Thank you very much for answering my questions.

Is there anything that you would like to ask me, or would you like to make any other comments about the things we have discussed today?

Thank you very much again for your time. I will now stop the recording.

<stop recording>

A.7 Draft analysis summary table

The table below shows a draft summary of the categories identified through the framework analysis process. This was used to inform the write up of the analysis, undergoing further refinement during the process of writing up.

Experiences and decision making	
Comprehensive care – healthcare teams generally supportive and perceived to be contactable, reassuring to know that there's a pathway and a team guiding decision making. Many felt grateful or lucky.	1E. Overall care and support Overall impression that HCPs generally supportive 1H. Feeling lucky or grateful Some described feeling lucky/grateful - that they hadn't experienced adverse effects from treatment, that they had had good care, and that they were given the opportunity for treatment, affording them more time 2A. Contacting team Those who have called reported generally positive experiences 2B. Explanations and information given Generally clear explanations for treatment choice, rationale for/against options Differences in preference for HCP attitude – blunt/straight suits some not others Limited use of jargon, explanations clear
System under pressure – impersonal at times and appointments rushed, pathways not always smooth, communication sometimes far from ideal, but awareness of the pressure in the system, particularly during COVID, and some forgiveness for this	1B. Influence of COVID-19 NHS under pressure (COVID) Missing out as a result - less face to face contact, less external support available, less opportunity for family to be present (generally - though one felt quicker diagnosis, another spent less on taxi fares) Additional burden - risk of COVID, vaccine side effects 1C. Navigating hospital, system, processes Some with no difficulties experienced challenges 001, 002, 003, 011
In the expert's hands – doctor as expert, employed to do a job, trust them to get it right, wouldn't offer treatment if not worthwhile, purpose of consent to cover people, patients abdicate responsibility – get out clause by not reading information. No real decision to be made, no viable alternatives, therefore go with their 'recommendation'. True of those with HLD and not, those who seek additional information and not.	1C. Navigating hospital, system, processes Consent par for the course, seen as necessity if want treatment - to cover others (012) 3A. Deliberation Often not a lot to think about, decision made there and then Assumption wouldn't be offered if no good Benefits (survival) prioritised 3B. Discussion of options

	No real choice to be made – no treatment not seen as valid option and not discussed in great detail Some based decision on prognosis with/without treatment 3F. Influences – personal including trust in HCPs Trust in the experts to get it right, it's their job, their responsibility Treatment wouldn't be offered if not worthwhile Mention of patient as expert but didn't seem to influence involvement (027) Personalities – determined, fighter vs. do as told – all accept treatment Age another key influence mentioned Few considered declining vs. out of question to say no – would sell self to devil, silly to say no, not gonna roll over and die 3G. Involvement in decision making General feeling that decision already made by healthcare professionals – it's their job, patient's role to agree to this. Declining seemed silly, alternative of death Most happy with this level of involvement Consent a necessity – one described 'get out clause' of not having read the information (021) 3H. Other Role of money – NHS wouldn't offer if not worthwhile 6C. Expectations Expectations of HCPs' role - to go over head if decision unwise, determine peoples' information needs
Treatment not so bad… - Treatment generally considered not to be as bad as expected, though participants often downplayed toxicities they had experienced.	1P. Treatment Most reported side effects, but considered small price to pay Not that bad despite quite significant toxicity Some reported tangible benefit from treatment 6C. Expectations Expectations different to reality - that chemo would be worse than is, or prognosis worse (037)
Particular challenges	
Psychological burden – shock at diagnosis, accepting diagnosis when feeling well, feelings of being let down/diagnosis missed, changing plans. Life aside from cancer – relationships, work. Uncertainty about the future – prognosis, how will feel, how will deteriorate, what next	1D. Other One participant felt a fraud when presenting to GP with symptoms Another described a fear of the unknown, that the experience was different in real life to what you read about, and that DNACPR decisions judge ones' worth One reported knowing the need to plan for the future, but feeling that is in a holding position as disease currently stable 1E. Overall care and support Some communication cold and lacking - memorable, particularly early on Emotional support not always available early on Relationships fragile - team annoyed by declining treatment/admission, raising concerns, asking for notes (highlighted elsewhere)

	1K. Shock Many described feeling shocked - primarily that diagnosis out of the blue (? relation to symptoms), but also at prognosis or toxicity 1L. Uncertainty Most participants reported a degree of uncertainty - commonly about the future - prognosis, how will feel, what next, but also about their current disease state or treatment 1M. Receiving diagnosis In some cases, descriptions of more negative experience seem to go along with fewer expressions of acceptance Early support important 3D. Influences - HCPs Notable examples - change in treatment plan creating doubt (005), pressure to agree/annoyed if not (042) 3L. Understanding situation and disease Uncertainty regarding prognosis and what the future holds – 037 – must think it's worth starting some treatment, will live long enough for that 4A. Accepting diagnosis Difficult to accept unwell/dying when feeling well (001) Difficult to accept diagnosis when healthy before Mind shuts down, can't take it in, why me? 4B. Curveballs or changes to plan Conflicting information and false reassurance Unexpected diagnosis/recurrence Changes to treatment plans 4C. Emotions affecting ability to process Difficult to take in and process information at beginning, getting head round diagnosis In a better place to take more in later Harder to take in when unwell, other things going on in life, or when plans changed 4G. Lack of familiarity Procedure and diagnosis all the more difficult as new and unfamiliar 4H. Let down Poor communication - style, insensitive, insufficient at times Perceived delayed diagnoses when treated for benign causes initially Inadequate support offered significant in some cases 6D. Other Home situation an additional challenge Hiding cancer diagnosis to spare others' feelings New need to be contactable

Getting the right information at the right time/meeting individuals' information needs/information unhelpful provided at odds with needs/overload/too much to take in – early stages of trying to process shock of diagnosis, lots of complex information and detail to take in about treatment, side effects, schedule. Going to agree regardless because silly not to. Information provided to facilitate consent, not necessarily the information wanted or needed by the patient – like support services, what comes next, what does the future look like, nor the information to help make a fully informed decision about valid alternatives or trajectory of disease. Some reported seeking additional information – generally using the internet, by those who have not faced difficulties with HL. Not always reliable, can stumble across information you do not want to see	1N. Seeking information Of those who did not seek additional info, all but one reported difficulty with HL (003 did not but questionable screening) Participants who sought more information tended to use the internet, but there was an awareness both from those who used it and those who didn't that the information was not always reliable, compared to the trusted information from the NHS 2A. Contacting team Not always clear who to call – overlap between hotline and CNS 2B. Explanations and information given Rationale for different investigations not always clear Verbal information on side effects limited at times, supported with written Specific answers not always satisfactorily given – what does future look like, what is rationale for follow up interval, why the wait for scan results etc 3C. Efforts by patients to understand options Those with HLD less commonly sought additional information and relied on information from HCPs – one (005) likely does not have HLD Some happy with just the basics, trust HCPs Some have accessed records – not always easy to understand, sometimes have to look up words 013 – HLD, relies on wife finding out additional information, prompting request for records 3I. Provision of information Reliance and trust placed in verbal information given, but a lot to take in and patients often selective. Written information sometimes useful to back this up, but not always read or perceived to be relevant. Generally easy to understand. 3K. Understanding of treatment offered Generally good understanding of aims of treatment Difficult to relate side effects – visualise at time of consenting Understanding of how treatments work and effect on body more lacking Some development of knowledge over time 3L. Understanding situation and disease Understanding not formally questioned General understanding that disease incurable (aside from 003, 013, 035 and adjuvant 034) Understanding of spread disease, and for some, relevance of disease location, but not always clear where. 003 very poor understanding 4D. Information – amount Information overload at the beginning, too much to process Later, more ready to take it in, harder to get hold of Sometimes so much that not read or confusing (contact numbers)

	Specific information needs not always met 4E. Information – difficult to understand Jargon and terminology can be confusing – registrar, stable Sometimes have to work hard to understand – don't always bother 4F. Information – type Good to have verbal information and potential for explanation, but would help to be able to refer back to what was said - to further understanding and to seek clarification Would help some to be able to keep track of disease with scan reports
Imbalance of power - hesitance to bother HCPs reinforced by negative experiences – diagnosis, doctors' annoyance at refusing treatment. Time with doctors is limited and precious – pressure to remember to ask everything, no contact between appointments, a lifeline	2A. Contacting team Hesitation to call so as not to be a burden, side effects were to be expected, unsure if related to treatment, no longer on treatment Those with HLD appeared generally more hesitant 2C. Speaking up and asking questions Hesitation by some to speak up - more so in those with HLD Unanswered questions - prognosis, the future Some rely on planned contacts 3G. Involvement in decision making One participant initially declined and felt judged for doing so (042) 4I. Other Suboptimal consultations – time, pressure, missed opportunities. Time with HCPs very valuable, contact a lifeline. Pressure to remember to ask everything, particularly when contact infrequent, but easy to forget. Can contribute to feeling alone/unsupported Declining treatment gave impression doctor annoyed - damaged communication 6A. Cultural values Not wanting to waste/take up HCPs' time Perception of being annoying, a menace, a pain, silly for asking questions
Recommendations	
Addressing emotional needs – giving time and space to process, ensuring easy access to support services, exploring and supporting life outside the hospital	5C. More time More time for appointments and to make decisions would help
Enabling control over information – too much initially, not able to process. Verbal information better as easier to take in than reading, but good to have something to refer back to, and this is often missing. Helpful to be able to monitor progress e.g., with scan reports or access to records to aid understanding. Might want to find out more in own time. NHS information trusted as base information.	5A. Changes to written information Plain English More personalised information would be useful to reduce confusion/information overload 6B. Control over information Preference for some not to know prognosis, and did not want/need treatment detail - implications for informed consent

	Difficult to take everything in at the beginning, more able to process over time, but not always easy to access at later date Having access to records/summaries to refer back to would help some feel more in control
Developing a partnership - breaking down the expert-layman barrier to create a more equal footing, greater emphasis on the patient as the expert in themselves (with support from friends, family etc), greater transparency of options and discussion of priorities	5B. Including family Involving family helps them to accept Friend acted as advocate, support group to share burden Important to have chance to discuss decisions with family
Involving others – in enhancing understanding, helping to seek additional information, supporting deliberation, but also influencing decisions. Advocates speaking up for patients, asking questions. Support groups/learning from others' experiences – useful for some but not all	1C. Navigating hospital, system, processes Support from friends/family 1N. Seeking information Mixed views of whether useful to learn from others' experiences or not - some would find it unhelpful/uncomfortable 3E. Influences - others Some influenced by thoughts of family/friends Charity/support groups helpful for some, not wanted by others Small amount of support from neighbours/colleagues 3J. Role of family, friends etc Friends and family play variety of roles – most had some sort of additional support but varied as to how much
Strategies	5D. Strategies Communication – easier language, hearing others' stories, detailed discussions Resources – alternatives to written information (video cards), lists of questions, medication schedule, option to see scans, progress report, list of support services, hospital helpline, copies of records/consultation record Organisational – more personalised correspondence, email rather than post, default issue of blood forms, multiple shorter appointments Other – looking up unfamiliar words, option to complete forms verbally, support to manage schedule, scheduled contact to raise issues

The subtheme 6E (below) was incorporated into an overall description of the participants' experiences.

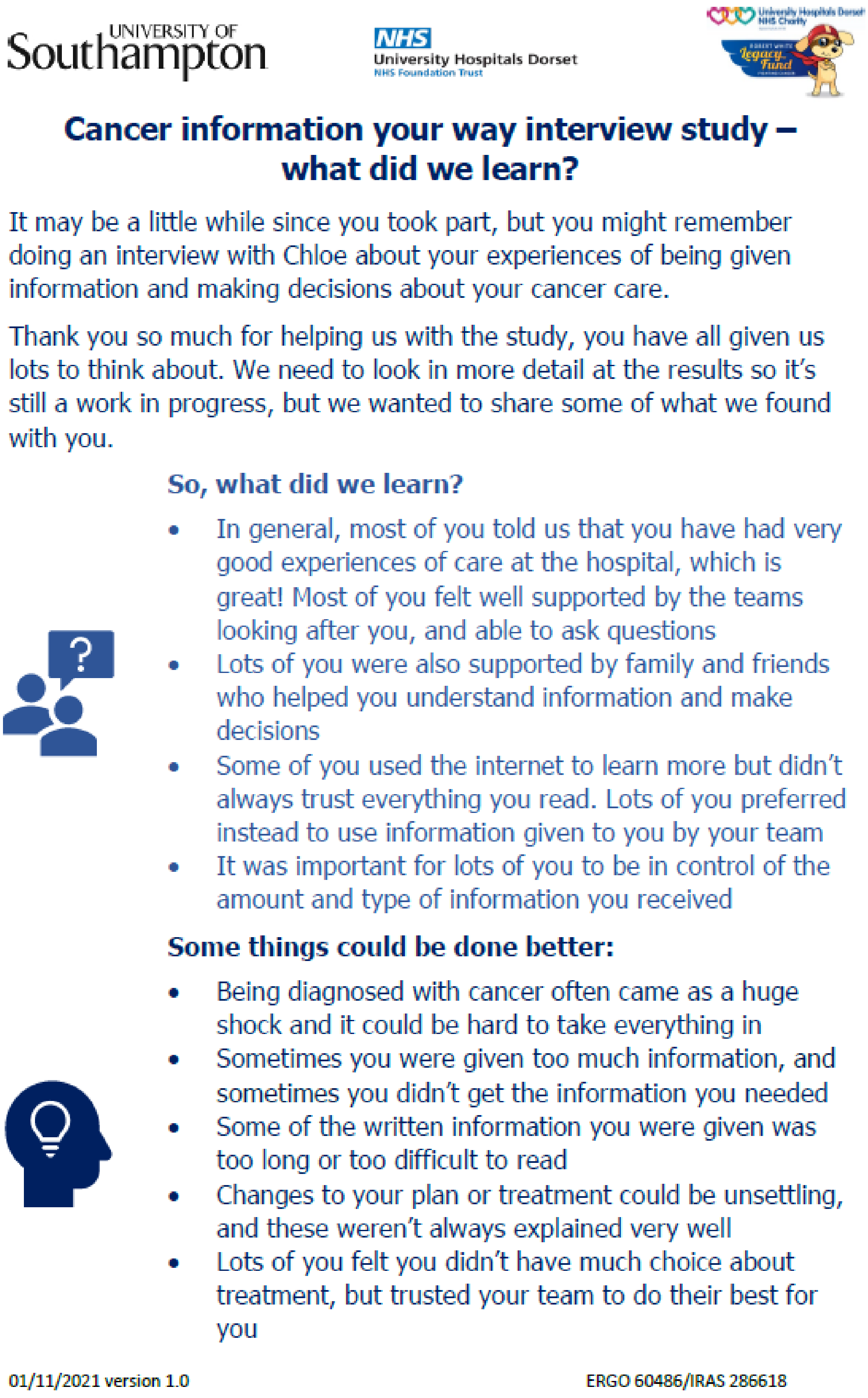
6E. Prior experience

Many participants had prior experience of care/hospital setting before diagnosis - through work, management of comorbidities

Family history led to both positive and negative responses, better understanding

Greater familiarity with the hospital/processes over time

A.8 Summary of results shared with surviving participants



Cancer information your way interview study – what did we learn?

It may be a little while since you took part, but you might remember doing an interview with Chloe about your experiences of being given information and making decisions about your cancer care.

Thank you so much for helping us with the study, you have all given us lots to think about. We need to look in more detail at the results so it's still a work in progress, but we wanted to share some of what we found with you.

So, what did we learn?

- In general, most of you told us that you have had very good experiences of care at the hospital, which is great! Most of you felt well supported by the teams looking after you, and able to ask questions
- Lots of you were also supported by family and friends who helped you understand information and make decisions
- Some of you used the internet to learn more but didn't always trust everything you read. Lots of you preferred instead to use information given to you by your team
- It was important for lots of you to be in control of the amount and type of information you received

Some things could be done better:

- Being diagnosed with cancer often came as a huge shock and it could be hard to take everything in
- Sometimes you were given too much information, and sometimes you didn't get the information you needed
- Some of the written information you were given was too long or too difficult to read
- Changes to your plan or treatment could be unsettling, and these weren't always explained very well
- Lots of you felt you didn't have much choice about treatment, but trusted your team to do their best for you

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What next?

- We will keep analysing the results to make sure we have learnt as much as we can from what you have told us
- We will then feed these combined results back to your cancer teams so they can learn from it too
- We will also write up what we have found and send it to a scientific journal, so that cancer teams around the world can also learn from your experiences
- Finally, we will work with patients and cancer teams to find a better way to:
  1. Help people get all the information they need and want, and
  2. Help people get involved in decisions about their care

We hope it has been interesting to see some of these results.

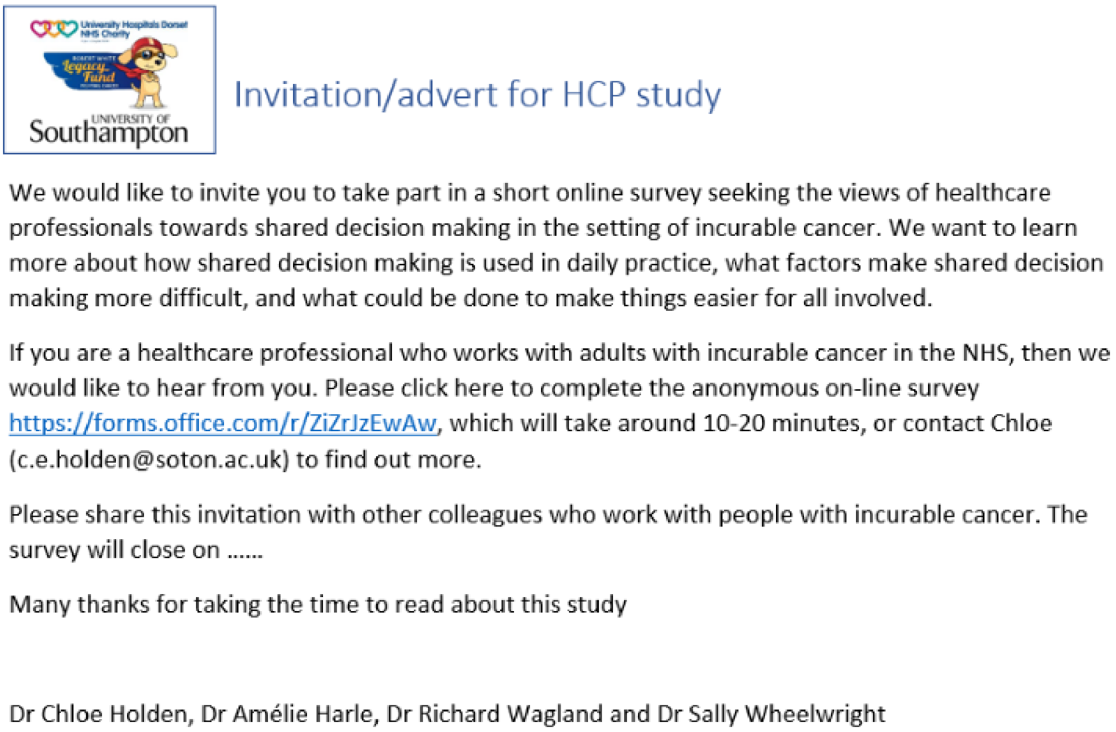
We want all patients to have the best experience possible at this difficult time, and hope that we will be able to use what we have learnt from your experiences to help make things better for everyone.

Thank you very much again for taking part, we are very grateful for your time and couldn't have done this without you.

Chloe and the research team

Appendix B Materials and supporting information for healthcare professional survey

B.1 Advert/invitation



Invitation/advert for HCP study

We would like to invite you to take part in a short online survey seeking the views of healthcare professionals towards shared decision making in the setting of incurable cancer. We want to learn more about how shared decision making is used in daily practice, what factors make shared decision making more difficult, and what could be done to make things easier for all involved.

If you are a healthcare professional who works with adults with incurable cancer in the NHS, then we would like to hear from you. Please click here to complete the anonymous on-line survey https://forms.office.com/r/ZiZrJzEwAw, which will take around 10-20 minutes, or contact Chloe (c.e.holden@soton.ac.uk) to find out more.

Please share this invitation with other colleagues who work with people with incurable cancer. The survey will close on ……

Many thanks for taking the time to read about this study

Dr Chloe Holden, Dr Amélie Harle, Dr Richard Wagland and Dr Sally Wheelwright

B.2 Participant information sheet

Study Title:	A survey of NHS healthcare professionals' views and experiences of shared decision making in the setting of incurable cancer
Researcher(s):	Chloe Holden, Amélie Harle, Richard Wagland, Sally Wheelwright
University email:	c.e.holden@soton.ac.uk
ERGO no:	65382
Version and date:	08/07/2021 Version 1

My name is Chloe Holden and I am a medical oncology registrar and PhD student at the University of Southampton in the United Kingdom. Along with my supervisory team, we would like to invite you to participate in a study seeking the views of healthcare professionals in the UK towards shared decision making in the setting of incurable cancer. We want to find out about what factors make shared decision making more difficult, how health literacy changes the way people approach shared decision making, and to hear about any useful strategies to support shared decision making in this setting.

This study was approved by the Faculty Research Ethics Committee (FREC) at the University of Southampton (ERGO No: 65382)

What will happen to me if I take part?

This study involves completing an anonymous survey which should take approximately 10-20 minutes. If you are happy to complete the survey, you will need to tick (check) the box to show your consent. As it is anonymous, the research team will not know who has participated, or what answers you provided.

Why have I been asked to participate?

You have received an invitation to participate either because a professional organisation you are a member of has agreed to share information about this study with you on the research team's behalf, or because the link has been shared with you through word of mouth. We want to learn about the experiences of healthcare professionals working with adults in the NHS who have been diagnosed with incurable cancer. If this is you, then please read on.

What information will be collected?

We will ask about your professional experience and time since qualification, as well as your experiences of using shared decision making in the setting of incurable cancer. Some of the survey questions contain textboxes where you will be asked to type in your own answers. Please note that in order for this survey to be anonymous, you should not include in your answers any information from which you, or other people, could be identified.

What are the possible benefits or risks of taking part?

If you decide to take part in this study, you will not receive any direct benefits; however, your participation will contribute to knowledge in this area of research. It is not expected that taking part in this study will cause you any psychological discomfort/distress, however, should you feel uncomfortable you can leave the survey at any time.

What will happen to the information collected?

All information collected for this study will be stored securely on a password protected computer and backed up on a secure server. Only the researcher and their supervisors will have access to this information. Research findings written up as part of the researcher's academic work and submitted for publication in a peer-reviewed journal will not include information that can directly identify you.

The University of Southampton conducts research to the highest standards of ethics and research integrity. In accordance with our Research Data Management Policy, data will be held for 10 years after the study has finished when it will be securely destroyed.

What if I change my mind?

You have the right to change your mind and withdraw prior to submission without giving a reason and without your participant rights being affected. Due to the anonymous nature of the survey, it will not be possible to withdraw your data after submission.

What if there is a problem?

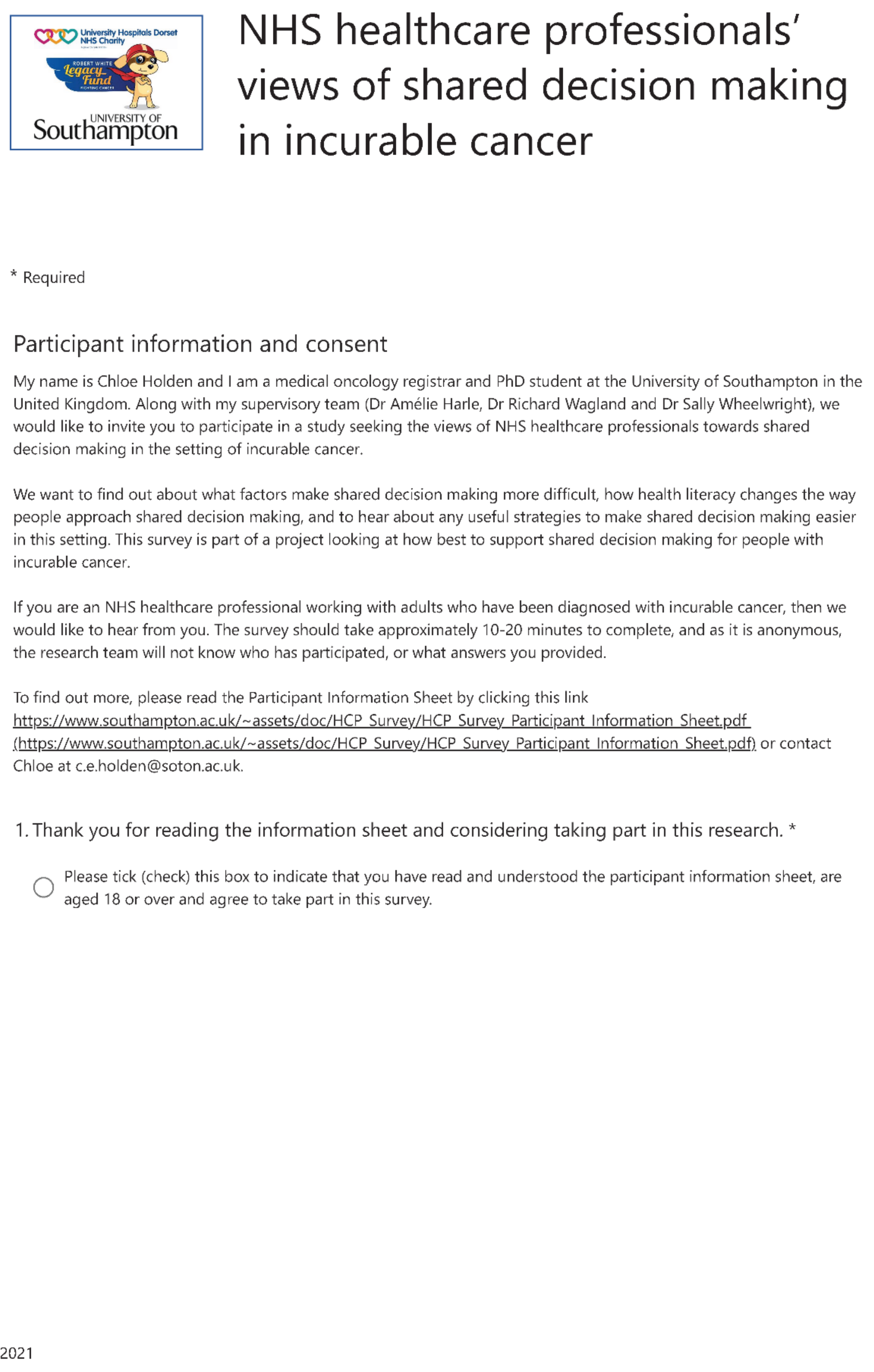
If you are unhappy about any aspect of this study and would like to make a formal complaint, you can contact the Head of Research Integrity and Governance, University of Southampton, on the following contact details: Email: rgoinfo@soton.ac.uk, phone: + 44 2380 595058. Please quote the Ethics/ERGO number above. Please note that by making a complaint you might be no longer anonymous.

More information on your rights as a study participant is available via this link:

https://www.southampton.ac.uk/about/governance/participant-information.page

Thank you for reading this information sheet and considering taking part in this study.

B.3 Final version of survey



NHS healthcare professionals' views of shared decision making in incurable cancer

* Required

Participant information and consent

My name is Chloe Holden and I am a medical oncology registrar and PhD student at the University of Southampton in the United Kingdom. Along with my supervisory team (Dr Amélie Harle, Dr Richard Wagland and Dr Sally Wheelwright), we would like to invite you to participate in a study seeking the views of NHS healthcare professionals towards shared decision making in the setting of incurable cancer.

We want to find out about what factors make shared decision making more difficult, how health literacy changes the way people approach shared decision making, and to hear about any useful strategies to make shared decision making easier in this setting. This survey is part of a project looking at how best to support shared decision making for people with incurable cancer.

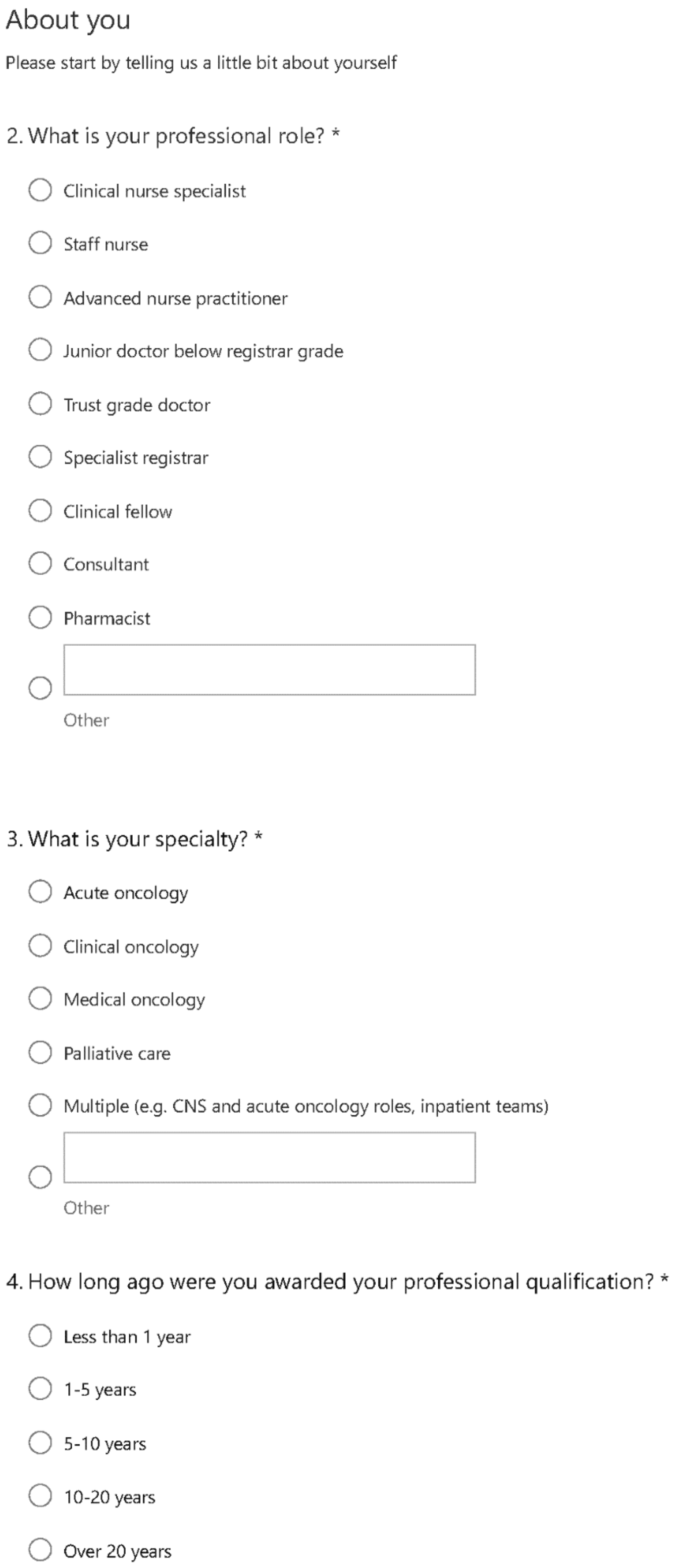
If you are an NHS healthcare professional working with adults who have been diagnosed with incurable cancer, then we would like to hear from you. The survey should take approximately 10-20 minutes to complete, and as it is anonymous, the research team will not know who has participated, or what answers you provided.

To find out more, please read the Participant Information Sheet by clicking this link https://www.southampton.ac.uk/~assets/doc/HCP_Survey/HCP_Survey_Participant_Information_Sheet.pdf (https://www.southampton.ac.uk/~assets/doc/HCP_Survey/HCP_Survey_Participant_Information_Sheet.pdf) or contact Chloe at c.e.holden@soton.ac.uk.

1. Thank you for reading the information sheet and considering taking part in this research. *

○ Please tick (check) this box to indicate that you have read and understood the participant information sheet, are aged 18 or over and agree to take part in this survey.

10/22/2021



About you

Please start by telling us a little bit about yourself

2. What is your professional role? *

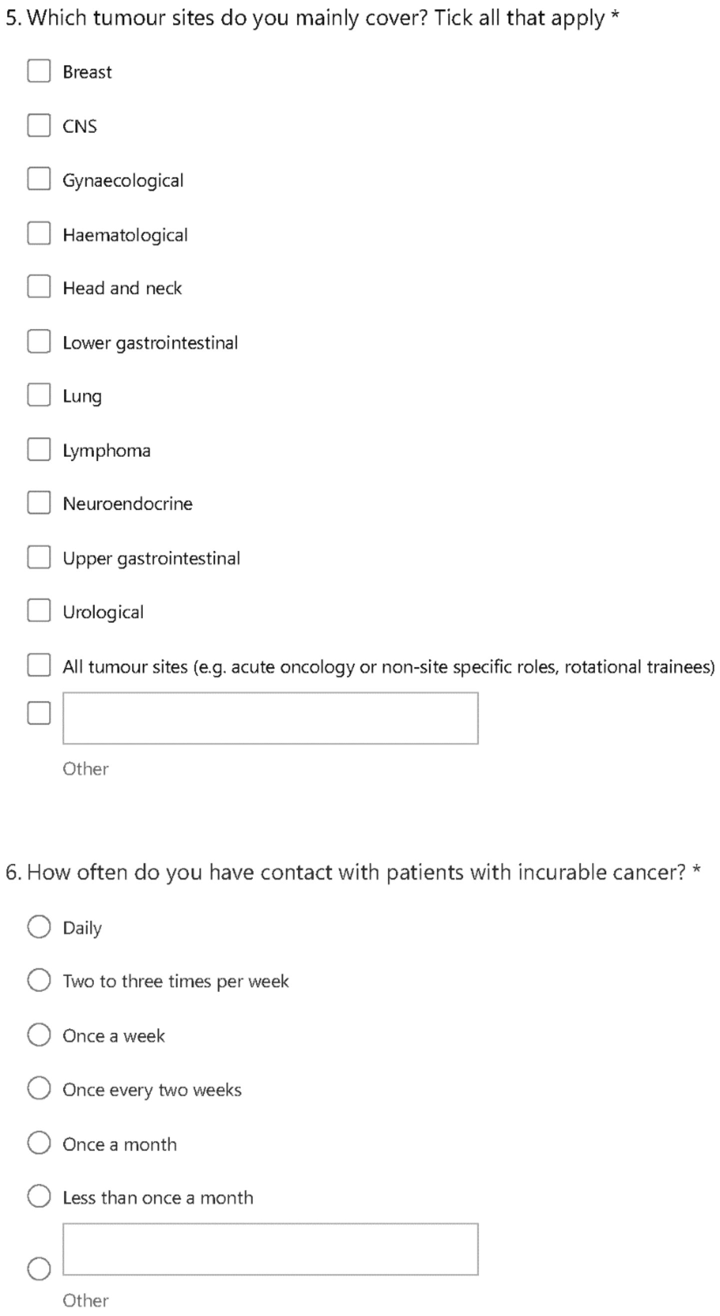
○ Clinical nurse specialist
○ Staff nurse
○ Advanced nurse practitioner
○ Junior doctor below registrar grade
○ Trust grade doctor
○ Specialist registrar
○ Clinical fellow
○ Consultant
○ Pharmacist
○ Other

3. What is your specialty? *

○ Acute oncology
○ Clinical oncology
○ Medical oncology
○ Palliative care
○ Multiple (e.g. CNS and acute oncology roles, inpatient teams)
○ Other

4. How long ago were you awarded your professional qualification? *

○ Less than 1 year
○ 1-5 years
○ 5-10 years
○ 10-20 years
○ Over 20 years



5. Which tumour sites do you mainly cover? Tick all that apply *

☐ Breast

☐ CNS

☐ Gynaecological

☐ Haematological

☐ Head and neck

☐ Lower gastrointestinal

☐ Lung

☐ Lymphoma

☐ Neuroendocrine

☐ Upper gastrointestinal

☐ Urological

☐ All tumour sites (e.g. acute oncology or non-site specific roles, rotational trainees)

☐ Other

6. How often do you have contact with patients with incurable cancer? *

○ Daily

○ Two to three times per week

○ Once a week

○ Once every two weeks

○ Once a month

○ Less than once a month

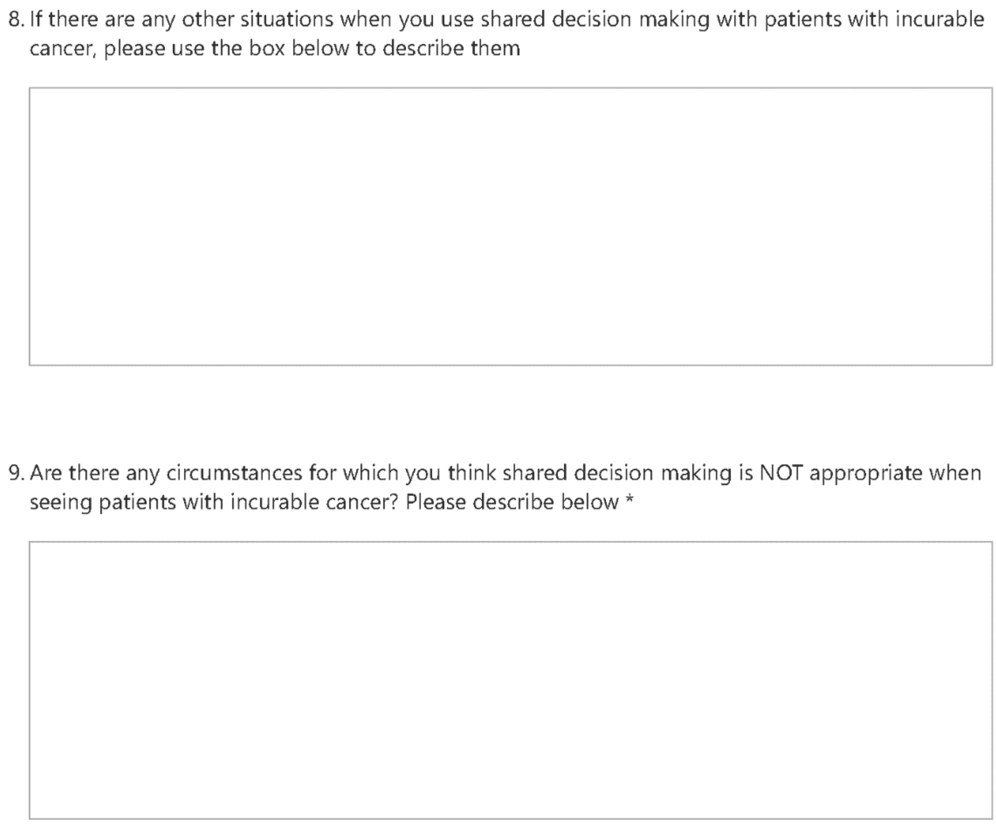
○ Other

Shared decision making in the setting of incurable cancer

Shared decision making involves the patient, sometimes supported by friends and family, and the healthcare professional working together to reach a decision regarding tests, treatments or management plans based on evidence, good information and patient preferences.

7. How often do you use shared decision making with patients with incurable cancer in the following situations? *

	Never	Rarely	Sometimes	Usually	Always	Not applicable
When offering treatment after initial diagnosis of incurable disease	○	○	○	○	○	○
When offering second or subsequent lines of treatment	○	○	○	○	○	○
When discussing cardiopulmonary resuscitation (CPR)	○	○	○	○	○	○
When discussing end of life	○	○	○	○	○	○
When offering referral to palliative care	○	○	○	○	○	○
When managing toxicities	○	○	○	○	○	○
When adjusting treatment doses	○	○	○	○	○	○
When considering the need for hospital admission	○	○	○	○	○	○
When deciding whether to continue treatment in the face of toxicity	○	○	○	○	○	○
When making plans/schedules for follow up	○	○	○	○	○	○
When discussing clinical trials	○	○	○	○	○	○
When discussing symptom control	○	○	○	○	○	○
When discussing the need for further invasive investigations	○	○	○	○	○	○

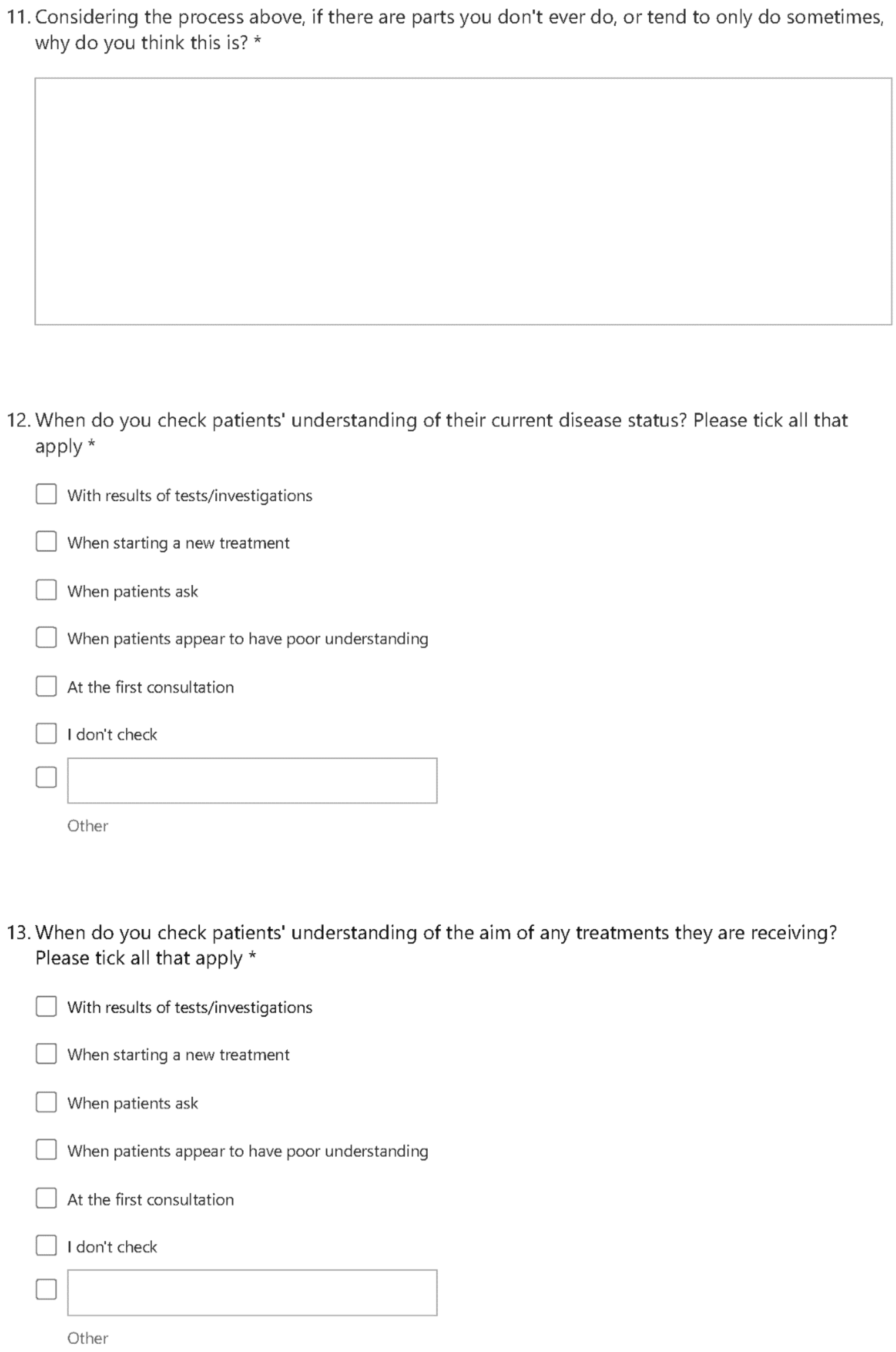


8. If there are any other situations when you use shared decision making with patients with incurable cancer, please use the box below to describe them

9. Are there any circumstances for which you think shared decision making is NOT appropriate when seeing patients with incurable cancer? Please describe below *

10. How often do you do the following when talking to patients with incurable cancer about decisions? *

	Never	Rarely	Sometimes	Usually	Always
Making patients aware that there is a decision to be made and that they can take part in the decision-making process as fully as they want	○	○	○	○	○
Encouraging patients to think about what is important to them and supporting them to express their preferences.	○	○	○	○	○
Explaining the available options (including the option of choosing no treatment or no change to what they are currently doing)	○	○	○	○	○
Discussing the risk and benefits of each option	○	○	○	○	○
Clarifying patient understanding and expectations of treatment, and addressing any misconceptions	○	○	○	○	○
Giving patients the opportunity to ask questions and allowing the time needed to consider their options.	○	○	○	○	○
Reaching an informed joint decision based on preferences	○	○	○	○	○
Offering people information in a way that they can understand, and using decision aids where available to support this process	○	○	○	○	○



11. Considering the process above, if there are parts you don't ever do, or tend to only do sometimes, why do you think this is? *

12. When do you check patients' understanding of their current disease status? Please tick all that apply *

☐ With results of tests/investigations

☐ When starting a new treatment

☐ When patients ask

☐ When patients appear to have poor understanding

☐ At the first consultation

☐ I don't check

☐ Other

13. When do you check patients' understanding of the aim of any treatments they are receiving? Please tick all that apply *

☐ With results of tests/investigations

☐ When starting a new treatment

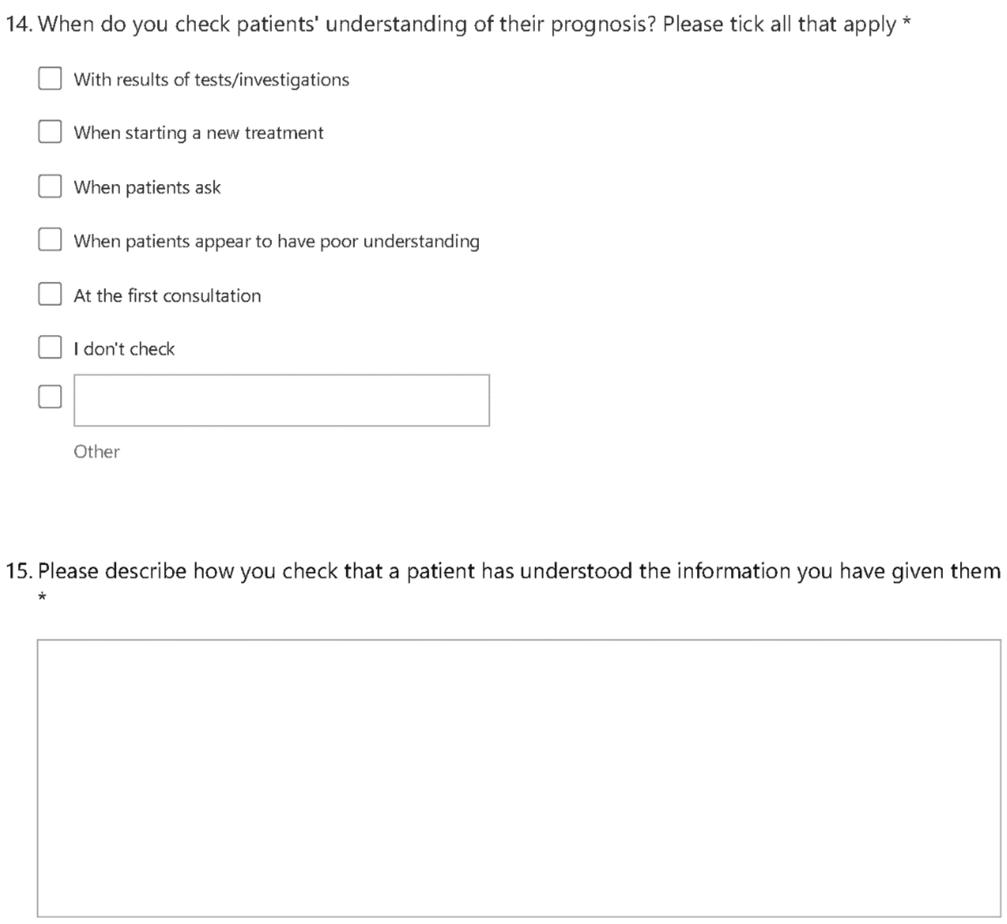
☐ When patients ask

☐ When patients appear to have poor understanding

☐ At the first consultation

☐ I don't check

☐ Other



14. When do you check patients' understanding of their prognosis? Please tick all that apply *

☐ With results of tests/investigations

☐ When starting a new treatment

☐ When patients ask

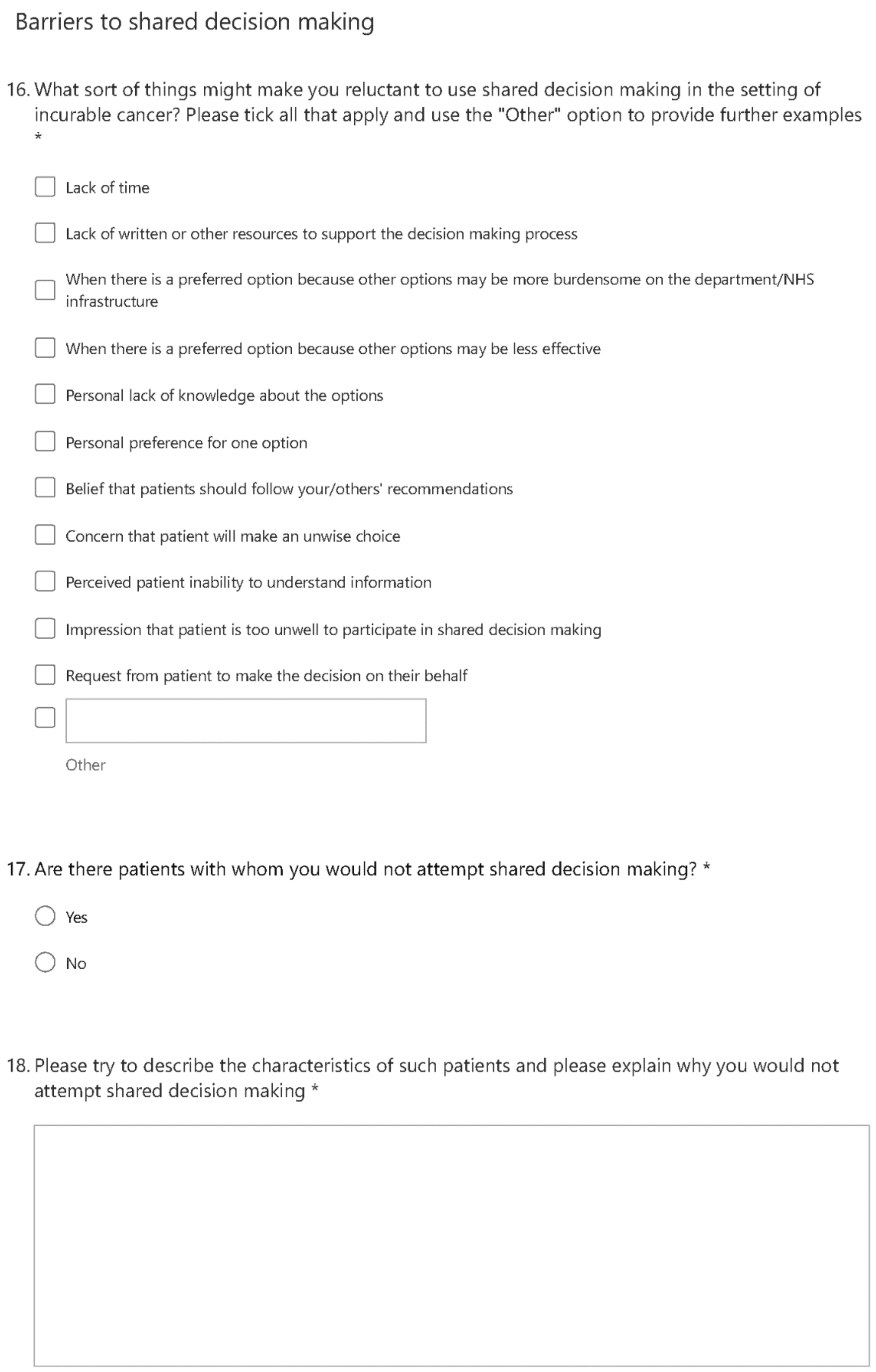
☐ When patients appear to have poor understanding

☐ At the first consultation

☐ I don't check

☐ Other

15. Please describe how you check that a patient has understood the information you have given them *



Barriers to shared decision making

16. What sort of things might make you reluctant to use shared decision making in the setting of incurable cancer? Please tick all that apply and use the "Other" option to provide further examples *

☐ Lack of time

☐ Lack of written or other resources to support the decision making process

☐ When there is a preferred option because other options may be more burdensome on the department/NHS infrastructure

☐ When there is a preferred option because other options may be less effective

☐ Personal lack of knowledge about the options

☐ Personal preference for one option

☐ Belief that patients should follow your/others' recommendations

☐ Concern that patient will make an unwise choice

☐ Perceived patient inability to understand information

☐ Impression that patient is too unwell to participate in shared decision making

☐ Request from patient to make the decision on their behalf

☐ ____________

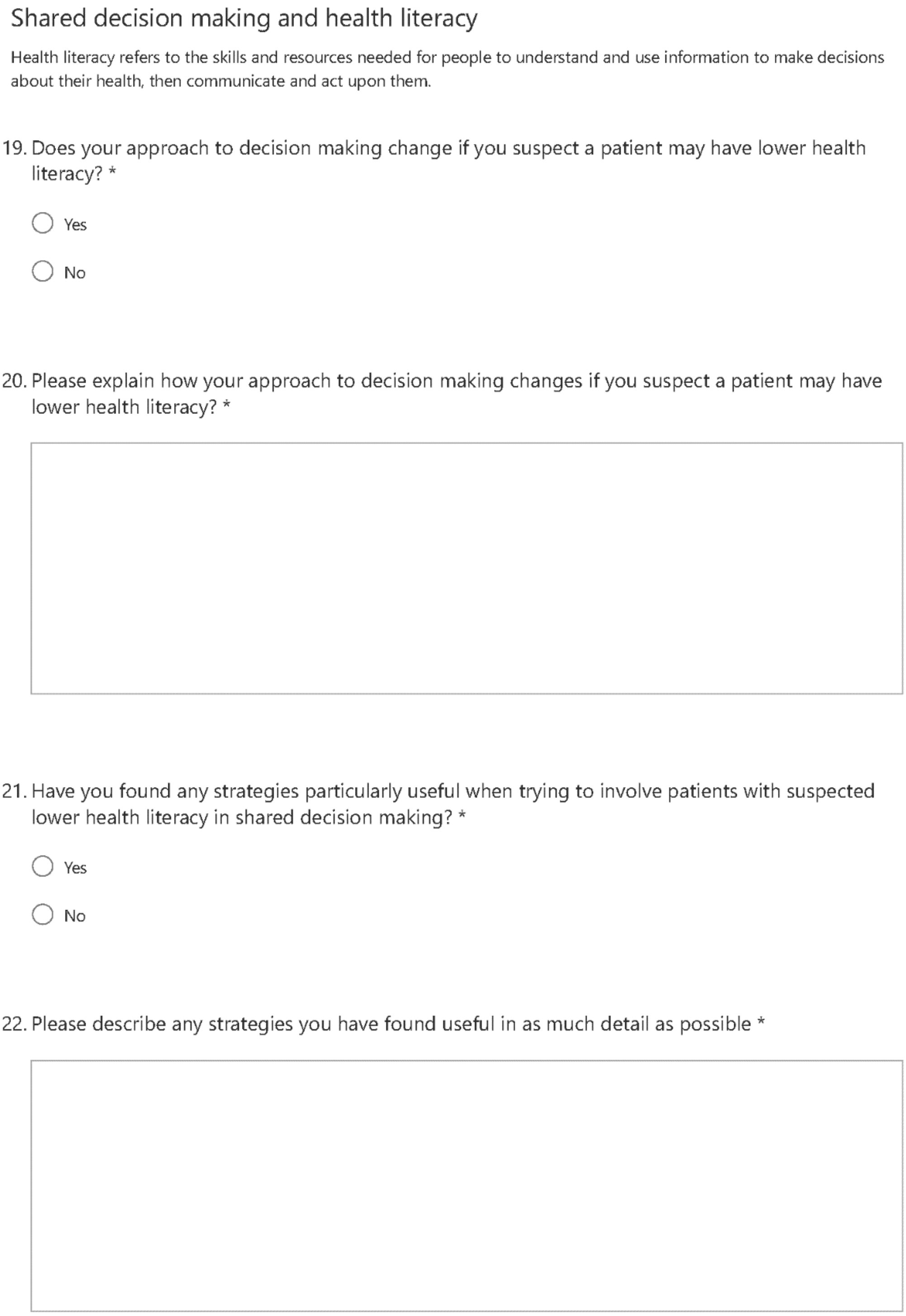
Other

17. Are there patients with whom you would not attempt shared decision making? *

○ Yes

○ No

18. Please try to describe the characteristics of such patients and please explain why you would not attempt shared decision making *



Shared decision making and health literacy

Health literacy refers to the skills and resources needed for people to understand and use information to make decisions about their health, then communicate and act upon them.

19. Does your approach to decision making change if you suspect a patient may have lower health literacy? *

○ Yes

○ No

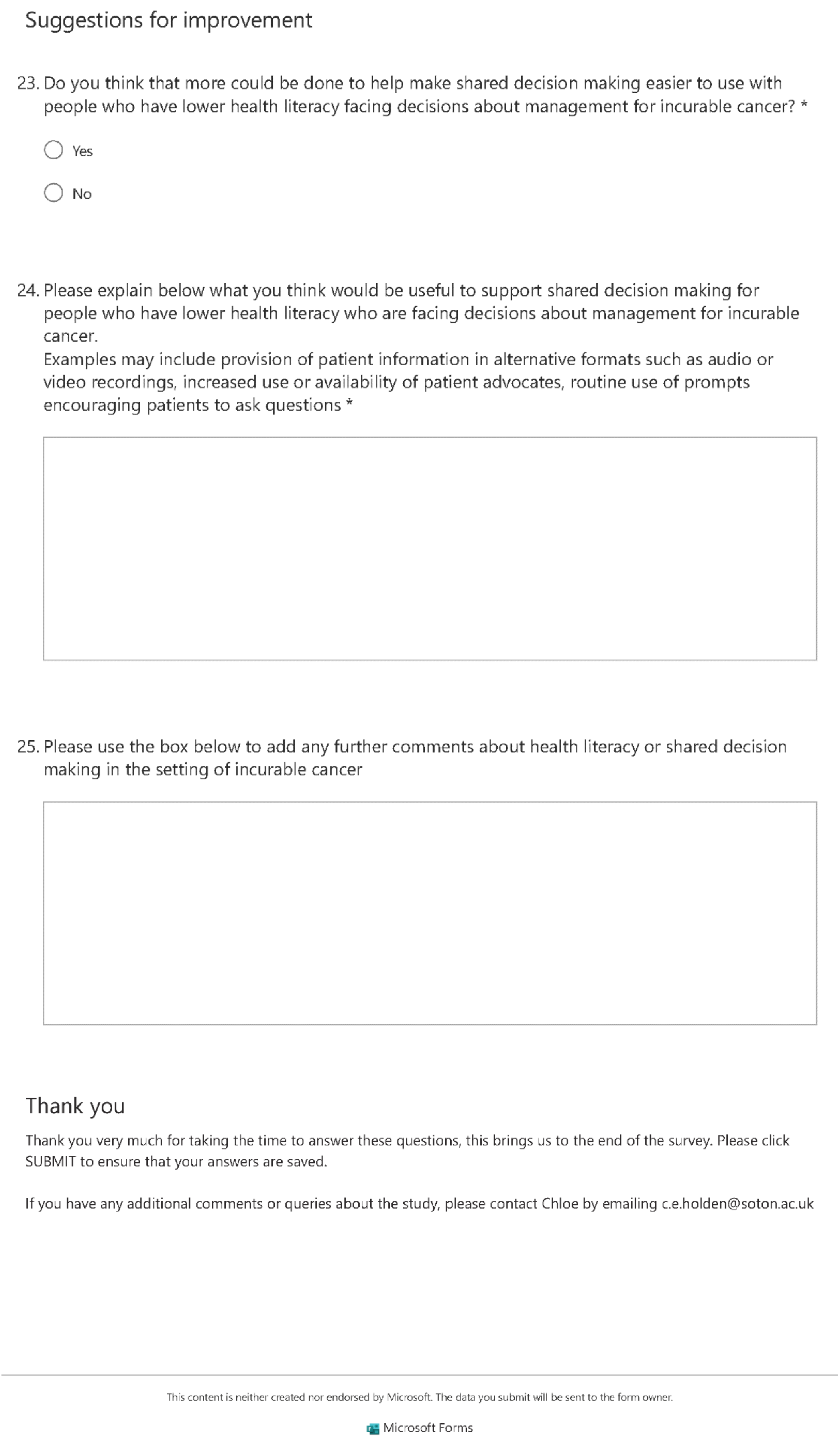
20. Please explain how your approach to decision making changes if you suspect a patient may have lower health literacy? *

21. Have you found any strategies particularly useful when trying to involve patients with suspected lower health literacy in shared decision making? *

○ Yes

○ No

22. Please describe any strategies you have found useful in as much detail as possible *



Suggestions for improvement

23. Do you think that more could be done to help make shared decision making easier to use with people who have lower health literacy facing decisions about management for incurable cancer? *

○ Yes

○ No

24. Please explain below what you think would be useful to support shared decision making for people who have lower health literacy who are facing decisions about management for incurable cancer.
Examples may include provision of patient information in alternative formats such as audio or video recordings, increased use or availability of patient advocates, routine use of prompts encouraging patients to ask questions *

25. Please use the box below to add any further comments about health literacy or shared decision making in the setting of incurable cancer

Thank you

Thank you very much for taking the time to answer these questions, this brings us to the end of the survey. Please click SUBMIT to ensure that your answers are saved.

If you have any additional comments or queries about the study, please contact Chloe by emailing c.e.holden@soton.ac.uk

Appendix C Materials and supporting information for expert panel meetings

C.1 Slide set for HCP meeting

Making decisions together when cancer can't be cured

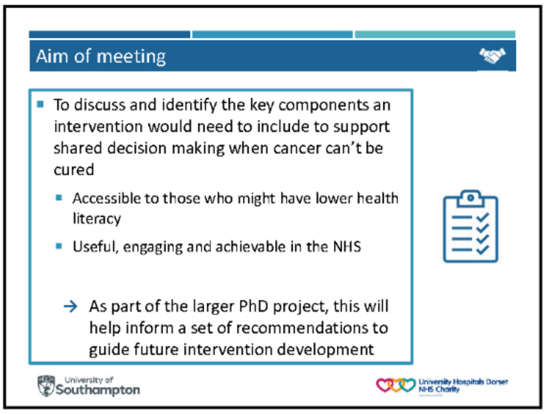
Monday 14th November

1

Welcome

- Welcome and thank you
- Introductions
  - Chloe Holden
    - Supervised by Amélie Harle, Sally Wheelwright and Richard Wagland
  - Richard Wagland
  - Group – who, where, role
- Housekeeping
  - Recording and note taking
  - Comments/feedback

2



Aim of meeting

- To discuss and identify the key components an intervention would need to include to support shared decision making when cancer can't be cured
  - Accessible to those who might have lower health literacy
  - Useful, engaging and achievable in the NHS

→ As part of the larger PhD project, this will help inform a set of recommendations to guide future intervention development

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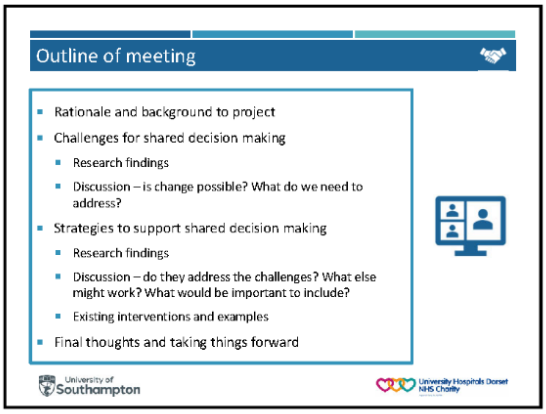

Outline of meeting

- Rationale and background to project
- Challenges for shared decision making
  - Research findings
  - Discussion – is change possible? What do we need to address?
- Strategies to support shared decision making
  - Research findings
  - Discussion – do they address the challenges? What else might work? What would be important to include?
  - Existing interventions and examples
- Final thoughts and taking things forward

4

Rationale and background to project

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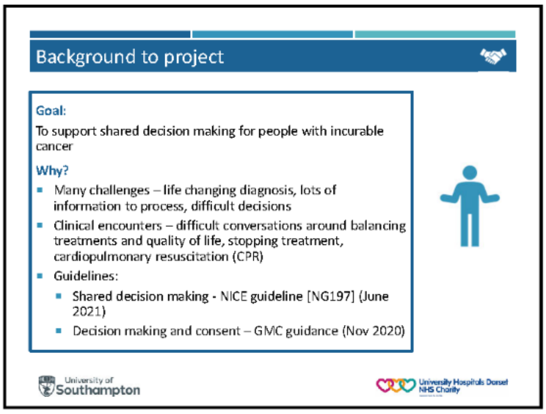

Background to project

Goal:

To support shared decision making for people with incurable cancer

Why?

- Many challenges – life changing diagnosis, lots of information to process, difficult decisions
- Clinical encounters – difficult conversations around balancing treatments and quality of life, stopping treatment, cardiopulmonary resuscitation (CPR)
- Guidelines:
  - Shared decision making - NICE guideline [NG197] (June 2021)
  - Decision making and consent – GMC guidance (Nov 2020)

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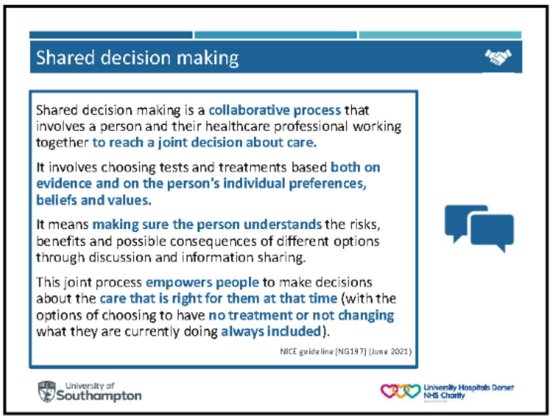
Appendix C



Shared decision making

Shared decision making is a **collaborative process** that involves a person and their healthcare professional working together **to reach a joint decision about care.**

It involves choosing tests and treatments based **both on evidence and on the person's individual preferences, beliefs and values.**

It means **making sure the person understands** the risks, benefits and possible consequences of different options through discussion and information sharing.

This joint process **empowers people** to make decisions about the **care that is right for them at that time** (with the options of choosing to have **no treatment or not changing** what they are currently doing **always included**).

NICE guideline [NG197] (June 2021)

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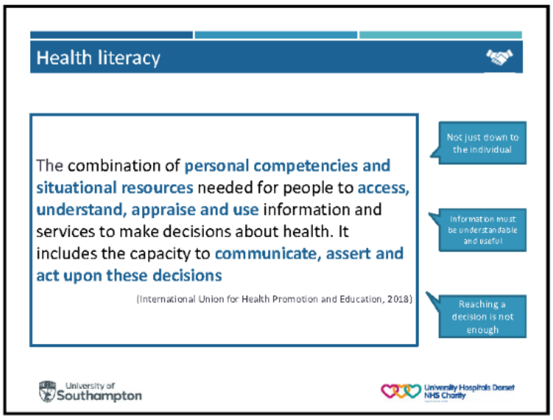

Health literacy

The combination of **personal competencies and situational resources** needed for people to **access, understand, appraise and use** information and services to make decisions about health. It includes the capacity to **communicate, assert and act upon these decisions**

(International Union for Health Promotion and Education, 2018)

Not just down to the individual

Information must be understandable and useful

Reaching a decision is not enough

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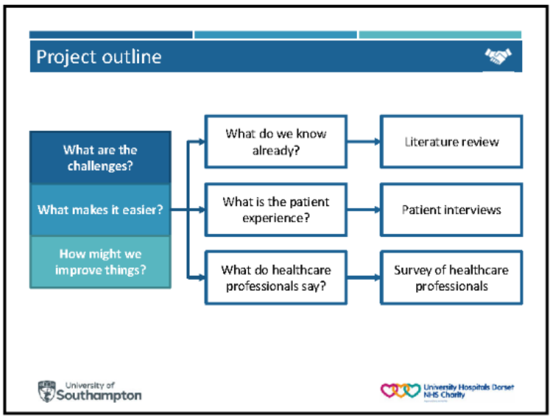

Project outline

What are the challenges?

What makes it easier?

How might we improve things?

What do we know already? → Literature review

What is the patient experience? → Patient interviews

What do healthcare professionals say? → Survey of healthcare professionals

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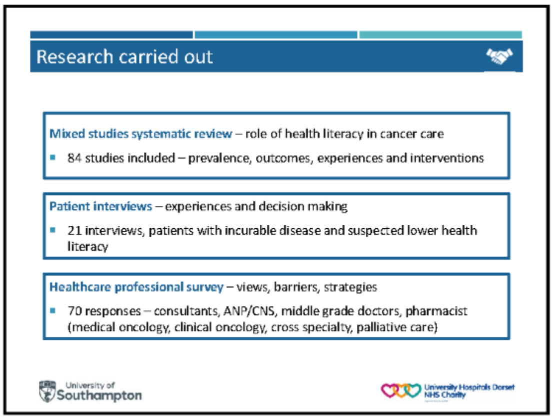

Research carried out

Mixed studies systematic review – role of health literacy in cancer care
- 84 studies included – prevalence, outcomes, experiences and interventions

Patient interviews – experiences and decision making
- 21 interviews, patients with incurable disease and suspected lower health literacy

Healthcare professional survey – views, barriers, strategies
- 70 responses – consultants, ANP/CNS, middle grade doctors, pharmacist (medical oncology, clinical oncology, cross specialty, palliative care)

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Challenges for shared decision making in advanced cancer

With a focus on health literacy

What are the issues that need to be addressed?

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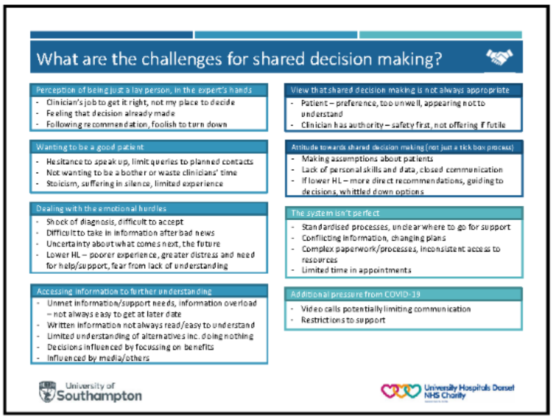

What are the challenges for shared decision making?

Perception of being just a lay person, in the expert's hands
- Clinician's job to get it right, not my place to decide
- Feeling that decision already made
- Following recommendation, foolish to turn down

Wanting to be a good patient
- Hesitance to speak up, limit queries to planned contacts
- Not wanting to be a bother or waste clinicians' time
- Stoicism, suffering in silence, limited experience

Dealing with the emotional hurdles
- Shock of diagnosis, difficult to accept
- Difficult to take in information after bad news
- Uncertainty about what comes next, the future
- Lower HL – poorer experience, greater distress and need for help/support, fear from lack of understanding

Accessing information to further understanding
- Unmet information/support needs, information overload – not always easy to get at later date
- Written information not always read/easy to understand
- Limited understanding of alternatives inc. doing nothing
- Decisions influenced by focussing on benefits
- Influenced by media/others

View that shared decision making is not always appropriate
- Patient – preference, too unwell, appearing not to understand
- Clinician has authority – safety first, not offering if futile

Attitude towards shared decision making (not just a tick box process)
- Making assumptions about patients
- Lack of personal skills and data, closed communication
- If lower HL – more direct recommendations, guiding to decisions, whittled down options

The system isn't perfect
- Standardised processes, unclear where to go for support
- Conflicting information, changing plans
- Complex paperwork/processes, inconsistent access to resources
- Limited time in appointments

Additional pressure from COVID-19
- Video calls potentially limiting communication
- Restrictions to support

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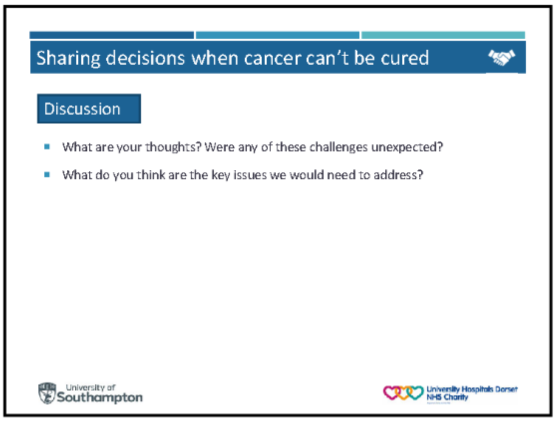

Sharing decisions when cancer can't be cured

Discussion

- What are your thoughts? Were any of these challenges unexpected?
- What do you think are the key issues we would need to address?

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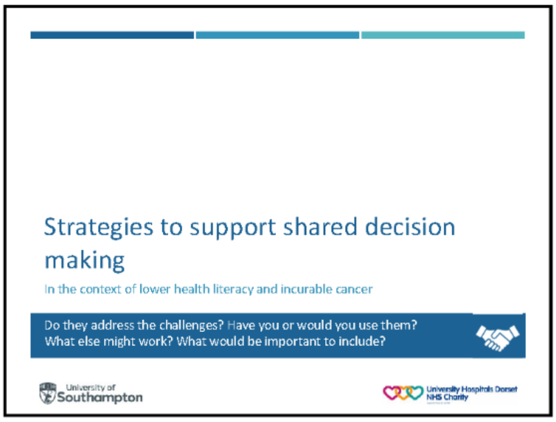

Strategies to support shared decision making

In the context of lower health literacy and incurable cancer

Do they address the challenges? Have you or would you use them?
What else might work? What would be important to include?

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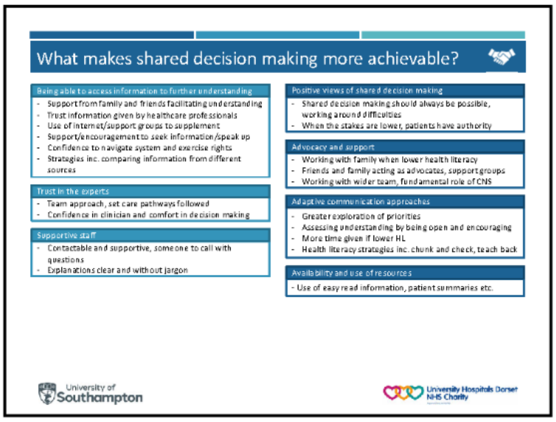

What makes shared decision making more achievable?

Being able to access information to further understanding

- Support from family and friends facilitating understanding
- Trust information given by healthcare professionals
- Use of internet/support groups to supplement
- Support/encouragement to seek information/speak up
- Confidence to navigate system and exercise rights
- Strategies inc. comparing information from different sources

Trust in the experts

- Team approach, set care pathways followed
- Confidence in clinician and comfort in decision making

Supportive staff

- Contactable and supportive, someone to call with questions
- Explanations clear and without jargon

Positive views of shared decision making

- Shared decision making should always be possible, working around difficulties
- When the stakes are lower, patients have authority

Advocacy and support

- Working with family when lower health literacy
- Friends and family acting as advocates, support groups
- Working with wider team, fundamental role of CNS

Adaptive communication approaches

- Greater exploration of priorities
- Assessing understanding by being open and encouraging
- More time given if lower HL
- Health literacy strategies inc. chunk and check, teach back

Availability and use of resources

- Use of easy read information, patient summaries etc.

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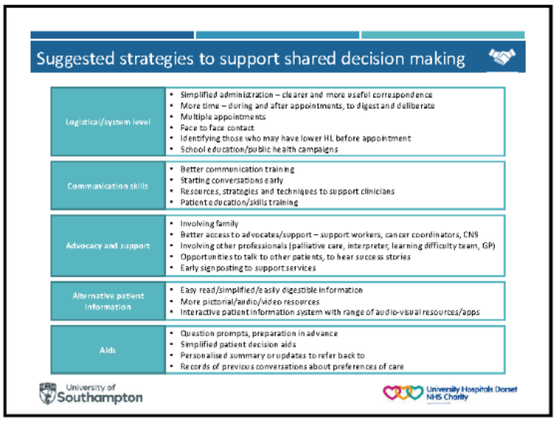

Suggested strategies to support shared decision making

Logistical/system level	• Simplified administration – clearer and more useful correspondence • More time – during and after appointments, to digest and deliberate • Multiple appointments • Face to face contact • Identifying those who may have lower HL before appointment • School education/public health campaigns
Communication skills	• Better communication training • Starting conversations early • Resources, strategies and techniques to support clinicians • Patient education/skills training
Advocacy and support	• Involving family • Better access to advocates/support – support workers, cancer coordinators, CNS • Involving other professionals (palliative care, interpreter, learning difficulty team, GP) • Opportunities to talk to other patients, to hear success stories • Early signposting to support services
Alternative patient information	• Easy read/simplified/easily digestible information • More pictorial/audio/video resources • Interactive patient information system with range of audio-visual resources/apps
Aids	• Question prompts, preparation in advance • Simplified patient decision aids • Personalised summary or updates to refer back to • Records of previous conversations about preferences of care

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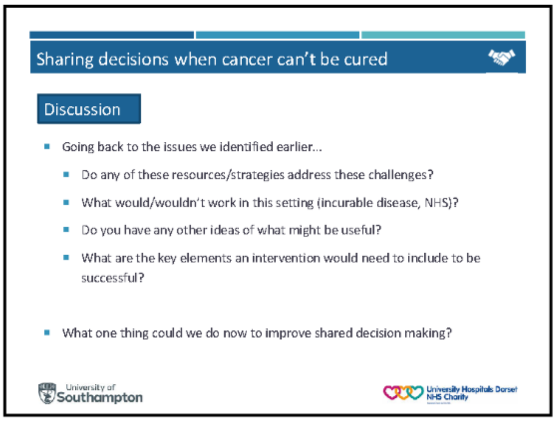

Sharing decisions when cancer can't be cured

Discussion

- Going back to the issues we identified earlier...
  - Do any of these resources/strategies address these challenges?
  - What would/wouldn't work in this setting (incurable disease, NHS)?
  - Do you have any other ideas of what might be useful?
  - What are the key elements an intervention would need to include to be successful?
- What one thing could we do now to improve shared decision making?

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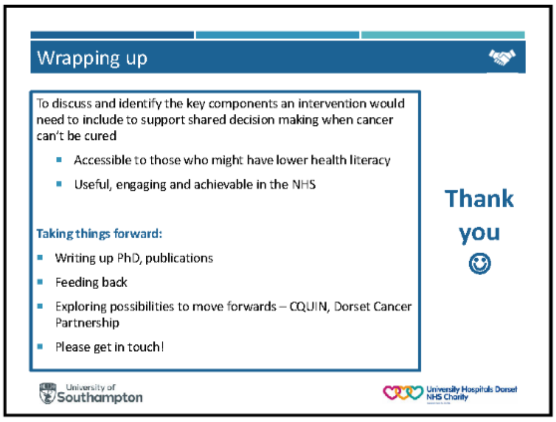

Wrapping up

To discuss and identify the key components an intervention would need to include to support shared decision making when cancer can't be cured

- Accessible to those who might have lower health literacy
- Useful, engaging and achievable in the NHS

Taking things forward:

- Writing up PhD, publications
- Feeding back
- Exploring possibilities to move forwards – CQUIN, Dorset Cancer Partnership
- Please get in touch!

Thank you ☺

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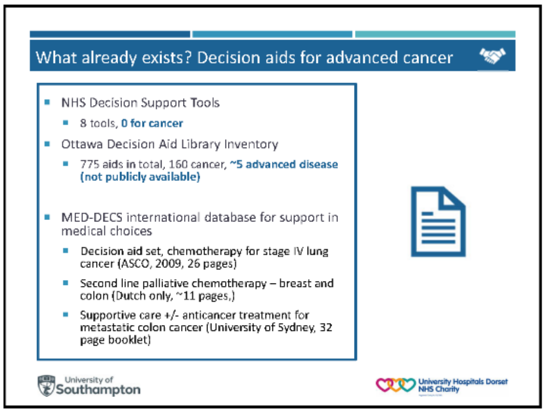
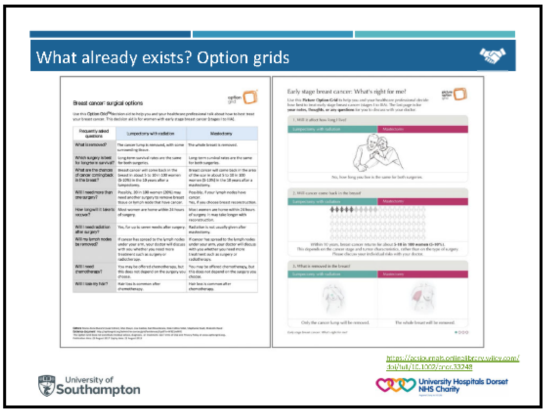
Appendix C



What already exists? Decision aids for advanced cancer

- NHS Decision Support Tools
  - 8 tools, **0 for cancer**
- Ottawa Decision Aid Library Inventory
  - 775 aids in total, 160 cancer, **~5 advanced disease (not publicly available)**
- MED-DECS international database for support in medical choices
  - Decision aid set, chemotherapy for stage IV lung cancer (ASCO, 2009, 26 pages)
  - Second line palliative chemotherapy – breast and colon (Dutch only, ~11 pages,)
  - Supportive care +/- anticancer treatment for metastatic colon cancer (University of Sydney, 32 page booklet)

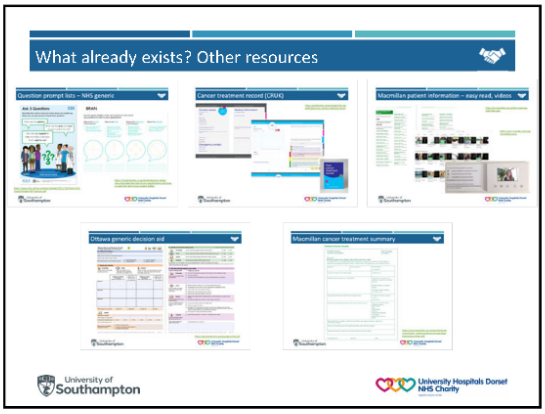


What already exists? Option grids

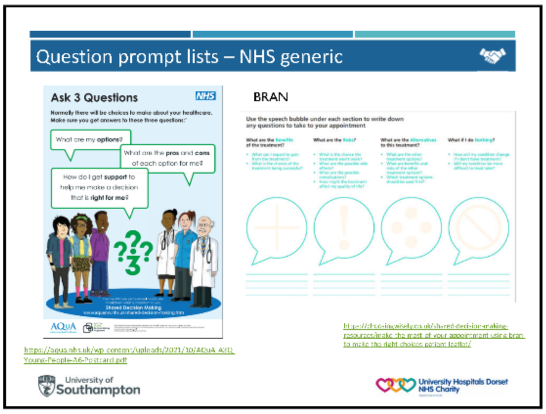
Breast cancer: surgical options

Early stage breast cancer: What's right for me?

https://acsjournals.onlinelibrary.wiley.com/doi/full/10.1002/cncr.33248



What already exists? Other resources



Question prompt lists – NHS generic

Ask 3 Questions NHS

Normally there will be choices to make about your healthcare. Make sure you get answers to these three questions:

What are my **options**?

What are the **pros** and **cons** of each option for me?

How do I get **support** to help me make a decision that is **right for me**?

Shared Decision Making

AQuA

https://aqua.nhs.uk/wp-content/uploads/2021/10/AQuA-A3Q-Young-People-A6-Postcard.pdf

BRAN

Use the speech bubble under each section to write down any questions to take to your appointment

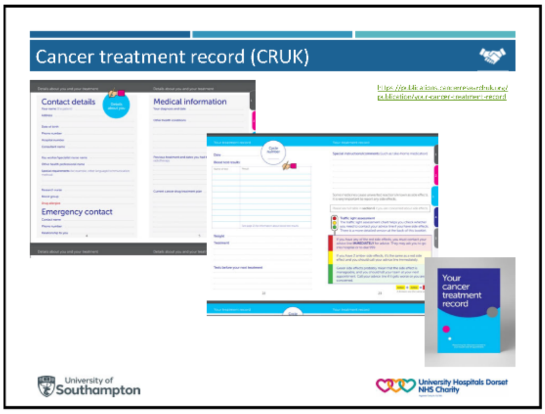
What are the Benefits of the treatment?

What are the Risks?

What are the Alternatives to this treatment?

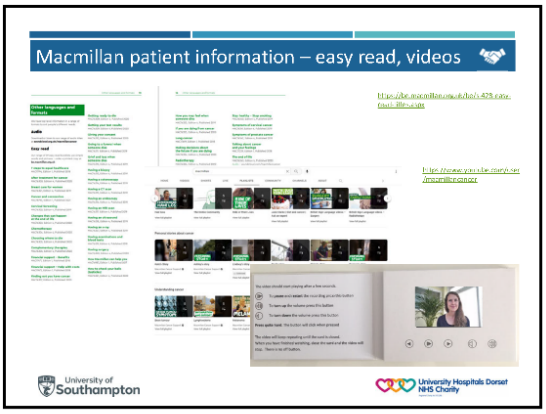
What if I do Nothing?

https://choosingwisely.co.uk/shared-decision-making-resources/make-the-most-of-your-appointment-using-bran-to-make-the-right-choices-patient-leaflet/



Cancer treatment record (CRUK)

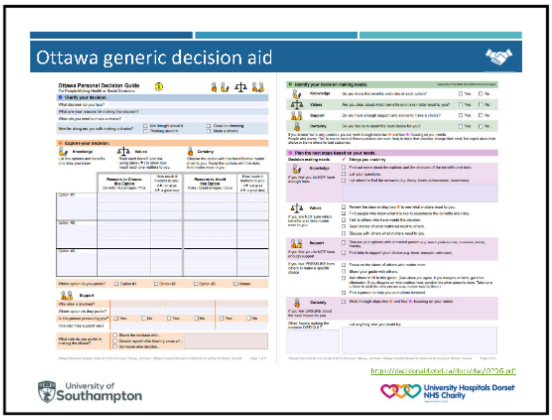
https://publications.cancerresearchuk.org/publication/your-cancer-treatment-record



Macmillan patient information – easy read, videos

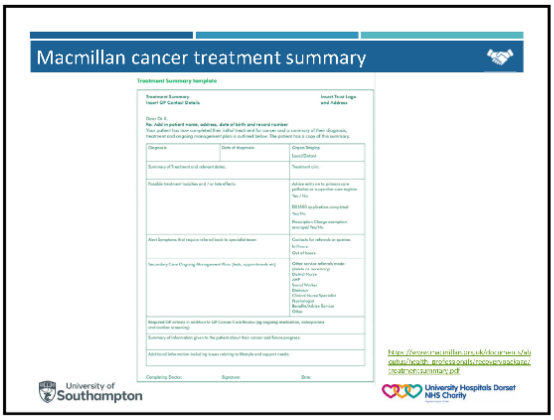
https://be.macmillan.org.uk/be/s-428-easy-read-titles.aspx

https://www.youtube.com/user/macmillancancer



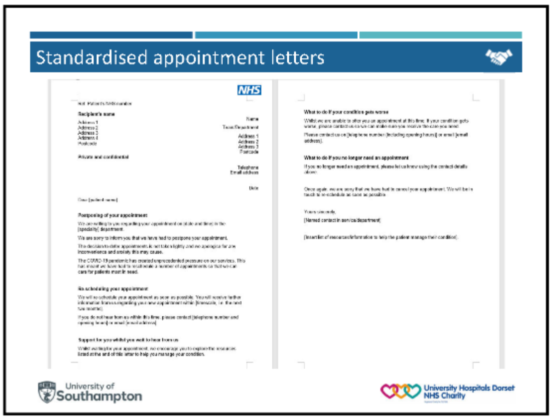
Ottawa generic decision aid

https://decisionaid.ohri.ca/docs/das/OPDG.pdf

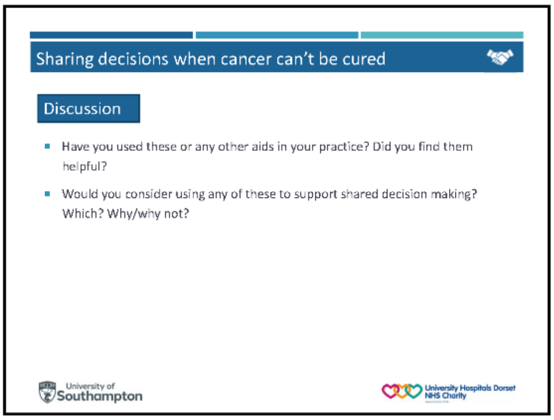


Macmillan cancer treatment summary

https://www.macmillan.org.uk/documents/ab
outus/health_professionals/recoverypackage/
treatmentsummary.pdf



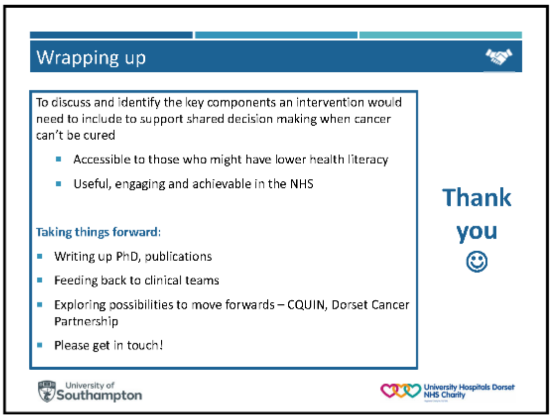
Standardised appointment letters



Sharing decisions when cancer can't be cured

Discussion

- Have you used these or any other aids in your practice? Did you find them helpful?
- Would you consider using any of these to support shared decision making? Which? Why/why not?



Wrapping up

To discuss and identify the key components an intervention would need to include to support shared decision making when cancer can't be cured

- Accessible to those who might have lower health literacy
- Useful, engaging and achievable in the NHS

Taking things forward:

- Writing up PhD, publications
- Feeding back to clinical teams
- Exploring possibilities to move forwards – CQUIN, Dorset Cancer Partnership
- Please get in touch!

Thank you ☺

C.2 Advertisement used to recruit patients and carers

Involving patients with terminal cancer in decisions about their care (Dr Chloe Holden)

Dr Chloe Holden, a cancer doctor and research student at the University of Southampton, is hosting a PPI meeting to discuss the findings of her research into how people with terminal cancer can be more involved in making decisions about their care.

The meeting will discuss what has already been done to improve care, and what more could be done to make the experience better for patients and their carers.

This PPI opportunity would be suitable for people who:

- Have experience of cancer that can't be cured (either as a patient or carer)
- Have been given information that was hard to understand
- Have not been involved in decisions as much as they would like to have been

The meeting will last 90 minutes with a short break in the middle. The date is yet to be finalised, but the meeting will likely take place in the week beginning the 21st of November

If you are interested in helping with this PPI activity, please email **PublicInvolvement@uhs.nhs.uk.**

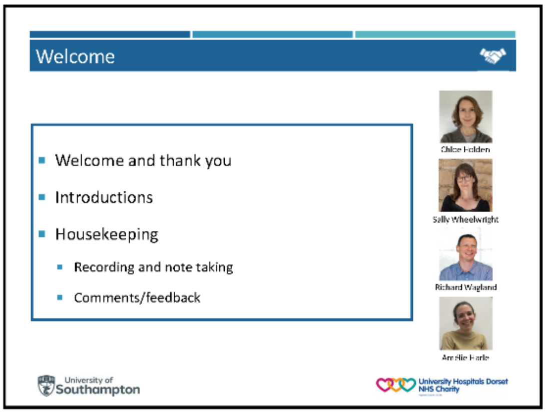
C.3 Slide set for patient and carer panel meeting

Making decisions together when cancer can't be cured

Thursday 24th November

University of Southampton

University Hospitals Dorset NHS Charity



Welcome

- Welcome and thank you
- Introductions
- Housekeeping
  - Recording and note taking
  - Comments/feedback

Chloe Holden

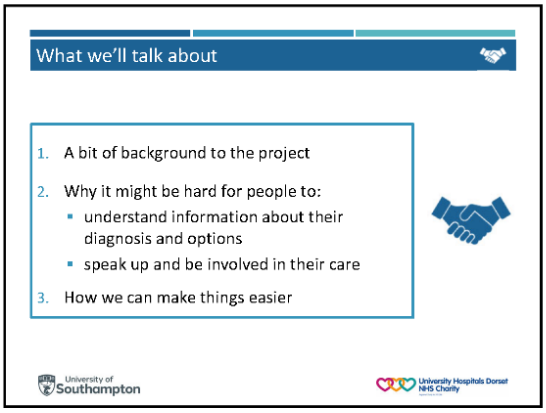
Sally Wheelwright

Richard Wagland

Amelie Harle

University of Southampton

University Hospitals Dorset NHS Charity



What we'll talk about

1. A bit of background to the project
2. Why it might be hard for people to:
   - understand information about their diagnosis and options
   - speak up and be involved in their care
3. How we can make things easier

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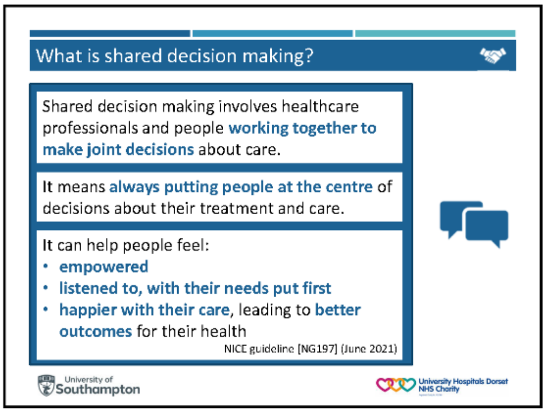

What is shared decision making?

Shared decision making involves healthcare professionals and people **working together to make joint decisions** about care.

It means **always putting people at the centre** of decisions about their treatment and care.

It can help people feel:

- **empowered**
- **listened to, with their needs put first**
- **happier with their care**, leading to **better outcomes** for their health

NICE guideline [NG197] (June 2021)

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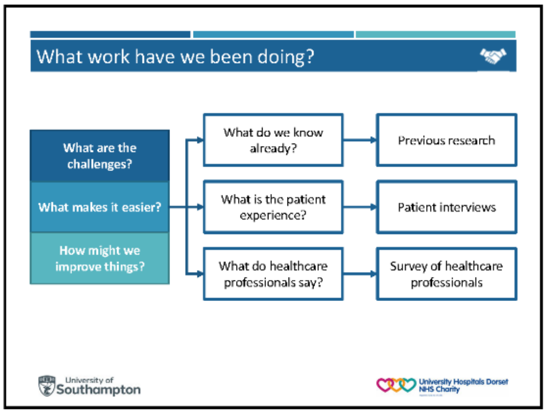

What work have we been doing?

What are the challenges?

What makes it easier?

How might we improve things?

What do we know already? → Previous research

What is the patient experience? → Patient interviews

What do healthcare professionals say? → Survey of healthcare professionals

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Why is shared decision making hard?

Traditional views of doctor-patient roles

Dealing with the emotional hurdles

Practical issues - the system isn't perfect

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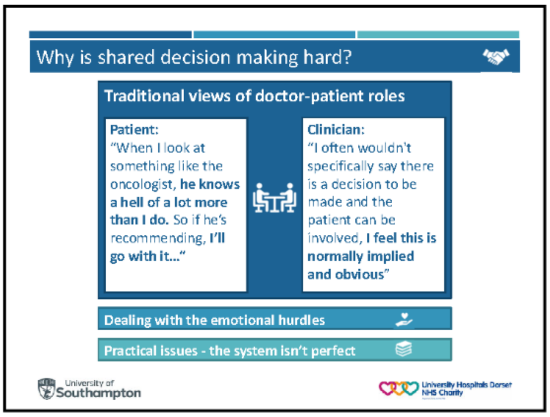

Why is shared decision making hard?

Traditional views of doctor-patient roles

Patient:
"When I look at something like the oncologist, **he knows a hell of a lot more than I do.** So if he's recommending, **I'll go with it…**"

Clinician:
"I often wouldn't specifically say there is a decision to be made and the patient can be involved, **I feel this is normally implied and obvious**"

Dealing with the emotional hurdles

Practical issues - the system isn't perfect

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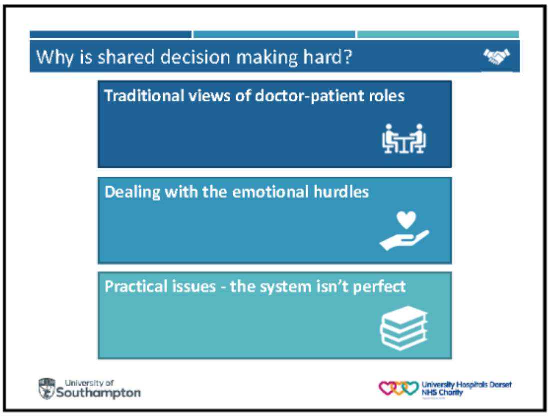

Why is shared decision making hard?

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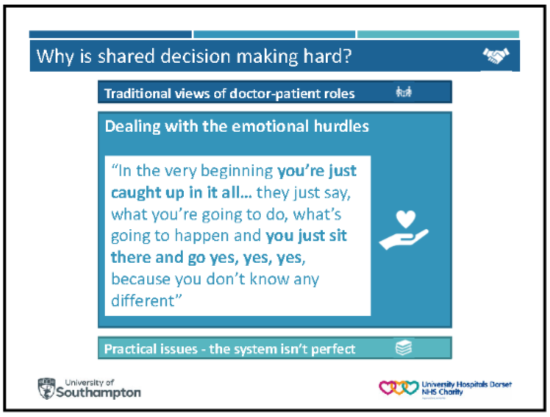

Why is shared decision making hard?

Traditional views of doctor-patient roles

Dealing with the emotional hurdles

"In the very beginning **you're just caught up in it all…** they just say, what you're going to do, what's going to happen and **you just sit there and go yes, yes, yes,** because you don't know any different"

Practical issues - the system isn't perfect

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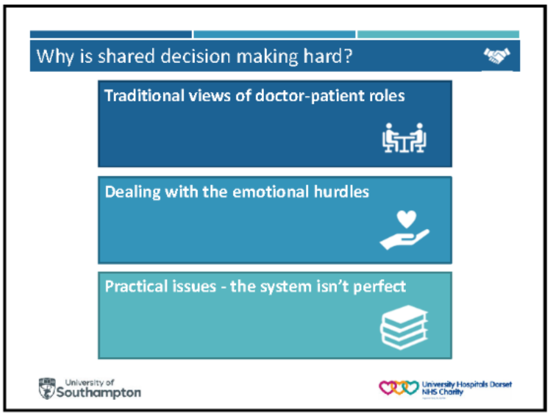

Why is shared decision making hard?

Traditional views of doctor-patient roles

Dealing with the emotional hurdles

Practical issues - the system isn't perfect

University of Southampton

University Hospitals Dorset NHS Charity

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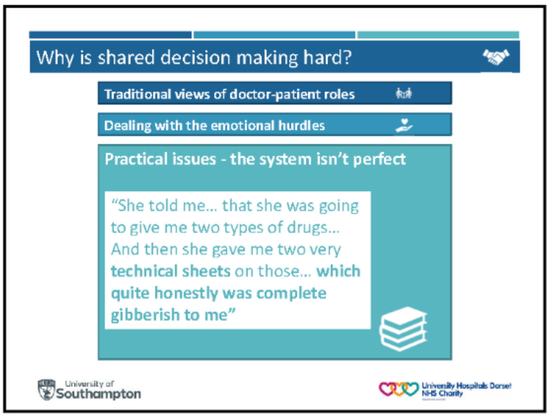

Why is shared decision making hard?

Traditional views of doctor-patient roles

Dealing with the emotional hurdles

Practical issues - the system isn't perfect

"She told me… that she was going to give me two types of drugs… And then she gave me two very **technical sheets** on those… **which quite honestly was complete gibberish to me"**

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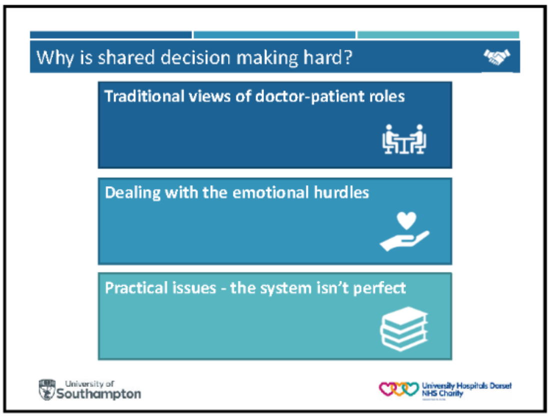

Why is shared decision making hard?

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Dealing with the emotional hurdles

Practical issues - the system isn't perfect

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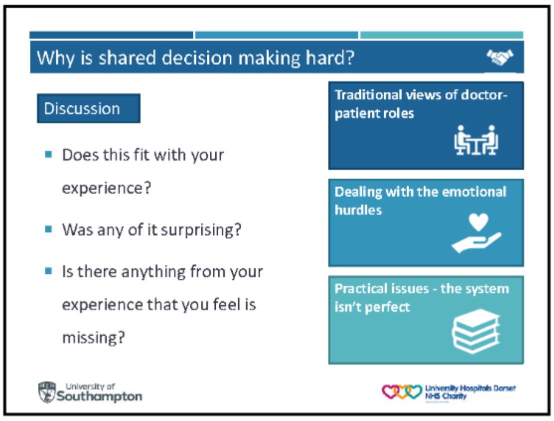

Why is shared decision making hard?

Discussion

- Does this fit with your experience?
- Was any of it surprising?
- Is there anything from your experience that you feel is missing?

Traditional views of doctor-patient roles

Dealing with the emotional hurdles

Practical issues - the system isn't perfect

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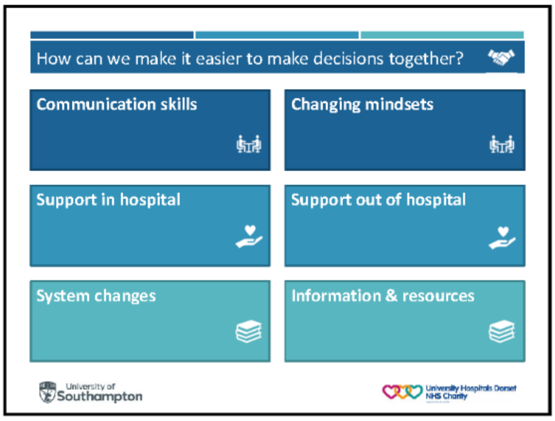

How can we make it easier to make decisions together?

Communication skills

Changing mindsets

Support in hospital

Support out of hospital

System changes

Information & resources

University of Southampton

University Hospitals Dorset NHS Charity

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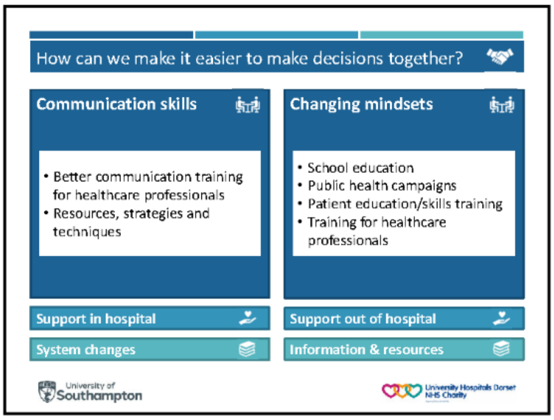

How can we make it easier to make decisions together?

Communication skills

- Better communication training for healthcare professionals
- Resources, strategies and techniques

Changing mindsets

- School education
- Public health campaigns
- Patient education/skills training
- Training for healthcare professionals

Support in hospital

Support out of hospital

System changes

Information & resources

University of Southampton

University Hospitals Dorset NHS Charity

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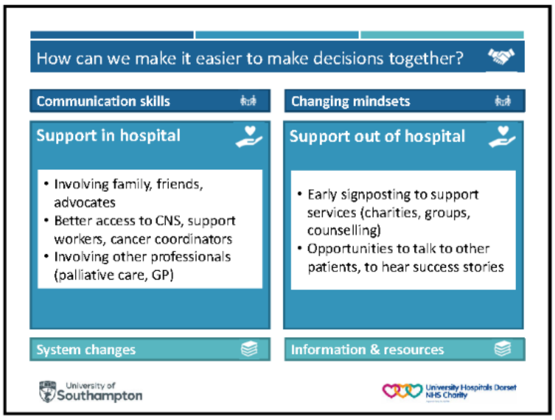

How can we make it easier to make decisions together?

Communication skills

Changing mindsets

Support in hospital

- Involving family, friends, advocates
- Better access to CNS, support workers, cancer coordinators
- Involving other professionals (palliative care, GP)

Support out of hospital

- Early signposting to support services (charities, groups, counselling)
- Opportunities to talk to other patients, to hear success stories

System changes

Information & resources

University of Southampton

University Hospitals Dorset NHS Charity

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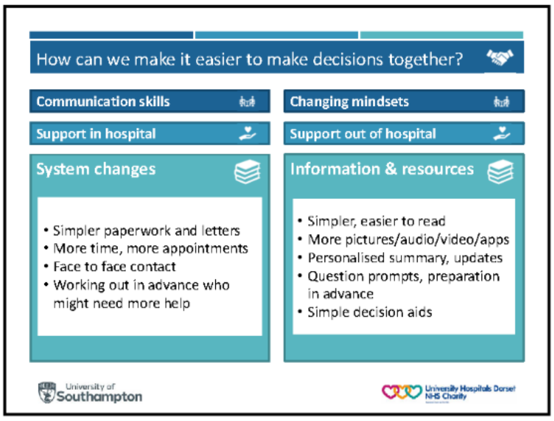

How can we make it easier to make decisions together?

Communication skills

Changing mindsets

Support in hospital

Support out of hospital

System changes

- Simpler paperwork and letters
- More time, more appointments
- Face to face contact
- Working out in advance who might need more help

Information & resources

- Simpler, easier to read
- More pictures/audio/video/apps
- Personalised summary, updates
- Question prompts, preparation in advance
- Simple decision aids

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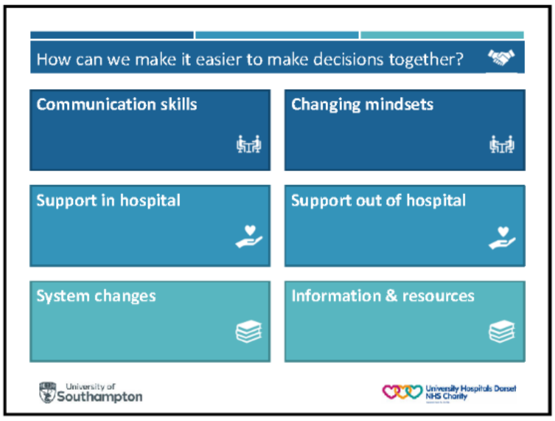

How can we make it easier to make decisions together?

Communication skills

Changing mindsets

Support in hospital

Support out of hospital

System changes

Information & resources

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How can we make it easier to make decisions together?

Discussion

- Would any of these have made it easier to:
  - understand what was going on?
  - get more involved in decisions?
- Do you have any other ideas of what might help?
- What one change could we make to make things easier?

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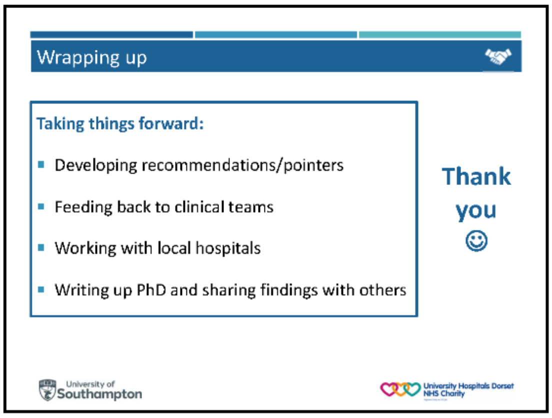

Wrapping up

Taking things forward:

- Developing recommendations/pointers
- Feeding back to clinical teams
- Working with local hospitals
- Writing up PhD and sharing findings with others

Thank you ☺

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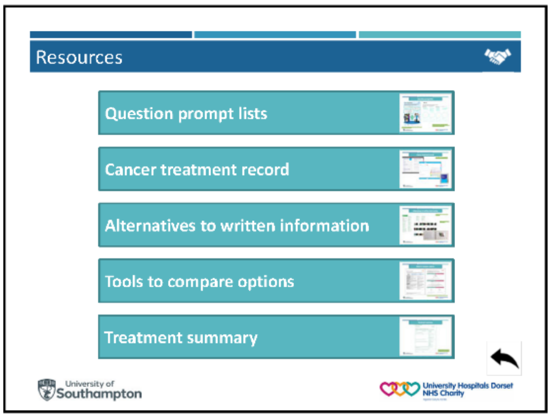

Resources

- Question prompt lists
- Cancer treatment record
- Alternatives to written information
- Tools to compare options
- Treatment summary

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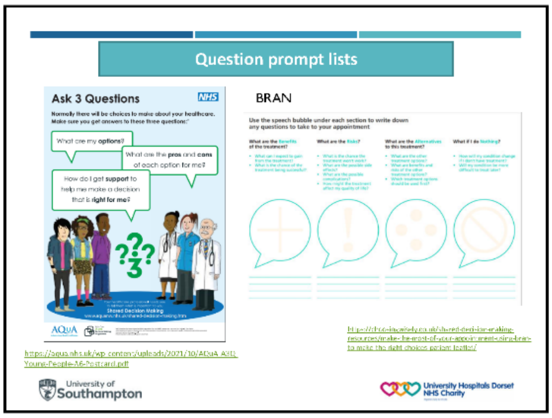

Question prompt lists

Ask 3 Questions

Normally there will be choices to make about your healthcare. Make sure you get answers to these three questions:

https://aqua.nhs.uk/wp-content/uploads/2021/10/AQuA-A3Q-Young-People-A6-Postcard.pdf

BRAN

Use the speech bubble under each section to write down any questions to take to your appointment

https://choosingwisely.co.uk/shared-decision-making-resources/make-the-most-of-your-appointment-using-bran-to-make-the-right-choices-patient-leaflet/

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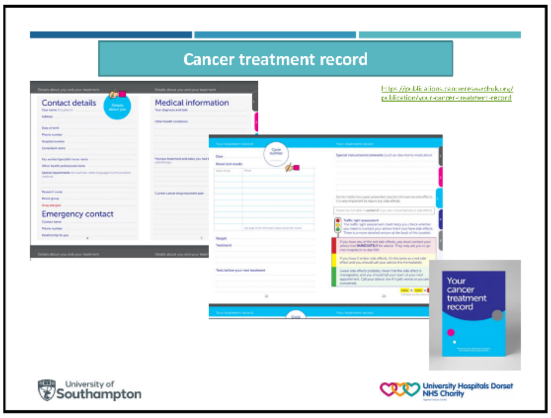

Cancer treatment record

https://publications.cancerresearchuk.org/publication/your-cancer-treatment-record

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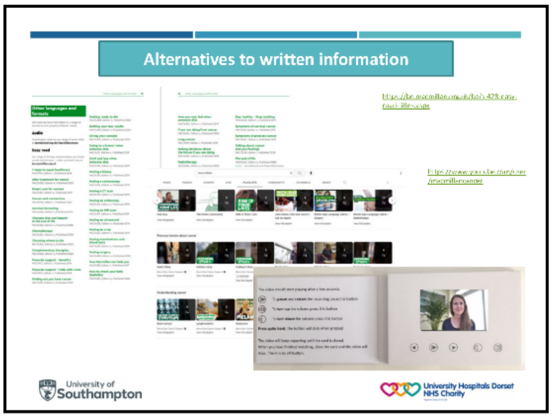

Alternatives to written information

https://be.macmillan.org.uk/be/s-428-easy-read-titles.aspx

https://www.youtube.com/user/macmillancancer

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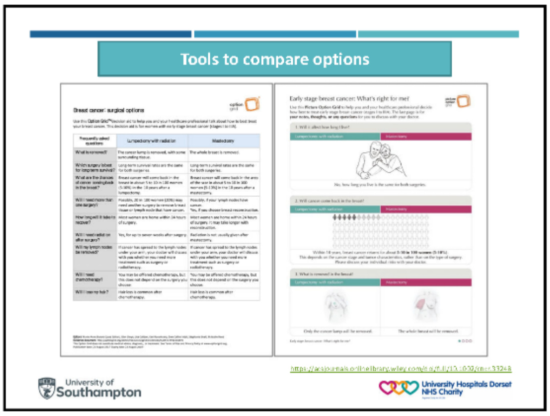

Tools to compare options

https://acsjournals.onlinelibrary.wiley.com/doi/full/10.1002/cncr.33248

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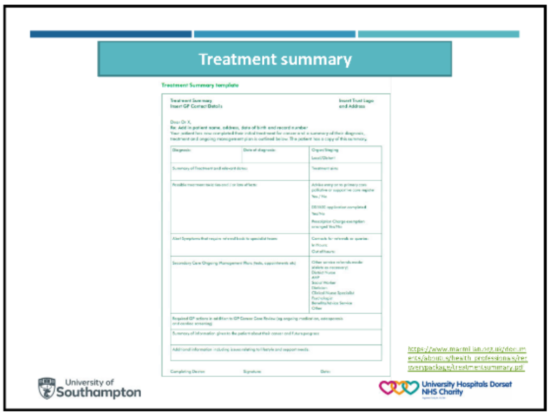

Treatment summary

https://www.macmillan.org.uk/documents/aboutus/health_professionals/recoverypackage/treatmentsummary.pdf

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