

‘Nobody knows *me* better than *me*’

**The development and pilot-testing of a patient-targeted
complex intervention to prepare patients to participate in
shared decision-making**



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Declarations

This work has not been submitted in substance for any other degree or award at this or any other university or place of learning, nor is being submitted concurrently in candidature for any degree or other award.

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Summary of Thesis

Clinicians are ‘medical knowledge experts’ who can use their training, their experience, and evidence based medicine to diagnose and determine healthcare options available to patients, but patients are ‘personal preference experts’. Shared decision-making (SDM) depends on the combination of the different clinician and patient expertise, but to date efforts to increase SDM have largely not addressed how to enable patients to contribute their expertise to the process. The work in this thesis describes the development and pilot-testing of a theory-based intervention, which aims to prepare patients to participate in SDM.

Development and pilot-testing was guided by the MRC’s framework for developing complex interventions. A systematic review revealed patient-reported barriers and facilitators to participating in SDM (key barriers included knowledge and perceived power imbalance) and a literature review found that existing interventions do not sufficiently address patient-reported barriers; thus there was scope to develop on more comprehensive theory-based intervention.

The Behaviour Change Wheel guide was used to develop a theory-based intervention: an 8-page booklet entitled ‘Your Health, Your Choice’. Pre-testing with lay users, clinicians and organisational representatives revealed positive responses to the booklet’s key messages and design. Preliminary pilot-testing in a breast care setting showed evidence of high reach, dose and usage, and potential for the intervention to change patients attitudes towards the patient role in consultations (i.e. *should* patients be involved in SDM). However, the booklet had less impact on patients’ perceptions of whether clinicians want patients to become more involved (i.e. *would* patients be able to become involved.)

Overall, preliminary findings suggest that the intervention could be a useful tool for preparing patients for SDM and for changing patients’ attitudes towards patient involvement. However, preparation for SDM must be followed by enablement by willing and skilled clinicians, and delivered within a supportive organisation.

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Abbreviations

ABUHB	-	Aneurin Bevan University Health Board
AE	-	Adrian Edwards (supervisor)
ASK	-	Ask Share Know
ASSIA	-	Applied Social Science Index and Abstracts
Bar	-	Barriers
BMJ	-	British Medical Journal
CCPP	-	Cancer Consultation Preparation Package
CINAHL	-	Cumulative Index to Nursing and Allied Health Literature
COM-B Model	-	Capability, Opportunity, Motivation – Behaviour Model
CPT	-	Consultation Planning Template
ESRC	-	Economic and Social Research Council
Fac	-	Facilitators
GE	-	Glyn Elwyn (supervisor)
GP	-	General Practitioner
ICCC	-	Intra-cluster correlation coefficient
ISDM	-	International Shared Decision Making Conference
MAGIC	-	Making Good Decisions in Collaboration
MeSH	-	Medical Subject Headings
MRC	-	Medical Research Council
NCN	-	Neighbourhood Care Network

NISCHR CRC	-	National Institute for Social Care and Health Research
NJW	-	Natalie Joseph-Williams (PhD Candidate)
NPT	-	Normalization Process Theory
PAM	-	Patient Activation Measure
PSHE Education	-	Personal, Social, Health and Economic Education
QoL	-	Quality of life
RCT	-	Randomised Controlled Trial
SAIL Databank	-	Secure Anonymised Information Linkage Databank
SDM	-	Shared Decision Making
TDF	-	Theoretical Domains Framework

Chapter 1

‘Nobody knows *me* better than *me*’: Thesis introduction and overview

‘It is much more important to know what sort of a patient has a disease than what sort of a disease a patient has.’

Sir William Osler

Clinicians are ‘medical knowledge experts’ who can use their training, their experience, and evidence based medicine to diagnose and determine healthcare options available to the patient, but patients are ‘personal preference experts’. Shared decision-making (SDM) depends on the combination of the different clinician and patient expertise, but to date efforts to increase SDM have largely not addressed how to enable patients to contribute their expertise to the process. Further, SDM does not appear to be happening routinely in NHS settings in the UK, or anywhere else in the world.

Even as early as the 19th Century, Sir William Osler understood and educated medical students in the importance of understanding the ‘whole patient’. His revolutionary bedside teaching techniques focused on interacting with and ‘knowing the patient’, achieved in part by taking a good history, effective observations of the patient, and asking the patient the right questions. Although he would not have been aware of this at the time, his quote above also underpins the philosophy of SDM. At the simplest level, SDM is defined a process whereby clinicians support patients to make healthcare decisions by providing them with evidence-based information about their options, eliciting and understanding the patient’s personal circumstances and preferences, and making sure that this knowledge is considered when supporting patients to choose from various different healthcare options.(1) If we do not understand what sort of patient we are working with, we will not know that the treatment they receive for their condition is right for them. Unfortunately, many healthcare professionals still focus predominantly on the disease and skills of diagnosis, not on the ‘whole patient’, skills of communication and interaction, or skills of diagnosing preferences.(2)

If understanding the patient and their preferences is key to the success of the SDM process, the same understanding is also essential when we are trying to design the best ways

to implement and support this process. Patients are key partners in SDM - unfortunately, little attention has been paid to what patients think would help or inhibit them from participating in the SDM process during intervention design and implementation. To date, research has focused on understanding and overcoming clinician perceived barriers to SDM implementation, understanding and addressing organisational restraints, and developing information provision tools for patients. This thesis will attempt to address this gap by developing a patient-targeted complex intervention to prepare patients for SDM with clinicians, based primarily on patient-reported barriers and facilitators to engaging with the SDM process.

1.1 From ‘Doctor knows best’ to ‘nobody knows me better than me’

It is evident from Sir William Osler’s quote above that some physicians have long recognised the importance of interacting with patients and understanding the patient as a whole. Despite this, the predominant model for doctor-patient interaction during much of the 20th Century was paternalistic.(3) The paternalistic approach has been classified as ‘activity-passivity’, whereby a clinician does something to the patient who is a passive recipient, and as ‘guidance-co-operation’, whereby a clinician tells the patient what to do, and the patient co-operates, or obeys.(4). The paternalistic model is hierarchical in nature, with the clinician placed in a position of power relative to the patient, and the patient does not challenge this authority. In this scenario, the clinician acts as guardian over the agent, they set the goals and agenda of the consultation, they dominate decision-making, and they assume patients’ preferences; (5, 6) however, it is trusted that the clinician acts on behalf of the patient in their best medical interests.

Medical beneficence remained largely unchallenged for most of the 20th Century, and it is only relatively recently that the principle of patient autonomy has emerged as the dominant ethos in healthcare. We have witnessed a move away from the predominant biomedical model in healthcare, where the focus is on understanding the medical condition or disease, to a patient-centred model, which treats the patient as an individual by considering his or her own ‘biography’.(7) In his book ‘The Lost Art of Healing’, Lown states, ‘medicine is the art of engagement with the human condition rather than with the disease.’(8) He believes the most important art in healing is developing the fundamental relationship

between doctor and patient, and the skill of listening to the patient should not be understated in medical education.

Since the 1960s and 1970s, within the social context of various anti-paternalistic rights movements demanding greater autonomy, patients' rights to autonomy and consent have been recognised.⁽⁹⁾ In the late 1980s, informed medical consent was increasingly being recognised as a legitimate right for all patients, where all patients were legally entitled to receive information about treatment or screening procedures before consenting. Originally, informed consent requirements were primarily concerned with avoiding harm, but more recently they have been concerned with the protection of autonomous patient choice.⁽¹⁰⁾ The Patient's Charter was published in 1991,⁽¹¹⁾ which highlighted several patients' rights in the UK Government's National Health Service (NHS). One of these includes the 'right to be given a clear explanation of any treatment proposed, including risks and any alternatives before you decide whether you will agree to the treatment'. Each nation in the UK also published their own version of the Patient Charter. The Welsh Charter took the promotion of patient autonomy one step further by stating that patients may expect 'to help choose care and treatment' that was appropriate to them. Further, it encourages patients to 'try to be well informed about your health condition' and to 'ask questions so you can make decisions based on better knowledge and understanding'.

The consumerism approach emerged around this time and was strongly advocated throughout health policy. In this approach, the typical power relationship between patients and clinicians is reversed, and the medical encounter is viewed as a marketplace transaction.⁽⁵⁾ In relation to healthcare decision-making, the promotion of consumerism translated to the informative model,⁽⁶⁾ also referred to as the informed decision-making model. ⁽¹²⁾ In short, this interaction involves the clinician providing the patient with all relevant information about their health state and the different options available, the patient making the decision (presumably by also considering their personal values), and the clinician executing the desired course of action. Patient autonomy in this model is conceptualised as the patient having complete control over the decision-making process.⁽⁶⁾ Although the consumerist approach recognises the importance of patients' preferences and autonomy in decision-making, some believed that this approach swung too far in the other direction from paternalism; the informed choice model leaves the clinician outside the decision-making process and limits their role to information transfer.

In response to this, healthcare writers increasingly advocated a model of ‘mutual participation’ in the clinical encounter, where both the clinician and the patient share decision-making responsibility and share power.⁽⁶⁾ This ‘deliberative model’,⁽⁶⁾ or ‘shared decision-making’(SDM) model as it is now widely referred to,⁽¹²⁾ is based on the principles of patient-clinician partnership. Various conceptual models of SDM have emerged over the years:^(1, 6, 12-14) the earliest attempt defines SDM as a process involving at least a clinician and patient, who share information and who jointly engage in the decision-making process to agree on a decision that is consistent with patient’s personal values and preferences.⁽¹²⁾ Elwyn and colleagues have published a model for clinical practice, which outlines three key steps in the SDM process: 1) introducing choice 2) describing options, often by integrating the use of patient decision support, and 3) helping patients explore preferences and make decisions.⁽¹⁾ More recent conceptualisations describe SDM broadly, as a component of patient-centred care; this most accurately reflects my interpretation of SDM throughout this thesis. The model of ‘collaborative deliberation’ describes five propositions for collaborative clinical communication processes: 1) constructive interpersonal engagement; 2) recognition of alternative actions; 3) comparative learning; 4) preference construction and elicitation; 5) preference integration.⁽¹⁵⁾ Fundamentally, all models of SDM recognise that there are two experts in the healthcare consultation: the clinician and the patient. Only when the two types of expertise are combined does SDM truly take place. The shift from paternalism to SDM indicates how we have moved, at least conceptually, from a position where ‘doctor knows best’, to the patient perception that ‘nobody knows me better than me’. Although this conceptual transition has taken place, this thesis will address current deficiencies in realising this in routine practice.

1.2 Supporting patients to participate in SDM – the implementation context

Decision support interventions, also known as decision aids, have been developed to help individuals participate in healthcare decisions that involve weighing the benefits and harms of treatment options, often with scientific uncertainty, or equipoise.⁽¹⁶⁾ They support the SDM process with a clinician by providing patients with information about the health condition, describing the features of the options, the likely outcomes, and supporting the patient to compare the options in relation to their personal values. Pioneer decision aids

appeared around 30 years ago, in the form of consultations structured by decision analysis,(17) preference elicitation techniques,(18) and the more common SDM programmes.(19) Since this time the number of decision support interventions that have been developed has increased exponentially, covering a wide range of formats (e.g. paper, video, web-based, face-to-face) and over 45 clinical decisions.(16)

The Cochrane systematic review of decision aids for patients facing health treatment or screening decisions now includes 115 randomised controlled trials evaluating the effectiveness of decision support interventions.(16) Results show that these tools result in increased knowledge, more accurate risk perceptions, greater congruence between preferences and option chosen, lower decisional conflict, reduced passivity, and greater uptake of conservative treatment options. These tools are widely available, and attempts have been made by various healthcare provider organisations, across the world, to integrate these into routine clinical practice. For example, Health Dialog, the USA based healthcare service provider, has created a suite of decision support interventions that is available to over 13 million of their customers.(20) In the UK, NHS Right Care have over 30 tools available in a web-based format to NHS patients.(21)

In recent years, a supportive policy context has emerged in the UK for the implementation of SDM. Following the formation of the Coalition Government in 2010, patient-centred care was prioritised in healthcare policy reform, and a number of healthcare strategies have outlined their ambitions for more patient-centred healthcare services in the UK (NHS). In 2010, the UK Government published its White Paper 'Equity and Excellence: Liberating the NHS'.(22) They state a number of key aims in relation to placing patients at the heart of the NHS, including giving patients 'access to the information they want, to make choices about their care', and making 'shared decision-making the norm: no decision about me without me'. In 2012, the Health and Social Care Act (England)(23) introduced a duty on commissioners to promote the involvement of patients in decisions about their care and treatment. It is important to note that responsibility for healthcare is devolved to the four nations of the UK, and the strategies discussed relate specifically to England. However, there is evidence that the healthcare reforms established in England are being replicated around the UK, especially with regards to supporting patients with long-term conditions to become more involved in self-management of their condition.(24-26) Further, whilst the policy context in the UK clearly supports the integration of SDM into routine care, at least

at a strategic level, this support is also being demonstrated in other countries, such as the USA(27) and Canada.(28)

In addition to UK healthcare policies promoting SDM, The NHS Constitution(29) sets out what patients, the public and staff can expect from the NHS, and what the NHS expects from them in return. Importantly, it states key rights as a patient of the NHS, which include: the right to make choices about NHS care and to information to support these choices; the right to be involved in discussions and decisions about healthcare, and to be given information to enable you to do this; and the right to be given information about proposed treatments in advance, including any significant risks and any alternative treatments which may be available, and the risks involved in doing nothing. Royal Colleges, such as the Royal College of General Practitioners, the Royal College of Physicians, and the Royal College of Nursing, are also exploring how they can support care planning, self-management and SDM. The General Medical Council, the regulatory body for doctors in the UK, have also stated in their Good Medical Practice Guidelines (2013)(30) the importance of listening to patients' preferences, providing information to patients in a way they can understand, and respecting a patient's right to be involved in the decision process. The National Institute for Health and Care Excellence (NICE) develop quality standards, which are designed to drive measurable quality improvements within specific areas of health or care in the UK. They also publish quality statements, and whilst these are not mandatory indicators with set targets, they still aim to improve quality of care. One of their quality statements is to ensure 'patients are actively involved in shared decision-making and supported by healthcare professionals to make fully informed choices about investigations, treatment and care that reflect what is important to them'. (31) This quality statement is accompanied by various structural, process and outcome measures that can be used to assess quality in this domain.

Significantly, whilst the rationale for doing SDM once rested upon propositions that the approach was ethically correct, it is increasingly being recognised that SDM is also a fundamental component in patient safety. Mulley and colleagues(2) discuss the problem of 'preference misdiagnosis', which occurs when patients are not fully informed about the options available and they would choose a different option should they be informed. They propose that 'preference misdiagnosis' is comparable to the more accepted 'medical misdiagnosis', and make a compelling case for why SDM is essential for providing safe and effective healthcare. Further, SDM has an equally compelling economic imperative. With

constrained resources and healthcare systems reaching a state of ‘allocative efficiency’ (i.e. unable to make someone better off without making someone worse off), SDM has the potential to guide population-level decisions about which services should be commissioned or decommissioned, and which should be increased or decreased.(32)

1.3 Implementation of SDM: have we forgotten that it takes ‘two to tango’?

In the current healthcare climate, very few healthcare workers and policy developers argue against the principle of involving patients in their own healthcare decisions. Recent healthcare policy reforms, outlined above, promote the notion of ‘patients as partners’, and have also provided a more supportive context for those who wish to implement SDM in their organisation. A large number of tools that can help to involve the patient in the SDM process exist, and their effectiveness has been demonstrated repeatedly.(16) Despite this, SDM does not appear to be happening routinely in NHS settings in the UK, or anywhere else in the world.

A key unanswered question was whether decision support interventions (‘tools’) were sufficient on their own to embed SDM into routine clinical care, and to encourage most patients to actively participate in the SDM process. Several implementation projects attempted to address this question, including the UK-based Making Good Decisions in Collaboration (MAGIC) programme.(33) MAGIC was commissioned by The Health Foundation to establish what worked, and what did not work, in embedding SDM into primary and secondary care settings. Using quality improvement methodology,(34) the MAGIC teams in Cardiff (Wales) and Newcastle (England) worked directly with clinical teams across the care spectrum to design and test interventions. These clinical areas included, primary care, breast cancer, head and neck cancer, prostate cancer, maternity, chronic kidney disease, and paediatric ears, nose and throat.

Key learning from the programme emphasised the importance of four broad areas: engagement, training, tools, and measurement / feedback.(33, 35-37) Organisational level engagement is key to driving cultural change. Senior local health organisation members driving SDM as an organisational initiative was important for the MAGIC programme. Senior members included the Chief Executive, the Medical Director, and the Director of

Patient Experience at the Cardiff and Vale University Health Board. Instead of being seen as a University based project that they were being asked, or told, to do, the work was seen as a health organisation programme that fitted in with the organisation's mission statement and objectives. This also reinforced the importance of the work to the clinical teams that were taking part. Clinical team level engagement and support are also critical if the approach is to be adopted and accepted, as is ownership over the interventions that are being used; the teams that are still routinely using the interventions, post-implementation phase, are those that were heavily involved in the initial design and testing. A dedicated SDM facilitator worked directly with the clinical teams, within their clinics, to support and motivate the teams through the SDM implementation process. The teams were involved in intervention conception, design, and testing, using quality improvement methodology.(34)

The SDM skills training package delivered to clinicians was a key driver in changing clinicians' attitudes towards patient involvement, and equipped them to work together with patients. Significantly, it moved a large number of clinicians from saying 'we do this *already*', to saying 'we could do this *better*'. The effectiveness of decision support interventions is well established,(16) but it became clear during the intervention design phase of the MAGIC programme that large, outside-consultation tools, were unlikely to be used by the teams, and questions arose over their ability to affect the discussion between the patient and clinician in a consultation. In response, the team developed brief *in-consultation* tools called Option Grids.(36) These present the key features of the options against the things that matter most to patients; they are designed to support patients to think about their options in relation to their own preferences and to encourage dialogue with the clinician. Finally, routine measurement (Decision Quality Measure) embedded into the teams also motivated clinicians to use the SDM approach, as it gave real-time feedback and enabled them to use the information to directly improve patients' care.

A key learning point from the MAGIC programme was 'skills trump tools, but attitudes trump skills'. In a follow-up paper, Lloyd et al discuss the challenges of changing the team culture and the clinicians' attitudes.(35) This showed that skills training and decision support tools were important interventions, but if you cannot change the attitudes of the individuals who are delivering the approach, SDM is unlikely to become embedded, or sustained, routinely. It is clear that this implementation programme invested a huge amount of energy in trying to understand the clinician and organisational barriers, and developing interventions that address these. However, this, and other, implementation programmes

have paid little attention to what patients' feel helps or stops them from being involved in healthcare decisions.

There is good evidence that patients' attitudinal barriers are hindering progress in implementing SDM, and this is a further crucial barrier yet to be overcome. Even when patients are well educated and well informed, many still find it difficult to use this knowledge to participate meaningfully in decisions about their healthcare.(38) The Francis report into failings at Mid Staffordshire Trust revealed that patients often feel prohibited from speaking up, even when they are extremely concerned about safety or the quality of care they are receiving.(39) Online blogs, publications, and social media campaigns (such as #hellomynameis)(40) show that even doctors are not immune to the power imbalance when they become patients, feeling that they represent a disease rather than that they are an individual, and aware of a pressure to be compliant and passive.(40-42) How then can we expect people to express their preferences about treatment options—especially when they often observe doctors assuming that they can act in their best interests, displaying unquestioned confidence?

To exemplify the importance of addressing patients' attitudes, in addition to clinicians' attitudes and organisational barriers: a decision support tool could exist for every clinical decision, in a variety of accessible formats; a SDM discussion could be initiated in every relevant consultation by a clinician who is receptive to the approach, who has undergone the relevant skills training, and has access to these decision support tools; and the clinician initiating SDM could work in an organisation that fully endorses the implementation of SDM, by aligning incentives to this approach and ensuring structural barriers are minimal e.g. sufficient time available in the consultation for this process. However, if the patient has long-standing beliefs, based on experiential experience and perceived social norms, that 'doctor knows best' and that it is not part of a patients' role to become involved in their healthcare decisions, then it will be difficult to engage that patient in the decision-making process. It is likely that many patients will still defer the decision-making to the perceived 'expert'; the clinician. The information that the patient is given might increase their knowledge about their options, but if they do not value the expertise that they bring to the decision process and believe they can become involved in making the decision, true SDM is unlikely to take place; instead the process will resemble information transfer.

Various models propose that health literacy is an action-orientated concept, whereby it is both a process and an outcome.(43, 44) The Health Literacy Pathway Model(43) describes

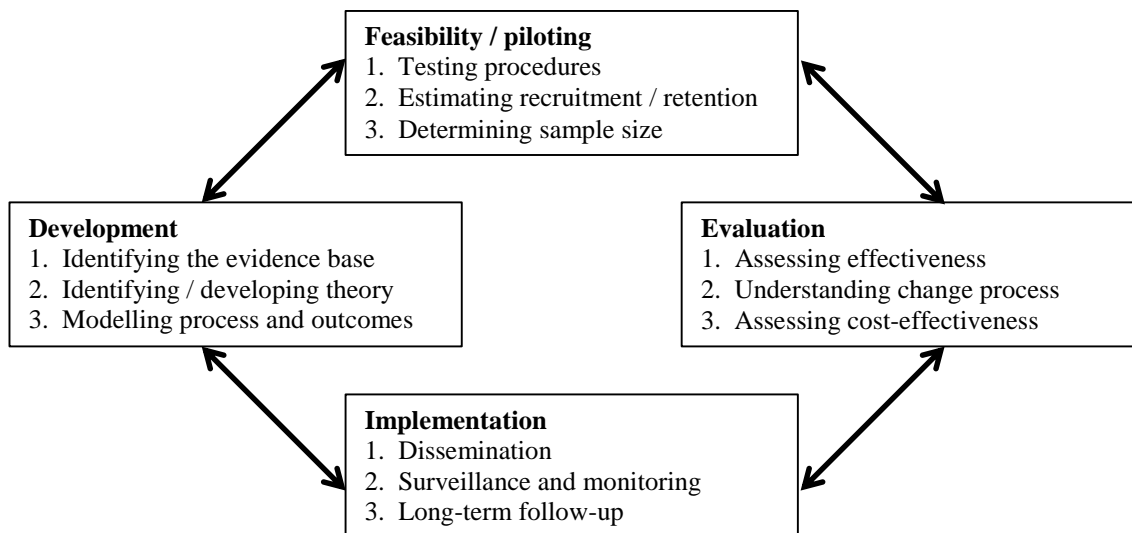
how health literacy develops in patients over time, moving along a trajectory from becoming informed about their condition, learning skills to become more involved, toward a point where they become active partners in decision-making process. As patients move through this pathway, they also become more empowered. In parallel with the Health Literacy Pathway Model,⁽⁴³⁾ SDM could be seen as a skill that develops, rather than an intellectual capability. Patients will become informed about their own specific health condition and their options (via information provision, verbal or decision support interventions), they will be supported by a clinician to become involved in the process and to develop the skills to do so (by considering personal preferences in relation to their options), and they will then actively participate in the decision-making process. However, I propose that the first essential step in this iterative process is to become aware of what SDM is, and what the process involves. This is just as important as, and should precede, information provision about treatment options and deliberation, as outlined in the SDM model for clinical practice.⁽¹⁾ If the patient does not understand what it means to be involved in SDM, and does not accept this approach (e.g. due to perceived social norms about involvement), the latter stages of information provision, preference elicitation, and active involvement in decision-making are unlikely to take place, or be effective in supporting SDM in that person.

Research suggests that patients with limited health literacy might become ‘disempowered’ in a consultation;⁽⁴³⁾ the same might be true for patients with limited understanding of the SDM process. If we offer the opportunity to become involved in SDM during a healthcare consultation, without preparation, this affords little time for attitudinal change among patients who believe that a paternalistic approach is ‘normal’; in other words, patients are being ‘thrown in at the deep end’. If the patient-perceived barriers are not also considered during SDM intervention development and implementation, it is unlikely to become the norm for most patients, or an approach that becomes embedded into the fabric of healthcare organisations. This thesis aims to understand patient-perceived barriers, and to develop an intervention that addresses these.

1.4 Developing and evaluating theory-based complex interventions

The Medical Research Council (MRC) has produced detailed guidance for the development of complex interventions.(45) This framework will be used to guide the development and feasibility testing of the intervention that will be described during this thesis. A complex intervention is defined as having several interacting components; complexity might relate to the range of possible outcomes, their variability in the target population, or the number of elements in the intervention package. The framework outlines four key stages involved in the systematic development – evaluation – implementation process of a complex intervention. The key stages of include: (1) development; (2) feasibility / piloting; (3) evaluation; and (4) implementation (see Figure 1.1 for further detail). The developers highlight the interactions between the stages and point out that the process will unlikely be linear in nature.

Figure 1.1 Key stages of the MRC framework for developing complex interventions



Adapted from Craig et al(45)

This thesis will focus on the development stage (Chapters 2, 3, 4, and 5) and the feasibility / piloting stage of the framework (Chapter 6). Each stage is described in more detail in the relevant thesis chapters. Recently, the MRC published guidelines for process evaluations of complex interventions.(46) A process evaluation is defined as a study that aims to

understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors. The MRC process evaluation framework was used to guide the feasibility / piloting stage (see Chapter 6).

1.5 Thesis aims and objectives

The aim of this thesis is to develop and pilot-test a patient-targeted complex intervention designed to prepare patients for SDM with clinicians, using the MRC frameworks for developing and evaluating complex interventions.(45, 46) The objectives of this thesis are:

1. Identify and describe patient reported barriers to participating in SDM with clinicians
2. Identify previously developed interventions that aim to prepare patients for SDM and evaluate if they address patient-reported barriers and facilitators
3. Develop a theory-based intervention designed to prepare patients for SDM using the Behaviour Change Wheel (BCW) Guide(47) and the MRC Framework for developing complex interventions(45)
4. Pre-test the prototype intervention with lay users and clinicians / organisational representatives
5. Pilot-test the intervention in a Breast Care Centre to assess the potential impact of the intervention, using a process evaluation method(46)

1.6 Thesis overview

This thesis contains seven further chapters. With the exception of Chapters 7 and 8, each chapter contains four main sections: background, methods, results, and discussion.

Chapter 2 – Patient reported barriers and facilitators to shared decision-making: a systematic review and thematic synthesis

The first key step in developing a complex intervention is to identify the evidence base. Chapter 2 systematically reviews patient-reported barriers and facilitators to patient

involvement in healthcare decisions. A thematic synthesis identified key barriers and facilitators that will need to be addressed by the patient-targeted complex intervention. A taxonomy of patient-reported barriers and facilitators is presented.

Chapter 3 - A review and critical evaluation of patient-targeted interventions designed to prepare patients for SDM: do they address patient-reported barriers and facilitators?

Chapter 3 builds on the evidence base from Chapter 2. It presents a literature review of existing interventions that aim to prepare patients for SDM. The included interventions were evaluated to determine if they address the key patient-reported barriers and facilitators identified in Chapter 2.

Chapter 4 – Using the Behaviour Change Wheel Guide to develop a patient-targeted intervention designed to prepare patients for shared decision-making

The next stage in developing a complex intervention is to identify appropriate theory. Chapter 4 describes the development of a theory-based intervention that aims to prepare patients to participate in SDM. It outlines the stages of the BCW Guide(47) that guided the development of the intervention. The resultant prototype intervention is an 8-page booklet entitled, ‘Your Health, Your Choice’.

Chapter 5 – Pre-testing the prototype ‘Your Health, Your Choice’ intervention with patients and clinicians: a qualitative study

Chapter 5 presents the results of the pre-testing qualitative study. Following the development of the prototype booklet, interviews were conducted with lay users and healthcare representatives (clinicians / organisational representatives) to assess reactions to the booklet’s content, design, readability, usability, and implementation. The results informed refinements to the booklet and implementation process that was used during the pilot-testing (Chapter 6).

Chapter 6 – Pilot-testing the ‘Your Health, Your Choice’ intervention: a process evaluation

Chapter 6 presents the pilot-testing of the ‘Your Health, Your Choice’ intervention, using a process evaluation method. The pilot-testing was conducted with women who had been referred to the Cardiff and Vale University Health Board Breast Care Centre.

Chapter 7 – Further research plans

Chapter 7 presents further research proposals that have arisen from the work that has been completed in Chapters 2 through 6, which are beyond the remit of this thesis. Several proposals are presented relating to the further development and evaluation of the ‘Your Health, Your Choice’ intervention. This culminates with the key research proposal; a cluster-randomised controlled trial and process evaluation of the ‘Your Health, Your Choice’ intervention, embedded in a SDM clinical pathway.

Chapter 8 – General discussion

Chapter 8 presents an overview of the thesis including a summary of key findings, a discussion of the strengths and weaknesses, and the clinical implications of the work.

Chapter 2

Patient-reported barriers and facilitators to SDM: a systematic review and thematic synthesis

*'Let me repeat: **choosing what risks to take is not a medical decision.** You will be qualified to make choices about how you wish to face these risks. After all, it is you who, for better or worse, will be cured, become sicker and suffer side effects...That decision should be the patients' choice because the trade-offs are personal value judgments, NOT medical science. All medicine can do is tell us the numbers – probabilities – but to make the choice is the patient's right.'*

Stephen H. Schneider, cancer patient, extract from 'The Patient From Hell' (2006)

In the field of medical shared decision-making (SDM), Mr Schneider might be considered the 'ideal patient'. He recognises that there is uncertainty surrounding different treatment options and that the patient plays a critical role in deciding which risks are acceptable to them. Most importantly, he acknowledges the valuable expertise that a patient can contribute to the discussion of treatment options: knowledge about their own body and mind; awareness of their current and future personal circumstances; their personal and family's values. Medical experts can use their training, experience, and evidence based knowledge to present the options that are appropriate to the patient, and the possible outcomes of those options. However, medical expertise must be considered in conjunction with personal expertise to ensure that patients' decisions are truly informed. But what does it take to get to this point: years of experience; adequate information provision; high levels of self-efficacy; supportive medical staff who encourage patient participation? The aim of this chapter is to systematically review and thematically synthesise those factors that prohibit or enable patients to become more involved in their healthcare decisions, in order to inform the development of a complex intervention to support this behaviour.

2.1 Introduction

SDM is viewed as fundamental to safe and effective healthcare. (2) *'No decision about me without me'*(22, 48) encapsulates the ambition of a more patient-centred healthcare system, and policies that support this ambition are emerging in the UK(23, 49, 50) and elsewhere,(51-54) but it is yet to be realised routinely in healthcare settings. Sufficient background work has assessed clinician-reported barriers and facilitators to implementing SDM,(55-58) and recent implementation studies report some successes, but implementation efforts still face considerable difficulties.(33, 59) Much of the implementation work to date is driven by a focus on embedding decision support tools into clinical pathways and the distribution of these tools (60-64), and considering factors that affect clinician (57, 65, 66) and organisational buy-in.(64) Surprisingly, implementation work has not considered the patient perspective in any detail. This review examines what patients think helps or hinders them from being involved in making healthcare decisions.

The relative lack of attention afforded to the patient perspective in implementation work does not mean that these data are not available. An initial search of the literature indicates that many studies have attempted to understand the factors that promote or hinder patients becoming more involved in healthcare discussions.(38, 67-69) What has not been achieved to date is a comprehensive synthesis of the data arising from these studies, many of which are qualitative, which could be used to complement the well-cited taxonomy of barriers and facilitators from the clinicians' perspective.(57) As discussed, much of the implementation work in this field has focused on understanding and overcoming clinician and organisational barriers to SDM, and whilst this work is also critically important, SDM is unlikely to become widespread and sustainable in practice, or the 'norm' in healthcare, if we do not also address the patient-reported barriers.

To exemplify this point: a decision support tool could exist for every decision, in a variety of accessible formats; a SDM discussion could be initiated in every relevant consultation by a clinician who has undergone the relevant skills training and has access to these decision support tools; and the organisation could fully endorse the implementation of SDM by aligning incentives and ensuring structural barriers are minimal e.g. time available in consultations for the process. However, if these interventions/initiatives do not address the patient perceived barriers, whether these are experienced or anticipated, the promotion of

patients being actively involved in their healthcare decisions will still not be an accepted practice that becomes embedded into the fabric of healthcare organisations.

Referring back to our ‘ideal patient’, Mr Schneider, we would anticipate that there are many barriers that need to be addressed in order to enable other patients to adopt this viewpoint. The fact that Mr Schneider refers to himself as ‘*the patient from hell*’, because of his desire and ability to be involved in his healthcare discussions, suggests that patients believe the active patient role is somewhat frowned upon by the medical profession. It also emphasises the potentially powerful influence of long-standing cultural beliefs of what behaviour is appropriate in the doctor-patient interaction. Further anecdotal evidence from working in this field also highlights patients’ fears of being involved: ‘I don’t want my card marked as one to *them* patients’ (Diabetes patient, 60+ years, personal correspondence). All of the enabling factors listed above could be in place, but if patients feel that they do not have permission to be involved, or should not be involved, changing clinicians’ attitudes and decision support provision alone is not going to result in the attitudinal and behavioural change needed to engage these patients in SDM.

A critical first step in developing a complex intervention is to understand the audience that you are targeting and those factors that might impact, positively or negatively, on achieving the desired behaviour.⁽⁴⁵⁾ The key aim of the complex intervention being developed in this thesis is to increase active patient participation in the decision-making process during their healthcare consultations. When I refer to active patient participation in healthcare decisions, I do not refer simply to the receipt of a SDM tool such as a decision aid; I refer to a demonstrable impact on the decision-making *dialogue* between the patient and the clinician during a healthcare consultation. As such, a necessary step in the intervention development is to understand patients’ motivations for actively taking part in SDM discussions with their clinician, and the factors that prevent them from so doing.

Previous reviews have identified the factors that might influence patients’ preferences for involvement in medical decision-making.⁽⁷⁰⁾ However, most studies included in this review are based on univariate and multivariate associations between patient characteristics (e.g. age, education, prognosis, coping style) and desired levels of involvement. Thus, most studies are not based on the actual views of patients. Benbassat and colleagues⁽⁷¹⁾ reported that demographic and personal characteristics such as age, illness severity, education and gender, only explain 20% or less of the variability in preferences. This supports the need to examine factors that might influence patient involvement through direct enquiry with

patients. It is likely that there will be some overlap between the factors used in correlational analyses and the patient-reported factors, but direct enquiry will allow us to examine why the particular factor is viewed as a facilitator or barrier by the patient. Further, whilst the previous review(70) provides useful insight into factors affecting the desire to be involved, preference is a precursor to involvement; this current review aims to build on previous work by also assessing those factors that affect actual involvement.

The aim of this chapter is to systematically review and thematically synthesise patient-reported barriers and facilitators to SDM and to develop a taxonomy of patient-reported barriers that could be considered during theory-based intervention development and implementation work. These data will be considered against the clinician-reported data, and both will form part of the theoretical foundation for intervention development (see Chapter 4).

2.2 Methods

2.2.1 Search strategies

To identify patient-reported barriers and facilitators to SDM, a systematic literature review was conducted. Nine electronic databases were searched (from database inception), with no language restrictions: ASSIA (1987>); CINAHL (1982>); British Nursing Index (1985>); Embase (1947>); Medline (1946>); Medline in Process; PsycINFO (1806>); Scopus (1966>); Web of Knowledge (1981>). Search strategies used a combination of free-text words and MeSH (Medical Subject Headings), or database equivalent, derived from the following broad topic areas: decision-making; barriers/facilitators; patient-reported. Free text words and MeSH used in the Medline search strategy were modified to search the remaining bibliographic databases (Search strategies for all electronic databases can be viewed in Additional Appendix 2.1 on included CD).

Follow-up searches included manual searches of the reference lists of papers included for full text analysis (see Figure 2.1) and of the contents lists of the most frequently cited journals of these papers (Health Expectations, Journal of General Internal Medicine, Patient Education and Counselling, and Social Science and Medicine). To ensure a thorough review of the field, including in-press articles, authors/researchers in the field of

SDM were contacted via known interest groups (e.g. Facebook, SDM listserv) and personal email to identify completed and on-going work.

2.2.2 Selection criteria

A study was eligible for inclusion in the review if: (i) it reports empirical data; (ii) participants were patients (or patient data could be separated from other types of participants e.g. clinicians); (iii) it reported patients' perceptions (barriers/facilitators, attitudes, experiences/expectations, preferences) of their involvement in decision-making about their healthcare (more general) or involvement in the decision-making process during a healthcare consultation (more specific); (iv) results were based on direct enquiry with patients (patient-reported); (v) published in a peer reviewed journal. The term patient is used to refer to anyone who is a potential recipient of healthcare; they do not have to be currently undergoing treatment/management or in the process of making a decision about their healthcare.

Studies were excluded if their results focused *solely* on any of the following: (i) factors that influence preferences for involvement in decision-making, rather than actual involvement; (ii) hypothetical scenarios/simulated patients; (iii) patient-reported barriers to involvement in other aspects of their healthcare (e.g. participation in clinical trials, health service planning, adherence to medication/treatment, daily care activities), or involvement in someone else's healthcare decision-making (unless they are the surrogate decision maker); (iv) outcomes of decision support interventions, without direct enquiry of the value of the intervention in facilitating SDM (e.g. studies that correlate use of decision support tools with increased self-reported involvement in decision-making). If the results presented in exclusion criteria (i)-(iv) formed only part of the overall data presented, and these data could be differentiated from data that were of interest to this study (see inclusion criteria), the study was included, but only data relevant to inclusion criteria were extracted.

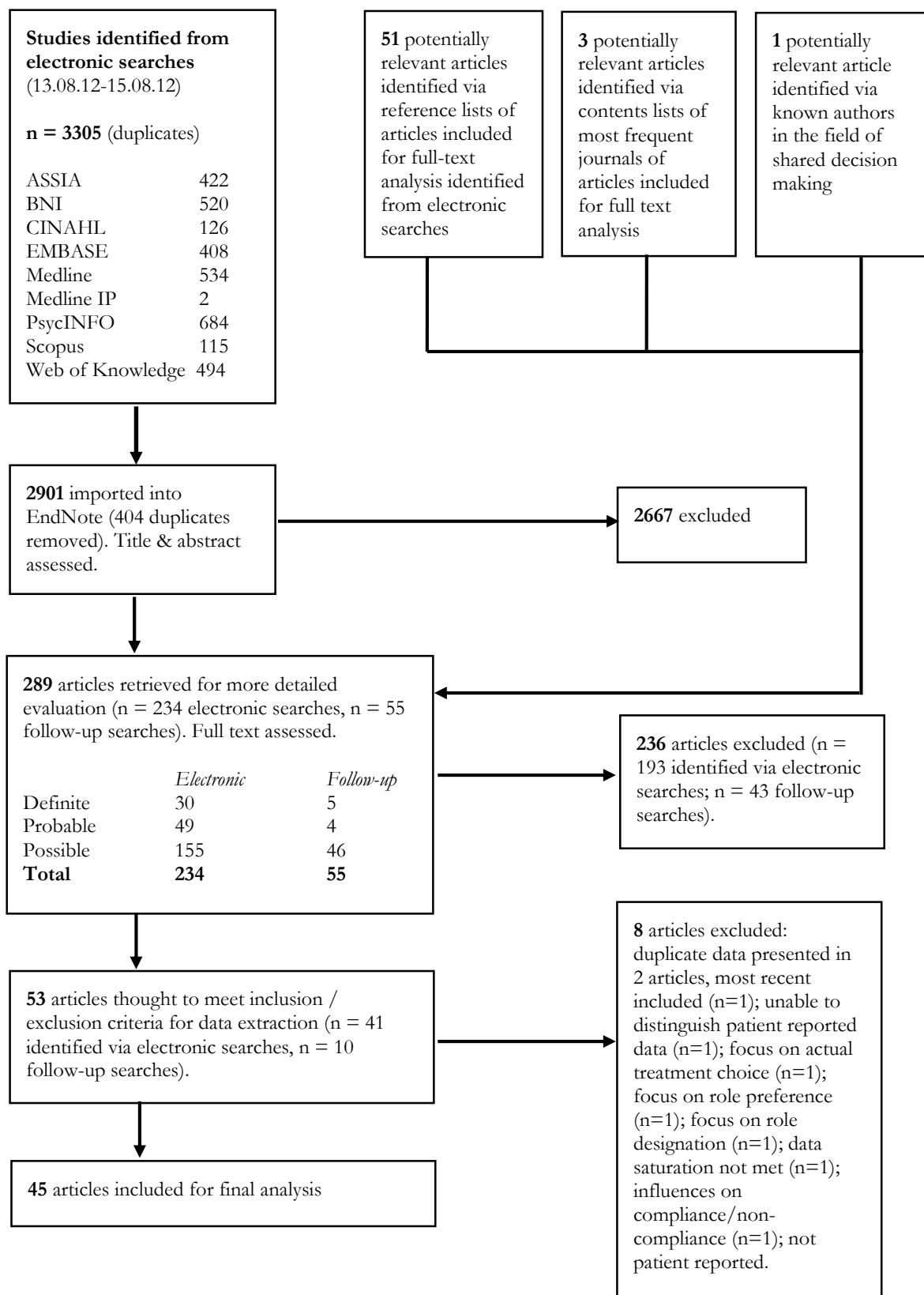
Studies were not excluded on the basis of their design, method, language or principal aim. Thus, all studies that could provide usable data to make a judgment of patient perceived barriers and facilitators to SDM were included, regardless of whether this was the principal aim. When the same data from a single study was described in more than one publication, the most recent publication was included. When new and complementary data from a single study were described in more than one publication, all publications were included.

2.2.3 Study identification and data extraction

The title and abstract of all references identified were screened for relevance. Full text articles of potentially relevant studies were obtained for detailed evaluation. Relevant information for data extraction was agreed and data extraction forms were piloted. Data were extracted under the following headings for all studies meeting the inclusion criteria: study characteristics (first author, year, title, publication details, country, language, principal aim, study design, methodological approach, data collection methods); participant characteristics (number, population, patient status, participant recruitment, inclusion/exclusion criteria, demographics, response rate); study context (setting, health condition, specific decision considered, based on self/surrogate and experiential/anticipated decision-making); operationalisation of healthcare involvement; theoretical base/conceptual framework used to assess barriers/facilitators; summary of main findings.

Study findings/results for each included paper were extracted verbatim and entered into QSR International's NVivo 10 software.⁽⁷²⁾ To our knowledge, there is no taxonomy of assessing patient-reported barriers/facilitators to involvement in SDM. As such, we conducted inductive thematic synthesis and did not use a priori codes. Additionally, we did not restrict our assessment to those barriers/facilitators explicitly identified by study authors. Data were examined independently and a judgment was made regarding aspects of the patient-reported data that could provide insights into the barriers and facilitators encountered, or perceived, by patients. Thematic synthesis⁽⁷³⁾ was conducted by two independent reviewers (NJW and AE or GE) to identify consistent codes across the studies. Discrepancies between coders were resolved during iterative discussions, or with a third reviewer. Most salient codes, descriptions, and the relationships between them were identified and aggregated into descriptive themes, followed by analytical themes. Descriptive data regarding the frequency of codes across the studies were also recorded.

Figure 2.1 - Flowchart of progress through the systematic review



2.3 Results

2.3.1 Included studies

Electronic and follow-up searches yielded 2956 unique references; 289 full-text articles were retrieved for detailed evaluation. Forty-five articles from 44 unique studies met inclusion criteria. Two articles presenting additional, but distinct data were from the same study;(74, 75) data were extracted from each article. Figure 2.1 describes the progress through the systematic review, including details of electronic database search outputs, articles identified via follow-up searches, the stages at which articles identified were assessed (title and abstract, full text) and excluded or underwent data extraction, and the final articles included in the analysis.

2.3.2 Study characteristics

Study characteristics are presented in Table 2.1. All studies were published in English. Studies originated from 15 different countries (in order of frequency; alphabetically): UK,(68, 76-87) USA,(8, 38, 74, 75, 88-93) Sweden,(69, 94-98) Canada,(99-101) Australia,(102, 103) Iran,(104, 105) Belgium,(106) China,(107) Finland,(108) Germany,(109) Indonesia,(110) Japan,(111) Norway,(112) South Korea,(113) The Netherlands(92, 114); one study was conducted in The Netherlands and the USA.(92) One study recruited patients from 11 European countries (Austria, Belgium, Denmark, France, Germany, Israel, The Netherlands, Portugal, Slovenia, Switzerland, UK).(106) This means the data set reports views of patients from a total of 22 different countries. The earliest published study was 1994;(76) 70% of studies were published between 2005 and 2012.

Study designs and data collection methods for each article can be viewed in Table 2.1. The most common study method was qualitative (n=38),(8, 38, 67-69, 74-91, 93-95, 97-103, 105, 106, 108-112, 114) followed by quantitative (n=5)(92, 96, 104, 107, 113); no studies identified barriers/facilitators using a mixed-methods design. Nine studies also included clinicians in the sample,(8, 90, 93, 100, 105, 107, 110, 113, 114) but patient-reported data were analysed separately.

Table 2.1 - Description of included articles that identified barriers / facilitators (n=45)

First author, Year of publication, Country of origin, Citation	Principal objective of the study	Reporting focus (barriers and/or facilitators)	Operationalization of involvement	Conceptual framework for barriers/facilitators assessment	Design/methods of study within which barriers and facilitators elicited	Setting(s) Health condition(s)	Participant characteristics
Aasen, 2011, Norway (112)	To explore how elderly patients with end-stage renal disease who are undergoing treatment with haemodialysis perceive patient participation in a dialysis unit.	Facilitators	Participation in the healthcare decision-making process.	Yes(84)	Cross-sectional. Qualitative. Semi-structured interviews.	Secondary care, outpatient. End Stage Renal Disease.	11 patients. 64% male, 36% female. Age range 74-90.
Adler, 1998, USA(88)	To focus on aspects of patient behaviour, specifically assertiveness, to examine how they influence patient-physician communication.	Barriers & facilitators	Patient-physician communication and patient activation.	No	Cross-sectional, Qualitative, Focus groups (n=4).	Secondary care, outpatient. Breast cancer.	29 female patients. Age range 63-85.
Agard, 2004, Sweden(94)	Explore patients' knowledge of heart failure and their attitudes toward medical information (prognostic information in particular) and to assess different patient-related factors that might hamper the improvement of patient's knowledge.	Barriers	Information disclosure to patients.	No	Cross-sectional. Qualitative. Semi-structured interviews.	Secondary care, outpatient. Chronic heart failure.	40 patients. 62% male, 38% female. Age range 60-80 (75 mean).
Anoosheh, 2009, Iran(104)	To investigate nurse-patient and environment-related communication barriers perceived by patients and nurses in Iranian nursing.	Barriers	Communication between nurses and patients. Communication is the application of words and conduct for making, transmitting and interpreting messages. Communication involves an interaction between the speaker and subject, and the environment influences this process. These three factors co-influence the communication outcome, and any barriers to them can result in ineffective communication.	Pos	Cross-sectional. Quantitative. Self-administered questionnaire/ investigator administered questionnaire.	Secondary care, inpatient. No specific health condition.	61 patients. 48% male, 52% female. Age not reported.
Avis, 1994, UK(76)	Examine the patients' perspective on making choices about treatment in a day surgical unit through the use of qualitative methods.	Barriers	Patient participation and making choices about treatment.	No	Cross-sectional. Qualitative. a) Observations b) Interviews	Secondary care, inpatient & outpatient. Hernia repair.	20 patients. Age range 15-70. a) 12 male patients b) 10 patients. 90% male, 10% female.

First author, Year of publication, Country of origin, Citation	Principal objective of the study	Reporting focus (barriers and/or facilitators)	Operationalization of involvement	Conceptual framework for barriers/facilitators assessment	Design/methods of study within which barriers and facilitators elicited	Setting(s) Health condition(s)	Participant characteristics
Barnard, 2007, UK(77)	To assess whether using a computerised touch screen assessment tool before outpatient consultation makes patients more active in consultations.	Barriers & facilitators	Patient centred care: eliciting the patients' concerns and activating the patient to contribute more to the consultation [using interactive education].	No	Cross-sectional. Qualitative. Self-administered questionnaire (open-ended questions).	Secondary care, outpatient. Diabetes.	53 patients. No further details reported for sub-set of patients who completed open-ended questions.
Bastiaens, 2007, Belgium* (106)	Explore the views of people aged over 70 years on involvement in their primary health care in 11 different European countries.	Barriers & facilitators	Patient involvement: enabling people to take an active role in deciding about and planning their care.	No	Cross-sectional. Qualitative. Semi-structured interviews.	Primary care. No specific health condition.	406 patients. 45% male, 55% female. Age range 70-96 (79 mean).
Beaver, 2005, UK(87)	To explore patient views on participation in treatment, physical care and psychological care decisions and factors that facilitate and hinder patients from making decisions.	Barriers & facilitators	Shared decision-making – participation in treatment decisions and care decisions.	No	Cross-sectional. Qualitative. Semi-structured interviews.	Secondary care. Colorectal cancer.	41 patients. 46% male, 54% female. Age range 37-84 years (62 mean).
Belcher, 2005, USA(89)	To explore views of older adults regarding participation in medication decision-making.	Barriers & facilitators	SDM is a model for the way in which the physician and patient participate in treatment decision-making. One of the core assumptions of this model is that the patient brings to the decision information that the physician cannot know without engaging the patient in the decision-making process. In this model, the physician and patient share information with each other. The physician provides information, or acknowledges uncertainty, regarding the harms and benefits of available treatment options and the patient provides information regarding beliefs and preferences; both	Pos	Cross-sectional. Qualitative. Semi-structured interviews.	Primary & community care. Multiple chronic conditions.	51 patients. 37% male, 63% female. Age range 65-89.

* Lead author from Belgium. Study recruited participants from 11 countries: Austria, Belgium, Denmark, France, Germany, Israel, The Netherlands, Portugal, Slovenia, Switzerland, UK

First author, Year of publication, Country of origin, Citation	Principal objective of the study	Reporting focus (barriers and/or facilitators)	Operationalization of involvement	Conceptual framework for barriers/facilitators assessment	Design/methods of study within which barriers and facilitators elicited	Setting(s) Health condition(s)	Participant characteristics
			participate in the decision-making process, although in different aspects.				
Bhavani, 2009, UK(68)	To examine patients' views about a variety of decision aids for different conditions (heart disease, osteoporosis, osteoarthritis and breast cancer) in order to inform a strategy to introduce them into general practice.	Barriers	Patient decision aids are interventions designed to help those people facing treatment or screening decisions make choices by providing information on the management options available and the possible health outcomes.	No	Cross-sectional. Qualitative. Focus groups (n=12).	Primary care. Heart disease and stroke, osteoarthritis, osteoporosis & breast cancer.	77 patients. 19% male, 81% female. Age range 42-83 (66 mean).
Caress, 2002, UK(79)	To explore preferred treatment decision-making roles, and rationales for role preference, and to identify perceived facilitators and barriers to attaining preferred role.	Barriers & facilitators	Participation in treatment decision-making.	No	Cross-sectional. Qualitative. Semi-structured interviews.	Primary & secondary care. Asthma.	32 patients. 53% male, 47% female. Age range 18-84 (47 mean).
Caress, 2005, UK(78)	Explore preferred and perceived levels of involvement in treatment decisions, rationales for role preference, perceived facilitators/barriers to involvement and the interrelationship of role preference and demographic variables in a sample of patients with asthma.	Barriers & facilitators	Participation in treatment decision-making.	No	Cross-sectional. Qualitative. Structured interviews.	Primary care & secondary care. Asthma.	230 patients. 42% male, 58% female. Age range 19-94 (52 mean).
Charles, 1998, Canada(99)	Exploratory study focusing on three related issues: 1) the extent to which women with early stage breast cancer perceived they had treatment options; 2) their understanding of the risks and benefits associated with different treatment options, and 3) the role they wanted for themselves and for their oncologists in the treatment decision-making process.	Barriers & facilitators	Patient participation in treatment decision-making: patients' being provided with information about their disease and treatment options, as well as opportunities to actively participate in treatment decision-making.	No	Cross-sectional case study. Qualitative. Interviews.	Secondary care. Early stage breast cancer.	20 female patients. Age range 42-78 (56 mean).
Claramita, 2011, Indonesia (110)	Explore the perceived ideal communication style for doctor-patient consultations and the reality of actual practice in a Southeast Asian context.	Barriers	The informed and SDM between doctors and patients is the substantial issue in the ideal style.	No	Cross-sectional. Qualitative. Interviews.	Primary, secondary and community care.	16 patients. No further details reported.

First author, Year of publication, Country of origin, Citation	Principal objective of the study	Reporting focus (barriers and/or facilitators)	Operationalization of involvement	Conceptual framework for barriers/facilitators assessment	Design/methods of study within which barriers and facilitators elicited	Setting(s) Health condition(s)	Participant characteristics
						Various medical conditions.	
Clover, 2004, Australia (102)	Explore patients' understanding of their discussions about end-of-life care with nurses in a palliative care setting.	Barriers & facilitators	Patient participation in discussions about end of life care and negotiation of preferences.	No	Cross-sectional. Qualitative. Interviews.	Secondary care, inpatient. Terminal illness.	11 patients. 64% male, 36% female. Age range 57-85 (74 mean).
Cohen, 2003, UK(80)	To gain an in depth understanding of the perspectives of men recently diagnosed with localised prostate cancer, and to explore the value of decision-making models in the setting of NHS practice.	Barriers	SDM: interchange of both information and attitudes between both parties.	No	Before and after. Qualitative. Semi-structured interviews.	Primary & secondary care. Localised prostate cancer.	19 male patients. Age range 58-88.
Curtis, 1997, USA(90)	Identify barriers and facilitators to communication about end-of-life care for patients with AIDS and their physicians.	Barriers & facilitators	Patient-physician communication about end-of-life care.	No	Cross-sectional. Qualitative. Focus groups (n=6).	Community care. AIDS.	47 patients. 66% male, 34% female. Age range 23-58 (38 median).
Decker, 2007, USA(91)	Describe cardiac patients' preferences for involvement in decision-making, and their informational needs, in the context of the myocardial infarction event continuum.	Barriers & facilitators	Two theories prevail in the patient involvement literature – SDM and informed choice. SDM is the more popular model and involves the patient and clinician 'sharing' in the decision-making process as opposed to decisions being made by the clinician only (paternalistic model) or the patient only (informed patient model).	Pos	Cross-sectional. Qualitative. Focus groups.	Secondary care. Myocardial infarction.	19 patients. 79% male, 21% female. Age range 38-70 (61 mean males; 44.5 mean females)
Doherty, 2005, UK(81)	To identify what involvement patients want in clinical decision-making and explore the underlying factors influencing that choice, thus identifying aids and barriers to increasing patients' involvement in decision-making.	Barriers & facilitators	Preferences for involvement in clinical decision-making. Three models described: the paternalistic model where the clinician decides what treatment to implement with the patient being given the amount of information that the clinician considers the require; the shared model where the patient and clinician share decision-making throughout the process with a two-way exchange of information, and the informed model where the clinician's role is to provide the patient with enough information in order that the patient can make his own choice of	No	Cross-sectional. Qualitative. Semi-structured interviews.	Secondary care. Various medical/surgical conditions.	20 patients. 55% males, 45% females. Age range 18-79 (66 mean).

First author, Year of publication, Country of origin, Citation	Principal objective of the study	Reporting focus (barriers and/or facilitators)	Operationalization of involvement	Conceptual framework for barriers/facilitators assessment	Design/methods of study within which barriers and facilitators elicited	Setting(s) Health condition(s)	Participant characteristics
			treatment option.				
Ekdahl, 2010, Sweden(95)	To deepen the knowledge of frail elderly patients' preferences for participation in medical decision-making during acute hospitalisation.	Barriers & facilitators	Patient participation in decision-making: MeSH defines patient participation as 'involvement in the decision-making process in matters pertaining to health.'	No	Cross-sectional. Qualitative. Semi-structured interviews.	Secondary care. No specific health condition.	15 patients. 34% male, 66% female. Age range 75-96 (84 mean).
Ekdahl, 2011, Sweden(96)	To investigate the preferred and actual degree of control i.e. the role elderly people with co-morbidities wish to assume and actually had with regard to information and participation in medical decision-making during their stay in hospital.	Barriers	Patient participation in decision-making.	No	Cross-sectional. Quantitative. Telephone administered questionnaire.	Secondary care. No specific health condition.	156 patients. 49% males, 51% female. Age range 75-98 (83 mean).
Eldh, 2006, Sweden(69)	To explore conditions for patients' experiences of participation and non-participation in their health care.	Barriers & facilitators	Patient participation and non-participation in health care: the foremost perspective of patient participation is that it represents taking part in decision-making. Note that patients' notion of participation is closer to dictionary definition 'whereby, patients contribute by sharing their unique knowledge'.	No	Cross-sectional. Qualitative. Self-administered questionnaire (open-ended questions).	Secondary care, inpatients and outpatients. No specific health condition.	212 patients. 40% males, 60% females. Age not reported.
Entwistle, 2008, UK(86)	To investigate the meaning of involvement in treatment decision – making for people with diabetes	Barriers & facilitators	Patient involvement in treatment decision-making.	No	Cross-sectional. Qualitative. Semi-structure interviews.	Primary & secondary care. Diabetes.	18 patients. 55% male, 45% female. Age range 20-79.
Farahani, 2011, Iran(105)	Explore communication barriers [health care] from perspectives of nurses, physicians and patients who were hospitalised, in cardiac care settings with either unstable angina or for evaluation of suspected acute myocardial infarction and their family members.	Barriers	Nurse-patient communication, for the purpose of patient education.	No	Cross-sectional. Qualitative. Semi-structured interviews.	Secondary care, inpatient. Cardiac disease.	9 patients and 4 family members. 64% male, 36% female (58.7 mean).
Fraenkel, 2007, USA(67)	To gain a more complete understanding of the essential elements, or the prerequisites, critical to active patient participation in medical decision-	Barriers & facilitators	SDM: where patients play an active role in decisions related to their health care.	No	Cross-sectional. Qualitative. Semi-structured interviews.	Secondary care, outpatient. Osteoporosis.	26 patients. 4% male, 96% female. Age range 49-76 (61

First author, Year of publication, Country of origin, Citation	Principal objective of the study	Reporting focus (barriers and/or facilitators)	Operationalization of involvement	Conceptual framework for barriers/facilitators assessment	Design/methods of study within which barriers and facilitators elicited	Setting(s) Health condition(s)	Participant characteristics
	making from the patients' perspective.						mean).
Frosch, 2012, USA(38)	To arrive at a better understanding of how patients perceive these communication tasks, specifically when considering clinical decisions that are sensitive to patients' preferences.	Barriers & facilitators	SDM.	Yes (115, 116)	Cross-sectional. Qualitative. Focus groups (n=6).	Primary care. No specific health condition.	48 patients. 38% male, 62% female. Mean age 65.
Henderson, 2002, Australia (103)	To explore and describe the phenomenon of patient participation within the context of hospital nursing in Western Australia.	Barriers & facilitators	Patient participation: being allowed to become involved in a decision-making process or in the delivery and evaluation of a service, or even simply being consulted on an issues of care such as activities of daily living, pain management or treatment options.	No	Cross-sectional. Qualitative. Semi-structured interviews & observations.	Secondary care, inpatient (after discharge). Various acute medical, surgical, extended care.	32 patients. 44 % male, 56% female. Mean age 59.
Janssen, 2011, The Netherlands & USA(92)	To compare quality of patient-clinician communication about end-of-life care, and endorsement of barriers and facilitators to this communication in the Netherlands and the USA.	Barriers & facilitators	Patient-clinician communication about end-of-life care.	No	Cross-sectional (baseline data from 3 datasets [†]). Quantitative. Self-administered questionnaire.	Secondary care. Chronic Obstructive Pulmonary Disease (COPD).	122 Dutch patients (62% males, 38% females; mean age 67) and 391 USA patients (92% males, 8% females; mean age 68).
Kawabata, 2009, Japan(111)	To reveal factors affecting the physician-patient relationship regarding patient participation in medical encounters in primary care.	Barriers & facilitators	Patient participation in medical encounters.	No	Cross-sectional. Qualitative. Focus group (n=1).	Primary care. No specific health condition.	5 female participants (patient representatives). Age range 45-59 (53 mean).

[†] Baseline data analysed included data from one longitudinal study. However, only baseline data considered, so overall design cross-sectional.

First author, Year of publication, Country of origin, Citation	Principal objective of the study	Reporting focus (barriers and/or facilitators)	Operationalization of involvement	Conceptual framework for barriers/facilitators assessment	Design/methods of study within which barriers and facilitators elicited	Setting(s) Health condition(s)	Participant characteristics
Kelsey, 2007, UK(82)	To explore young people's perceptions of their involvement in healthcare decisions affecting their management of care.	Barriers & facilitators	Involvement in healthcare decisions affecting the management of care.	No	Cross-sectional. Qualitative. Interviews & patient audio diaries.	Secondary care, inpatient. Various medical/surgical conditions.	10 patients. 60% male, 40% female. Age range 13-16.
Larsson, 2011, Sweden(97)	To explore barriers for patient participation in nursing care with a special focus on adult patients with experience of inpatient physical care.	Barriers	Participation in nursing care: active patient involvement in all aspects of own care.	No	Cross-sectional. Qualitative. Focus groups (n=6).	Secondary & community care. No specific health condition.	26 patients. 69% male, 31% female. Age range 32-87.
Lown, 2009, USA(8)	To explore how patients and physicians describe attitudes and behaviours that facilitate SDM.	Facilitators	SDM: interaction between patients and physicians when both parties wish to participate in making a decision about health care tests or treatments, and in which both physician and patient are both involved in the process, both shared information and express preferences, and both agree about the decision plans.	Pos	Cross-sectional. Qualitative. Research work groups (n=4).	Primary care. Various chronic conditions.	44 patients. 32% male, 68% female. Age not reported.
Newsome, 2012, USA(93)	To examine the use of decision aids and uncover barriers to greater decision aid utilisation in primary care.	Barriers	SDM: involvement of both the patient and the doctor, a sharing of information by both parties, both parties taking steps to build a consensus about the preferred treatment, and reaching an agreement about which treatment to implement.	No	Cross-sectional. Qualitative. Focus groups.	Primary care. Various conditions.	37 patients. Gender & age not reported.
Nordgren, 2001, Sweden(98)	To describe patients' perceptions of how self-determination finds expression in the context of care.	Barriers & facilitators	Self determination: within health care, self determination has been described in terms of patient participation in decisions concerning their own lives without a controlling involvement from others.	No	Cross-sectional. Qualitative. Semi-structured interviews.	Secondary care, inpatient. Various surgical/medical conditions.	17 patients. 65% male, 35% female. Age range & mean not reported.
O'Brien, 2011, Canada(100)	To identify patients' and physicians' perceptions of physician-related verbal and nonverbal facilitators and barriers to patient involvement in treatment decision-making, during encounters for women with early stage breast cancer.	Barriers & facilitators	Involvement in treatment decision-making.	Pos	Cross-sectional. Qualitative. Semi-structured interviews.	Secondary care. Early stage breast cancer.	40 female patients. Phase 1: Age range 40-70 (62 mean). Phase 2: Age range 48-79 (61

First author, Year of publication, Country of origin, Citation	Principal objective of the study	Reporting focus (barriers and/or facilitators)	Operationalization of involvement	Conceptual framework for barriers/facilitators assessment	Design/methods of study within which barriers and facilitators elicited	Setting(s) Health condition(s)	Participant characteristics
							mean).
Park, 2005, South Korea(113)	Investigate the communication barriers perceived by older hospitalised patients and nurses in Korea, with the aim of identifying disparities between the two parties.	Barriers	Communication between patients and nurses: Communication involves an interaction between the speaker and the subject and the environment influences this process.	No	Cross-sectional. Quantitative. Self-administered questionnaire.	Secondary care, inpatient. Various medical/surgical/ophthalmology conditions.	100 patients. 59% male, 41% female. Mean age 68.
Peek, 2009, USA(75)	To explore barriers and facilitators to SDM among African-Americans with diabetes.	Barriers & facilitators	SDM: a process where both patients and physicians share information, express treatment preferences and agree on a treatment plan.	Yes (12, 117-119)	Cross-sectional. Qualitative. a) Focus groups (n=5) b) Semi-structured interviews	Primary care. Diabetes.	51 patients overall. 18% male, 82% female. Mean age 62. a) 27 patients b) 24 patients
Peek, 2010 [‡] , USA(74)	To explore barriers and facilitators to SDM among African-Americans with diabetes.	Barriers & facilitators	SDM models contain three domains: information sharing, deliberation/physician recommendation, and decision-making.	Yes (12, 117-119)	Cross-sectional. Qualitative. a) Focus groups (n=5) b) Semi-structured interviews	Primary care. Diabetes.	51 patients overall. 18% male, 82% female. Mean age 62. a) 27 patients b) 24 patients
Ruan, 2008, China(107)	Identify the major communication barriers (nurse-related, patient-related, environment-related) perceived by both nurses and elderly patients and to determine the perceived differences in the level of importance of the communication barriers between nurses	Barriers	Nurse patient communication: communication is the use of words and behaviours to construct, send and interpret messages. It is a process by which one individual may affect another through written, verbal and non-verbal means.	No	Cross-sectional. Quantitative. Investigator administered questionnaire.	Secondary care, inpatient. Various conditions.	56 patients. 64% male, 36% female. Age range 69-88 (79 mean).

[‡] Peek 2010 and Peek 2009 use same sample, but Peek 2010 reports additional data obtained from additional questions/prompts used during focus groups and semi-structured interviews.

First author, Year of publication, Country of origin, Citation	Principal objective of the study	Reporting focus (barriers and/or facilitators)	Operationalization of involvement	Conceptual framework for barriers/facilitators assessment	Design/methods of study within which barriers and facilitators elicited	Setting(s) Health condition(s)	Participant characteristics
	and elderly patients.						
Sainio, 2001, Finland (108)	Explore the views and experiences of adult cancer patients about patient participation in care and decision-making and the preconditions for this participation.	Barriers & facilitators	Active patient participation in decision-making and care.	No	Cross-sectional. Qualitative. Semi-structured interviews.	Secondary care, inpatient. Various cancer diagnoses.	34 patients. 53% male, 47% female. Age range 24-54 (44 mean).
Simon, 2006, Germany (109)	Investigate depressed patients' perceptions of the treatment decision process with general practitioners (GPs).	Barriers	Involvement in the treatment decision-making process. In SDM at least two individuals are involved in partnership to share the process of making a treatment decision.	No	Cross-sectional. Qualitative. Semi-structured interviews.	Inpatient and outpatient. Depression.	40 patients. 40% male, 60% female. Age range 18-70 (43 mean).
Skea, 2004, UK(83)	To explore women's views of decision-making relating to hysterectomy.	Barriers & facilitators	Various aspects of decision-making relating to hysterectomy.	No	Cross-sectional. Qualitative. Semi-structured interviews.	Secondary care. Hysterectomy.	20 female patients. Age range 36-53).
Thompson, 2007, UK(84)	Examine the views and preferences of citizens, as patients, members of voluntary groups, or neither, on involvement in health care delivery (role they wish to play and their conceptual meanings behind them). Develop a taxonomy based on this.	Barriers & facilitators	Patient involvement and participation in health care consultations.	No	Cross-sectional. Qualitative. a) Semi-structured interviews b) Focus groups (n=36) c) Workshops (n=12)	Primary and community care. Various health conditions, including chronic conditions.	355 patients overall. a) 44 patients b) 190 patients c) 121 patients Gender & age not reported.
Thorne, 2012, Canada(101)	To contribute to the evolving dialogue on optimising cancer care communication through systematic analyses of patients' perspectives.	Barriers & facilitators	SDM.	No	Longitudinal. Qualitative. Interviews.	Secondary care. Various cancer diagnoses.	100 patients. 28% male, 72% female. Age range 23-83 (65% between 50-69)

First author, Year of publication, Country of origin, Citation	Principal objective of the study	Reporting focus (barriers and/or facilitators)	Operationalization of involvement	Conceptual framework for barriers/facilitators assessment	Design/methods of study within which barriers and facilitators elicited	Setting(s) Health condition(s)	Participant characteristics
Van Staa, 2011, The Netherlands [§] (114)	To integrate findings of mixed methods research (MMR) into preferences and competencies for communication during consultations of adolescents with chronic conditions, in order to demonstrate the added value of MMR for health communication research.	Barriers & facilitators	Triadic communication during healthcare consultations.	No	Cross-sectional. Qualitative. Semi-structured interviews.	Secondary care. Various chronic conditions.	31 patients. 52% males, 48% females. Age range 12-19 (15 mean).

[§] Mixed methods study – reported barriers and facilitators derived from one method only so logged as qualitative/quantitative (as appropriate) for the purposes of this review.

Table 2.1 provides details on the study aim and reporting focus e.g. barriers and/or facilitators. The principal aim of 30 studies was to identify patient-reported barriers/facilitators to involvement in decision-making (determined by the reported primary objective or by existence of direct questioning during data collection).(8, 38, 67, 69, 74, 75, 78, 79, 81, 86, 88-90, 92-94, 96, 97, 100, 103-109, 111, 113, 114) Thirteen publications reported barriers only,(68, 76, 80, 93, 94, 96, 97, 104, 105, 107, 109, 110, 113) two reported facilitators only,(8, 112) and 30 reported both barriers and facilitators.(38, 69, 74, 75, 77-79, 81-86, 88-92, 95, 98-103, 106, 108, 111, 114).

2.3.3 Barriers & facilitators - main themes

Key descriptive themes were grouped under two broad analytical themes: (1) ‘how is the healthcare system organised?’ (i.e. factors that are largely outside of patients’ and clinicians’ control, such as time, continuity of care, workflow and the healthcare setting) and (2) ‘what happens during the decision-making interaction?’ (i.e. factors more influenced by the participants taking part in the decision-making interaction, such as predisposing factors, interactional influences, preparation for the SDM encounter, and preparation for the SDM process). The two analytical themes will be discussed in turn, including the main descriptive themes and sub-themes that emerged. The number of studies in which each theme/sub-theme was identified as a factor affecting participation is presented in parentheses (See Table 2.2 for an overview of the main themes and sub-themes, including the number of studies each theme was identified as a barrier/facilitator and their associated references).

Table 2.2 - Patient reported barriers & facilitators to SDM: overview of analytical, descriptive & sub-themes (no. of studies / 44 identified as factor) (no. of references identified as a factor)

How is the healthcare system organised? (27)

Analytical theme

<i>Descriptive themes</i>			
(a) Time (20) (38, 67, 68, 74, 78, 79, 81, 83, 85, 86, 89, 95, 98, 100, 106, 108, 110-113)	(b) Continuity of care (15) (74, 78, 79, 81, 83, 86, 87, 89, 92, 95, 97, 101, 104, 106, 108)	(c) Workflow (9) (67, 68, 79, 81, 86, 93, 100, 108, 111)	(d) Characteristics of the healthcare setting (7) (67, 69, 81, 83, 89, 107, 113)
<ul style="list-style-type: none"> • Clinicians are too busy^(38, 67, 81, 83, 86, 87, 89, 95, 98, 106, 108, 110-113) • Lack of time during consultation^(38, 67, 78, 79, 83, 89, 98, 106, 108, 111) • Adequate time in the consultation (fac)^(74, 78, 83, 89, 100, 106, 112) 	<ul style="list-style-type: none"> • Inability to choose clinician to do SDM with⁽⁸⁹⁾ • Too many clinicians involved in care^(81, 86, 87, 89, 92, 95, 97, 104, 106, 108) • Lack of continuity in the informational flow between clinicians⁽⁹⁷⁾ • Clinician does not know the patient^(83, 86, 106) • Being known by the clinician (fac)^(78, 79, 89, 101, 106) 	<ul style="list-style-type: none"> • Distributing SDM among different clinicians e.g. nurse takes part in SDM with patient (fac)^(79, 81, 108, 111) • System does not offer multiple-consultation model that may be needed for SDM^(68, 93, 100) • Appropriate consultations for SDM (fac)⁽⁶⁷⁾ 	<ul style="list-style-type: none"> • Inadequate environmental conditions e.g. noisy, lack of privacy^(81, 83, 107, 113) • Not paying for healthcare (bar) / paying for healthcare (fac)⁽⁶⁷⁾ • Overspecialization of doctors⁽⁸⁹⁾ • Lack of reimbursement for clinician undertaking SDM^(69, 89)

What happens during the healthcare consultation? (44)

Analytical theme

<i>Descriptive themes</i>			
(a) Predisposing factors (33) (74, 76, 78-82, 84-86, 88-92, 94-97, 100, 102-114)	(b) Interactional context factors (39) (8, 38, 67-69, 74, 76, 78-82, 85, 86, 88, 89, 92-95, 97-100, 102-108, 110-113)	(c) Preparation for a SDM encounter (32) (8, 38, 67-69, 74, 76, 78-84, 86-89, 92, 95, 97-103, 106, 108, 109, 112, 114)	(d) Preparation for the SDM process (36) (8, 67-69, 74, 76-84, 86-89, 93, 95-103, 105-109, 111-113)
Patient characteristics (29) (74, 76, 78, 79, 81, 82, 84, 85, 88-90, 92, 94-97, 103-114) <ul style="list-style-type: none"> • Being in poor health^(78, 79, 81, 82, 89, 95-97, 106, 108, 109, 113) • Being in good health (fac)⁽¹⁰⁸⁾ • Cognitive / physical impairments^(78, 79, 97, 106, 107, 113) • Prior exposure to illness / decision-making 	Power imbalance in the patient-clinician relationship (36) (8, 38, 67-69, 74, 76, 78-86, 88, 89, 93-95, 97-103, 106-108, 110-114) <p><i>Presumptions about the patient role</i></p> <ul style="list-style-type: none"> • Expectation of the clinician making the decisions^(67, 68, 74, 76, 78-81, 84, 88, 89, 94, 96, 98, 102, 103, 112) • Desire to act like a ‘good’ patient driven by a fear of consequences^(38, 67, 68, 74, 76, 80, 88, 97, 98, 101-103) 	Perceived need for preparation (30) (8, 38, 67-69, 74, 76, 78-84, 86-89, 92, 95, 98-102, 106, 108, 109, 112, 114) <ul style="list-style-type: none"> • Patient is not entitled to a choice^(67, 76, 78, 82, 87, 88, 92, 98, 100, 102, 109) • Patient is not explicitly offered a choice or it is presented in a biased way^(80, 83, 86, 87, 101, 102, 112) • ‘Doing nothing’ is not an option^(80, 83, 87, 99) • Patient does not <i>want</i> to or <i>need</i> to participate 	Providing information about options (27) ^(67, 69, 74, 76, 78-84, 86-89, 95, 97-103, 106, 108, 111, 112) <ul style="list-style-type: none"> • Insufficient information about condition, options and outcomes^(69, 74, 76, 78, 80, 81, 83, 86, 87, 89, 95, 97, 98, 100-103, 111, 112) • Sufficient information about condition, options and outcomes (fac)^(67, 69, 74, 78, 79, 81, 82, 84, 86-88, 95, 100, 101, 106, 108) • Clinician does not explain the options and outcomes^(67, 69, 74, 80, 82, 83, 86, 87)

point (fac) (74, 92)

- Age (older/younger) (78, 79, 88, 95, 103, 106, 108, 111, 114)
- Ethnicity (74, 88)
- Lower level of Education (79, 94, 106, 110)
- Poor articulation (76, 78, 81, 106, 107)
- Difference in personal characteristics (95-97, 104, 105)
- Health condition – stigma / discrimination (84, 86, 90, 104)
- Long term patient (bar⁽¹¹²⁾ & fac (78, 79))

Decision characteristics (18)

(78, 80-82, 84-86, 90-92, 100, 102, 103, 105, 106, 108, 109, 111, 114)

- Timing along the illness trajectory (bar & fac) (84, 85, 91, 102, 103, 111)
- Major decisions (bar (78, 81) & fac (78, 81, 108))
- Minor decisions (bar (81) & fac (78, 81))
- Embarrassing or sensitive topics (90, 105, 106)
- Shock of receiving diagnosis (80, 84, 86)
- Time to come to terms with diagnosis (fac) (80, 100)

103, 106, 108, 112)

- Perceived acceptability of asking the clinician questions (bar (38, 74, 76, 78, 80, 82, 86, 88, 89, 95, 99, 102, 103, 111) & fac (8, 67, 74, 82-84, 86, 88, 89, 95, 98, 100, 103, 106, 108, 110, 111))
- Belief that clinicians do not want patients involved (38, 67, 68, 85, 86, 88, 89, 95, 98, 101, 106, 111-113)
- Clinician reinforces passivity by rewarding this behaviour (80, 102, 106, 107)
- Not having explicit ‘permission’ to participate in SDM (38, 67, 74, 82, 83, 89, 93, 98, 100, 103, 110, 114)
- Having explicit ‘permission’ to participate in SDM (fac) (8, 67, 69, 74, 78, 86, 89, 100, 101, 103, 106, 108)

Patients undervalue their expertise relative to clinicians

- ‘Doctors know best’ and patients’ have ‘inferior’ knowledge (38, 67-69, 74, 76, 78-85, 88, 89, 94, 95, 97-99, 102, 103, 106, 108, 110-112, 114)
- Patients are not capable of understanding medical/technical information (76, 85, 94, 97, 114)
- Recognize that there are two experts in the medical encounter (fac) (8, 67, 74, 78, 79, 81, 82, 84, 86, 88, 89, 99, 101, 102, 110)

Interpersonal characteristics of the clinician(s) (35)

(8, 38, 67, 69, 74, 76, 78-84, 86, 88, 89, 92, 95, 97-108, 110-114)

- Authoritarian clinicians (38, 74, 83, 89, 97, 98, 103, 106, 112, 113)
- Equal relationship (fac) (8, 38, 69, 74, 78, 79, 84, 86, 88, 89, 98, 99, 101, 110)
- Clinician does not listen to patient’s concerns (38, 69, 74, 78, 79, 81, 82, 84, 89, 97, 98, 100, 102, 103, 106, 107, 110, 112, 113)
- Clinician listens to patient’s concerns (fac) (8, 69, 74, 78, 79, 86, 89, 98, 101, 106)
- Clinician with poor interpersonal skills (38, 74, 78, 79, 81, 83, 86, 89, 97, 101, 102, 104-108, 113)
- Clinician with positive interpersonal skills (fac) (74, 79, 83, 86, 100, 101, 106, 108)
- Good relationship with clinician (fac) (8, 67, 74, 78, 79, 81, 84, 86, 92, 98, 101, 108)
- Poor relationship with clinician (108)
- Lack of individualized approach and not asked about preferences (38, 69, 80, 81, 86, 89, 97, 108, 111, 112)
- Individualized approach where clinician seeks

in SDM (68, 69, 76, 80-82, 84, 88, 89, 92, 95, 98, 101, 106, 114)

- Accepting responsibility to be involved in decision-making (fac) (8, 38, 67, 78, 79, 82, 84, 86-89, 99, 101, 106, 108, 114)
- Not knowing what to expect from the SDM consultation (74, 81, 83, 92)

Expectations of the outcome of being involved in SDM (21)

(67, 68, 74, 76, 80, 83, 84, 86, 87, 89, 92, 95, 97, 99, 101-103, 106, 108, 109, 114)

- Perceiving that there are ‘right’ and ‘wrong’ decisions (not wanting responsibility for wrong decision) (68, 76, 80, 84, 87, 89, 95, 97, 99, 102, 103, 106, 114)
- Recognizing equipoise and uncertainty (fac) (67, 83, 89, 101, 106, 108)
- Fear of accepting reality of diagnosis (68, 74, 84, 87, 89, 92, 97, 102, 106, 108, 109)

- Clinician explains the options and outcomes (fac) (67, 78, 82-84, 86, 87, 89, 99-101, 106)

Terminology used by HCPs (17)

(67, 69, 74, 76, 78, 81, 82, 84, 87, 89, 95, 97, 98, 105, 107, 109, 113)

- Clinician uses medical terminology (67, 74, 76, 78, 81, 84, 89, 96-98, 105, 107, 109, 113)
- Clinician uses simple terminology (fac) (69, 74, 82, 84, 87, 89)

Decision support (8)

(8, 68, 77, 83, 89, 93, 100, 111)

- Lack of written decision support (bar) (83, 100, 111)/ written decision support (fac) (68, 77, 100)
- Purpose of the decision support tool is unclear (93)
- Decision support from others e.g. family, other clinicians (fac) (8, 83)

patient's preferences (fac) ^(8, 69, 78, 84, 86, 89, 92, 98, 100, 101, 106)

- Clinician does not address patient directly ^(82, 97, 114)

Trust (24) ^(8, 67, 68, 74, 76, 78-81, 84, 86-89, 92, 94, 95, 97-99, 102, 106, 107, 112)

- Trust in clinician (bar ^(67, 68, 78-81, 84, 87-89, 94, 95, 97, 98, 102, 112) & fac ^(8, 67, 74, 86, 89, 92, 97, 106))
 - Lack of trust in clinician (bar ^(74, 89, 107) & fac ^(67, 78, 84))
-

2.3.3.1 How the healthcare system is organised

Four key themes relating to the way in which the healthcare system is organised were identified by patients as either facilitating or hindering participation in SDM (see Table 2.2). Most of these factors are potentially modifiable, but would require significant organisational level change, rather than change at the individual level.

a) Time (20/44 studies)

Some patients feel that the limited time allocated for consultations is insufficient for SDM. Limited time is a barrier to becoming informed, processing information received, and discussing issues with the clinician. For instance, in a study by Frosch et al(38), men felt that insufficient time with their physicians was a barrier to asking questions and voicing concerns, as well as a barrier to processing and reflecting on information given during a visit. Patients in Fraenkel et al's(67) study believed lack of time was a barrier to providing effective healthcare and reported that there 'doesn't feel like there's ever room in the system anymore for real dialogue'. Conversely, adequate time for discussion can facilitate involvement in SDM.(78, 83, 100, 106) Patients in Peek et al's study(74) also felt that adequate time afforded opportunities for relationship building, which was deemed important for effective communication with the clinician. Patients frequently reported that clinicians seemed too busy and hurried (85, 86), and they did not want to bother them. Interestingly, patients were often sympathetic to clinicians' high workloads, felt guilty about taking up their time,(38) pity because they are so busy,(112) and terminated consultations more quickly when waiting rooms were busy. (106, 110)

b) Continuity of care (15/44)

Some patients believe that a lack of continuity in their care is a barrier to SDM. For instance, patients in Belcher et al's(89) study felt that inability to choose a doctor with whom to actively participate in decisions affected their participation, whilst other patients feel that there are too many clinicians involved in their care to participate.(81, 108) Other patients feel that the lack of continuity in the informational flow between clinicians was a barrier (e.g. sub-optimal handovers)(97) and some felt it was difficult to participate when the clinician did not know them personally.(83, 85, 106) Conversely, patients in several studies perceived continuity in care as a facilitator, especially being known by the clinician. (78, 79, 89, 101, 106)

c) Workflow (9/44)

Although not a predominant theme, patients identified how workflow processes could be amended to facilitate greater involvement, such as distributing the SDM process between different clinicians. Some patients believe that nurses play an important role in explaining the information provided by doctors, and they also provide greater support in listening to patients' preferences and concerns.(79) Patients refer to the nurses as 'mediators' or 'intermediaries' who can explain information provided by doctors to the patients, (81, 111) and provide the doctors with important information about the patient's preferences. This therefore somewhat contrasts with the view that lack of continuity is a barrier to involvement. In terms of barriers, some patients suggest that the healthcare system is not set-up for the multiple consultation model needed to support SDM e.g. to receive the decision support tool, have time to think about options, have the opportunity to ask clarifying questions at a later date. Having appropriate appointments for SDM, e.g. longer appointment times available for those situations, would support and encourage involvement.

d) Characteristics of the healthcare setting (7/44)

Poor environmental conditions, such as a noisy environment,(107, 113) lack of privacy,(81) and requiring physical examinations(83) were not conducive to involvement in decision-making. Some patients believe that their right to participate in SDM depends on whether they pay for their healthcare or not.(67) Other healthcare setting-related barriers reported by patients include overspecialisation of doctors and lack of reimbursement for clinicians undertaking SDM.(89)

2.3.3.2 What happens during the decision-making interaction

Ten key elements relating to the decision-making interaction were identified by patients as either facilitating or hindering participation in SDM. These are grouped under four descriptive themes: (see Table 2.2)

a) Pre-disposing factors (33/44)

(i) Patient characteristics (29/44)

Various patient characteristics have been cited as either facilitating or hindering patient involvement in SDM. Some characteristics are non-modifiable, as their presence or absence

could not be influenced by interventions designed to promote SDM. Non-modifiable barriers include the presence of cognitive impairments(79, 97, 110) and being in poor health;(78, 81, 89, 106, 108, 113) patients in several studies reported that they were happy to relinquish decision-making control when they felt very ill.(82, 95-97) Non-modifiable facilitators include being in good health,(108) and prior exposure to the illness or decision-making point.(74)

Most patient characteristics are, however, potentially modifiable. Age is reported by patients to influence involvement in SDM. Whilst age per se is not modifiable, most barriers related to age were linked to attitudinal issues or prejudices that could be addressed. Patients in several studies report that being in an older age group restricted their involvement, citing various reasons for this: some older patients report that they are less interested in their own life than they were when they were younger;(95, 108) some feel that they receive discriminatory treatment or they are not listened to because they are old;(88, 103) whilst some believe that they are part of an age cohort which accepts the authority of the clinician and should not question this authority.(106, 111) However, some studies have shown that being in a younger age group can also limit involvement, mainly because of the triadic relationship children and adolescents encounter. In these situations, some young people feel that they do not need to be involved because their parent will adopt the decision-making role, some felt that they were not capable of representing themselves or were not interested in taking part, whilst some felt that their parents' interference restricted discussion.(114)

Two studies looked specifically at issues of ethnicity in SDM, and similar modifiable attitudinal issues have been identified.(74, 75) Patients in these studies reported that the power imbalance in the relationship between patient and clinician was exacerbated by ethnic difference. They believed that African-Americans were more likely to defer to authority, less likely to experience information exchange, and were less likely to have their concerns validated by the clinician. Having poor articulation,(76, 78, 106, 107) a lower level of education,(79, 94, 106) and differences in personal characteristics between the patient and the clinician (e.g. dialect/accents, age, sex)(95-97, 104, 105) were also reported as barriers to SDM. In some studies, patients report that the nature of their health condition impacts negatively on their level of involvement because of stigma and discrimination, for example, infectious diseases,(104) drug addiction,(90) alcoholism.(84) Asthma patients in two studies believe that having the condition for a long time facilitated involvement;(78, 79) however, patients in another(112) study believe that being a long-term patient is a barrier to

involvement as it is more difficult to obtain information and the healthcare team has lost interest or forgotten about them. Again, whilst these characteristics are unchangeable (e.g. we cannot change a patient's level of education, health condition, length of time with condition), they are modifiable if we provide alternative ways to support these patients and focus on attitudinal change at the levels of patient, clinician and organisation.

(ii) Decision characteristics (19/44)

Several decision characteristics were identified as barriers to SDM. Patients in Thompson's(84) and Clover et al's(102) studies reported that not everyone aspires to be involved at all times and in all situations and patients use different approaches depending on the decision being made, suggesting involvement in SDM is contextually dependent. Acute myocardial infarction patients in Decker et al's(91) study were asked to describe preferred involvement and information needs along the continuum of myocardial infarction care. Results indicate that involvement in decision-making progresses from the acute event to recovery and is influenced by time; progressing from active when seeking emergency care, to passive when hospitalised and receiving treatment, back to active when making decisions about rehabilitation and recovery. Significant decisions were identified as both a barrier and facilitator to involvement: some patients in Doherty et al's(81) study report that they would like to be more involved in major decisions (e.g. cancer) than minor decisions (e.g. asthma), whilst others preferred less involvement when a major decision had to be made. These issues are non-modifiable; it is logical that patients in, for example, an emergency situation, will not be involved in decision-making, and we cannot change the severity of the disease or a patient's stated preference of involvement in relation to this; however, it is possible that these factors could change over time.

However, most decision characteristics reported as barriers are potentially amenable to change. For example, Farahani et al(105) reports how embarrassing topics can be a barrier to discussion; a patient was not told that sexual impotence was a potential side effect of prostate cancer treatment because of the cultural stigma associated with discussing sexual problems. There is also some evidence that patients might be less inclined to participate in decisions about sensitive issues, such as end-of-life discussions and advanced directives.(92) Again, the focus here is on attitudinal change, either at the individual belief or subjective norm level.

Timing of the decision can also act as a barrier or facilitator to involvement. For instance, men diagnosed with prostate cancer in Cohen et al's(80) study reported that the consultation was 'overshadowed' by the shock of receiving the threatening news. As such, they could not absorb any information that they were given after the diagnosis and they could not attend to a decision-making discussion, even if this had taken place. Having time to come to terms with the diagnosis before option presentation was felt to facilitate involvement in the decision-making process,(85) as was having time to go away and think about the decision, especially when the clinician reinforced that the decision did not need to be made that day.(83, 100) However, it is worth noting that one breast cancer patient felt that the time between diagnosis and start of treatment was too short and did not facilitate the use of decision aids as a means to provide decision support.(68) Timing barriers are potentially modifiable for most situations, if we can reconsider where SDM fits in the clinical pathway or patient's disease trajectory, and provide time before considering options after a diagnosis, if feasible.

b) Interactional context factors (39/44)

(i) *Power imbalance in the patient-clinician relationship* (36/44)

- *Presumptions about the patient role*

Several modifiable barriers relating to patients' presumptions of the 'normal', expected patient role were identified. Many patients believe that 'normal' patients are passive and *expect* clinicians to make decisions.(76, 78, 81, 95, 98, 112) For example, a patient in Bhavnani et al's(68) study reports that she would not go to the doctor having read a decision aid and highlight what treatment she would like; she believes you go to the doctor to be asked questions, provide answers to those questions, and to be told what treatment to have. In many studies, it is clear that patients have an expectation of being told what to do by the clinician.(76, 78, 81, 95) The use of terms such as 'accept', 'trust', and 'should' indicate that patients are quite often accepting of this role, but sometimes they perceive they have no option to be involved, even if they wanted to. For example, patients in Nodgren et al's(98) study perceived that they had no other choice but to comply with the treatment put forward by staff. A patient in Aasen et al's(112) study stated, 'even if we wanted to decide...it doesn't mean we could. You must listen to those who are supposed to help you or else it won't work'.

Many patients' desire to act like a 'good' patient is driven by a fear of bad consequences if they step outside of this traditional patient role. For example, palliative care patients in Clover et al's(102) study reported concern that staff labelled them as inflexible, troublesome, and hard to manage when they made their preferences clear. Similarly, patients in Frosch et al's(38) study feared that questioning behaviour would result in them receiving a long-term reputation as a difficult patient. The fear of being described as a difficult patient is frequently accompanied by a fear of retribution; patients feel that being labelled difficult is in some way associated with poorer quality care or avoidance from medical staff.(38, 67, 103) Wanting to be a 'good' patient even resulted in patients undertaking covert work to inform themselves, as they did not want to 'rock the boat'.(38) The desire to be a 'good' patient is also driven by the perceived benefits that might arise, such as lack of conflict in the encounter,(38, 103) and having the clinician 'on your side' at a time of great need.(88)

Perceived unacceptability of asking the clinician questions and raising options can act as a barrier to SDM. Patients frequently reported that they should not ask their doctors questions or make attempts to be involved. Some patients believe that hospital is a place where you do not ask questions(76) and medical staff do not want to be questioned, (86, 89) even using phrases like 'dare ask'.(95, 102) The perception that you cannot, or should not, ask questions is discussed in relation to how it would undermine the skills of the clinician,(38, 76) show a sign of distrust,(38, 99) or a lack of respect(78, 80, 88). Linked to this barrier is the belief that clinicians do not want patients involved in their healthcare.(86, 89, 111, 112) For example, patients in Ekdahl et al's(95) study felt that doctors and consultants, who are at the top of a hierarchical system, believe they do not need to communicate with patients.(95) A patient in Nordgren et al's(98) study described how the healthcare team just did things to them without asking, deciding the course of action beforehand. Sometimes, passive behaviour is directly reinforced by clinicians e.g. where compliant, non-questioning individuals are called 'easy' or 'best' patients.(88)

Not having explicit 'permission' or encouragement to be involved in decision-making is another barrier commonly cited by patients. Patients in Peek et al's(74) study, for example, believed that they do not have 'the right' to be involved in healthcare decisions. Other patients note that because the doctor did not ask how they felt about the treatment option, they could not initiate that dialogue.(38) Adolescents in van Staa's(114) study, who participated in triadic consultations, report that the clinician did not tell them to play

a more active role, and thus they did not think it was necessary. On the other hand, explicit encouragement from clinicians with a positive attitude to patient involvement is frequently cited as a facilitator to being more active in the consultation.(67, 74, 82, 86, 89, 103, 108, 110) Bastiaens et al's(106) study of older people reports that a key facilitator to involvement was a doctor who willingly encouraged patients to ask questions and take part in decisions; patients in this study believed that part of the doctor's role was to initiate SDM.

- *Patients undervalue their expertise relative to that of the clinician*

Many patients believe 'doctor knows best', and that their own knowledge is superfluous to the decision-making process, being trumped by medical expertise and experience. Patients in several studies repeatedly state that they rely on the clinician to make the decision because they are the ones who have had many years of medical training, who know about the illness and the treatments, and who have years of clinical experience; they are the 'experts', 'professionals', 'specialists', and 'skilled technicians'.(74, 76, 78-81, 84, 87, 88, 94, 98, 99, 102, 103, 106, 112) There is an expectation that the clinician should know what they are doing, and they are therefore in the best position to make a decision because patients are not educated in the field of medicine. As a patient in Henderson et al's(103) study expressed: 'I am an engineer and I know my area of work, the nurses and doctors know theirs'. When patients discuss their knowledge relative to the clinicians', they often talk about themselves, or their knowledge, as being inferior to the 'gods in white'.(89, 106) They undervalue their contribution using sentences such as 'what do I know'(88), 'I don't think anyone would take me seriously enough',(89) 'the average lay person knows nothing you know',(67) and 'they know more about it than I do'.(84) Some patients also perceive that they are not capable of understanding the 'complex and technical' information needed to make a decision, even if they are offered it.(76, 94) As such, some patients make no attempt to attain a higher level of knowledge(76, 94).

When a patient undervalues their own expertise compared to the clinician, whether that be their level of medical knowledge or their failure to recognise the complementary expertise they can bring to the decision-making process, this acts as a barrier to involvement. On the contrary, when patients do recognise that there are two experts in the decision-making encounter, and that the patient is an expert in their own body, mind, and social circumstances, this acts as a facilitator to SDM.(67, 74, 79, 81, 82, 86, 87, 89,

99, 101, 102) For example, a patient in Caress et al's study states: 'Obviously I haven't got...the range or depth of knowledge to make a decision on my own...but it's my body, so I should have a very big say in what happens. So a balance is probably best'.(78) Other patients talk about wanting to be told the treatment options available by the medical experts, but then making 'the other half' of the decision.(74) One patient highlights the complexity of their personal belief system noting that it has taken a lifetime to build up, so they would never consider letting anyone else telling them what to do.(101)

Clearly, factors relating to how patients perceive their role in the patient- clinician relationship and belief in their own ability to participate are potentially modifiable; many of the cited barriers could be addressed through attitudinal change at the level of the patient and the clinician, possibly at the organisational level, and complemented by the promotion of self-efficacy in patients.

(ii) Interpersonal characteristics of the clinician(s) (35/44)

Patients report various attitudes and behaviours exhibited by clinicians that might facilitate or restrict involvement in decision-making. It is likely that many of these are not directly linked to participation in SDM, but negative attitudes and behaviours displayed by doctors will impact on general patient-doctor communication, which is an essential precursor to SDM. The most frequently cited barrier was encountering authoritarian clinicians who dominate the decision-making encounter. Patients in several studies report how clinicians with an authoritarian, superior, dominating, overbearing, and intimidating manner restrict their level of involvement.(38, 86, 87, 89, 97, 103, 113) One patient describes how patients are at a disadvantage and they have to struggle and 'take a beating mentally'.(98) However, when patients feel that they are in an equal relationship with the clinician and their opinion is respected, this acts as a facilitator to involvement. For one patient in Thompson's study, being part of a team that respects the patient and values their opinions is key to involvement.(84) Others describe how the decision-making interaction with a clinician should be more like a discussion with a friend, where both of the participants are equals. (74, 110)

Some patients believe that the presence of an advocate in the consultation can support their involvement in decision-making.(8, 38, 74, 81, 89, 106, 108) For some, the support can help to overcome practical barriers, such as forgetfulness or inability to remember all of the information by oneself, but for others it is seen as a form of social support or back up that

may help to redress the power imbalance, especially for those patients who lack confidence. Two studies report not having a family member or caregiver in the consultation as a barrier to participation.(107, 113) Patients cite authoritative clinicians as a barrier to SDM, but some patients believe that the whole hospital or healthcare unit is an institution of power and control that restricts involvement.(84, 95, 98, 112) They refer to the hospital as a 'jail'(112) and as having certain rules and regulations that you have to follow.(98)

Another frequently cited barrier is when clinicians do not listen to the patient's concerns.(69, 74, 78, 79, 82, 89, 108, 110) Patients in various studies report situations whereby the clinician was dismissive of their concerns, many of which related to the treatment being received. For example, a patient in Claramita et al's(110) study reports how a doctor continued to prescribe a drug, even though the patient has told them on several occasions that they have an adverse reaction to that drug. Breast cancer patients in O'Brien et al's(100) study believed that their involvement in the decision-making process was compromised when the physicians did not appear interested in their concerns about the disease or the treatment. When genuine concerns are not acknowledged or are 'called into question' by clinicians, patients feel as though they have lost their self-determination.(98) Some elderly patients feel that the staff treated them like children, or 'silly old ladies', and did not value their opinions or respect the elderly.(103, 107) This perceived unwillingness to listen to the patient's concerns, and to acknowledge the patient's expertise in their own body, is seen as an important barrier to involvement. Conversely, listening to the patient and respecting their views is frequently cited as helping patients to become involved in their care.(69, 78, 79, 86, 89, 98, 106) Some patients believe that having health concerns 'heard' and validated by the clinician creates a sense of partnership, which in turn facilitates SDM.(74)

Clinicians with poor interpersonal skills are frequently reported as inhibiting participation. Negative verbal and non-verbal communication behaviours displayed by clinicians made patients feel that they could not be involved. They use phrases such as 'abrupt',(89) 'aggressive'(104), 'arrogant',(108) 'dismissive',(89) 'uncaring',(97) 'bossy',(102) 'unfriendly'(107), and 'lack of empathy'(105) to describe the attitudes and behaviours of these clinicians. Thorne et al(101) describe how the tone, or atmosphere set by clinicians' non-verbal behaviours can impact on the verbal communication that follows. Other patients describe how the 'general kind of atmosphere' created by clinicians with poor interpersonal skills can restrict them from feeling able to ask questions.(106) On the other hand, clinicians who display positive interpersonal skills facilitate involvement. Being 'friendly', 'positive', and

'genuinely concerned' are seen as important factors in encouraging involvement.(108) Peek et al(74) report how interpersonal skills were deemed essential for establishing a good relationship with the professional and for creating a positive environment where patients felt comfortable participating in the decision-making dialogue.(74) Patients in several studies viewed having a good relationship with the clinician as an important facilitator to patient involvement.(8, 67, 78, 79, 81, 108) Some patients felt that it was easier to talk about treatment preferences when you have built up a relationship, sometimes over many years.(74) Patients in one study reported that a poor relationship with the clinician would restrict participation in decision-making.(108) It is likely that the ability to establish a 'good' relationship is linked with the interpersonal skills both of the patient and the clinician.

An individualised and tailored approach, whereby the clinician seeks to understand the patient's needs and preferences, is another important facilitator to involvement.(69, 78, 92, 101, 106) Patients in Eldh et al's(69) study were asked to report the essential conditions for participation in healthcare; making a decision based on own knowledge and needs and being regarded as an individual were two of the key conditions. Patients value having their own perspective and insight acknowledged, and emphasise the need to be treated as a person who has goals, rather than a disease. Patients in Thorne et al's(101) study describe 'being recognised for the uniqueness as central to their ability to operate within somewhat foreign relationships with the professionals...'. When patients are not asked about their preferences, and thus not regarded as individuals, this is seen as a barrier to participation.(69, 80, 89, 97, 111, 112) Patients in several studies describe how this impacted on their ability to become involved in the consultation. In these situations, patients describe being treated as an 'object' or a 'disease'.(69, 89, 108) The focus on treating individual diseases and numbers was perceived to impede patient participation in medication decision-making in some cases.(89) For some patients, maintaining a good quality of life was more important than maximising their life span, but they struggled to have their preferences heard by the medical team and were sometimes scolded for these decisions.(112)

Although not a key barrier, patients report that participation in decision-making is compromised when the clinician does not address the patient directly. This was specifically identified in situations of triadic communication e.g. consultations with children/adolescents and their parents.(82, 114) The young people expressed frustration that the clinician addressed the parent, rather than them directly. Another study reports how a patient was faced with 'secretiveness' when the nurse discussed issues with their relatives 'behind their

back'. Again, most factors related to interpersonal characteristics of the clinician are modifiable, with a focus on addressing clinicians' attitudes towards patient involvement and improving the way in which they communicate and interact with patients.

(iii) Trust (24/44)

Trust is a complex issue where both the presence and absence of trust can be a facilitator or a barrier to participation respectively, depending on the individual. Some patients report that trust in the healthcare team leads them to act more passively in the medical encounter, and often refer to 'leaving their lives in the hands of the professionals' because they trust them. Patients in several studies reported that they trust the clinicians because they are the experts with the knowledge and have had many years of training.(78, 79, 84, 94, 102) Some patients report a 'blind trust' in the clinician, having faith that they will act in their best interests.(68, 79, 80, 89, 95) Patients in these studies use phrases such as 'if he tells me this is good for me then I believe them',(89) 'they do what they think they have to do...what they think is best for me',(95) 'trust...in the doctor means you should accept what the doctor says'.(89) Patients in Nordgren et al's(98) study report that they trust the clinician like they trust their parents, again indicating an unconditional trust. For other patients, trust is something that is based on positive past experience with the clinician or having a good reputation. (67, 79, 88) Some patients refer to a 'need' to trust the clinicians as a way of coping: a patient in Charles et al's(99) study describes how she had to trust the physician to make the decision as that was the only way she could live with the decision.

Patients also cite trust as a facilitator to greater involvement in healthcare decisions. Patients in several studies report that a trusting relationship with the clinician would make them more willing to ask questions, share personal information, and discuss their personal concerns.(8, 67, 74, 89) Patients in Peek et al's(74) study refer to trust in the physician's medical knowledge and skills as a facilitator: patients would be more likely to discuss treatment options, because they believe the options would be based on evidence based information. Similarly, patients have cited lack of trust as a barrier to involvement.(74, 89, 107) Interestingly, lack of trust also appears sometimes to encourage involvement in decision-making, and inadvertently act as a facilitator. Patients in Fraenkel et al's(67) study report that they would ask questions in a consultation if they did not trust their doctor. Whilst question asking is not the same as SDM, it does suggest that these patients are more inclined to engage in discussion with the doctor, which is essential for SDM. Patients with a negative

past experience who do not trust clinicians stated they wanted to be more involved, as did patients who did not trust the medical profession more generally, because of the control they are perceived to try to exert on patients.(84)

Clearly trust is a complex issue, especially when trust and lack of trust are both barriers and facilitators to SDM. Trust is an essential component of any effective relationship, but it can make patients act more passively. Clearly, I would not advocate promotion of distrust to increase levels of participation in these patients; instead, interventions should focus on promoting trusting relationships between the patient and clinician (e.g. via more open communication) in conjunction with promoting positive attitudes among patients towards involvement, reinforced by clinicians who encourage this behaviour. As such, issues related to trust are modifiable, but cannot be addressed in isolation due to its complexity.

c) Preparation for a SDM encounter (32/44)

This theme differs from the next ('preparation for a SDM process'), as it identifies the preparation needed for a patient to have *opportunity to participate* in SDM, rather than participation in the *actual SDM process*.

(i) *Perceived need for preparation* (30/44)

Perceiving there is no decision to be made is a barrier to SDM and can arise for several reasons. Sometimes, patients believe that they are not entitled to a choice, or they were not offered a choice, and therefore did not make any attempts to be involved as there was no (perceived) decision to be made.(67, 76, 82, 98, 102) However, the perception of 'no choice' is also related to the way in which the clinician presents the options e.g. if they indicate a clear preference or present them in a biased way.(80, 83, 86, 87, 102, 112) For some patients, the options available determine whether they perceive there is a decision to be made. For example, breast cancer patients in one study believed that 'doing nothing' was not an option, and a choice is only made when there are meaningful treatment options with equal value, as perceived by the patient, to choose from.(99)

Patients' acceptance of the SDM patient role will also influence their readiness to share decision-making. Feeling that you do not *want* to be involved in healthcare decisions is an important barrier. Various different reasons indicating why patients do not want to be involved have been reported, including: general preference for passivity and wanting to be told what to do;(76, 84, 89, 95) not wanting to receive or understand the information;(68,

101, 106) medical information is too distasteful;(76, 81, 88) involvement in decision-making may delay treatment.(68) One patient described how some people like ‘happy talk’ and to be ‘kept in the dark’ and some people like the ‘facts’, with the former being less likely to participate.(101)

Perceiving that you do not *need* to be involved is another, related barrier. Some patients presume that everything will get done for them, and thus they do not need to be prepared to play an active role in decision-making.(88) This was found to be the case in a study of adolescents where they felt involvement was not necessary, as their parents would take on that role.(114) On the other hand, recognising the SDM patient role, and accepting the responsibility to be involved is a key facilitator. As we would expect, the greater emphasis the patient puts on him or herself as the person responsible for making decisions, the more likely they are to be involved. Patients talk about a desire to be involved in their own healthcare in a sense that they are accepting responsibility.(67, 79, 86-89, 106) Some patients refer to this as wanting to have ‘control over your own destiny’(78), and some believe that having control over a situation is important when you are ill, and active involvement is key to this.(84) A patient in Frosch et al’s(38) study shows how responsibility to be involved sometimes goes beyond receiving options and discussing them; they believed that they had a responsibility to educate themselves and carry out their own research.

Some patients were unsure about what it is they can expect from a SDM consultation and do not know what to prepare for. If they have never encountered SDM before, and thus do not know what it is they should be involved in, they do not know what information and support they can expect to receive ahead of making a decision.(74, 81) It therefore seems important to address patients’ expectations by explaining to them ahead of time what it is they can, and should, expect from a SDM consultation.

(ii) Expectations of the outcome of being involved in SDM (21/44)

When patients perceive that there are ‘right’ and ‘wrong’ decisions, this acts as a barrier to SDM. Some patients use the term ‘right’ to describe decisions that are made by their doctor. (80, 99, 103, 106) Patients report that they do not want to be involved in the decision-making process because they do not want responsibility for a ‘wrong’ decision,(76, 80, 87, 99, 103) suggesting that they want to avoid any potential regret. Some patients talk about being able to ‘blame’ clinicians for ‘bad’ outcomes if they are not active participants in the decision-making process.(99) On the other hand, when patients recognise that there are no

right or wrong decisions in situations of equipoise, just ‘decisions that are right for me’, this acts as a facilitator to involvement. This acceptance of uncertainty, and recognition that certain decisions are based on personal values, encouraged patient involvement (67, 83, 89, 101)

For some patients, a fear of accepting the reality posed by the diagnosis (e.g. diabetes,(74) cancer(108)) is a barrier to involvement. They may have anxiety towards certain examinations or treatment,(106) or they may feel unable to cope with the diagnosis that they have been given.(89, 102) Patients in Peek et al’s(74) study described how fear and denial are important barriers in SDM, with several patients reporting that they would rather not know the truth, and thus do not want information about the diagnosis or the likely outcomes of the different options. In the context of advanced care planning (e.g. end of life decisions) some patients would simply rather not think about the future: ‘I would rather concentrate on staying alive than talking about death.’(92)

Overall, most factors related to preparation for a SDM consultation are modifiable, and can be addressed by seeking to change attitude or subjective norm beliefs e.g. clearly outlining the concept of equipoise, emphasising patients’ roles/responsibilities and the need to participate, outlining what is involved in the SDM process. However, some factors will remain non-modifiable by an intervention to encourage involvement e.g. the shock after receiving a cancer diagnosis.

d) Preparation for a SDM process (36/44)

(i) Information provision about options (27/44)

Many patients feel they cannot be involved in decisions when they do not have information about the specific condition, when they are unaware of the options and what they entail, or do not know the possible outcomes. For example, Nodgren et al(98) described how patients’ self-determination in the care context was limited, because they lacked knowledge about their disease and the available treatments. One patient noted, ‘I don’t think I had received enough information about the risks to be able to make a decision about the operation’(98). Skea et al (83) explored women’s views of decision-making relating to hysterectomy, and similarly found that limited information provision, especially about the possible treatment outcomes, restricted patients’ abilities to participate in the decision-making process.

Equally, provision of sufficient information to address individual information needs was a key facilitator. Eldh et al(69) explored conditions for patient participation in healthcare by asking patients to describe previous situations in which they participated, or did not participate, and to explain the reasons why. Being informed according to individual needs was one of the main conditions for participation cited by patients in this study. Peek et al(74) explored barriers and facilitators to SDM among African-Americans with diabetes. They found that informed patients reported more self-efficacy, not only in participating in decision-making with their physicians, but also in their confidence to ask questions about the various treatment options, thus actively participating in the dialogue. Similarly, Thorne's(101) study of cancer patients highlighted how patients felt better prepared to engage effectively in consultations when they were appropriately informed according to their individual needs. Earlier provision of information, e.g. before consultations, was reported by some patients as an important factor in being prepared for a SDM process.(83)

The way in which clinicians present the available options was another frequently cited barrier and facilitator. When the clinician did not take time to explain each option, patients found it difficult to participate in the decision-making process. For instance, hysterectomy patients in Skea et al's(83) study described how they were not given sufficient information about the alternative options available to be able to make a shared decision. One patient reported that she was given very little information regarding how the laser treatment option would work compared to the surgical option, and she did not know what the possible side effects or outcomes of the laser treatment would be. Another patient reported a similar situation regarding the medication options; she received no information about how these options worked compared to the surgical options. Additionally, she received no information about the possible disadvantages of any of the options, leaving her unsure as to whether there were any disadvantages of surgery, and thus unable to make an informed decision.

Conversely, when the clinician clearly presents the available options and discusses what the options entail (e.g. procedure, possible outcomes), patients feel much better prepared to take part in medical decision-making. Most early stage breast cancer patients in the first phase of O'Brien et al's(100) study felt that the surgeon helped them to be involved in treatment decision-making when they discussed their surgical options. Individual patients commented on the helpfulness of being presented with the personalised outcome data and the opportunity to view the 'stats' to make a judgement on the outcomes of each option e.g. highest possibility of recovery. Survey respondents in Caress et al's(78) study of asthma

patients indicated that active participation was linked to how much patients felt they knew about their condition and the available treatments. Participants in Thompson's(84) study were asked to describe what happens in their healthcare consultations, and to identify factors that helped or hindered the process. Patients described situations of being involved as being told your diagnosis and having somebody take the time to explain the available options, along with the side effects. Significantly, the patients refer to their involvement as being part of a 'team', within which their opinions are valued.

(ii) Terminology used by clinicians (17/44)

Patients feel that it is difficult to be involved in the decision-making process when clinicians use medical jargon instead of simple terms that patients can understand.(81, 87) Doherty et al(81) describe a situation whereby a patient who wanted to participate in SDM felt unable to do so because they were intimidated by the doctors' use of medical terminology during ward rounds. Further studies highlight this problem, whereby patients feel that the clinicians are 'talking another language'(98) or 'talk so far over patients' heads'.(67) In some situations, unexplained medical terminology can lead patients to misinterpret the procedures that are being offered, and thus hinder their ability to make reasoned decisions about them. In Farahani et al's(105) study, one patient described how many patients thought that an angiography was a dangerous operation with the possibility of dying, as opposed to a type of x-ray.

On the other hand, patients frequently cited the use of simple, non-technical language as a facilitator to involvement in the decision-making process. Patients in Eldh et al's(69) study discussed the importance of being informed according to personal needs, but they also highlighted the importance of receiving this information in a way that the patient could grasp it. Patients' quotes indicate that the use of ordinary language and alternative information presentations, such as diagrams, facilitated involvement. Similarly, patients in Peek et al's(74) study stressed the importance of discussing medical problems in 'layman terms', which could also be facilitated through the use of diagrams. Patients in this study talk about bringing the doctor down to the level of the patient, or the doctor bringing the patient up to their level, suggesting a compromise whereby each participant in the SDM encounter attempts to ease the information exchange process: clinicians use simple terms and they also help patients to become more informed in the medical terminology. Importantly, Kelsey et al's(82) study of

hospitalised young people highlighted the impact of providing information at an appropriate level for perceived, and possibly real, empowerment and autonomy in the young people.

(iii) Decision Support (8/44)

Lack of written decision support can act as a barrier to involvement, because it is difficult to remember the information presented.(100, 111) Barnard et al(77) showed that patients valued decision support materials as they helped them to remember information, focus on points of concern, think about issues they wish to discuss in the consultation, and thus facilitated SDM. Decision aids are also seen as a good starting point to promote discussion with clinician, and thus involvement in the SDM dialogue.(68) However, it is important to note that whilst some patients view decision support materials as helpful, others felt that they make the consultation feel impersonal and false, and they favoured the direct information exchange from the doctor(68, 77) The facilitative potential of decision support materials is reduced if patients feel that the purpose of the tool is unclear,(93) and patients also commented on the difficulty of ‘keeping up’ with rapidly evolving medical information. (89) Decision support also refers to the support that the patient is offered from alternative sources e.g. family, friends, other patients, non-doctors; patients in two studies highlighted the importance of discussing your treatment options with other people.(8, 83)

The factors related to preparation for the SDM process are modifiable; many of the listed barriers could be addressed through adequate information provision about the options available (whether this be decision support tools or from the clinician), a balanced presentation of options, and use of non-medical terminology by the clinician when discussing the options.

2.4 Discussion

The results suggest that most patients currently *can't* participate in healthcare, due to various structural, pre-disposing, interactional, and preparatory factors, rather than the more common view among clinicians that patients *won't* participate because they *don't want* to. Patient-reported barriers and facilitators to SDM relate to how the healthcare system is organised (i.e. time available, continuity of care, organisation of workflow, and the setting itself) and to what happens in the consultation (i.e. predisposing factors such as patient characteristics, interactional influences including the power imbalance between patient and

clinician, and preparation for the SDM encounter and the process itself, including knowledge gain). These need to be considered alongside clinician-reported factors(57) during intervention development and implementation. Predominant themes were patients' knowledge and the power imbalance in the clinician-patient relationship. Significantly, most patient-reported barriers and facilitators are potentially modifiable, and many can be addressed by attitudinal changes at the levels of patient and clinician/health care team, or cultural change at the organisational level.

An 'informational paradox'

An important information paradox has been identified. Unsurprisingly, the principal enabler to SDM is having informational needs met at an appropriate level for the individual. However, we cannot consider this in isolation from other relevant factors because of their complex interactions. Patients report that they need to have their informational needs met in order to participate, but they also undervalue their ability to acquire this knowledge, and undervalue any knowledge gain relative to that of the clinician. The prevailing view is that 'doctors know best'. Patients feel that they are unable to acquire the complex medical information that doctors own, and any knowledge they acquire will always be trumped by the doctors' expertise; thus inevitably patients tend to defer medical decisions to the clinician. Patients place physicians on a pedestal with regard to their 'superior' knowledge, and there is some evidence that patients feel more comfortable when they perceive their doctor to be 'all-knowing'. A recent article found that patients derogate physicians who use a clinical decision support, as they deem them less capable than those who do not use a tool to aid diagnosis.(120) A contributing factor is that patients also place much emphasis on medical information provided, but do not recognise, or undervalue, the complementary expertise that they can bring to the SDM encounter i.e. personal preferences and circumstances. This suggests that the only expertise patients recognise as legitimate in the healthcare consultation is the medical expertise.

Therefore, information provision alone appears insufficient for SDM; patients need to be supported so they feel that they are capable of acquiring and understanding knowledge about the available options, and so that they value their personal knowledge contribution in this process. In relation to Nutbeam's levels of health literacy (functional, critical, interactive),(44) the focus for interventions should be on developing interactional health literacy, which encourages the development of personal skills so that people can actively use the knowledge

acquired, as opposed to functional health literacy, where the focus is on transmission of factual information.

'Covert contracts' in the patient-clinician relationship

Interacting with this informational paradox are the 'covert contracts' that patients develop with clinicians, usually physicians, which are not typically acknowledged. Many patients enter into an unspoken contract with the clinician, adopting the role of a 'good patient', characterised by passivity and compliance. This chapter does not elucidate the reasons why these contracts exist (e.g. socialisation to patient role, previous experience, social/cultural norms, the media).(121) Nonetheless, presumptions about the 'normal' patient role emerged as an important barrier, with many patients believing that they should not or cannot be involved. In Foucauldian terms,(122) we may be able to change discursive practices regarding expected patient roles if patients experience discursive practices regarding where they are encouraged to avert the traditional 'clinical gaze', by considering their own preferences and developing skills of self-representation. Therefore, implementation attempts should also focus on providing patients with explicit permission to change these 'contracts' and promote their self-efficacy, or confidence, in achieving this.

This approach would reflect a generative 'asset' model of health literacy,(43, 44) where it is proposed that health literacy skills, which are needed to engage in SDM,(43) are an asset that develops over time. As outlined in the Health Literacy Pathway Model,(43) health knowledge, or a basic understanding of the health information, is just the first of five stages in being able to participate in SDM: there are other skills that the patient needs to develop, or enhance, in order to appraise this information and to engage in a discussion with the clinician. As such, once patients have been given this permission to participate, we will need to support the development of the necessary skills, and promote their self-efficacy in participating.

Knowledge does not equal power

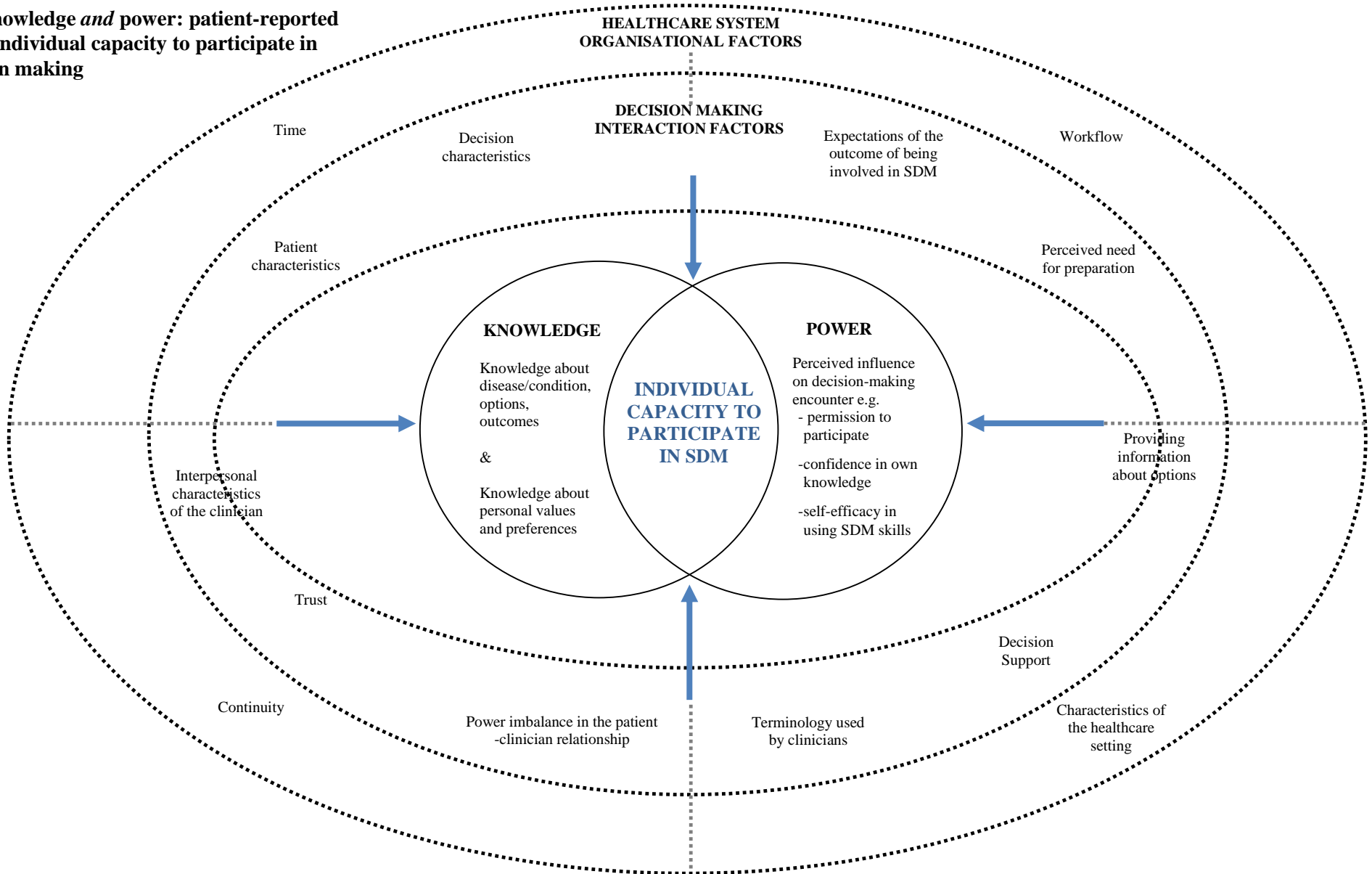
As we have seen, knowledge provision, acquisition, and expectation to contribute personal preferences are done in the context of a power imbalance between clinicians and patients. Therefore, information provision and values clarification exercises (e.g. in decision support tools) alone are unlikely to promote SDM for most patients. We must also address the power imbalance that exists so that people feel that they can and want to use this knowledge.

Contrasting the well-known phrase, it would appear that knowledge does *not* equal power (*Sir Francis Bacon, 1597*), at least in the discourse of medical decision-making: patients need knowledge *and* power in order to participate in SDM. Individual capacity to participate is linked to how much knowledge a patient has (i.e. knowledge about treatment options and knowledge about their own personal circumstances) *and* how much power they have, or perceived capacity to influence the decision-making encounter (e.g. having permission to participate, confidence in own knowledge, having necessary skills, and self-efficacy in using these skills). All other factors (e.g. interpersonal characteristics of the clinician, patient characteristics, time) will promote or inhibit this capacity depending on their presence or absence (see Figure 2.2) Again, this approach has parallels with action orientated models of health literacy,(43, 44) in which there is a focus on motivational aspects, and not just intellectual capacity: it is about getting patients to actually use the information that they are given, by understanding and promoting the motivating factors and skills that will enable them so to do.

Comparison with clinicians' views

The three most commonly cited clinician-reported barriers are time, lack of agreement with the applicability of the approach to the patient, and lack of agreement with the applicability of the approach to the clinical situation,(57) suggesting clinicians presume that many patients will not benefit from SDM, or do not wish to take part. Whilst patient characteristics such as desire to participate emerged as factors in this review, factors other than desire were much more prominent (e.g. knowledge, power imbalance, interpersonal characteristics of the clinician). This supports Legare's suggestion that interventions should be patient-focused, encouraging patients to take a lead in decision-making, in order to avoid clinicians making sometimes erroneous, *a priori* judgements about lack of ability or desire for involvement. However, it also highlights the importance of understanding the patient-reported barriers, as they are distinct from the clinicians' barriers literature. This again lends more support to the view that patients currently *can't* participate, rather than they *won't* participate because they do not want to.

Figure 2.2 - Knowledge and power: patient-reported influences on individual capacity to participate in shared decision making



Preparation for what?

Another important distinction that emerged concerned the different types of preparation needed for SDM: preparation to participate in the decision-making process itself, but also the attitudinal preparation needed to present a patient with the opportunity to participate in SDM. To date, it appears that many of the interventions designed to encourage patients to participate in SDM focus on preparation for the decision-making process.(16) In fact, the barriers cited in relation to process, such as lack of information about options and use of medical terminology, have largely been addressed by these interventions; thus the use of these would help to overcome these specific barriers. However, it appears that interventions have largely overlooked the attitudinal preparation that is also needed, which interacts with the power imbalance evident in the patient-clinician relationship. Power imbalance and the associated attitudes towards patient involvement were a key barrier; if attitudinal preparation to address beliefs and perceived social norms about the passive patient role does not take place before information provision, it is unlikely that that patients will change their behaviour and actively engage in the decision-making discussion.

2.4.1 Implications

The discussion above pertains to the key themes and interactions that have emerged from this review; there are many additional barriers and facilitators that have been identified through other literature (e.g. clinician perspectives)(57) that will also need to be considered during intervention development, and these will be discussed in further detail in Chapter 4. However, it is clear from this review that many of the patient-reported barriers are attitudinally based, and are therefore potentially modifiable. Given the significance of patients' beliefs and normative attitudes towards SDM, behaviour change theories are an appropriate guide for intervention development and evaluation. Many behaviour change theories include these concepts as key drivers of behaviour, including the BCW Guide.(47) This is discussed further in Chapter 4.

It should be acknowledged that many behaviour change theories account for change at the individual level. Therefore, it is critical that a behaviour change intervention is embedded within the wider implementation context. First, I have identified 'pre-disposing' factors relevant to the patient and the decision, which will determine the relevance (or not) of SDM to that situation e.g. preference-sensitive decision, emergency situation, health-literacy level,

perceived self-efficacy, patient with cognitive impairment. These need to be considered when initiating a SDM interaction, but the modifiable nature of some of these factors suggests that they should not necessarily act as a barrier to offering SDM (e.g. 'age' as a barrier might be related to subjective norms about what it means to be a 'good' patient, rather than age per se). Second, I have identified clinician-related attitudinal and behavioural factors that will facilitate or impede SDM depending on their presence or absence: this is in addition to the published taxonomy of clinician reported barriers/facilitators.(57) Third, I have identified organisational factors that might also impact on patients' ability to participate in SDM e.g. time.

An intervention may be successful in changing attitudes and subjective norms, so that a patient intends to carry out SDM, but patients might be incapable of carrying out the intended behaviour if, for example, the doctor has a negative attitude towards involvement or they are not afforded the time need to engage in the process. What is clear from this current review is that organisational and clinician attitudinal/behavioural changes alone will not support SDM: as such, an intervention focused on patient attitudinal/behavioural change, implemented in the context of these wider changes, should be used to guide intervention development as it addresses the attitudinal and behavioural changes needed at the patient level.

2.4.2 Strengths and weaknesses

To my knowledge, this is the first systematic review to focus exclusively on patient-reported barriers and facilitators to SDM, and direct enquiry with patients in the primary studies is a significant strength of this study. This review does not focus on characteristics that are correlated with a greater desire to be involved, or greater actual involvement; it examines what patients have reported to be significant factors in helping them or stopping them from being more involved in their healthcare consultations. Direct enquiry might miss more subtle barriers and facilitators that are not directly obvious to patients (e.g. coping style), but I am confident that the key factors influencing participation have been identified, supported by their consistency across a large number of studies using various research methodologies.

Although systematic searches were used, this is not a well-indexed field of research and researchers have varying interpretations of SDM: as such some articles might have been missed in this review. Synthesising qualitative data derived from the systematic review

approach is also an emerging field of research, whereby the methodologies are not as well defined as, for example, systematic reviews of effect sizes using randomised controlled trials.(123) However, this review has used a well-documented approach developed by the ESRC for analysing the qualitative data from our review(73), and the process has been described. I used an inductive approach to analysing the data because no pre-existing taxonomy of patient-reported barriers/facilitators to SDM existed, which ensures that key themes were derived directly from the data. The resultant taxonomy of patient-reported barriers and facilitators can be used to complement the clinician taxonomy.(57)

In this review, some patients have said that they do not want to be involved in decision-making. However, it is not clear from our review if these patients have made an ‘informed’ decision not to be involved; in other words, these patients may state that they do not want to be involved because they have never been afforded the opportunity to be, and thus do not know what it means to be involved. It is possible that many of the ‘do not’ want to participate individuals are actually ‘cannot’ participate individuals, because their participation is limited by their lack of knowledge of what it is to be involved. This fits with findings from Longo et al’s discrete choice experiment study, whereby patients placed greater value on SDM consultations once they had experienced them.(124) This highlights the importance of informing all patients about what a SDM consultation involves and offering them the opportunity to participate; a patient-targeted guide to a SDM consultation could help patients to make more informed choices about whether or not they want to participate.

2.4.3 Conclusion

This review found that patients need knowledge *and* power to participate in SDM. One of the most significant barriers to SDM was inadequate information provision.** To date, researchers appear to have ‘picked off’ the most prominent patient-reported barrier to involvement, that being inadequate information provision, and have perhaps wrongly assumed that they can address this barrier in isolation from the many other interacting factors: as demonstrated by a focus on developing patient decision aids(16) and the content and development process for these.(125, 126) Decision aids are successful at supporting patients in the SDM process, but they fail to address the essential first step of ‘preparing for

** This chapter forms the basis of two published articles in Patient Education and Counseling and the BMJ. These can be viewed in Appendix 2.2 and Appendix 2.3, respectively.

the SDM encounter', including perceiving the opportunity and personal ability to be involved. Knowledge provision and encouragement to think about personal values alone are unlikely to support actual involvement in SDM for a large number of people. Power imbalance in the clinician-patient relationship and perceived acceptability of patient involvement are also key barriers. These must be addressed too if patients are to change their long-established behaviours and actively engage in decision-making discussions.

In one of the earliest papers published in this field, Charles and colleagues wrote about what it means to be involved in SDM.⁽¹²⁾ Fundamentally, at least two participants, a clinician and patient, need to be involved. Attempts to develop tools to support this interaction have been successful, but SDM researchers and implementers seem to have forgotten that 'it takes at least two to tango' when conducting implementation work. The focus on addressing clinician and organisational factors has meant that little value has been afforded to what patients actually think about implementing this approach; what do they think helps or stops them from taking part? This Chapter has taken steps to explore this and Chapter 4 will ensure that this viewpoint is integrated with existing implementation literature to form a strong theoretical foundation for developing a complex intervention to support SDM. However, SDM researchers and implementers must remember that patient-reported factors cannot be addressed by focusing on patients alone: significant structural and attitudinal changes at the organisational and clinician level are still needed, and clinicians will have a valuable contribution to changing the subjective norms of patients.

Chapter 3

A review and critical evaluation of patient-targeted interventions designed to prepare patients for SDM: do they address patient-reported barriers and facilitators?

3.1 Introduction

'Doctor knows best' is perhaps one of the most clichéd terms used to describe patients' perceptions of the doctor-patient relationship, but the consequences of this view on patients' capacity to participate in shared decision-making (SDM) should not be underestimated. As highlighted in Chapter 2, patients need knowledge *and* power to participate in SDM. Attitudinal factors, such as perceived social norms about appropriate behaviour in the doctor-patient interaction and not having 'permission' to participate, were key patient-reported barriers to participation. Significantly, the results indicated that providing decision options and knowledge to patients does not empower them to participate in SDM if they do not know what to do with the knowledge, or feel that they cannot do anything with that knowledge. It was concluded that an intervention designed to promote patient participation in SDM should focus in the first instance on addressing patients' attitudinal factors, before information provision about options. This review aims to identify and critically evaluate existing interventions that focus primarily on attitudinal change and preparing patients to engage in a SDM discussion.

A Cochrane Review of patient decision aids now includes over 100 randomised controlled trials of interventions that focus primarily on information provision and values clarification; most of these trials show favourable outcomes for patients, including improved knowledge and more realistic perceptions of treatment outcomes.(16) Implementation programmes have also focused on integrating decision support interventions into clinical pathways and distributing these tools.(60-64) The considerable number of decision aids that exist for various healthcare decisions, and the integration of these into clinical systems, indicates that researchers have focused on addressing one of the key patient-perceived barriers to SDM -

knowledge. However, researchers have paid less attention to ‘entry-level’, or ‘gatekeeping’ factors that will determine whether patients actually engage in a SDM discussion, and use their acquired knowledge. In other words, interventions have focused on addressing the ‘knowledge’ deficit, as opposed to the ‘power’ or attitudinal barriers (e.g. having ‘permission’ to participate, perceiving the patient role as active in the decision-making process, belief in own knowledge and ability to acquire knowledge about the options).

For many patients, participation in SDM signals a significant attitudinal and behavioural shift from what they are used to (e.g. expectation of being passive and being told what to do by the clinician). When we look at health-related behavioural change literature, there is a focus on understanding the motivations and barriers for conducting positive health behaviours, in order to understand how negative health behaviours can be changed (e.g. (116, 117) Whilst SDM is not typically viewed as a health behaviour, not participating in the decision-making process could be viewed as a negative health behaviour that has potential negative outcomes e.g. decisions misaligned with the patient’s preferences, receiving treatment that you do not want or need, or outcomes that you did not expect.

If a clinician were faced with a long-term smoker, it is unlikely that they would hand them an intervention (e.g. nicotine patches, medication) with some information about how they are used, and expect them to change their attitudes and behaviours to smoking immediately. They would need to make sure that the smoker was ready to participate in the behaviour change first, understand their motivations and barriers for doing so, and offer support to change their attitudes about the negative health behaviour. On the other hand, decision support tools are handed out to patients, which provide the necessary tools and knowledge to become involved, without first making sure that the patient is ready or prepared to be involved. Implementation researchers have also tended to neglect patients’ motivations and barriers for becoming involved in SDM, and therefore have little understanding of what factors will actually lead to a behavioural change: a perspective that Chapter 2 has synthesised. A taxonomy of patient-reported barriers and facilitators to SDM was proposed (see Figure 2.2, Chapter 2),(127) which allows us to understand the patient-perceived motivating and impeding factors that must be addressed in order to change attitudes about SDM among patients, and subsequently behaviours. Interventions should consider these in conjunction with clinician-perceived factors and organisational perspectives.(33, 57)

A key step in developing a complex intervention is to understand the existing evidence base and available interventions.(45) Given the abundance of interventions designed to address the knowledge barrier, this chapter focuses on interventions that prepare patients for a SDM encounter by addressing attitudinal and normative factors, before information provision. The decision specific interventions addressing knowledge (i.e. decision aids) should be used as adjuncts to the attitudinal interventions, but results from Chapter 2 indicate that they are unlikely to promote SDM for most people in isolation from such attitudinal interventions.(127) The aim of Chapter 3 is to identify, describe and critically evaluate patient-focused interventions that aim to prepare patients for a SDM encounter by primarily focusing on attitudinal and normative factors. Specifically, I will assess:

- a) Characteristics of included interventions
- b) To what extent the identified interventions address patient-reported barriers and facilitators to SDM
- c) Evaluations of effectiveness of these interventions, focusing primarily on patient reported and health outcomes

3.2 Methods

3.2.1 Search strategies

Targeted literature and online follow-up searches were used. Previous Cochrane Reviews have been conducted that identify the following: decision aids for people facing health treatment or screening decisions;(16) interventions before consultations for helping patients to address their information needs;(128) SDM interventions for people with mental health conditions;(129) and interventions for improving older patients' involvement in primary care episodes.(130) Broadly, these reviews identify patient-focused interventions that have been designed to promote active patient participation in SDM during healthcare consultations. Specifically, these may include some interventions that have been delivered before consultations that explicitly aim to prepare patients to take part in a SDM by focusing on attitudinal change.

Each previous review has used inclusion and exclusion criteria that are relevant to their specific aim e.g. interventions delivered *before* the consultation(128) or interventions for

patients with *mental health conditions*.⁽¹²⁹⁾ Additionally, Cochrane Reviews tend to employ stricter criteria regarding study design e.g. only randomised controlled trials are considered (see Additional Appendix 3.1 on included CD for full details of inclusion/exclusion criteria used in previous reviews). Cochrane guidelines state that the associated publication should report studies that were excluded from the review, as well as those studies that were included.⁽¹³¹⁾ Therefore, for the purposes of the current review, publications noted as included and excluded in each review were considered. Publications noted in the reference lists as ‘awaiting assessment’, as they are on going, were also consulted. An update of one of the reviews was being conducted at the time of this work⁽¹²⁸⁾, so the results of this update were also considered (available via personal communication).

Targeted follow-up searches were conducted to complement the searches of previously published reviews. These included: consulting websites and publications of organisations known to promote patient involvement or healthcare improvement (e.g. Informed Medical Decision Making Foundation, Expert Patients Programme); consulting health related Government websites and policy documents; consulting departmental/organisational websites of authors from the book ‘Shared Decision Making in Health Care: Achieving Evidence Based Patient Choice’;⁽¹³²⁾ examining abstracts from the 2013 International Shared Decision Making Conference (Peru, June 2013); and manual searches of the reference lists of papers included for full text analysis (see Figure 3.1).

3.2.2 Selection criteria

A study/intervention was eligible for inclusion in this review if:

- (i) the intervention was patient-focused, or focused on the patient and their representative e.g. carer, surrogate decision maker, partner;
- (ii) the intervention is delivered *before a* consultation (in which the decision is discussed);
- (iii) the intervention aims to prepare patients for a SDM encounter with a clinician (i.e. increasing readiness to participate) by focusing on attitudinal change towards patient involvement in SDM (i.e. a patient’s beliefs/expectations about being involved in the SDM process).

Evidence of this intention could include, for example:

- highlighting the active patient role in decision-making as accepted and expected; explaining what SDM is/outlining the process;
- outlining the patient role in the SDM process;
- promoting favourable attitudes towards participation in SDM.

For inclusion, the attitudinal change tasks must be followed-up by information provision about the available options and preference clarification tasks, but attitudinal change tasks must be distinct from and precede information provision/values clarification support. This is based on results from Chapter 2, which indicate that attitudinal change acts as a potential gatekeeper to actual engagement with information about treatment options and exploration of personal values. Also, knowledge about the available options is essential if a patient is to fully engage in the decision-making process.

Studies were excluded if the intervention:

- (i) aimed to improve general communication and information exchange in the healthcare consultation, without specific focus on the decision-making processes i.e. those that do not intend to impact on the decision-making dialogue between the patient and the clinician(s);
- (ii) is provided during or after a consultation;
- (iii) solely provides information about treatment options and/or promotes values clarification, in the absence of attitudinal preparation, or if attitudinal tasks do not precede information provision/preference clarification tasks;
- (iv) only encourages patients to consider treatment options away from the consultation (promoting autonomous rather than SDM);
- (v) is targeted solely at clinicians (e.g. skills training) or for individuals attending group consultations/activities (e.g. antenatal classes).

Interventions were also excluded if they aimed to promote any of the following: treatment adherence; compliance with a certain option; informed consent; patient involvement in other aspects of healthcare (e.g. service design, clinical trial participation); general involvement in self-management/self-care. Interventions were excluded if the intervention description, content and process of delivery, was not sufficient enough (after contact with author/developer) to determine if the intervention aimed to prepare patients for a SDM encounter by focusing on attitudinal change. Studies/interventions were not excluded on the basis of study design, method or language. When the same intervention is described in more

than one publication, the original development publication was included, or the earliest publication describing intervention format/use/evaluation in the absence of a developmental publication. All additional papers were considered as background papers during data extraction for details on intervention content, use, and effectiveness etc.

3.2.3 Intervention identification and data extraction

The title and abstract of all references identified through reference lists of previously published reviews(16, 128-130) were screened for relevance. Full text articles/full intervention details of potentially relevant studies/interventions were obtained for detailed evaluation. When sufficient information was not provided in associated publications, intervention developers were contacted to obtain a copy of the intervention, information regarding its development, and information on its current use and implementation in healthcare settings. Relevant information for data extraction was agreed and data extraction forms were piloted. Data were extracted under the following headings for all interventions meeting the inclusion criteria (data derived from main development publication and/or background publication(s)): intervention characteristics (developer, year, country of origin, language, name/title, aim, intervention description, format, method of delivery, timing/point of delivery, target audience/healthcare setting, generic versus decision specific intervention); development process/formative research; theoretical base/conceptual framework used; evaluation process/plans. Additional data were also extracted regarding the associated publications i.e. those publications that described either the development, pilot-testing, implementation or effectiveness of the intervention, including: author, year of publication, country, publication details, principal aim, study design, methodological approach, data collection methods, setting, participant details, and outcomes.

3.2.4 Intervention evaluation

The included interventions were assessed against the patient-reported barriers and facilitators to SDM identified in Chapter 2 (see Table 2.2) in order to examine the extent to which the interventions addressed the identified factors. Interventions were assessed against each barrier/facilitator using the following question: to what extent could the intervention, or the way in which the intervention is used, address the barrier/facilitator? A 4-point Likert-like scale was used: 1 = not at all; 2 = very little; 3 = moderately; 4 = to a great extent. An

‘unsure’ option was also available, if it was felt that there was not enough information available regarding the intervention or the way in which it is used to make a judgment. Details regarding the exact component(s) of the intervention and/or the intervention implementation process that addressed the barrier/facilitator were also extracted. When the intervention was not available after contact with the developer/author, scores were based solely on the associated publications. Interventions were not evaluated against non-modifiable barriers and facilitators that could not be influenced by any intervention (e.g. patient-targeted, clinician-targeted, organisational change intervention). These include: being in poor health, being in good health, cognitive impairments, prior exposure to the illness / decision-making point, difference in personal characteristics between the patient and the clinician. After the interventions were scored using the 4-point Likert-like scale, a ‘traffic light’ system was used to categorise the *barriers/facilitators* as follows:

- a) Green indicates that the barrier/facilitator has been addressed sufficiently by interventions;
- b) Amber indicates that the barrier/facilitator has been addressed to some extent, but there are areas for improvement; and
- c) Red indicates that the barrier/facilitator has not been addressed sufficiently by previous interventions.

A further category (grey) was assigned when a barrier/facilitator had not been addressed, but it was felt that either a patient-targeted intervention would have little direct influence on that factor, or the factor is only relevant in very specific situations. The effectiveness of the interventions was determined by assessing evaluation methods and impact on decision outcomes.

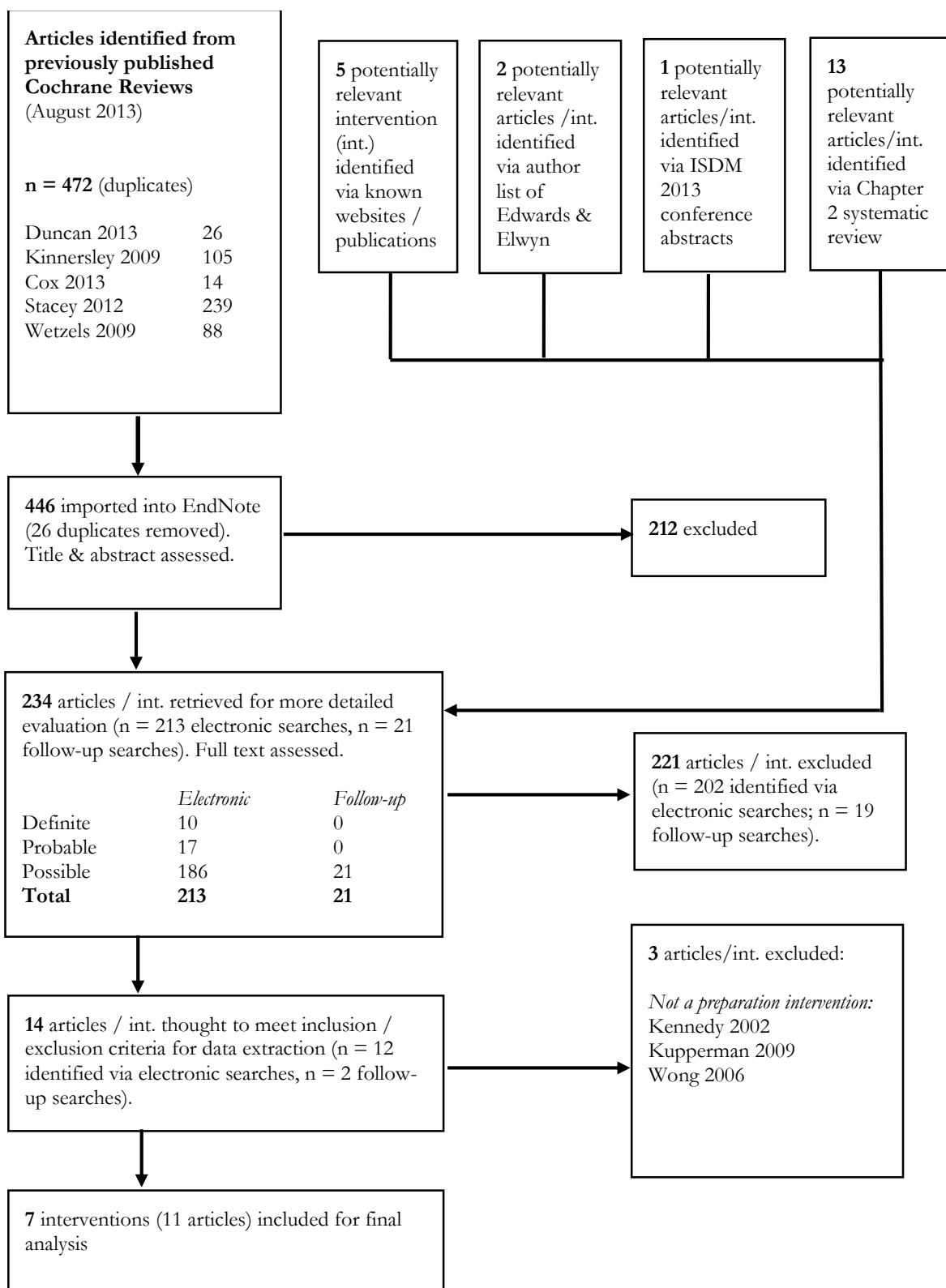
3.3 Results

3.3.1 Included interventions

Searches of previously published reference lists(16, 128-130) (including unpublished update, available via personal communication) yielded 446 unique references; 215 full-text articles/intervention details were retrieved for detailed evaluation. Seven interventions were included from electronic (n=5)(17, 133-137) and follow-up (n=2)(33, 138) searches. One

intervention has been evaluated in two separate trials. (17, 135) Three additional background/evaluation papers were included for the Sepucha(137) intervention.(139-141) Figure 3.1 describes the progress through the review, including details of articles/interventions identified via reference lists of previously published reviews, articles/interventions identified via follow-up searches, the stages at which articles/interventions were assessed (title and abstract, full text) and excluded or underwent data extraction, and the final articles/interventions included in the analysis.

Figure 3.1 - Flowchart of progress through literature review



3.3.2 Intervention and study characteristics

Seven different interventions were evaluated in the review (17, 33, 133, 134, 136-138), and four additional papers that describe the evaluation of included interventions were included.(135, 139-141) Three out of the seven interventions were developed in Australia, (133, 134, 138) three in the USA, (17, 136, 137) and one in the UK. (33) The earliest intervention was published in 1985; (17) the most recent were made available in 2012. (33, 138) Two interventions are now publicly available campaigns, (138, 142) whilst five interventions have been developed and tested solely in a research setting. (17, 133, 134, 136, 137) All of the interventions are generic (i.e. they can be used for any health condition), but three of the interventions contain disease specific elements (e.g. algorithms, question prompt lists). (17, 134, 136) The interventions have been used in various settings, including: cancer, (33, 134, 137) diabetes, (135, 136) female cancer, (33, 133, 137) maternity,(33) musculoskeletal,(33) paediatric ears nose and throat,(33) peptic ulcer disease,(17) primary care,(33, 137) renal,(33) reproductive and sexual health, (138) and urology.(33) Full details of intervention characteristics can be found in Table 3.1. A brief summary of each intervention is provided below.

3.3.2.1 Ask 3 Questions ⁽³³⁾

Ask 3 Questions is a patient activation marketing campaign, designed to increase patients' awareness of SDM and to change their expectations about patient involvement. It is intended to 'activate' patients before healthcare consultations by encouraging them to ask three key questions about their healthcare options:

- 1) What are my options?
- 2) What are the possible benefits and risks of those options?
- 3) How can we make a decision together that's right for me? / how likely are the benefits and risks of each option to occur?

The questions are reinforced with the statement, 'we want to know what's important to you', in order to emphasise the importance of patients' preferences. Originally from Australia,(143) the campaign was further developed in the UK (Cardiff and Newcastle) as part of an SDM implementation programme called MAGIC,(33) which used a quality improvement methodology; subsequently, local level testing and adaptation led to variations of the campaign questions. Various promotional materials were developed to display the

three questions, including posters, booklets (explaining the rationale for SDM and promoting active patient role) and a promotional video for use in waiting rooms.

It is used as both an intervention to be handed out to patients ahead of their consultation (with appointment letter or on arrival at appointment) and a general awareness campaign used across the local healthcare organisations. The campaign was implemented as part of a range of packages including, SDM skills training for clinicians, organisational engagement strategies and decision support tool development (e.g. Option Grids).(35) Ask 3 Questions has since been made publicly available for use or adaptation by other healthcare or voluntary organisations.(142, 144)

3.3.2.2 Ask Share Know (ASK) (138)

Ask Share Know (ASK) is a patient targeted campaign designed to encourage and empower people to be involved in decisions about their health. It has three main components, Ask, Share, and Know, but also explains and provides a rationale for SDM. The Ask component encourages patients to ask three key questions when they are given healthcare options:

- 1) What are my options? (one option will always be wait and watch);
- 2) What are the possible benefits and harms of those options?
- 3) How likely are each of those benefits and harms to happen to me?

The Share component encourages patients to share personal information with the clinician, so that they are aware of the patients' individual lifestyle preferences and needs. The Know component emphasises the importance of knowing all of the information you need to (e.g. possible outcomes, likelihood of outcomes, personal preferences) in order to make an informed decision. This section also contains a patient consultation summary tool to help structure the consultation around ASK. Various promotional materials have been developed including a website, video clips and magnets (with the website details). These materials are distributed to patients immediately before their consultation. ASK was originally developed as part of a research program, but it is also publicly available online (138) and the materials have been distributed by various patient organisations.

3.3.2.3 Cancer Consultation Preparation Package (CCCP) (134)

The Cancer Consultation Preparation Package (CCPP) contains several interventions, which aim to provide patients with a conceptual framework of evidence based SDM, and to inform

patients about their potential role in that process. The aim is to change patients' behaviour by making them more active in the consultation, with the intention of changing clinicians' behaviours. The package consists of the following:

- 1) An eight page booklet titled 'How Treatment Decisions are Made', which outlines the principles of evidence based medicine and the importance of patient involvement and preferences in the decision-making process
- 2) A brochure titled 'Your Rights and Responsibilities as a Patient', which outlines the legal rights of patients in Australian hospitals;
- 3) A cancer specific Question Prompt List, which provides 19 suggested questions.

The package was developed for use in a research setting, and is delivered to patients at least 48 hours before their initial consultation.

3.3.2.4 Greenfield 1985 Intervention ⁽¹⁷⁾

The intervention developed by Greenfield and colleagues in a research setting is designed to alter the traditional patient role in the patient-clinician relationship. The intervention is coach-led, whereby a clinic assistant works together with the patient during a 20-minute session through several key tasks, including:

- 1) a review of the most recent visit in the medical record;
- 2) a treatment algorithm (disease specific), which helps to identify relevant medical decisions that are likely to arise during the consultation; and
- 3) coaching patients to overcome common barriers to involvement, including embarrassment, fear of appearing foolish, forgetting to bring up an issue, or intimidation by the clinician. The patient is also encouraged to focus on treatment issues that could be affected by their lifestyle preferences.

The intervention is delivered directly before the scheduled appointment. Upon completion, the patient proceeds directly to their appointment, and receives a copy of their record and treatment algorithm at the end of the appointment to take home.

3.3.2.5 'How Treatment Decisions are Made?' booklet plus videotape ⁽¹³³⁾

The intervention developed by Brown and colleagues is designed as an 'advanced organiser', which provides a framework for patients' understanding of the structure of the decision-

making process. It consists of two key components: an eight-page booklet titled 'How Treatment Decisions are Made' and a 15-minute videotape. The booklet has also been used as part of a different intervention included in this review: Cancer Consultation Preparation Package (see above). (134) The booklet outlines the principles of evidence-based medicine, the importance of patients' preferences in the decision-making process, and encourages patients to play an active role in their healthcare consultations. The videotape portrays eight experienced medical oncologists discussing treatment options with patients. It is designed to model different patient styles, and to demonstrate that physicians are comfortable with both active and passive styles. The intervention is delivered immediately before a scheduled consultation.

3.3.2.6 Rost 1991 Intervention ⁽¹³⁶⁾

The intervention developed by Rost and colleagues is a coach-led intervention, which aims to enhance patient information seeking and decision-making during hospitalisation. It is adapted from the intervention developed by Greenfield et al (also included in this review; see above), (17) and consists of two key parts: the 45-minute individual session delivered the day before planned discharge and a 1-hour instructional package delivered at home after discharge. The first part of the intervention is almost identical to the Greenfield intervention listed above,(17) but it takes 45-minutes instead of 20-minutes to deliver, and the coach (i.e. nurse) also elicits examples where the patient has taken an active role in influencing the course of their care with positive results, and examples of past difficulties with communicating with physicians. The one-hour instructional package, delivered at home after discharge before the next outpatient visit, addresses and reinforces skills introduced in the earlier session. It includes a self-assessment of three question asking skills that patients can use to effectively communicate with their physicians (question construction, question introduction, and question clarification), and is followed by three modules that teach these skills. It is also delivered as part of a comprehensive 3-day evaluation and education programme, which constitutes usual care, but no further details are provided. Unlike the other interventions, this intervention is designed specifically for inpatients before discharge.

3.3.2.7 Consultation Planning Template (CPT) ⁽¹³⁷⁾

The intervention developed by Sepucha and colleagues is coach-led, and aims to prepare patients for their consultation by using the Consultation Planning Template (CPT). A nurse (or other trained facilitator) uses the guide to elicit and record patients' questions and

concerns for upcoming medical consultations. The structured outline includes prompts for the patient to generate decision-focused agendas for their consultation. The main sections include: Process Issues (goals for consultation, desired participation, timeline); Diagnosis and Prognosis (Test result, further testing, baseline prognosis); Treatment Choices (treatment spectrum, complementary therapy, treatment interactions); Treatment Implications (benefits and harms, impact on daily life, ranking the treatments), Values and Preferences (trade-offs, treatment goals, hopes, and fears, thoughts and feelings); and Next Steps (treatment selection, action items, barriers and resources). The sub-topics can be adapted for the specific clinical setting. The intervention is delivered immediately before a scheduled consultation. Following the session (which last approximately 35 minutes), the facilitator organises the agenda to produce the Consultation Plan for the patient, which they can then take to their consultation.

Table 3.1 - Characteristics of interventions included for evaluation

Intervention title (key reference) ^{††}	Developers/ Authors, Year, Country, References	Decision specific / generic	Intervention aim	Intervention description & format	Intervention use & evaluation	Healthcare setting(s)	Development process & theoretical/ conceptual base
Ask 3 Questions (33)	The Health Foundation (Cardiff University, Cardiff & Vale University Health Board, Newcastle University, Newcastle upon Tyne Hospitals NHS Foundation Trust), 2012, UK (33, 142, 144-146)	Generic	To raise awareness among patients about their role in SDM and encourage them to ask three key questions about their health and healthcare options	<p>Patient-targeted awareness raising campaign promoting patient involvement in SDM, consisting of 3 questions (two versions).</p> <p>Version 1: 1) what are my options?; 2) what are the possible risks and benefits of those options?; 3) how likely are the risks and benefits of each option to occur? Version 2: 1) what are my options?; 2) what are the possible risks and benefits?; 3) how can we make a decision together that's right for me? Both versions reinforced with statement: 'We want to know what's important to you.'</p> <p>Questions provided to patients in various formats, including: posters (in public areas and consultation rooms), A5 flyers (also contain blank list for patient's own questions), business cards, booklets (describes briefly: rationale for 3 questions campaign, why decisions and options are available in healthcare, importance of personal values in making decisions, examples of patients/clinicians who have found intervention helpful, that clinicians want patients to be involved in decisions and want to understand what is important to patients). Accompanying websites available with similar information (adapted for different audiences and the version used). Promotional video, intended for use in waiting rooms, and video vignettes with patient and clinician views of the campaign.</p>	<p>Designed primarily to be delivered ahead of a decision-making consultation (e.g. with appointment letter or by reception staff when attending clinic). Generally delivered ahead of a consultation as part of a clinical pathway (various according to setting), but also used as a general awareness raising tool across healthcare organisations and patient groups.</p> <p>Designed to be used and adapted by healthcare/voluntary organisations (e.g. AQuA adapted original materials.) (144) Different versions of questions used in different locations. Format of 3 question materials (e.g. posters, booklets, flyers) generally consistent across locations, design varies.</p> <p>Used in implementation / quality improvement programmes. Not tested in research study. No formal evaluation available.</p>	<p>Reported as used in various settings, including: breast cancer, paediatric tonsillectomy, head and neck cancer, urology, maternity, primary care, renal, musculoskeletal.</p> <p>Intervention available free for use and adaptation across NHS England & Wales via The Health Foundation – might also be used in other settings with different format, use etc.</p>	<p>Developed as part of an implementation / learning programme using a quality improvement (PDSA) methodology. Involved clinical teams, research teams and patient groups.</p> <p>3 questions based on questions originally developed by Shepherd et al 2011.(143)</p> <p>No theoretical model specified by developers. Original questions based on principles of decision analysis. (147)</p>
Ask Share	CemPED,	Generic	To encourage	Online patient-targeted awareness raising campaign promoting	Designed for use ahead of decision-	Reproductive and	Developed by a team based in

^{††} Publication that describes the development of the intervention or earliest publication describing intervention format/use/evaluation in the absence of a developmental publication

Know (ASK) (138)	Sydney University & Family Planning NSW, 2012, Australia (138, 143, 148)		and empower people to be involved in decisions about their health, by helping people to get the information they need to share medical decisions with clinicians.	<p>patient involvement in SDM. 3 distinct components to the interventions: 'Ask', 'Share' & 'Know'.</p> <p>Ask - encourages patients to ask 3 questions: 1) what are my options? (one option will always be wait and watch); 2) what are the possible benefits and harms of those options? 3) how likely are each of those benefits and harms to happen to me? A brief explanation of each question is provided to the patient.</p> <p>Share: encourages patients to share personal information with the clinician i.e. personal preferences and values. Emphasises that there are two experts in a consultation and the complementary knowledge patients can contribute. Highlights importance of medical history, individual risk factors, & lifestyle preferences in decision-making. Also describes what lifestyle preferences and needs are, and how they can impact on the decision made (with examples).</p> <p>Know: emphasises the importance of knowing the information that you need to make an informed decision e.g. outcomes, likelihood of outcomes, personal preferences, and general information given by clinician. Provides examples of strategies / tools that help patients to remember the information. Also provides 'consultation summary' worksheet – patient can log answers to 3 questions, what they shared with the clinician, and what they know / decided to do with the information.</p> <p>Also on website: description of and rationale for SDM; statement that medical decisions are a combination of professional's knowledge and patient's knowledge; examples of typical healthcare decisions; explanation of and rationale for 'wait and watch' option; description of individual lifestyle preferences and needs; video clips displaying 3 questions in action.</p>	<p>making consultations. In feasibility study, video-clip, consultation summary worksheet and magnet with website details given to patient immediately before a consultation.</p> <p>The intervention is also currently available as an online public awareness campaign. Possible those resources are not only used immediately ahead of a specific consultation. Resources also distributed by various patient advocacy groups.</p> <p>The 3 questions element of ASK have been tested in a cross-over trial with trained actors, but not with real patients.(143)</p> <p>ASK has been evaluated in a feasibility study (unpublished) examining demand, implementation and practicality of the intervention being distributed before a consultation (video clip, consultation summary & magnet with website details).</p>	sexual health. Intervention also publically available – likely to be used in various settings.	Australia from a West Australian consumer advocacy program (Patient First Program) and a consumer health advice book, 'Smart Health Choices'. (148) 3 questions tested with trained actors in family practice setting, Sydney.(143) 3 questions and the 'know' element of the intervention are based on principles of decision analysis. (147) When combined with the 'share' element, which enables patients to integrate the information with their own preferences, the intervention promotes aims of evidence-based SDM. (149)
Cancer Consultation Preparation Package (CCPP) (134)	Butow et al, 2004, Australia, English (133, 134, 150)	Generic / Specific (Question Prompt List)	To inform patients of their rights, posing questions that they might choose to ask, and outlining evidence based decision-making. It aims to change patient	The Cancer Consultation Preparation Package (CCPP) consists of 3 main components, designed to provide a conceptual framework for patients about evidence based clinical decision-making and to inform patients about their potential role in decision-making. 1. Booklet - How Treatment Decisions are Made (see Brown 2004 below for full description). 2. Brochure: 'Your Rights and Responsibilities as a Patient'. The brochure presents the legal rights of patients in an Australian hospital, and avenues for resolving complaints and disputes. 3. Question Prompt Sheet (QPL): endorses question asking and includes 19 suggested question and a recommendation to prepare a list of questions for the consultation.	Delivered at least 48 hours before the initial oncology consultation. Evaluated in 2-arm RCT.	Cancer patients attending first oncology consultation.	Development of booklet ('How Treatment Decisions are Made') outlined above (Brown 2004). Development of brochure 'Your Rights and Responsibilities as a Patient' not reported (existing publication developed by another institution). Development of QPL reported in Brown 1999.(150) The questions were derived from a

			behaviour, and through these changes, change physician behaviour	CCPP also includes the control booklet, which informs patients about the physical and spatial characteristics, staffing and procedures of the Sydney Cancer Centre (Sydney, Australia).			content analysis of 20 taped consultations and consultation with four experts: two medical oncologists and two psychologists experienced in cancer research. These questions were grouped according to their content using a method of categorization. No theoretical / conceptual base reported. Knowledge based solution strategies in medical reasoning referenced in previous publication detailing the booklet, 'How Treatment Decisions are Made' .(151)
Greenfield 1985 (17)	Greenfield et al, 1985, USA, English (17, 135)	Generic, used in conjunction with disease specific algorithms	Designed to alter the traditional patient role in the physician-patient interaction	<p>The intervention is designed to both inform patients about the logic of the medical care process and to improve their information seeking skills so they would interact more effectively with their physicians.</p> <p>20-minute session conducted by clinic assistant included: a review of the patient's medical record; a review of a treatment algorithm for chronic ulcer disease; and a behaviour change strategy designed to increase patient involvement in the physician-patient interaction.</p> <p>The clinic assistant reviews the most recent visit recorded in medical record with patient. They use an algorithm to help the patient identify relevant medical decisions in their care that are likely to arise during the current visit. The patient is encouraged to focus on treatment issues that could be affected by their lifestyle and preferences. Patients are explicitly encouraged to ask questions, recognise relevant medical decisions, and to share decision-making with the physician.</p> <p>Assistants coach patients to overcome common barriers to involvement including embarrassment, fear of appearing foolish, forgetting to bring up an issue, and intimidation by the physician. Goal is to teach recognition of relevant medical decisions and to reinforce assertive behaviours during visits with physicians. At conclusion, patient proceeds to scheduled consultation. At the end of the consultation they are given a copy of their medical record</p>	<p>Delivered during a 20-minute session immediately prior to a scheduled consultation.</p> <p>Evaluated in two RCTs: peptic ulcer disease(17) and diabetes(135)</p>	Peptic ulcer disease and diabetes.	<p>Not reported in detail. Developed as part a randomised controlled trial.</p> <p>Theoretical / conceptual basis not reported.</p>

				and the treatment algorithm.			
How Treatment Decisions are Made (+videotape) (133)	Brown et al, 2004, Australia, English (133, 134)	Generic	To promote SDM. To operate as an 'advanced organiser' that lays the framework for the patients' understanding of the overall structure of the decision-making process. Designed to provide a structuring of knowledge regarding clinical decision-making and sufficient cues to activate the learning achieved in the context of the consultation.	8-page booklet - describes decision-making in the context of evidence based medicine, treatment options, and patient preferences. It describes: a) the importance of evaluating treatments before they are widely used; b) different stages of research that are conducted to evaluate the safety and efficacy of new treatments; c) levels of evidence; d) how the Doctor decides which treatments to recommend, including a synopsis of factors other than evidence that may influence these options; e) the importance of patient involvement in treatment decision-making, if that is desired; f) a list of suggested questions to ask the Doctor about treatment options; g) explicit encouragement of active patient involvement. 15-minute videotape also part of the package – portrays eight experienced medical oncologists discussing treatment options with patient. Designed to model different patient styles and demonstrate that oncologists were comfortable with both active and passive styles.	Delivered immediately before a scheduled consultation (patients asked to turn up 30 minutes earlier). Booklet and videotape evaluated in 2-arm randomised controlled trial (RCT). Booklet also evaluated as part of a different package in Butow 2004 (134) (see below)	Female cancer patients (any site, any stage).	Developed in consultation with an international panel of experts in the fields of evidence-based medicine, psych oncology, and consumer involvement. Piloted with 24 female cancer patients for acceptability, salience and clarity. Also provided to panel of experts (2 patient advocates, 2 experts in evidence based medicine, 2 oncologists, 2 psycho oncologists). Field-tested with 164 cancer patients before first oncologist meetings as part of a range of interventions in another study. (134) No theoretical / conceptual base specified explicitly by authors, but they reference knowledge based solution strategies in medical reasoning. (151)
Rost 1991 (136)	Rost et al, 1991, USA, English (17, 136)	Generic, used in conjunction with disease specific algorithms	To enhance patient information seeking and decision-making during hospitalisation	Two key components: 1st component: 45-minute individual session between patient and nurse day before planned discharge. Nurse reviews physician's admission notes and laboratory values with the patient and introduces decision tree, which indicates treatment choices in managing various problems related to diabetes. Nurse elicits examples where patients have taken active roles in influencing the course of their care with positive results, and examples of past difficulties in communicating with physicians. Common obstacles to active patient participation and strategies to overcome these obstacles are discussed. The nurse closes the session by requesting that patient write down questions for the physician and suggesting that they review the decision diagram to identify treatment	Delivered the day before planned discharge consultation. Evaluated in randomised trial (136)	Insulin-dependent and non-insulin-dependent diabetic patients	Adapted from Greenfield 1985 (see above) (17). Notes that package was piloted and revised before the trial, but not clear which elements were piloted. No further information about intervention development provided.

				<p>decisions they would like to influence.</p> <p>2nd component: 1-hour instructional package the patient independently completes at home before their next outpatient visit (after discharge). Addresses skills introduced in the earlier intervention session. Includes self-assessment of 3 question asking skills patients can use to effectively communicate with their physicians: question construction, question introduction, question clarification. Self-assessment followed by three modules that teach the skills.</p> <p>Delivered as part of a routine comprehensive 3-day evaluation and educational programme (received by controls); no further details.</p>			
<p>Consultation Planning Template (CPT) (137)</p>	<p>Sepucha et al, 2003, USA, English(139-141)</p>	<p>Generic</p>	<p>Nurses use the Consultation Planning Template (CPT) to help prepare patients for their consultations</p>	<p>The CPT consists of a structured outline that prompts patients to generate decision-focused agendas for their meetings with healthcare providers. The main sections include: Process Issues, Diagnosis and Prognosis, Treatment Choices, Treatment implications, Values and Preferences, and next steps. In each section the subtopics can be tailored to the clinical setting where the template is being used.</p> <p>Trained facilitators (nurses, patient navigators, or resource centre staff members) use the CPT as a guide to elicit and record patients' questions and concerns for upcoming medical consultations. The consultation plan can be structured as a table, structured outline, or flowchart. During consultation planning sessions, facilitators use the focused questions from the CPT, as well as open-ended follow-up questions, to elicit patients' agendas for medical visits.</p> <p>Facilitators then organise and format the agenda to produce a consultation plan. They do not provide medical information - they focus on eliciting and organising what the patients know and the key questions they have.</p> <p>Last approximately 35 minutes. Patient given a copy of the CP and one attached to medical records for physician to see.</p>	<p>Delivered before a consultation within which treatment options will be presented.</p> <p>Evaluated in 3 studies. (139-141)</p>	<p>Generally used with breast cancer patients; also used with other cancer patients and in a community setting</p>	<p>Developed originally as part of doctoral thesis. The authors translated standard meeting facilitation processes that have been well validated in the business community to the medical consultation.(152, 153)</p> <p>Then the developers qualitatively integrated decision analysis to structure the discussion about treatment decisions and action science to promote open communication. (154-158)</p>

Table 3.2 - Intervention evaluation: the extent to which interventions address the patient-reported barriers and facilitators to SDM^{‡‡}

Patient-reported barriers & facilitators (descriptive themes & sub-themes)			Ask 3 Questions ⁽³³⁾	Ask Share Know ⁽¹³⁸⁾	Cancer Consultation Preparation Package (CCPP) ⁽¹³⁴⁾	Greenfield 1985 ⁽¹⁷⁾	How Treatment Decisions are Made + videotape ⁽¹³³⁾	Rost 1991 ⁽¹³⁶⁾	Consultation Planning Template (CPT) ⁽¹³⁷⁾
How the healthcare system is organised									
Time	Clinicians are too busy		3	2	3	1	1	1	1
	Inadequate/ adequate time in the consultation (bar / fac)		3	3	3	3	3	3	3
Continuity of Care	Inability to choose a clinician to do SDM with		1	1	1	1	1	1	1
	Too many clinicians involved in care		1	1	1	1	1	1	1
	Lack of continuity in informational flow between clinicians		1	1	1	1	1	1	1
	Clinician does not know / knows the patient (bar / fac)		1	2	1	1	1	1	1
Workflow	Distributing SDM among different clinicians (fac)		1	1	1	2	2	3	3
	System does not offer multiple-consultations model that may be needed for SDM / appropriate consultations for SDM (bar / fac)		Unclear	Unclear	Unclear	4	Unclear	4	3
Characteristics of healthcare setting	Inadequate environmental conditions		Unclear	Unclear	4	4	Unclear	Unclear	3
	Not paying / paying for healthcare (bar / fac)		1	1	1	1	1	1	1
	Overspecialisation of doctors		1	1	1	1	1	1	1

^{‡‡} 4-point rating scale (1=not at all, 2=very little, 3=moderately, 4=great extent). Green = barrier/facilitator sufficiently addressed by previous interventions, Amber = barrier/facilitator addressed to some extent, Red = barrier/facilitator not sufficiently addressed, Grey = not applicable. The following interventions were not available from the developer/author and scores were based on the information provided in the associated publications: Cancer Consultation Preparation Package, How Treatment Decisions are Made + videotape.

	Lack of reimbursement for clinicians undertaking SDM		1	1	1	1	1	1	1
What happens during the decision-making encounter?									
Predisposing factors									
Patient characteristics	Age (older / younger)		3	1	1	1	1	1	1
	Ethnicity		3	1	1	1	1	1	1
	Lower level of education		2	2	2	1	2	1	1
	Poor articulation		2	2	2	3	2	3	3
	Health condition – stigma / discrimination		1	1	1	1	1	1	1
	Long term patient (bar / fac)		1	1	1	2	2	2	2
	Physical impairments		1	1	1	1	1	1	1
Decision characteristics	Embarrassing or sensitive topics		1	1	1	2	2	2	2
	Shock of receiving diagnosis (bar) / time to come to terms with diagnosis (fac)		Unclear	Unclear	3	3	3	3	Unclear
Interactional context factors									
Power imbalance in the patient-clinician relationship	<i>Presumptions about the patient role</i>								
	Expectation of the clinician making the decisions		3	4	3	3	3	3	3
	Desire to act like a ‘good’ patient driven by a fear of consequences		2	2	2	2	2	2	2
	Perceived acceptability of asking the clinician questions (bar / fac)		4	4	3	4	4	4	4
	Belief that clinicians do not want patients involved		4	4	3	3	4	3	3
	Clinician reinforces passivity by rewarding this behaviour		1	1	1	1	1	1	1
	Having (fac) / not having explicit permission to participate in SDM (bar)		4	3	3	4	3	4	3
	<i>Patients undervalue their expertise relative to clinicians</i>								
‘Doctor knows best’ & patients’ have ‘inferior’ knowledge (bar)/ recognise that there are 2		2	4	2	2	2	2	2	

	experts in medical encounter (fac)								
	Patients are not capable of understanding medical/technical information		1	2	2	1	2	2	3
Interpersonal characteristics of the clinician	Authoritarian clinician		1	1	1	1	1	1	1
	Equal relationship (fac)	*	3	3	3	3	3	3	3
	Clinician does not listen to patient's concerns (bar) / clinician listens to patient's concerns (fac)		2	2	2	2	2	2	2
	Clinician with poor interpersonal skills (bar) / clinician with positive interpersonal skills (fac)		1	1	1	1	1	1	1
	Good relationship (fac) / poor relationship with clinician (bar)		1	1	1	1	1	1	1
	Lack of individualised approach & not asked about preferences (bar) / individualised approach and asked about preferences (fac)	*	3	3	3	3	3	3	3
	Clinician does not address patient directly		1	1	1	1	1	1	1
Trust	Trust in clinician (bar / fac)		1	1	1	1	1	1	1
	Lack of trust in clinician (bar / fac)		1	1	1	1	1	1	1
Preparation for the SDM encounter									
Perceived need for preparation	Patient is not entitled to a choice		4	4	4	3	3	3	3
	Patient is not explicitly offered a choice / presented in biased way by clinician	*	3	3	3	3	3	3	3
	Patient does not want or need to participate in SDM		2	2	2	1	1	1	1
	Accepting responsibility to be involved in decision-making (fac)	*	1	2	3	3	3	3	3
	Not knowing what to expect from the SDM consultation		3	3	3	3	4	4	4
Expectations of the outcome of being involved in SDM	Perceiving that there are 'right' & 'wrong' decisions, not wanting responsibility for a wrong decision (bar)/ recognising equipoise and uncertainty (fac)		2	2	2	1	2	1	1
	Fear of accepting reality of diagnosis		1	1	1	1	1	1	1
Preparation for a SDM process									
Providing information	Insufficient (bar) / sufficient information about condition, options, & outcomes (fac)	*	3	3	3	3	3	3	3

about options	Clinician does (fac) / does not explain options & outcomes (bar)		Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Terminology used by clinician	Clinician uses medical terminology (bar) / clinician uses simple terminology (fac)		1	1	1	1	1	2	1
Decision support	Written decision support (fac) / lack of written decision support (bar)		Unclear	Unclear	1	2	1	2	3
	Purpose of decision support tool is unclear		Unclear	Unclear	1	1	1	1	Unclear
	Decision support from others e.g. family, other clinicians (fac)		3	3	1	2	1	2	2

3.3.3 Intervention evaluation

3.3.3.1 To what extent do the interventions address patient-reported barriers and facilitators to SDM?

The interventions and associated documentation detailing the use and/or evaluation of the interventions were examined to assess the extent to which they could potentially address the patient-reported barriers and facilitators identified in Chapter 2 (see Table 2.2). Table 3.2 provides an overview of the scores awarded to each intervention against each barrier/facilitator. Two of the interventions were unavailable for review, after contact with the developers, so the scores are based on the information available in the associated publications.^(133, 134) The interventions were assessed against 51 different barriers/facilitators in total (27 barriers, four facilitators, and 20 combined barriers/facilitators). However, only 18 of the 51 factors were deemed appropriate for a patient-targeted intervention focusing on preparing patients for a SDM consultation to address in isolation, and this is used as the denominator when assessing how many barriers/facilitators were addressed.

Due to the relative homogeneity of scores across interventions, the ‘traffic light’ system was used to categorise at the barrier/facilitator level. Using the traffic light system, six of the 18 barriers/facilitators were categorised green (addressed well by previous interventions), two were categorised amber (have been addressed to some extent by previous interventions, with room for improvement), and ten were categorised red (not been sufficiently addressed by previous interventions).

Thirty-three of the total 51 barriers and facilitators were deemed as not appropriate for a patient-targeted intervention to address in isolation. However, interventions were scored against these factors to assess whether they have been addressed. Twenty-eight of the 33 factors were categorised as grey; these are factors that were not addressed well, but I would not necessarily expect a patient-targeted intervention to directly influence. A further five of the 33 barriers/facilitators I would not expect a patient-targeted preparation intervention to address were categorised as amber, because they were thought to address the factor to some extent (these are indicated with an asterisk in Tables 3.2 and 3.4).

Table 3.3 - ‘Green’ barriers/facilitators: factors that have been addressed sufficiently by previous interventions

Barriers / Facilitators		Intervention Score (1 – 4 or unsure)						
		Ask 3 Questions (33)	Ask Share Know (138)	Cancer Consultation Preparation Package (134)	Greenfield 1985 (17)	How Treatment Decisions are Made + videotape (133)	Rost 1991 (136)	Consultation Planning Template (137)
Sub-theme: <i>Presumptions about the patient role</i>	Perceived acceptability of asking the clinician questions (bar / fac)	4	4	3	4	4	4	4
	Expectation of the clinician making the decision	3	4	3	3	3	3	3
	Belief that clinicians do not want patients involved	4	4	3	3	4	3	3
	Having / not having permission to participate in SDM (bar / fac)	4	3	3	4	3	4	3
Sub-theme: <i>Perceived need for preparation</i>	Patient is not entitled to a choice	4	4	4	3	3	3	3
	Not knowing what to expect from the SDM consultation	3	3	3	3	4	4	4

Six of the 18 barriers/facilitators have been sufficiently addressed by existing interventions, with most interventions receiving a score of 3 or 4 for these factors (see Table 3.3 above). Four of these factors relate to patients’ *‘presumptions about their role in the medical encounter’*, and two relate to patients’ *‘perceived need for preparation’*. The factor receiving the highest score across all interventions was the *‘perceived acceptability of asking the clinician questions’*. All but one intervention(134) received a score of 4 for this factor, indicating that this is an area previous interventions address well. When patients feel that it is acceptable and appropriate to ask clinicians questions, this facilitates involvement in SDM. All interventions directly encourage patients to ask questions in the healthcare consultation, and use various techniques to achieve this: two interventions coach patients to overcome common barriers to asking questions, such as forgetfulness and embarrassment; (17, 136) four interventions provide patients with lists of questions that they can use if they are given treatment options (two

generic,(33, 138) two condition specific (17, 136)); two interventions include video clips demonstrating patients asking the clinician questions during a consultation;(133, 138) the aim of the CPT is to elicit patients questions about the decision-making process;(137) the Ask 3 Questions intervention includes statements from clinicians that have found this approach useful and uses the strapline ‘we want to know what’s important to you’.(33) All of these techniques indicate that it is acceptable for patients to ask questions about their options, and that clinicians are receptive to this.

Another barrier that has been addressed well is the *‘expectation of the clinician making the decision’*. All the interventions emphasise the importance of patient involvement in decision-making and encourage patients to take part in the decision-making process, thus indicating that the clinician does not necessarily make the decisions. Some address this issue directly: The ASK intervention explicitly states repeatedly that patients should be involved in healthcare decisions *together* with clinicians;(138) two interventions describe how medical professionals have changed from being more paternalistic, to now expecting patient involvement;(33, 138) two interventions use an algorithm to help patients to identify decisions about their care that they may wish to discuss with the clinician in the subsequent appointment.(17, 136) Some also address this issue more implicitly: the Ask 3 Questions intervention(33) encourages patients to get the answers to three questions and highlights the importance of personal values, the CPT process involves patients creating an agenda for their decision-making appointment,(137) whilst another intervention includes video clips portraying patients who are actively involved.(133) These indicate that the patient can be involved in the decision-making process, without explicitly stating that patients should make decisions together with clinicians.

Interventions have also addressed patients’ *‘belief that clinicians do not want patients involved’* in the decision-making process. The Ask 3 Questions intervention achieves this by using the strapline ‘we want to know what’s important to you’ (where ‘we’ represents the clinician/team/organisation) and stating ‘your healthcare professional needs you to tell them what’s important to you’.(33) The ASK intervention encourages patients to be involved and states that clinicians *will* share the decision-making with patients.(138) The intervention developed by Brown et al provides video examples of consultations where the patient is either active or more passive, making it clear that the clinician is comfortable with both types of consultation.(133) The remaining interventions do not address this barrier directly, but the

fact that the patient is being encouraged to become more involved, and sometimes even coached, suggests that the clinicians are receptive to the approach.

Another barrier addressed particularly well by existing interventions is *'not having permission to participate in SDM'*. In three of the interventions, 'permission' to be involved in SDM comes directly from the clinicians involved in the patient's care. For example, Ask 3 Questions includes the message 'we want to know what's important to you', and displays the materials in the waiting areas and consultations rooms.(33) Three interventions are delivered by coaches, who are members of the healthcare team, and they provide direct verbal encouragement to be involved in decision-making.(17, 136, 137) Two of the interventions use language that promotes patient involvement in their written materials and use video clips displaying patients who are active in the decision-making process.(133, 138) These three interventions were awarded a score of 3 as the 'permission' to be involved was not as explicit and did not come directly from the clinicians involved in the patient's care.

All interventions have taken steps to address the following barrier: *'patient is not entitled to a choice'*. Three of the interventions directly address this issue by emphasising that patients will sometimes be faced with choices about their healthcare, thus they are entitled to make decisions together with clinicians.(33, 134, 138) The remaining four do not explicitly state this entitlement to choice, but the fact that the interventions either encourage patients to actively identify relevant decision points(135, 136) or provide a framework of patient involvement in the decision-making process(133, 137) indicates that patients are entitled to choice.

Some patients report that *'not knowing what to expect from a SDM consultation'* is a barrier to involvement. All of the interventions provide at least a brief outline of what a patient can expect from a SDM consultation, including the key SDM components e.g. presentation of choice, options available, a discussion of options in relation to the patient's preferences etc. However, this is sometimes done quite briefly and it is not always presented in a way that might be easy to understand (e.g. interventions use text rather than diagrammatic presentation of the process). Two interventions have addressed this barrier to a greater extent by presenting patients with video examples of SDM consultations, and were awarded a score of 4.(133, 136)

Table 3.4 - 'Amber' barriers/facilitators: factors that have been addressed to some extent, with room for improvement

Barriers / Facilitators		Intervention Score (1 – 4 or unsure)						
		Ask 3 Questions (33)	Ask Share Know (138)	Cancer Consultation Preparation Package (134)	Greenfield 1985 (17)	How Treatment Decisions are Made + videotape (133)	Rost 1991 (136)	Consultation Planning Template (137)
Sub-theme: <i>Time</i>	Inadequate / adequate time in the consultation (bar / fac)	3	3	3	3	3	3	3
Sub-theme: <i>Patient characteristics</i>	Poor articulation	2	2	2	3	2	3	3
Sub-theme: <i>Interpersonal Characteristics clinician</i>	Equal relationship*	3	3	3	3	3	3	3
	[Lack of] individualised approach & [not] asked about preferences (bar / fac)*	3	3	3	3	3	3	3
Sub-theme: <i>Providing information about options</i>	Insufficient / sufficient information about condition, options & outcomes (bar / fac)*	3	3	3	3	3	3	3
Sub-theme: <i>Perceived need for preparation</i>	Patient is not explicitly offered a choice or it is presented in a biased way*	3	3	3	3	3	3	3
	Accepting responsibility to be involved in decision-making (fac)*	1	2	3	3	3	3	3

Two of the 18 barriers/facilitators have been addressed to some extent by the existing interventions. A further five barriers/facilitators that I would not expect a patient-targeted preparation intervention to address were also categorised amber, as they addressed the factor to some extent (total of eight categorised amber). These are marked with an asterisk in Table 3.4 above. All of the interventions received a score of 3 for the barrier/facilitator '*adequate time in the consultation*' as they are delivered ahead of the main consultation with a clinician. This could potentially reduce pressure on the time available in the actual clinical consultation by preparing patients to engage in the SDM process before they are asked to discuss the

options. However, as will be discussed below, these interventions do not address the barrier that *'clinicians are too busy'*; they increase the burden on overall time available to clinical teams, especially the coaching interventions that take 20-45 minutes to administer.(135-137). *Poor articulation*' has been cited as a barrier to participating in SDM. None of the interventions were designed specifically for this group, but three of the seven interventions provide coaching, which might help patients with poor articulation.(135-137) The coaches help patients to identify and rehearse questions that they want to ask about their options, and to overcome issues of embarrassment and forgetting. Poor articulation could also be addressed by the use of pre-set question prompt lists or encouragement to develop a list of questions, as used in the other interventions,(33, 133, 134, 138) but it is unlikely to be as effective as direct coaching, and thus received lower scores.

Patients have reported that *'accepting responsibility to be involved in decision-making'* is a facilitator to SDM. All of the interventions encourage involvement, but there is no direct assessment as to whether the patient has actually *accepted* the role. Therefore, proxy measures, such as preference to be involved, increased involvement in the consultation (e.g. question asking), improved decision quality, and likelihood of stating treatment preferences were used. Four of the interventions provide clear evidence of their impact via pilot studies, controlled studies or randomised controlled trials (RCTs) (See Table 3.6 for full details on intervention effectiveness): Greenfield et al found a significant difference in involvement preferences between the intervention and control group in two RCTs;(17, 135) intervention patients were significantly more likely than control patients to report involvement and treatment preferences for two of the interventions;(133, 134) Rost found a significant difference in the number of questions asked during the consultation between the intervention and control groups, indicating that intervention patients are more likely to become involved;(136) studies evaluating the CPT found higher decision quality scores compared to controls,(141) higher satisfaction in patients using the CPT,(139, 140) and decreased communication difficulties with clinicians.

Some of the barriers/facilitators identified by patients are dependent on the way in which the clinician interacts with the patient and uses the intervention, thus we could not expect the identified interventions to address the barrier/facilitator in isolation (marked with asterisk in Table 3.4). However, despite this reliance on clinicians' attitudes and behaviours, the included interventions scored reasonably well on the following barriers/facilitators: *'equal relationship'*, *'insufficient information about the condition, options and outcomes'*, *'lack of individualised*

approach and not asked about preferences, and *'not explicitly offered a choice or choice being presented in a biased way'*. The interventions would have no direct impact on whether the clinician made the patient feel that they are in an equal relationship, as this is also dependent on the interpersonal skills and behaviour of the clinician. However, all of the interventions highlight the importance of patients' contribution to the decision-making process, which may go some way to reassuring the patient that the clinician wants the patient's involvement, and there is a more even distribution of power.

Similarly, the interventions included in this review do not tend to focus on information provision because they are focusing on preparing patients for a SDM consultation, ahead of the decision-making process. However, they all introduce the notion of options and potential outcomes, which should indicate to patients that there will be information available; some interventions directly encourage patients to ask for this information (e.g. Ask 3 Questions(33) and ASK(138) both encourage patients to obtain this information from the clinician) and one is designed to be used in conjunction with in-consultation decision support tools.(33) The interventions would have scored higher if it were clear that they are consistently used by a clinician trained in SDM skills, who may or may not use a decision support tool for information provision. Another related barrier is *'not being explicitly offered a choice or choice being presented in a biased way'*. Again, this factor can depend on the individual clinician and how they frame choice and the options available. However, the interventions do go some way to addressing this barrier by highlighting that there are clear and legitimate options available to patients, which have the potential to reduce the likelihood of biased presentation. The barrier *'lack of individualised approach and not being asked about personal preferences'* will also depend on the clinician's behaviour in the consultation, but the interventions scored relatively well on this factor. All of the interventions encourage patients to consider their individual preferences when making decisions, which might reduce the likelihood that the patient perceives that they are not receiving an individualised approach and being treated as a 'disease'.

Table 3.5 - 'Red' barriers/facilitators: factors that have not been sufficiently addressed

Barriers / Facilitators		Intervention Score (1 – 4 or unsure)						
		Ask 3 Questions ⁽³³⁾	Ask Share Know ⁽¹³⁸⁾	Cancer Consultation Preparation Package ⁽¹³⁴⁾	Greenfield 1985 ⁽¹⁷⁾	How Treatment Decisions are Made + videotape ⁽¹³³⁾	Rost 1991 ⁽¹³⁶⁾	Consultation Planning Template ⁽¹³⁷⁾
<i>Sub-theme:</i> Time	Clinicians are too busy	3	2	3	1	1	1	1
<i>Sub-theme:</i> Patient Characteristics	Age (older / younger)	3	1	1	1	1	1	1
	Ethnicity	3	1	1	1	1	1	1
	Lower level of education	2	2	2	1	2	1	1
<i>Sub-theme:</i> Presumptions about the patient role	Desire to act like a 'good' patient; fear of consequences	2	2	2	2	2	2	2
<i>Sub-theme:</i> Patients' undervalue their expertise relative to clinicians	'Doctor knows best' & patients have 'inferior' knowledge / recognise that there are two experts in the medical encounter	2	4	2	2	2	2	2
	Patients are not capable of understanding medical/technical information	1	2	2	1	2	2	3
<i>Sub-theme:</i> Perceived need for preparation	Patient does not want or need to participate in SDM	2	2	2	1	1	1	1
<i>Sub-theme:</i> Expectations of the outcome of being involved in SDM	Perceiving that there are 'right' and 'wrong' decisions (not wanting responsibility for a wrong decision)	2	2	2	1	2	1	1
<i>Sub-theme:</i> Decision support	Decision support from others e.g. family,	3	3	1	2	1	2	2

	carer, other clinicians (fac)							
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Ten of the 18 barriers/facilitators that I would expect a patient-targeted pre-consultation intervention to cover have not been addressed well by previous interventions. Most of the interventions were awarded low scores for the barrier *'clinicians are too busy'*. As discussed above, interventions received higher scores for the barrier 'lack of adequate time in the consultation' because the interventions are delivered before the main clinical consultation. This prepares patients ahead of the discussion about options, which could potentially reduce the time needed during the consultation. However, the interventions still increase the workload of clinical teams as a whole, and they do little to address the fact, and patients' perceptions, that clinicians are too busy. This is especially true for coaching interventions(135-137) and interventions that require patients to view a video before the consultation.(133, 138) Only two interventions scored 3 on this barrier as they are relatively simple, self-administered interventions, which require little resource from clinical teams to administer.(33, 138)

Under the sub-theme *'patient characteristics'*, all but one of the interventions were awarded a score of one for the barriers *'age'* and *'ethnicity'*.(33) Results from Chapter 2 indicate that these barriers are largely related to attitudinal issues; for example, people of an older age group believe that they are part of an age cohort that should not question the authority of clinicians and some young people feel that they do not need to be involved because their parent will make the decision for them. The Ask 3 Questions intervention(33) goes some way to addressing these attitudinal issues; the promotional materials include character illustrations that represent different age groups and ethnic backgrounds, intended to indicate that SDM is an approach that can be used by everyone. However, the interventions do not directly address these attitudes towards involvement held by some people in older and younger age groups. None of the interventions were designed specifically for groups with *'lower levels of education'* and do not report testing in this group; therefore they received low scores for this barrier. Some of the written materials for two of the interventions were developed for reading age ten, and so address this barrier to some extent, but not sufficiently.(133, 134) Two of the interventions include an algorithm component, which might be difficult to understand, so they were awarded the lowest score. (135, 136)

The *'desire to act like a 'good' patient'*, due to a fear of the consequences of stepping outside this traditional patient role, is a frequently cited patient-perceived barrier to participation in SDM. All of the interventions encourage patients to become involved in the decision-making process, and some highlight the move away from paternalistic approaches in healthcare,(33, 138) but none of the interventions directly address the fear of retribution. For many patients, it is fear of the negative outcomes, such as reduced quality of care or being labelled a 'difficult' patient, which drives this desire to act like a 'good' patient. None of the interventions take steps to reassure patients that the quality of treatment that they receive from the healthcare team will not be affected in a negative way, should they make the decision to participate.

A sub-theme of barriers that has not been addressed well is *'patients undervaluing their expertise'*. This was a significant factor that emerged from the systematic review of patient-reported barriers and facilitators, as it impacts on patients' perceived levels of influence on the decision-making process, and thus their individual capacities to participate. This sub-theme is made up of two key factors: patients perceiving that *'doctor knows best'* because they have inferior knowledge and patients believing that they are *'not capable of understanding 'complex' medical information about the options'*. With the exception of the ASK intervention, all of the interventions were awarded low scores for the first of these two factors. The interventions highlight the importance of patients' personal values and preferences, and encourage patients to let the clinician know about these and consider them during the decision-making process. However, they do not explicitly emphasise that patients' expertise (about personal preferences) is just as important as medical professionals' expertise (about the options available). The ASK intervention, on the other hand, addresses this factor well by explicitly describing how both the patient and the clinician are experts in their own right, and that both types of expertise are of equal value in the decision-making process.(138)

All of the interventions received a low score for the second of these two barriers. Patients frequently report that they feel incapable of understanding 'complex' information about the treatment options, and thus defer the decision to experts. Although some of the interventions make attempts to support patients to overcome barriers such as embarrassment and forgetfulness, none of the interventions contain components that specifically promote patients' self-efficacy in *understanding* information about the options available. Question prompt lists are useful tools for promoting assertiveness and information exchange in a consultation, but they do not necessarily mean that the patient *will feel capable of*

understanding the information that they are given. Even when the interventions are designed for use in conjunction with a decision support tool that focus on information provision about options (e.g. decision aid), this does not equate to patients *feeling that they are able to understand* the information that they will be given. The interventions lack motivational or cognitive elements that encourage patients to believe that they are capable of understanding the information, before being given the information (by the professional or via a decision support tool). Such elements could help to ensure that patients do not make a decision to not be involved and defer the decision to the clinician based on the belief that they are incapable of understanding the information. Further, the interventions do not provide reassurance that clinicians will present the information in a way that the patient can easily understand, or reassure patients that it is acceptable to ask clinician to explain the information in a different way if they do not understand.

None of the interventions explicitly address the barrier '*patients do not want to or need to participate in SDM*'. All of the interventions encourage involvement and highlight the importance of patients' preferences in the decision-making process. These therefore go some way to highlighting patients' responsibility to be involved in decision-making about their own healthcare. One intervention includes a component entitled 'your rights and responsibilities as a patient', but this appears to focus on patients' legal rights in hospital, and avenues for complaints and disputes.⁽¹³⁴⁾ None of the interventions provide an explicit rationale for being involved in the SDM process in a way that might challenge those patients who feel that they do not need to be involved. Obviously, there will also be patients who state that they do not want to be involved in SDM, and this should be accepted if it is an informed decision. However, there will be patients who state that they do not want to be involved, who actually feel that they cannot be involved. The interventions do little to ensure that patients are making an informed decision about whether to be involved in the decision-making process, after understanding what involvement in the decision-making process entails.

When '*patients perceive that there are 'right' and 'wrong' decisions*' and they do not want to accept responsibility for a wrong decision, this can act as a barrier to SDM. On the other hand, when '*patients recognise equipoise and uncertainty in medical decision-making*', this facilitates SDM. The importance of patients' values in the decision-making process is emphasised throughout all of the interventions, which implies that there may not necessarily be a clinically preferable option available. However, equipoise is an unfamiliar concept for many patients, and none

of the interventions explicitly or sufficiently cover what this means, and why patients are being offered healthcare options. Further, none of the interventions reinforce that neither the patient nor the clinician will be ‘blamed’ for the outcomes of the decision, especially as these cannot always be predicted. One intervention uses the phrase ‘decision that is right for you’, which does imply that there are no right and wrong decisions but decisions that are best for the patient, but it also uses the phrase ‘make the right decision’, which conflicts with this idea.(33) The final factor that has not been addressed sufficiently by previous interventions is the *‘facilitative role of decision support from others’*, such as family members, carers, or other clinicians. Two of the interventions suggest that family members and carers might also have questions if the patient is asked to make a decision, but they do not explicitly encourage the patient to consider involving them in the decision-making process.(33, 138) The remaining interventions do not refer to the support that other people can offer the patient when they are asked to make a decision.(159)

Twenty-eight of the total 51 barriers/facilitators were categorised as grey. These are factors that I would either not expect a patient-targeted intervention to address in isolation from interventions targeting clinician attitudes/behaviours or organisational structures, or they are only relevant to very specific situations that do not apply to most patients. Interventions were still scored against these factors to determine if they had been used in conjunction with other interventions that could potentially address such factors e.g. a SDM skills training package for clinicians using the patient-targeted interventions (factors that have been addressed in this way are marked by an asterisk in Tables 3.2 and 3.4). The full list of factors categorised as grey can be viewed in Table 3.2. In summary, these factors relate largely to improving continuity of care, adapting workflow processes so that there are appropriate appointments for SDM discussions (i.e. multiple consultations), fixed patient characteristics (e.g. the presence or absence of a long term condition or cognitive impairments such as dementia), and attitudes and behaviours of the clinician (e.g. authoritative, poor interpersonal skills, use of medical terminology, reinforcement of passive behaviour). There are also some factors that are relevant only in specific circumstances, including whether a patient pays for their healthcare, stigma and discrimination associated with certain diseases/conditions, and poor environmental conditions during physical examinations for SDM.

3.3.3.2 What is the effectiveness of existing interventions?

Four of the seven interventions were evaluated in randomised controlled trials.(17, 133, 134, 136) ASK (138) has been evaluated in a feasibility study(160) and the CPT has been evaluated in pilot and controlled studies.(139-141) Ask 3 Questions(33) has not been formally evaluated. Table 3.6 summarises the evaluation of each intervention, including study design, sample, outcome measures, and key findings.

Table 3.6 - Effectiveness of included interventions

Intervention (study references)	Study design / intervention	Outcome measures	Key findings
Ask 3 Questions (33)	Not formally evaluated	-	-
Ask Share Know (ASK) (138)	Cross-over feasibility trial. 123 patients attending family planning clinic	<ul style="list-style-type: none"> • Use of the 'Ask' component during the consultation • Whether patient had made a decision • Information & involvement preferences • Recall of questions used in 'Ask' component 	<p>Limited info available - only conference abstract available and feasibility study (no comparison group)</p> <ul style="list-style-type: none"> • Questions 1, 2 and 3 (of the ASK component) were asked in 66, 63 and 51 consultations respectively. • Most participants found questions helpful (72%) and would recommend them to others (94%). 50% reported recalling questions two weeks after consultation.
Cancer Consultation Preparation Package (134)	Two-arm randomised controlled trial (RCT). 164 cancer patients.	<p><i>Before consultation</i></p> <ul style="list-style-type: none"> • Satisfaction with the intervention • Information & role preferences <p><i>During consultation</i></p> <ul style="list-style-type: none"> • Patient information seeking behaviour (self-report & coded transcripts) • Physician behaviour (coded transcripts) <p><i>After consultation</i></p> <ul style="list-style-type: none"> • Achievement of role preferences • Patient satisfaction with the consultation • Patient and physician satisfaction with the decision-making process <p><i>Before & after consultation</i></p> <ul style="list-style-type: none"> • Anxiety • Depression 	<ul style="list-style-type: none"> • Regarding 10 active patient behaviours coded, patients in the intervention group asked significantly more questions ($P = .009$) & challenged information significantly more often ($P = .05$) than control group. No significant difference between groups for other behaviours, or when behaviours were summed. • No significant difference between groups in reported involvement and achievement of role preference, but results suggest trend that patients receiving intervention were less likely to achieve role preference ($P = .06$). • No significant impact of intervention on: patient or physician satisfaction with decision-making process, patient satisfaction with consultation, physician behaviour, or post consultation anxiety / depression scores.
Greenfield 1985 (17)	<p><i>Greenfield 1985(17)</i> Two-arm RCT. 45 patients with peptic ulcer disease.</p> <p><i>Greenfield 1988(135)</i> Two-arm RCT. 59 diabetic patients.</p>	<p><i>Greenfield 1985</i></p> <ul style="list-style-type: none"> • Patient interaction indicators • Role preference • Knowledge of disease • Patient satisfaction with care • Physical & role limitations due to health status • Pain <p><i>Greenfield 1988</i></p> <ul style="list-style-type: none"> • Patient interaction indicators • Diabetes control • Disease severity • Health-related quality of life • Changes in treatment regimen 	<p><i>Greenfield 1985</i></p> <ul style="list-style-type: none"> • Patients in the intervention group were significantly more effective at information seeking than controls ($P < 0.001$), significantly more likely to prefer an active role in decision-making ($P < 0.001$), and had better knowledge of disease ($P < 0.01$). • Intervention patients reported significantly fewer physical and role limitations than controls ($P < 0.05$). Difference between groups related to ulcer pain was in same direction, but not significant. • No significant difference between groups in levels of patient satisfaction. <p><i>Greenfield 1988</i></p> <ul style="list-style-type: none"> • Patients in the intervention group report significantly fewer functional limitations ($P < 0.01$), had significantly better blood sugar control ($P = 0.001$), and were significantly more active during their visit than controls ($P < 0.05$). • No significant difference between groups in knowledge

		<ul style="list-style-type: none"> • Patient satisfaction • Knowledge of diabetes 	of disease or patient satisfaction.
How Treatment Decisions are Made (+videotape) (133)	Two-arm RCT. 65 female cancer patients.	<p><i>Before consultation</i></p> <ul style="list-style-type: none"> • Information & role preferences <p><i>During consultation</i></p> <ul style="list-style-type: none"> • Patient & physician behaviours during consultation <p><i>After consultation</i></p> <ul style="list-style-type: none"> • Achievement of information & role preferences • Patient satisfaction with the consultation • Patient & doctor satisfaction with decision-making • Decisional conflict <p><i>Before & after consultation</i></p> <ul style="list-style-type: none"> • State anxiety • Depressive symptoms 	<ul style="list-style-type: none"> • Regarding active patient behaviours, interventions participants were significantly more likely than controls to declare their perspectives on the costs & side-effects ($P = 0.04$) and benefits ($P = 0.03$) of treatment, • Intervention participants were more likely than controls to declare their preferences for information ($P = 0.09$) and treatment during the consultation ($P = 0.10$), although this was not significant. The intervention had no impact on other patient behaviours, including stating role preference or asking questions. • Doctors tended to introduce more themes in the intervention group, but this was not significant ($P = 0.06$). • No significant impact of intervention on: post-consultation involvement and information preferences; patient & doctor satisfaction with decision-making; patient satisfaction with the consultation; decisional conflict; post consultation depressive symptoms / anxiety.
Rost 1991 (136)	Two-arm RCT. 61 patients with diabetes mellitus.	<ul style="list-style-type: none"> • Frequency of patient information seeking and decision-making behaviours • Patient satisfaction • Perceptions of specific doctor-patient behaviours • Patient recall of medication and self-care recommendations • Physician's satisfaction with the patient's hospitalisation • Patient's physical and psychological functioning 	<ul style="list-style-type: none"> • Intervention patients asked significantly more questions at discharge than control patients ($P < 0.001$). • No significant difference in patient-reported involvement in information seeking and decision-making at discharge. • No significant impact of the intervention on: patient recall of medication or self-care recommendations; patient satisfaction. • Intervention participants reported significantly better physical functioning than controls ($P = 0.02$) • Trend for interventions physicians to report more dissatisfaction with the context of care than physicians in the control group, although not significant ($P = 0.09$)
Consultation Planning Template (CPT) (137)	<p><i>Sepucha 2000</i> Pilot study (with control group). 24 patients with early stage breast cancer.</p> <p><i>Sepucha 2002</i> Controlled trial. 94 breast cancer patients.</p> <p><i>Belkora 2006</i> Retrospective descriptive study. 67 patients (breast cancer and unknown cancer diagnosis)</p>	<p><i>Sepucha 2000</i></p> <p><i>Before intervention</i></p> <ul style="list-style-type: none"> • Decision Quality <p><i>After Consultation Planning</i></p> <ul style="list-style-type: none"> • Decision Quality <p><i>After consultation</i></p> <ul style="list-style-type: none"> • Satisfaction with consultation • Decision Quality (+ physicians agreement with this) <p><i>Sepucha 2002</i></p> <p><i>Before intervention</i></p> <ul style="list-style-type: none"> • Scale of communication barriers <p><i>After Consultation Planning</i></p> <ul style="list-style-type: none"> • Scale of communication barriers • Satisfaction with interview <p><i>After consultation</i></p> <ul style="list-style-type: none"> • Patient-doctor Interaction • Physician satisfaction with the consultation <p><i>Belkora 2006</i></p> <p><i>After Consultation Planning / consultation</i></p> <p>Patient satisfaction with intervention</p>	<p><i>Sepucha 2000</i></p> <ul style="list-style-type: none"> • Patients in intervention group achieved significantly higher decision quality scores compared with control patients ($P = .008$) and significantly higher level of intersubjective agreement with their physicians about decision quality ($P = <.0001$). <p><i>Sepucha 2002</i></p> <ul style="list-style-type: none"> • Patients in both intervention and control group reported significant reduction in communication barriers after sessions ($P = <.001$). • Patients in the intervention group reported significantly higher satisfaction than the control group <p><i>Belkora 2006</i></p> <ul style="list-style-type: none"> • Patients were highly satisfied with CPT consultations

3.4 Discussion

This review identified seven interventions that prepare patients for a SDM discussion with a clinician. Of the 18 barriers/facilitators that I would expect a patient-targeted preparation intervention to address, six have been adequately addressed by previous interventions, two have been addressed to some extent with room for improvement, and 10 have not been adequately addressed. Five additional factors were categorised as amber (total of eight factors categorised amber); these were factors that I would not expect a patient-targeted preparation intervention to address, but they have been addressed to some extent by the included interventions. Of the total 51 barriers/facilitators identified by patients that are potentially modifiable, 28 were deemed unfeasible for a patient-targeted preparation intervention to address in isolation, or they are only relevant to highly specific situations. Trial outcomes suggest that these interventions have a positive impact on patient engagement in the consultation,(17, 133-137, 139, 141) but only one of the interventions provides evidence of use in routine clinical practice, outside the research setting.(33)

Analysis indicates that there is scope to develop a patient-targeted preparation intervention that addresses all, or more, of these barriers and facilitators more comprehensively. Interventions also need to be grounded in behaviour change theory in order to address patient attitudinal factors identified in Chapter 2. Interventions tend to be more effective when theoretically grounded;(161) lack of theoretical basis impedes the possibility of understanding behaviour change, and the processes that underlie effective interventions. The large number of factors that could not be addressed by a patient-targeted preparation intervention in isolation also highlights the need to develop such interventions as part of a 'SDM bundle', where they are implemented in the context of organisational support and alongside complementary interventions targeting clinician attitudes and behaviours (e.g. SDM skills training), and knowledge provision (e.g. decision support interventions).

In Chapter 2, I showed that individual capacity to participate in SDM depended on two key factors: knowledge *and* power. In the decision-making context, power refers to the patients' perceived capacity to influence the decision-making encounter including factors such as valuing one's own knowledge and its contribution to the decision-making process, and self-efficacy in one's ability to acquire medical knowledge about the condition or options. Without perceived power, provision of information about options is unlikely to support SDM in a large number of patients. One of the key unaddressed gaps identified in the

current review relates to patients undervaluing their expertise relative to that of the clinician. The two factors related to perceived power in the consultation have not been sufficiently addressed by previous interventions – these are patients perceiving that ‘doctor knows best’ whilst they have ‘inferior knowledge’ and patients believing that they are not capable of understanding ‘complex’ medical information about the options. Only one intervention explicitly states that patients’ knowledge is just as important as medical expertise,(33) and none of the interventions sufficiently promote patients’ self-efficacy in understanding the knowledge about treatment options, before being given the information. Given the significance of these factors in determining individual capacity to participate in SDM, this is an important gap that needs to be addressed. Future interventions will need to ensure patients are adequately prepared and *feel that they are capable* of understanding the information about their options, before attempts to provide this information. If patients do not feel capable at the point of being presented with this information, it is likely that they will be less willing to make attempts to understand the information and more likely to defer the decision-making to the clinician. Interventions could also benefit from explicitly explaining the rationale for and the importance of the patients’ personal contribution (i.e. about preferences), rather than simply stating that the medical and patient expertise is of equal value.

Another key factor identified in Chapter 2 relates to the ‘covert contract’ that patients develop with clinicians, mainly physicians. Many patients feel that they need to adopt the role of a ‘good patient’, which is characterised by passivity and compliance. Attempts to encourage patients to move away from this perception of the ‘good patient’ role and to become more active in the decision-making process can be hampered by patients’ fear of retribution. This key barrier has not been sufficiently addressed by previous interventions, as indicated by the low scores awarded. The interventions encourage patient involvement, and some even acknowledge the move away from the traditional passive patient role, but none of the interventions directly address the fear of retribution, which is often driving compliance with the traditional role.(38) If fear of negative consequences is stopping patients from adopting a more active role in decision-making, future interventions need to reassure patients that the quality of treatment that they receive from the medical team will not be affected in a negative way should they decide to participate, and they will not be perceived negatively by the team (e.g. they will not be perceived as a ‘difficult’ patient). Attempts should be made to normalise the active patient role so that patients perceive that it is expected and accepted by clinicians and other patients.

Failure to address the above barriers is important, given their significance in the review of patient-reported barriers and facilitators to SDM (Chapter 2).(127) However, several other factors were also not addressed well and will also need to be covered by future interventions. These include: overcoming the perception that there are ‘right’ and ‘wrong’ decisions for certain medical conditions or procedures, and explicitly and clearly describing to patients what equipoise means; reinforcing that SDM is suitable for everyone, and should not depend on, for example, your age, ethnic background, or level of education; changing patients’ perceptions that they do not ‘need’ to participate in SDM; and disentangling those patients who have made an informed decision not to participate, from those who have not, or those who actually feel that they cannot participate because of various factors.(121)

In addition to the clear gaps identified by the review, Table 3.3 includes those barriers/facilitators that have been addressed well by previous interventions. In summary, these factors relate to patients’ presumptions about the patient role and their perceived need for preparation. The interventions provide patients with permission to participate and indicate that clinicians want patients involved, they emphasise patients’ entitlement to choice, they highlight the acceptability of asking clinicians questions, and they help patients to understand what they can expect from the SDM process. Although most patient-reported factors relating to presumptions about the patient role are covered adequately, fear of retribution has not been covered, as outlined above. Therefore, even if all of the other factors related to perceptions of the patient role are addressed adequately by an intervention, it is possible that patients will still be apprehensive to become involved until they are reassured that there will not be negative consequences. This highlights the importance of comprehensively addressing as many of the barriers/facilitators as possible in an intervention.

It should also be noted that whilst all of the interventions scored highly on these factors, the same interventions scored lower on the barriers related to time. Two of the interventions include a coaching element ranging from 30-45 minutes in duration,(17, 136) two of the interventions include video clips that are viewed directly before the consultation,(133, 138) and two interventions include video clips on accompanying websites.(33, 138) Whilst these interventions addressed the above factors well, coaching sessions and video clips are time and cost intensive interventions that will place additional burden on already busy clinical teams. Therefore, the feasibility of these interventions in routine clinical practice is questionable, and we need to find alternative ways to address these elements in future

interventions so that they also address organisational barriers such as time and clinical workflow.

A large number of factors identified as barriers and facilitators relate to attitudinal change at the level of the patient. In the SDM field, researchers have invested a lot of time and effort into developing and delivering SDM skills training programmes for clinicians. Person-centred care is also becoming incorporated into the medical and nursing curriculum at several centres (e.g. Cardiff University, University of Ottawa). SDM implementation programmes highlight the importance of both changing clinicians' attitudes towards SDM and providing the tools to support SDM. However, SDM is more complex than delivery of patient decision support interventions alone.⁽³⁵⁾ Further, implementation research has shown that normalisation of SDM in clinical teams requires considerable effort, engagement and facilitation, especially to achieve the attitudinal shifts among clinicians necessary to support this work.⁽³⁵⁾ Unfortunately, the same level of investment in attitudinal change at the patient level has not been recognised. It takes considerable effort to move clinicians from thinking SDM is something they do already, to seeing it as different to current practice and something that they could do better.⁽³⁵⁾ Among some of the more resistant clinicians, who have long-standing beliefs about appropriate roles in the doctor-patient relationship, significant attitudinal shift is required before they accept that SDM is the correct way to approach decision-making with patients.⁽³⁵⁾

A SDM consultation is considerably different to the consultations that many patients are used to, and may even be comfortable with, yet they are just expected to 'get it' and change their usual and long established behaviours when they are presented with an opportunity to participate in the decision-making process. Patients are presented with the decision support tools that support the decision-making process before we are certain that they are ready to be presented with this opportunity. Researchers and implementers have invested a large amount of time in making sure clinicians have undergone the necessary attitudinal shift for SDM to take place, with variable success, and that they are provided with the necessary tools to support the process, but we have not invested the same effort in preparing patients attitudinally for this different way of engaging with the healthcare system. Instead, researchers have focused on providing the tools to support the process, as evidenced by the large number of knowledge based tools included in the Cochrane review of patient decision aids.⁽¹⁶⁾ These are of course valuable for patients to participate in SDM, but they are unlikely to support SDM for the large number of patients unless 'entry-level' attitudinal

factors are addressed first.(127) It is acknowledged that structured training programmes are available that support patients to become more involved in their healthcare management (such as the Expert Patient Programme), but these tend to be targeted at patients with long-term conditions, and not the general patient population who are asked to make discrete medical decisions.

The relatively few interventions that have attempted to prepare patients for the SDM encounter have not addressed the patient-identified barriers/facilitators comprehensively. A significant finding from this review was the number of barriers/facilitators against which we could not assess a patient-targeted preparation intervention. Many of these factors were related to organisational structures (e.g. creating systems that accommodate SDM pathways) or the attitudes and behaviours of clinicians. It would be unrealistic to expect a patient-targeted intervention preparing patients for a SDM consultation to address these in isolation, and scores on these factors would depend largely on whether the interventions had been used with complementary interventions that target clinicians' attitudes and behaviours, and whether wider organisational change and support had also been initiated. This highlights the challenge of addressing the wide range of patient-reported factors.(127) Further, even if an intervention were to address the 20 patient-reported barriers/facilitators that I would expect it to cover, there are still a large number of patient-reported factors that will not be addressed, and this is before the wider literature on clinician and organisational barriers is considered.(33, 35, 57)

The theoretical basis of existing interventions is unclear (not reported). If interventions are not theoretically grounded, this impedes the possibility of understanding the behaviour change processes that underlie effective interventions i.e. the active and effective ingredients. Due to the absence of explicitly reported theoretical models, it is difficult to determine which components of the existing interventions might be effective, or less effective. The results from Chapter 2 suggest that attitudinal and behavioural change appears to be a key factor in increasing patient involvement in decision-making. As such, it is important that the intervention is theory-based and systematically developed. This will ensure that the determinants of the target behaviour(s) are identified, and that the intervention components addressing each determinant are explicitly stated, which allows the potential to explore associations between these intervention components and intervention effects.

The results of this review emphasise the need for a holistic approach to intervention development that addresses multiple levels of barriers/facilitators simultaneously. To date, most patient-targeted preparation interventions have been developed in isolation and tested in controlled trial settings. We need to move away from this approach and develop patient-targeted preparation interventions as part of a ‘SDM bundle’. These bundles will include a range of complementary interventions including, but not exclusive to, patient decision support interventions and SDM skills training for clinicians. They will be implemented in the context of wider clinical team engagement and organisational support. The development process that will lead to the development of the intervention will need to consider the patient-reported factors(127) in conjunction with clinician-reported(57) and organisational factors(33, 35) to ensure that as many factors as possible are considered. These may apply to the content of the intervention, the way in which it is implemented, or the wider context within which it is implemented.

3.4.1 Strengths and Weaknesses

I did not conduct a systematic review using new search strategies. However, the results have been derived in part from previously conducted Cochrane systematic reviews, which adhere to strict guidelines,(131) and the review has been supplemented by vigorous follow-up searches of academic and non-academic institutions that are involved in shared decision-making work. Given the scope of the previous reviews, I am confident that the interventions suitable for this review would be a sub-set of those identified previously. The relative homogeneity of scores across interventions at the barrier/facilitator level confirms the significance of key gaps identified by this review; when a barrier has not been addressed well by one intervention, it tends to have not been addressed well by other interventions.

However, since my review was carried out (August 2013), two further Cochrane Reviews have been published, which could have served to identify interventions.(162, 163) My review of existing interventions preceded and informed the intervention development phase (see Chapter 4); as such, it was not feasible to repeat the literature review of interventions when the new reviews were identified. However, I did examine the two reviews to identify if there are any studies / interventions that meet the inclusion criteria, which were not included in my original review conducted in August 2013.

From the Legare et al review,(66) two of the included studies meet the inclusion criteria of my review. One has already been included in my review,(134) the other was not included (or identified from my search strategies).(164) This intervention is delivered in the waiting area before a consultation and explains what a decision is, it prompts patients to select a topic of focus for the current healthcare visit, and to list / prioritise questions for their healthcare professional. A quick examination of this intervention suggests that its inclusion in the review would not change the results of the review: there is still scope to develop a more comprehensive intervention that addresses the key patient barriers identified in Chapter 2, ahead of consultations (ideally before patient arrives at appointment).

From the Coulter et al review,(162) no further studies met the inclusion criteria of my review. Many of the interventions focus on changing health behaviours related to the person's long-term condition (e.g. lifestyle, exercise habits, diet), goal-setting, and general information exchange during a consultation. Whilst the promotion of self-efficacy and goal setting might impact on SDM during a consultation, the specific aim of the intervention was not to change attitudes regarding patient involvement in SDM. Many are also delivered during a consultation, rather than before, they are not patient-focused (e.g. skills training of the clinical team), and they are delivered in a group setting.

A large number of factors were included in the evaluation that I would not necessarily expect a patient-targeted preparation intervention to address in isolation. This is acknowledged in the results presentation, and their inclusion serves to highlight the importance of a holistic approach to the development of future interventions. It is also acknowledged that a duplicate study selection and data extraction process was not used for the current review. However, the purpose of the review is to describe and evaluate features of existing interventions, rather than prediction of the effect of interventions. It was therefore deemed appropriate for one reviewer experienced in the evaluation of SDM interventions (i.e. International Patient Decision Aids Standards Instrument rater),(126, 165) who developed to the taxonomy of patient-reported barriers/facilitators, to conduct the evaluation.

3.4.2 Conclusion

Previously developed patient-targeted interventions designed to prepare patients for a SDM discussion do not adequately address patient-reported barriers and facilitators. Neglect of 'entry-level' factors such as attitudinal change among patients, a focus on information

provision about options, and the development of patient-targeted interventions in isolation from other interventions may explain why SDM implementation attempts are still facing considerable roadblocks. Previous interventions lack theoretical basis, thus making it difficult to delineate the intervention components that might be most effective. The gaps identified by the evaluation indicate that there is scope to develop a theory-based intervention that more comprehensively addresses these barriers so that we can adequately prepare patients for a SDM discussion. Significantly, patient-targeted preparation interventions only form one piece of a very complex puzzle. The intervention that will be developed in Chapter 4 will need to be developed and implemented as part of a ‘SDM bundle’, within a context of wider organisational engagement and support.

Chapter 4

Using the Behaviour Change Wheel Guide to develop a patient-targeted intervention designed to prepare patients for SDM

4.1 Introduction

This chapter outlines the theoretical development of a patient-targeted intervention designed to prepare patients and increase patient involvement in shared decision-making (SDM). Chapter 2 identified various patient-reported barriers and facilitators to SDM: power imbalances in the clinical encounter (perceived or real) and the view that ‘doctor knows best’ were key factors hindering involvement, even when informational needs were met. Chapter 2 concluded that a patient-targeted intervention designed to promote patient participation in SDM should focus in the first instance on addressing patients’ attitudinal factors.

Chapter 3 reviewed current interventions to establish whether they addressed patient-reported barriers and facilitators, especially attitudinal factors related to power imbalances. Chapter 3 highlights a number of factors that current interventions fail to address, and a number of ways in which future interventions could be improved. First, key barriers relating to power imbalances and social norms about acceptable patient behaviour need to be addressed more effectively. These include perceptions that ‘doctor knows best’ and that patients have inferior knowledge (i.e. failure to recognise that there are two ‘experts’), beliefs that ‘good’ patients are passive, and lack of confidence in being able to understand the information about options.

Second, whilst some existing interventions have addressed many of the barriers / facilitators, they are cost and time-intensive. Some are delivered directly before a consultation, which leaves little time for attitudinal / behaviour change, and / or they lack a systematic distribution model (e.g. posters in waiting room). The intervention proposed in this thesis will need to be cost-effective and fit into current clinical pathways with minimum disruption, to ensure that it is feasible. It should also be delivered before patients attend for clinical appointments, to maximise the potential for attitudinal change. Third, existing interventions

tend to be developed and implemented in isolation from other interventions, or in controlled trial settings. The proposed patient-targeted intervention will need to be implemented in real-life clinical settings, in conjunction with a range of complementary interventions that tackle factors that are not related to patients' attitudes (e.g. skills training for clinicians, decision support tools for information provision).

Finally, the theoretical basis of existing interventions is unclear (not reported). The current intervention will be a behaviour change intervention, which are defined as 'coordinated sets of activities designed to change specified behaviour patterns'.⁽¹⁶⁶⁾ Behaviour change interventions tend to be complex, involving many interacting components,⁽¹⁶⁶⁾ and tend to be more effective if interventions are based on evidence-based principles of behaviour change (theoretically grounded).⁽¹⁶¹⁾ If interventions are not theoretically based, this impedes the possibility of understanding the behaviour change processes that underlie effective interventions i.e. the active and effective ingredients. Therefore, the development of the current intervention will be grounded in behaviour change theory.

The UK Medical Research Council (MRC) guidance for developing complex interventions informed by theory has been used to guide the development of this intervention,⁽⁴⁵⁾ but it does not provide detailed guidance on which theory to use. A large range of behaviour change theories exist, such as the Theory of Planned Behaviour⁽¹¹⁷⁾ and the Health Belief Model.⁽¹⁶⁷⁾ However, selecting one or two theories or approaches to guide the intervention development will not cover the full range of possible influences, and thus key determinants of behaviour might be missed.⁽¹⁶⁶⁾ In a review of nineteen behaviour change frameworks that classify behaviour change interventions, Michie et al⁽¹⁶⁶⁾ concluded that none of the existing frameworks were comprehensive or conceptually coherent. As a result, they developed an integrated framework, which combines 33 theories and 128 theoretical constructs of behavioural change: the Behavioural Change Wheel Guide.^(47, 166) This framework has also been designed for use in clinical implementation settings.

4.1.1 Developing a theory-informed intervention: the Behavioural Change Wheel Guide

The Behavioural Change Wheel Guide⁽⁴⁷⁾ proposes a systematic approach to theory-based intervention development, using a combination of *four* behaviour change 'technologies':

1. The COM-B model of behaviour;^(47, 166)

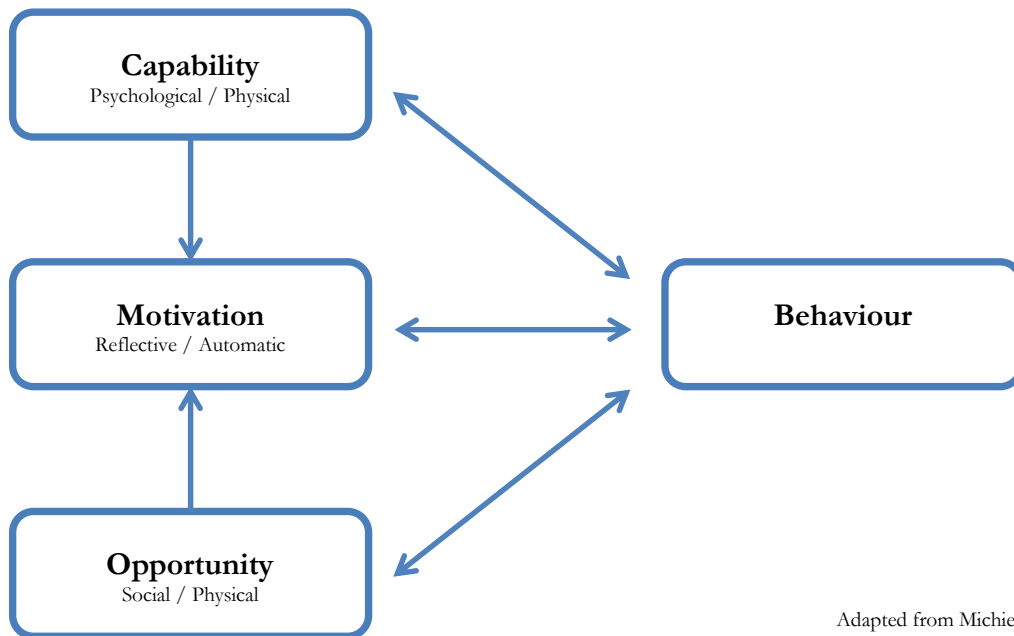
2. The Theoretical Domains Framework (TDF);(168, 169) 3)
3. The Behaviour Change Wheel (BCW);(47, 166) and
4. The Behaviour Change Techniques Taxonomy (v1.0).(170)

These behaviour change technologies are used to answer the following questions during the design process:

1. What behaviour are you trying to change and in what way?
2. What will it take to bring about the desired change?
3. What types of intervention are likely to bring about the desired change?; and
4. What should be the specific intervention content?

The guide is based on the ‘COM-B’ model of behaviour, which proposes that behaviour is dependent on the interaction between three necessary conditions: capability, opportunity, and motivation (Figure 4.1).(166) Capability is defined as the individual’s physical or psychological ability to enact the behaviour, and includes having the necessary knowledge and skills (psychological capability being the capacity to engage in the necessary thought processes). Motivation is defined as the reflective and automatic mechanisms that activate or inhibit behaviour. Reflective processes involve evaluations and plans (conscious decision-making), and automatic processes involve emotions and impulses that arise from associative learning and/or innate dispositions. Opportunity relates to factors that lie outside the individual’s control that enable or prompt the behaviour. This is sub-divided into the physical opportunity afforded by the environment, and social opportunity afforded by the social environment that influences how we think about things. The model highlights potential influences between the different components: both opportunity and capability can influence an individual’s motivation; all three components can influence the enactment of a behaviour; and enacting a behaviour can in turn alter capability, motivation and opportunity.(166)

Figure 4.1 - The COM-B system - a framework for understanding behaviour



This COM-B model of behaviour also provides a basis for designing interventions aimed at behaviour change, as it may help to identify the theoretical domains that are likely to be important in changing behaviour. The TDF is an elaboration of the COM-B model, and was developed in order to make the COM-B model more usable for implementation researchers designing and evaluating behaviour change interventions.(168, 169) Through a consensus process, the integrative framework was developed from 33 theories and 128 theoretical constructs of behavioural change.(169) The refined framework comprises 14 domains of theoretical constructs: knowledge; skills; social/professional role and identity; beliefs about capabilities; optimism; beliefs about consequences; reinforcement; intentions; goals; memory, attention, and decision processes; environmental context and resources; social influences; emotion; and behavioural regulation.(168) Table 4.1 provides a description of each domain and illustrates how the domains map to the COM-B components.

Table 4.1 - Mapping the COM-B model to the TDF domains

COM-B Component		TDF Domain	Description
Capability	Psychological	<i>Knowledge</i>	An awareness of the existence of something
		<i>Cognitive & interpersonal skills</i>	An ability or a proficiency acquired through practice
		<i>Memory, attention & decision processes</i>	The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives
		<i>Behavioural regulation</i>	Anything aimed at managing or changing objectively observed or measured actions
	Physical	<i>Physical Skills</i>	An ability or a proficiency acquired through practice
Opportunity	Social	<i>Social influences</i>	Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours
	Physical	<i>Environmental context & resources</i>	Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behaviour
Motivation	Reflective	<i>Social/professional role & identity</i>	A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting
		<i>Beliefs about capabilities</i>	Acceptance of the truth, reality, or validity about an ability, talent, or facility that a person can put to constructive use
		<i>Optimism</i>	The confidence that things will happen for the best or that desired goals will be attained
		<i>Beliefs about consequences</i>	Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation
		<i>Intentions</i>	A conscious decision to perform a behaviour or a resolve to act in a certain way
	<i>Goals</i>	Mental representations of outcomes or end states that an individual wants to achieve	
	Automatic	<i>Reinforcement</i>	Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus
		<i>Emotion</i>	A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event

The COM-B model and the TDF sit at the centre of the integrated BCW (Figure 4.2). Around this central hub are nine intervention functions (each includes one or more

behaviour change techniques) and seven policy categories (that could enable or support these interventions to occur) (see Table 4.2 for definitions of interventions and policies). Put simply, interventions are those activities that are designed to change behaviours, and policies are decisions made by authorities concerning interventions.(166) The authors emphasise that it is not a linear system, but one where components of the behaviour system at the hub interact with each other, as do the functions within the intervention layer and the categories within the policy layer.

Figure 4.2 - The Behaviour Change Wheel

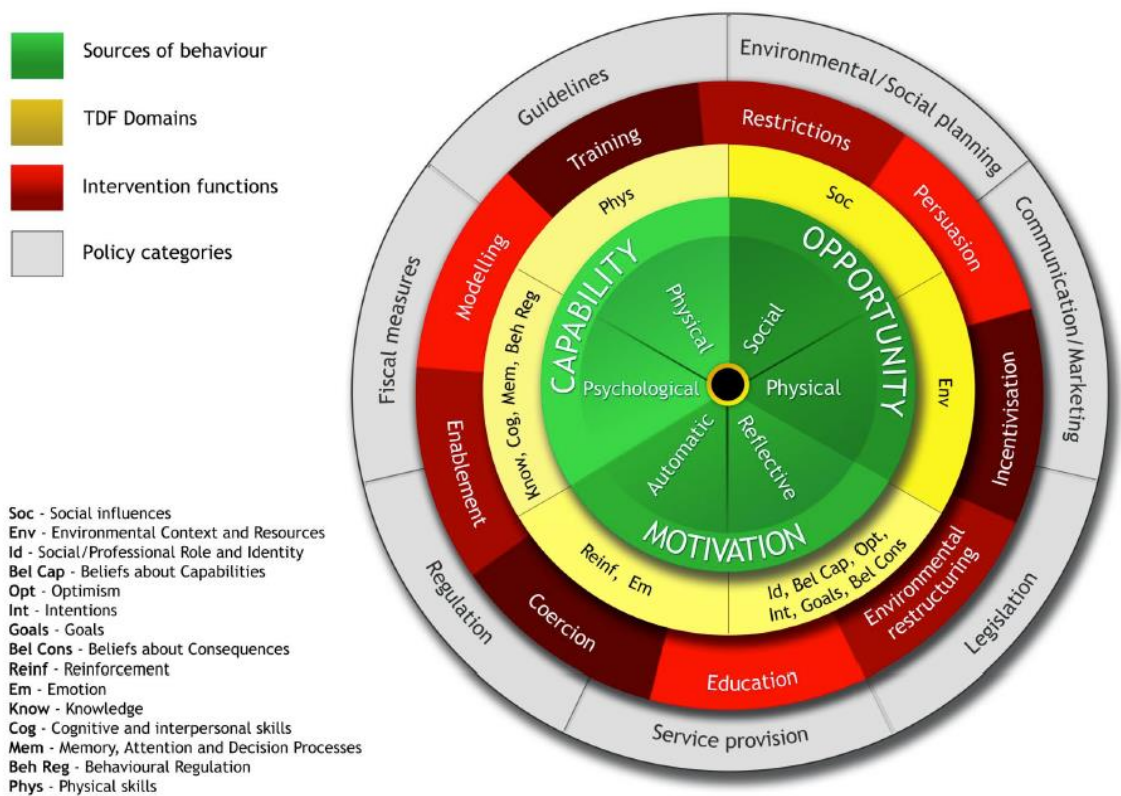


Table 4.2 - Definitions of interventions and policies

Interventions	Definitions
Education	Increasing knowledge or understanding
Persuasion	Using communication to induce positive or negative feelings to stimulate action
Incentivisation	Creating an expectation of reward
Coercion	Creating an expectation of punishment or cost
Training	Imparting skills
Restriction	Using rules to reduce the opportunity to engage in the behaviour (or to increase behaviour by reducing opportunity to engage in competing behaviours)
Environmental restructuring	Changing the physical or social context
Modelling	Provide an example for people to aspire to or emulate
Enablement	Increasing means or reducing barriers to increase capability (beyond education or training) or opportunity (beyond environmental restructuring)
Policies	Definitions
Communication /marketing	Using print, electronic, telephonic, or broadcast media
Guidelines	Creating documents that recommend or mandate practice. This includes all changes to service provision
Fiscal	Using the tax system to reduce or increase the financial cost
Regulation	Establishing rules or principles of behaviour or practice
Legislation	Making or changing laws
Environmental / social planning	Designing and/or controlling the physical or social environment
Service provision	Delivering a service

This chapter describes how the Behavioural Change Wheel Guide(47, 166) has been used, in conjunction with MRC Guidelines for complex interventions,(45) to systematically develop a theory-based intervention designed to prepare patients for a SDM consultation with a clinician.

4.2 Methods

Using the BCW Guide, a four-step approach was used (see Table 4.3):

1. Identifying the problem (what behaviour are you trying to change, and in what way?)

2. Assessing the problem (what are the barriers/facilitators, and what will it take to bring about the desired change?)
3. Forming possible solutions (what types of intervention are likely to bring about the desired change?); and
4. Deciding on the specific intervention content (using a taxonomy of behaviour change techniques).

The fifth step involves ‘planning the intervention evaluation’ (how can behaviour change be measured and understood?). The focus of the current chapter is on intervention prototype development; Chapter 5 describes pre-testing and refinement of the intervention, Chapter 6 describes pilot-testing using a process evaluation, and details regarding the intervention implementation plan and proposed evaluation (or Step 5) can be found in Chapter 7.

Table 4.3 - Steps used to develop intervention content

STEP	KEY TASKS
STEP 1: Identifying the problem – what behaviour are you trying to change, and in what way?	<ul style="list-style-type: none"> • Identify the evidence-practice gap • Specify the behaviour change needed to reduce the evidence-practice gap • Specify the group whose behaviour needs changing
STEP 2: Assessing the problem – what are the barriers/facilitators, and what will it take to bring about the desired change?	<ul style="list-style-type: none"> • Review potential barriers and facilitators to the behaviour • Use the TDF and COM-B model to identify the pathway(s) of change to the behaviour
STEP 3: Forming possible solutions – what types of intervention are likely to bring about the desired change?	<ul style="list-style-type: none"> • Use the BCW to identify potential behaviour change techniques (intervention and policy level) to overcome the barriers and enhance the facilitators • Use the APEASE criteria to select those intervention functions and policies that are most appropriate
STEP 4: Deciding on specific intervention content – using a taxonomy of behaviour change techniques	<ul style="list-style-type: none"> • Use the Behaviour Change Techniques taxonomy to select specific intervention content and mode of delivery • Use the APEASE criteria to select those behaviour change techniques that are most appropriate

4.2.1 Step 1: Identifying the problem – what behaviour are you trying to change, and in what way?

First, the target behaviour was selected and specified in detail by asking the following questions: What is the behaviour (or series of linked behaviours) that you will change? Who performs the behaviour(s)? What do they need to do differently to achieve the change? When, where and in what contexts do they perform the behaviour? Who do they perform the behaviour with? Behaviour is defined as:

‘Anything a person does in response to internal or external events. Actions may be overt (motor or verbal) and directly measurable, or covert (activities not viewable but involving voluntary muscles and indirectly measurable). Behaviours are physical events that occur in the body and are controlled by the brain.’(171)

Candidate behaviours were listed, and considered in terms of the following: likely impact on outcome if the behaviour was changed; how easy it is to change; effects of changing the behaviour (positive or negative) on other behaviours; and whether it can be measured.

4.2.2 Step 2: Assessing the problem – what barriers and facilitators need to be addressed?

Patient-perceived barriers and facilitators to increased involvement in SDM were reported in Chapter 2, and have been published elsewhere.(127, 172) A behavioural analysis was conducted to understand how the reported barriers/facilitators might affect performance of the target behaviour (active participation in SDM by the patient) and potential pathways of change. The behavioural analysis involved retrospectively coding patient-reported barriers/facilitators according to the domains of the TDF, which map to the COM-B model (See Table 4.1). This coding was checked and ratified in discussion with supervisors. It was possible for individual barriers/facilitators to be coded under multiple TDF domains/components of the COM-B model. This coding exercise helped to identify the pathways of change that were likely to influence the target behaviour, and informed the selection of intervention components and policies in Step 3.

4.2.3 Step 3: Forming possible solutions - which intervention components could overcome the modifiable barriers and enhance the facilitators?

Following the TDF/COM-B coding exercise in Step 2, the BCW (see Figure 4.2) was used to identify which of the nine intervention categories and seven policy categories could potentially overcome the barriers and enhance the facilitators. An intervention function matrix (see Table 4.4) was used to determine the most appropriate intervention functions for each component of the COM-B model. For example, if a barrier was coded as ‘Psychological Capability’ in the TDF /COM-B coding exercise, the intervention function matrix suggests that ‘Education’, ‘Training’, or ‘Enablement’ would be suitable intervention components.

Table 4.4 - COM-B Intervention Function Matrix

Model of Behaviour: sources	Intervention Functions								
	Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
Physical Capability									
Psychological capability									
Physical opportunity									
Social opportunity									
Automatic motivation									
Reflective motivation									

Each source of behaviour can be addressed by more than one intervention function, and it would not be feasible to use all of the intervention functions to address a given barrier/facilitator. Therefore, I made a judgement about the most appropriate functions using the BCW APEASE criteria:

- **Affordability** – can it be delivered to budget?
- **Practicability** – can it be delivered as designed?
- **Effectiveness and Cost-effectiveness** – does it work (ratio of effect to cost)?
- **Acceptability** – is it judged appropriate by relevant stakeholders (publicly, professionally, politically)?
- **Side-effects/safety** – does it have any unwanted side-effects or unintended consequences?
- **Equity** – will it reduce or increase the disparities in health/wellbeing/standard of living?

The most appropriate intervention functions were selected for each barrier and recorded. The policy categories matrix (see Table 4.5) was then used to identify how policy categories map to the intervention functions; using the APEASE criteria, a decision was made about which policies would support the delivery of the intervention. Policy categories relate to the way in which the interventions are implemented.

Table 4.5 - COM-B Policy Categories Matrix

Policy Categories	Intervention Functions								
	Education	Persuasion	Incentivisation	Coercion	Training	Restriction	Environmental restructuring	Modelling	Enablement
Communication/Marketing									
Guidelines									
Fiscal									
Regulation									
Legislation									
Environmental/social planning									
Service provision									

4.2.4 Step 4 - Deciding on the specific intervention content – using the Behaviour Change Techniques Taxonomy

Step 3 identifies the broad level intervention functions and policy functions that will be used and addressed by the intervention e.g. education will be provided to patients about the benefits of SDM, and local health board communication channels will be used to deliver the message. Step 4 focuses on establishing the specific behaviour change techniques that will be used, the exact content of the intervention, and the specific mode of delivery. The Behaviour Change Techniques Taxonomy (v1.0)(170) comprises 93 hierarchically-clustered techniques, clustered into 16 groups: 1) Goals and planning; 2) Feedback and monitoring; 3) Social support; 4) Shaping knowledge; 5) Natural consequences; 6) Comparison of behaviour; 7) Associations; 8) Repetition and substitution; 9) Comparison of outcomes; 10) Reward and threat; 11) Regulation; 12) Antecedents; 13) Identity; 14) Scheduled consequences; 15) Self-belief; 16) Covert learning.

The taxonomy was developed using a Delphi-exercise in response to the under-reporting and inconsistency of reporting content in behaviour change interventions.(170) The taxonomy was used to guide the selection of specific intervention content that could potentially address each barrier/facilitator. Again, the APEASE criteria were used to ensure selected techniques were locally relevant, feasible, and could be delivered as a cohesive intervention. When the specific content for each barrier/facilitator was agreed, the taxonomy was used to code the content. This standardised framework ensured consistency of labelling the techniques used to address different barriers/facilitators, and the ability to identify if there was overlap in the techniques used. It also helps to specify the active ingredients of the intervention, which is essential when planning intervention evaluation (for further details, see Chapter 6), and useful for intervention replication.

4.3 Results

4.3.1 Step 1: Identifying the problem – what behaviour are you trying to change, and in what way?

Previous chapters have shown that most current SDM interventions have been clinician/organisation targeted or dependent, and/or are delivered during or after clinical encounters e.g. patient-targeted decision support tools(16). The results of Chapter 2 demonstrate that patients' attitudes are a significant barrier to SDM,(127) and Chapter 3 concluded that patient-targeted preparation interventions delivered before SDM encounters show promise for changing patients' attitudes and behaviour. Based on this, the patient was chosen as the target for behaviour change: the patient-targeted intervention that is being developed will be used within a wider SDM implementation programme (MAGIC),(33, 35) which has focused on changing clinicians' attitudes / behaviours and restructuring the organisational environment.

The target behaviours for the intervention arose from models and definitions of SDM,(1, 15, 118) as well as questionnaires that aim to determine if SDM has taken place during a clinical encounter.(173, 174) These models / definitions / questionnaire items were examined to establish key behaviours that need to happen for SDM between a patient and a clinician to take place. There are many different ways that patients could be more involved in healthcare decisions, but target behaviours were selected on the basis that they were observable and/or measurable. Behaviours that indicated that a patient had actively participated in the decision-making process with a clinician were selected:

- Display positive and receptive behaviours towards involvement in the decision-making process when offered treatment choice by the clinician
- Communicate personal preferences (things that matter most to the patient) to the clinician(s), during and/or after the clinical encounter (e.g. during a follow-up home visit with a nurse)
- Use of the intervention (booklet) before, during, or after the next clinical appointment with a clinician e.g. use of the notepad / checklist

I chose these target behaviours because they had strong supporting evidence (i.e. that performance of these behaviours leads to outcomes associated with SDM, such as increased

knowledge, integration of preferences, congruence between personal preferences and choice), were potentially modifiable at the patient level, and were unlikely to have a negative impact on other behaviours e.g. clinicians' behaviour in the consultation.

4.3.2 Step 2: Assessing the problem – what barriers and facilitators need to be addressed?

In Chapter 2, a total of 44 unique barriers/facilitators were identified by the systematic review of patient-perceived factors.⁽¹²⁷⁾ The 44 barriers/facilitators were coded against the TDF/COM-B model (Table 4.6). Frequencies of barriers/facilitators coded under the TDF/COM-B model are: Knowledge (10); Cognitive & interpersonal Skills (7); Memory, attention and decision processes (6); Behavioural regulation (3); Physical skills (0); Social influences (15); Environmental context and resources (43); Reinforcement (6); Emotion (6); Social/professional role and identity (11); Beliefs about capabilities (9); Optimism (1); Beliefs about consequences (15); Intentions (5); Goals (3).

The coding exercise revealed that certain pathways of change were more significant than others (in terms of frequency). The key areas for change relate to: provision of knowledge about options; social norms about acceptable behaviour in a clinical encounter and participation of certain groups (e.g. older age group); how patients perceive clinicians' and their own role and identity in a clinical encounter; beliefs about ability to be involved in a decision-making process; beliefs about the potential negative consequences of being involved (e.g. retribution); and, clinician-related attitudinal factors.

For the purposes of the current coding exercise, all barriers/facilitators were coded against the TDF/COM-B model. However, it would not be feasible to address all 44 barriers/facilitators identified with a patient-targeted intervention; for example, some of the factors are non-modifiable, and others can only be addressed by a clinician-targeted intervention. In the results section of Chapter 3, several different categories were established, which indicated the potential modifiability of the barriers and facilitators. Using these categories, and the APEASE criteria, factors that would have the biggest influence on behaviour/attitudinal change in patients (i.e. attitudinal factors about social norms) and that could be addressed by a patient-targeted intervention, were selected as targets for the intervention (see Table 4.6 for list of selected factors).

The remaining factors were organised according to several sub-categories, and are also presented in Table 4.6: non-modifiable patient/decision related characteristics, beyond remit of current intervention; factors that can be addressed by complementary patient-targeted intervention; factors that can be addressed by complementary clinician-targeted intervention; and, organisational factors beyond scope of patient-targeted intervention (but to be considered during implementation).

4.3.3 Step 3: Forming possible solutions - which intervention components could overcome the modifiable barriers and enhance the facilitators?

Forty-four barriers/facilitators were identified by the review in Chapter 2 and were coded against the TDF/COM-B model. Nineteen factors were selected to be addressed by the intervention. The remainder were considered either non-modifiable or contextual factors, not significant factors determining patients' behaviour or factors that need to be addressed by complementary interventions e.g. clinician skills training (see Table 4.6).

Following the coding exercise in Step 2, the intervention matrix (Table 4.4) was used to identify the range of suitable intervention functions that could be used to address the selected barriers/facilitators. Table 4.6 indicates how selected barriers and facilitators were mapped to the COM-B model and TDF in Step 2 (column A&B), the range of possible intervention functions, as suggested by the intervention mapping matrix (column C), and the selected intervention functions (column C, indicated in bold). The possible and selected intervention functions in column C are grouped according to how they map to the COM-B model e.g. restriction maps to Opportunity-social and Opportunity-physical.

Selected intervention functions were agreed using the APEASE criteria, in discussion with supervisors. For example, one of the patient-perceived barriers was 'patients perceiving that there are 'right' and 'wrong' decisions and not wanting responsibility for wrong decisions'. This barrier was mapped to the domains 'knowledge' (Capability-psychological) and 'beliefs about consequences' (Motivation-reflective). The intervention matrix (Table 4.4) suggests that these domains could be addressed by education/training/enablement and education/persuasion/incentivisation/coercion, respectively. Using the APEASE criteria, it was deemed that this barrier would be best addressed by 'education' and 'enablement'. This is reported in bold in column C of Table 4.6.

The policies that would support the delivery of the intervention were then considered. The four key intervention functions selected were (in order of frequency), Persuasion (Per), Education (Edu), Environmental Restructuring (Env R), and Enablement (Enb). Using the Policy Categories Matrix (Table 4.5), these intervention functions map to the following policy categories:

- Communication / marketing: Edu, Per
- Guidelines: Edu, Per, Env R, Enb
- Fiscal: Edu, Per, Env R, Enb
- Regulation: Edu, Per, Env R, Enb
- Legislation: Edu, Per, Env R, Enb
- Environmental / social planning: Env R, Enb
- Service provision: Edu, Per, Enb

Using the APEASE criteria, I considered communication /marketing, guidelines, and service provision to be the policies that would be most likely to have an impact. The key aim of the intervention that is being developed is to change patients' attitudes towards patient involvement in healthcare decision-making. The key areas for change identified by the coding exercise related to challenging social norms about patient involvement, redefining the patient role in healthcare consultations, emphasising clinician approval of patient involvement, and reassuring patients that there would not be negative repercussions of involvement. These key messages would be best suited to text-based materials, using principles of social marketing, such as a branded booklet that could be given to patients ahead of their consultation.

Addressing the Service Provision category would also have an impact on the implementation of the intervention. If I change the way in which the service is provided, to incorporate SDM, I could integrate the intervention into the clinical care pathway with relative ease. Similarly, by addressing the Guidelines category, I could change the clinical care pathways of the teams that are involved, to mandate that every eligible patient is sent the intervention ahead of their consultation with the consultant / nurse specialist. Some categories could help to support the implementation of the intervention, but they are too broad for the initial pilot-testing stage, and would not be practicable. Regulation (i.e. establishing rules or principles of behaviour in practice) is possible in the long term (e.g. implementing the intervention at a whole health care organisation level), but it is beyond the remit of pilot-

testing. Legislation at a national healthcare policy level would also be beneficial, but it is again not practicable at the team-level pilot-testing stage. Further, the fiscal measures category (e.g. using the tax system to reduce or increase the financial cost) would not be relevant to the current intervention

Table 4.6 - Barriers / facilitators mapped to TDF / COM-B model, selected intervention components and behaviour change techniques used by the intervention

A Barriers/ Facilitators	B Which theoretical domains / COM-B constructs do they map to?	C Possible / selected intervention components (selected in bold)	D Content description	E Behaviour Change Techniques coding
BARRIERS / FACILITATORS TO BE ADDRESSED BY INTERVENTION				
<i>Predisposing factors</i>				
Age (older / younger)	O-So Social Influences; O-Ph Environmental context & resources; M-Re Social/prof role & identity; M-Re Beliefs about capabilities	Restriction (O-So/O-Ph), env. restructuring-So/O-Ph , modelling (O-So), enablement O-SO/O-Ph), training (O-Ph), restriction O-SO/O-Ph), education (M-Re), persuasion (M-Re) , incentivisation (M-Re), coercion (M-Re)	<p>Characters who range in age have been used in the booklet. This will indicate that SDM is for patients of all ages (for example, Page 3 depicts an older female patient, and page 6 depicts characters from older age, middle age, and younger age groups).</p> <p>A quote from a patient in an older age group has been included. This quote indicates that it is okay for patients (including older patients) to change the way that they interact with clinicians, and to work together with them (see quote on Page 3 accompanied by older female patient character: ‘we want to get the message out there that it’s okay to interact differently with healthcare workers...we can work together with them as part of a team.’</p>	6.2 Social comparison 6.3 Information about others’ approval
Ethnicity	O-So Social influences; M-Re Social/prof role & identity; O-Ph Environmental context & resources	Restriction (O-So/O-Ph), env. restructuring (O-So/O-Ph), modelling (O-So), enablement (O-So/O-Ph), education (M-Re), persuasion (M-Re) , incentivisation (M-Re), coercion (M-Re), training (O-Ph), restriction (O-Ph)	Characters from a range of ethnic backgrounds have been included to promote inclusivity for all ethnic backgrounds (for example, see characters on Page 3, Page 5, and Page 6).	6.2 Social comparison
Lower level of education	C-Ps Cognitive & interpersonal skills; O-Ph Environmental context & resources; M-Re Beliefs about capabilities	Education (C-Ps/M-Re), training C-Ps/O-Ph), enablement (C-Ps/O-Ph) , restriction (O-Ph), env. restructuring (O-Ph) , persuasion (M-Re), incentivisation (M-Re), coercion (M-Re)	The booklet’s content has been written in a clear and concise manner. The Flesch Reading Ease Score is 80/100, and the Flesch Reading Grade is 5.	N/A Not associated with a behaviour change technique.
Poor articulation	C-Ps Cognitive & interpersonal skills; C-Ps Memory, attention & decision processes	Education (C-Ps/M-Re), training (C-Ps), enablement (C-Ps) , persuasion (M-Re) , incentivisation (M-Re), coercion (M-Re)	<p>Tools that encourage patients to: a) write down any questions before the appointment, b) write down what is important to them and what they think about each option (see ‘What can help me get more involved section’, Page 7).</p> <p>Encouragement to share the questions and/or what is important to them with other people</p>	1.4 Action planning 2.3 Self monitoring of behaviour 3.1 Social support

			<p>e.g. clinician, family, and friends (see ‘what matters to me?’ section in Table, ‘What will I have to do?’ section, Page 6).</p> <p>Reminder that they can bring a family member/friend to the appointment if it would help them to communicate their questions/preferences ‘Don't forget, you can always bring someone along to your appointment with you’, Page 7.</p>	<p>(practical)</p> <p>4.1 Instruction on how to perform the behaviour</p> <p>12.5 Adding objects to the environment</p>
Long term patient (bar/fac)	<p>C-Ps Knowledge; C-Ps Cognitive & interpersonal skills; C-Ps Behavioural regulation; O-So Social influences; O-Ph Environment context & resources; M-Re Social/prof role & identity; M-Re Beliefs about capabilities; M-Re Beliefs about consequences</p>	<p>Education (C-Ps/M-Re), training (C-Ps/O-Ph), enablement (C-Ps/O-Ph), restriction (O-So), env. restructuring (O-So/O-Ph), modelling (O-So), persuasion (M-Re), incentivisation (M-Re), coercion (M-Re)</p>	<p>Persuasive language to emphasise that SDM is for everyone, regardless of whether you have a long term condition or not (see page 2, ‘It doesn't matter if you have along term condition, if you are making an important decision for the first time, or if you are simply deciding which medicine to take - everyone can be more involved when they have healthcare choices.’)</p>	<p>6.3 Information about others' approval</p> <p>9.1 Credible source</p>
Interactional context factors				
Expectation of the clinician making decisions	<p>C-Ps Behavioural regulation; O-So Social influences; M-Re Social/prof role & identity</p>	<p>Education (C-Ps/M-Re); training (C-Ps), enablement (C-Ps/O-So); restriction (O-So), env. restructuring (O-So); modelling (O-So); persuasion (M-Re); incentivisation (M-Re); coercion (M-Re).</p>	<p>Information about the expected patient and clinician role is provided. This emphasises why the clinician cannot make the decision on their own, without the patient's input. Challenge existing beliefs about passive patient role (see ‘Why should I get involved?’ section, Page 4). Provide rationale for involvement (see ‘Let's work together...so we can provide care that's right for you’ section, Page 3).</p> <p>A guide on how to take part in a SDM consultation, and what to expect, is provided in a table (see ‘What will I have to do?’ section, Page 6).</p> <p>Present common barriers to SDM stated by patients and challenge these perceptions; one includes perception that clinicians should make the decision (see ‘Doctor knows best, what do I know’ quote, ‘I'm still not sure...’ section, Page 5). Acknowledge that the role may not be what patients are used to (see opening paragraph ‘I'm still not sure...’ section, Page 5).</p> <p>Patient quote emphasising that patients should/can work together as a team with clinicians (see quote from asthma patient, ‘We want to get the message out there that it's okay to interact differently with healthcare workers...we can work together with them as part of a team’, Page 3).</p> <p>Present numbers of other patients who would prefer SDM, over clinician/patient making the decision (see infographic, bottom of Page 2)</p> <p>Information throughout booklet framed from perspective of local health board clinicians - provides confirmation that clinicians want patients to be more active in the decision-making process.</p>	<p>4.1 Instruction on how to perform the behaviour</p> <p>6.2 Social comparison</p> <p>6.3 Information about others' approval</p> <p>9.1 Credible source</p>

Desire to act like a good patient driven by fear of consequences	O-So Social influences; O-Ph Environmental context & resources; M-Au Reinforcement; M-Re Beliefs about consequences	Restriction (O-So/O-Ph); env. restructuring (O-So/O-Ph/M-Au) , modelling (O-So); enablement (O-So/O-Ph/M-Au); training (O-Ph/M-Au); persuasion (M-Au/M-Re) ; incentivisation (M-Au/M-Re); coercion (M-Au/M-Re); education (M-Re)	Information about the expected patient and clinician role is provided. Challenges existing beliefs about passive patient role (see 'Why should I get involved?' section, Page 4). Information in booklet framed from perspective of local health board clinicians - provides confirmation that clinicians want patients to be more active in the decision-making process. Gives patients 'permission' to be involved (e.g. see quotes '...we need you to share, so we can provide better care', Page 4). Challenges patients' perceptions of potential negative outcomes if they do take part in SDM (see quote 'I don't want to be a difficult patient & annoy the doctor' and 'I don't want to be responsible for a wrong decision', 'I'm still not sure...' section, Page 5). Emphasise benefits of being involved in the decision-making process (see 'Some benefits of being involved...', 'Why should I get involved?' section, Page 4)	4.1 Instruction on how to perform the behaviour 5.1 Information about health consequences 5.2 Information about emotional consequences 6.3 Information about others' approval 9.1 Credible source
Perceived acceptability of asking the clinician questions	O-So Social influences; O-Ph Environmental context & resources; M-Au Reinforcement; M-Re Beliefs about consequences	Restriction (O-So/O-Ph); env. restructuring (O-So/O-Ph/M-Au) , modelling (O-So); enablement (O-So/O-Ph/M-Au) ; training (O-Ph/M-Au); persuasion (M-Au/M-Re); incentivisation (M-Au/M-Re); coercion (M-Au/M-Re); education (M-Re)	Convey the message that question asking is acceptable behaviour and that clinicians are happy to respond to patients' questions when they have them (see quote 'If you're not sure why you have a choice, just ask' and 'If you don't understand the options, just ask', Table in section 'What will I have to do?', Page 6). Present common barriers to SDM stated by patients and challenge these beliefs; one includes perception that patient will annoy clinician if they get involved/ask questions (see 'I don't want to be a difficult patient and annoy the doctor' quote, 'I'm still not sure...' section, Page X). Tools that encourage patients to ask specific questions about their options and to write down any questions before the appointment (see 'What can help me get more involved section', Page 7 and Appointment Checklist, Page 8). Information in booklet framed from perspective of local health board clinicians - provides confirmation that clinicians want patients to be more active in the decision-making process.	1.4 Action planning 4.1 Instruction on how to perform the behaviour 6.3 Information about others' approval 9.1 Credible Source 12.5 Adding objects to the environment
Belief that clinicians do not want patients involved	O-So Social influences; O-Ph Environmental context & resources; M-Au Reinforcement; M-Re Social/prof role & identity	Restriction (O-So/O-Ph); env. restructuring (O-So/O-Ph/M-Au) , modelling (O-So); enablement (O-So/O-Ph/M-Au); training (O-Ph/M-Au); persuasion (M-Au/M-Re) ; incentivisation (M-Au/M-Re); coercion (M-Au/M-Re); education (M-Re)	Use of persuasive language throughout booklet, framed from perspective of local health board clinicians, that they do want patients involved in their healthcare decisions (See the following quotes/content: 'A patient's guide to becoming more involved in healthcare decisions - written by patients and healthcare workers for you', Page 1; 'Let's work together, so we can provide care that's right for you' heading, Page 3; '...we need you to share, so we can provide better care', Page 4; 'I don't want to be a difficult patient and annoy the doctor' quote, Page 5). Information about the expected patient and clinician role is provided. This emphasises why the clinician cannot make the decision on their own, without the patient's input. Challenge existing beliefs about passive patient role (see 'Why should I get involved?' section).	6.3 Information about others' approval 9.1 Credible source
Not having explicit permission to participate	O-So Social influences; O-Ph Environmental context & resources; M-Re Beliefs about	Restriction (O-So/O-Ph); env. restructuring (O-So) ; modelling (O-So/O-Ph); enablement (O-So/O-Ph); training (O-Ph); education (M-Re); persuasion (M-Re) ; incentivisation (M-	Persuasive language used throughout the booklet conveying the message that patients have the right to participate in their decisions - this will act as 'permission' to become involved, framed from the local health board clinicians. (See the following quotes/content: 'A patient's guide to becoming more involved in healthcare decisions - written by patients and healthcare workers for you', Page 1; 'Let's work together, so we can provide care that's right for you' heading, Page 3; '...we need you to share, so we can provide better care',	6.3 Information about others' approval 7.1 Prompts/cues 9.1 Credible source

	consequences	Re); coercion (M-Re)	Page 4; 'I don't want to be a difficult patient and annoy the doctor' quote, Page 5). Checklist indicates that patients are expected to participate and have permission to check that they have been involved (see Appointment Checklist, Page 8).	
'Doctor knows best', patients have 'inferior' knowledge (bar) / Recognise that there are two experts in the medical encounter (fac)	C-Ps Knowledge; O-So Social influences; O-Ph Environmental context & resources; M-Re Beliefs about capabilities	Education (C-Ps/M-Re) ; training (C-Ps/O-Ph); enablement (C-Ps/O-So/O-Ph) ; restriction (O-So/O-Ph), env. restructuring (O-So); modelling (O-So/O-Ph); persuasion (M-Re) ; incentivisation (M-Re); coercion (M-Re)	Describe the different, but complementary knowledge that patients and clinicians have, which is needed for the decision-making process. Emphasise the importance of patients' knowledge and explain that there are 'two experts' in healthcare consultations (see 'Why should I get involved?' section, Page 4). Present common barriers to SDM stated by patients and challenge these perceptions; one includes perception that the doctor has superior knowledge (see 'Doctor knows best, what do I know' quote, 'I'm still not sure...' section, Page 5).	6.3 Information about others approval 9.1 Credible source
Patients are not capable of understanding medical/ technical information	C-Ps Cognitive & interpersonal skills; C-Ps Memory, attention & decision processes; O-So Social influences; M-Re Social/prof role & identity; M-Re Beliefs about capabilities	Education (C-Ps/M-Re); training (C-Ps); enablement (C-Ps/O-So) ; restriction (O-So); env. restructuring (O-So); modelling (O-So); persuasion (M-Re) ; incentivisation (M-Re); coercion (M-Re)	Use persuasive language to encourage the patient to believe that they are capable of understanding the information about options. Emphasise that SDM is for 'everyone' (see opening section, Page 2 '...everyone can be more involved when they have healthcare choices'). Present common barriers to SDM stated by patients and challenge these perceptions; one includes perception that patients are not capable of understanding the information if they are given it (see 'I can't understand medical jargon' quote, 'I'm still not sure...' section, Page 5). Reassure patient that the clinician will take time to explain the information, and it is okay to ask if they do not understand it first time/would prefer a different format (see 'What will I have to do?' section, Page 6). Provide tools to help make patients feel more capable of understanding the information (see 'What can help me get more involved?' section, Page 7, and Appointment Checklist, Page 8).	6.3 Information about others approval 9.1 Credible source 15.1 Verbal persuasion about capability 12.5 Adding objects to the environment
Preparation for the SDM encounter				
Patient is not entitled to a choice	O-So Social influences; M-Re Social/prof role & identity	Restriction (O-So); env. restructuring (O-So); modelling (O-So); enablement (O-So); education (M-Re) ; persuasion (M-Re) ; incentivisation (M-Re); coercion (M-Re)	Use persuasive language throughout booklet to emphasise that patients are entitled to a choice about their healthcare decisions (e.g. see quote '...everyone can be more involved when they have healthcare choices', opening section, Page 2; '...but, most of the time you will have choices', Page 3; '...you can choose the option that fits best with what you prefer', Page 3). Acknowledge that many patients are surprised when they are offered a choice because it is not what they are used to (see opening paragraph, 'I'm still not sure...' section, Page 5). Present numbers of other patients who would prefer SDM, to the clinician/patient making the decision (see infographic, bottom Page 2).	6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source
'Doing nothing' is not an option	C-Ps Memory, attention & decision processes; O-So Social influences; M-Re Beliefs about consequences	Education (C-Ps/M-Re) ; training (C-Ps); enablement (C-Ps/O-So); education (C-Ps/M-Re); env. restructuring (O-So); persuasion (M-Re) ; incentivisation (M-Re); coercion (M-Re)	Explain that inaction (doing nothing) is sometimes an appropriate action when making healthcare decisions (see diagram 'What will I have to do?' section, Page 6).	9.1 Credible source

Patient does not <i>want</i> to or <i>need</i> to participate in SDM	O-Ph Environmental context & resources; M-Au Reinforcement; M-Re Social/prof role & identity; M-Re Beliefs about consequences; M-Re Intentions	Training (O-Ph/M-Au); restriction (O-Ph); modelling (O-Ph/M-Au); enablement (O-Ph/ M-Au); persuasion (M-Au/M-Re) ; incentivisation (M-Au/M-Re); coercion (M-Au/M-Re); env. restructuring (M-Au); education (M-Re)	Use persuasive language throughout booklet to promote positive attitudes towards patient involvement in SDM and to establish patient involvement as the norm. Emphasise benefits of being involved and highlight potential negative outcomes of not being involved (see ‘Why should I get involved?’ section, page 4’). Describe the different, but complementary knowledge that patients and clinicians have, which is needed for the decision-making process. Emphasise the importance of patients' knowledge and explain that there are ‘two experts’ in healthcare consultations (see: ‘Why should I get involved?’ section, Page 4; ‘Doctor knows best, what do I know’ quote, ‘I’m still not sure...’ section, Page 5). Present numbers of other patients who would prefer SDM, to the clinician/patient making the decision (see infographic, bottom Page 2).	5.1 Information about health consequences 6.2 Social comparison 6.3 Information about others' approval 9.1 Credible source
Accepting responsibility to be involved in SDM	M-Re Intentions	Education , persuasion, incentivisation, coercion (all M-Re)	Provide a description of a typical SDM consultation using a table explaining how patients can get involved, when they accept the role (see Table ‘What will I have to do?’ section, Page 6). Tools that are designed to be completed before/during/after a consultation; completion would indicate that the patient has accepted that responsibility (see ‘What can help me get more involved?’ section, Page 7, and Appointment Checklist, Page 8).	4.1 Instruction on how to perform the behaviour 7.1 Prompts/cues 12.5 Adding objects to the environment
Not knowing what to expect from the SDM consultation	C-Ps Knowledge, M-Re Beliefs about consequences; M-Re Intentions; M-Re Goals	Education (C-Ps/M-Re) ; training (C-Ps); enablement (C-Ps) ; persuasion (M-Re); incentivisation (M-Re); coercion (M-Re)	Provide a description of a typical SDM consultation using a diagram, allowing patients to know what to expect if they are offered healthcare choices (see diagram, ‘What will I have to do?’ section, Page 6). Provide an appointment checklist, listing key elements of a SDM process/consultation, and encouraging patients to make sure they were involved (see ‘Appointment Checklist’, page 8).	1.4 Action planning 4.1 Instruction on how to perform the behaviour 7.1 Prompts/cues
Perceiving that there are ‘right’ & ‘wrong’ decisions/ recognising equipoise & uncertainty	C-Ps Knowledge; M-Re Beliefs about consequences	Education (C-Ps/M-Re) , training (C-Ps), enablement (C-Ps) ; persuasion (M-Re); incentivisation (M-Re); coercion (M-Re)	Explain ‘equipoise’ to patients and provide a rationale for choice, and also highlight situations when there may not be choices (see ‘Let’s work together...so we can provide care that’s right for you’ section, Page 3). Emphasise that there are no right or wrong decisions in situations of equipoise; the decision will depend on personal preferences. Highlight the potential positive outcomes of being involved, and the potential negative outcomes if not involved (see ‘Why should I get involved?’ section, Page 4). Present common barriers to SDM stated by patients and challenge these perceptions; one includes perception that there are right and wrong decisions (see ‘I don’t want to be responsible for a wrong decision’ quote, ‘I’m still not sure...’ section, Page 5).	5.1 Information about health consequences 5.3 Information about social and environmental consequences 9.1 Credible source
Preparation for the SDM process				
Decision support from others	O-So Social influences	Restriction, env. restructuring , modelling, enablement (all O-So)	Remind patients that they can bring a family member / friend to an appointment if they want. This could be for emotional or practical social support (see ‘What can help me get more involved?’ section, page 7). Encourage patients to discuss their decision and what's important to them with a family	3.2 Social support (practical) 3.3 Social support

			member / friend / other clinician (see ‘What will I have to do?’ section, page 6).	(emotional) 12.2 Restructuring the social environment
NON-MODIFIABLE PATIENT / DECISION CHARACTERISTICS, BEYOND REMIT OF CURRENT INTERVENTION OR UNLIKELY TO HAVE SIGNIFICANT IMPACT (NOT KEY BARRIER / FACILITATOR)				
Poor / good health (fac)	C-Ps Cognitive & interpersonal skills; O-Ph Environmental context & resources; M-Au Emotion			
Cognitive impairments	C-Ps Cognitive & interpersonal skills			
Physical impairments	O-Ph Environmental context & resources			
Prior exposure to illness / decision-making point (fac)	C-Ps Knowledge, C-Ps Cognitive & interpersonal skills; C-Ps Behavioural regulation; M-Re Social / prof role & identity; M-Re Beliefs about capabilities; M-Re Beliefs about consequences; M-Re Intentions; M-Re Goals			
Difference in personal characteristics	O-Ph Environmental context, M-Re Social / prof role and identity			
Embarrassing or sensitive topics	O-So Social influences; O-Ph Environmental context & resources; M-Au Emotion			
Health condition stigma / discrimination	O-So Social influences; O-Ph Environmental context & resources; M-Re Social / prof role and			

	identity			
Timing along the illness trajectory	O-Ph Environmental context and resources			
Major (bar/fac) / minor (bar/fac) decisions	C-Ps Memory, attention & decision processes; M-Au Emotion; M-Re Beliefs about capabilities; M-Re Beliefs about consequences			
Shock of receiving diagnosis / time to come to terms with diagnosis (fac)	C-Ps Memory, attention & decision processes; O-Ph Environmental context & resources; M-Au Emotion			
Fear of accepting reality of diagnosis	M-Au Emotion; M-Re Optimism; M-Re Beliefs about consequences			
BARRIERS / FACILITATORS THAT CAN BE ADDRESSED BY A COMPLEMENTARY PATIENT-TARGETED INTERVENTION (e.g. decision support intervention)				
Insufficient/ sufficient information about condition, options & outcomes/ clinician does/does not explain the options/ outcomes	C-Ps Knowledge; O-Ph Environment context & resources			
Written decision support (or lack of)	C-Ps Knowledge; C-Ps Memory, attention & decision processes; O-Ph Environmental context & resources			
Purpose of the decision support tool is unclear	C-Ps Knowledge			
BARRIERS / FACILITATORS THAT CAN BE ADDRESSED BY A COMPLEMENTARY CLINICIAN-TARGETED INTERVENTION (e.g. SDM skills training)				
Clinician reinforces passivity by rewarding	O-Ph Environment context & resources;			

behaviour	M-Au Reinforcement			
Authoritarian clinicians	O-Ph Environmental context & resources			
Equal relationship (fac)	O-Ph Environmental context & resources			
Clinician does not listen to patients' concerns	O-Ph Environmental context & resources; M-Re Optimism; M-Re Beliefs about consequences			
Clinician with poor (bar) / positive (fac) interpersonal skills)	O-Ph Environmental context & resources			
Good (fac) / poor (bar) relationship with clinician	O-Ph Environmental context & resources; M-Au Reinforcement			
Individualised approach & asked about personal preferences (fac; or lack of, bar)	O-Ph Environmental context; M-Re Beliefs about consequences			
Clinician does not address patient directly	O-Ph Environmental context & resources			
Patient is not explicitly offered a choice, or it is presented in a biased way	O-Ph Environmental context & resources			
Clinician does (fac) / does not (bar) explain the options & outcomes	C-Ps Knowledge; O-Ph Environmental context & resources			
Clinician uses medical terminology (bar) / uses simple terminology (fac)	O-Ph Environmental context & resources			
ORGANISATIONAL FACTORS BEYOND SCOPE OF PATIENT-TARGETED INTERVENTION – TO BE CONSIDERED DURING IMPLEMENTATION OF INTERVENTION				
Time available in the consultation	O-Ph Environmental context & resources			

Inability to choose clinicians to do SDM with	O-Ph Environmental context & resources			
Too many clinicians involved in care	O-Ph Environmental context & resources			
Lack of continuity in informational flow between clinicians	O-Ph Environmental context & resources			
Being know (fac) / not being know (bar) by the clinician	O-Ph Environmental context & resources			
Distributing SDM among different clinicians (fac)	O-Ph Environmental context & resources			
Appropriate, multiple consultations for SDM (fac; or lack of, bar)	O-Ph Environmental context & resources			
Inadequate environmental conditions	O-Ph Environmental context & resources			
Paying (fac) / not paying (bar) for healthcare	O-Ph Environmental context & resources			
Overspecialisation of doctors	O-Ph Environmental context & resources			
Lack of reimbursement for clinicians doing SDM	O-Ph Environmental context & resources			

4.3.4 Step 4 - Deciding on the specific intervention content using the Behaviour Change Techniques Taxonomy (v1.0)

4.3.4.1 The prototype intervention

The results of Step 3 included selecting the broad intervention / policy categories (column C). Using the Behaviour Change Techniques Taxonomy (V1) as a guide (see Additional Appendix 4.1 on included CD), the exact format of the intervention and the content were selected. The exact content of the prototype intervention (including location in the intervention) is reported in Table 4.6 (column D). This table shows how the intervention content maps to the intervention categories selected.

The prototype intervention is an 8-page A5 booklet (see Figure 4.3 for front cover; see Appendix 4.2 for full booklet). This would be accessible to a larger number of patients, cost-effective, and could be easily integrated into current clinical pathways. The booklet will be sent to patients ahead of their clinical appointments (preferably at least one week before the appointment). During the pre-testing stage (see Chapter 5) participants' views on alternative formats were explored. For feasibility, a booklet was chosen for the pilot-testing, with scope to develop additional formats with the same content at a later date e.g. tablet app, phone app, website.

Figure 4.3 - Front cover of ‘Your Health, Your Choice’ booklet



Draft content was developed with supervisors. This was circulated for comment to members of the Healthcare Communication and Quality Research Group, based in Cardiff University's School of Medicine. The nine respondents included a mix of researchers (offering a 'patient' perspective) and clinical members of staff. Comments were sought on the purpose of the booklet (e.g. to prepare patients to take part in SDM), the textual content (e.g. readability), and proposed specific elements (e.g. prompt and space for patients to write down what is important to them). All suggestions for appropriate use and improvement were integrated into the next draft, and / or considered during implementation planning (see Chapter 6).

In August 2014, a graphic designer / illustrator was commissioned to develop the booklet, integrating the agreed content with graphic and character design. The initial version was received, and further feedback was sought from the Healthcare Communication and Quality Group. Feedback focused specifically on the layout, various design elements (e.g. colour scheme, style), character design, and usability. Three iterations were produced in order to incorporate the feedback. The final prototype version that was used in pre-testing (see Chapter 5) was received mid-August 2014.

The draft title for the prototype booklet is ‘Your Health, Your Choice’. There are seven key sections to the booklet.

1. This leaflet explains...(page 2)

This section (see Figure 4.4) explains what the booklet will cover i.e. why patients have healthcare choices, what they can expect from a SDM consultation, and how they can work together with clinicians. It emphasises that SDM is something that everyone can take part in. The infographic highlights the number of patients that said that they would share decision-making with a clinician, compared to those who would rather make the decision by themselves, or let the clinician make the decision. This provides an element of social comparison for patients, where they can see what other patients have chosen to do in a similar situation. They can see that most other patients preferred to share the decision, and this also provides confirmation that other people approve of the behaviour.

2. Let’s work together...(page 3)

This section (see Figure 4.4) provides the rationale for patients becoming more involved in healthcare decisions. It makes comparisons to other day-to-day decisions that most people would be familiar with and comfortable making, and parallels healthcare decision-making to these ‘normal’ decisions. This section begins to challenge patients’ perceptions of clinicians’ and patients’ roles in the healthcare consultation. At a high-level, it highlights that patients can be involved in decision-making about their healthcare. This section also includes a quote from an older female asthma patient, which emphasises that patients and clinicians can work together as part of a team. This challenges social norms that patients cannot be involved, thus normalising SDM, whilst providing social support and evidence of others’ approval.

Figure 4.4 - Pages 2 & 3 of the 'Your Health, Your Choice' booklet

Find your appointment checklist on the back!

Let's work together...
so we can provide care that's right for you

This leaflet explains...

- ? why you sometimes have choices to make about your health
- ? what you can expect from your appointment if you have choices, and
- ? how you can work as part of a team with us, your healthcare workers

It doesn't matter if you have a long-term condition, if you are making an important decision for the first time, or if you are simply deciding which medicine to take - **everyone** can be more involved when they have healthcare choices.

When we asked 100 other people like you about decision making...

51	23	26
said they wanted to share decision making with a healthcare worker	said they wanted to make the decision on their own	said they wanted a healthcare worker to make the decision

"We want to get the message out there that it's okay to interact differently with healthcare workers...we can work together with them as part of a team"
- Asthma patient

Sometimes, doctors, nurses and other healthcare workers have to make quick decisions to help you - Like when you are taken to A&E in an emergency.

But, most of the time **you will have choices.**

It doesn't mean that the people looking after you don't know what to do - It means that there is more than one way they can help you, and you can choose the option that fits best with what you prefer.

Figure 4.5 - Pages 4 & 5 of the 'Your Health, Your Choice' booklet

Why should I get involved?

There are **two experts** in healthcare appointments.

As healthcare workers, we know a lot about treatments and tests that can help you, and we know a lot about your illness or condition. But, we don't know about the things that **matter most to you and your family.**

Some patients are surprised when they have a choice, but the fact is, nobody knows you better than you, so...

we need you to share, so we can provide better care!

Other patients tell us that when they were not involved in decisions about their care, they sometimes ended up receiving treatments they didn't want, or outcomes they didn't expect.

Some benefits of being involved:

- ✓ You will know about your options and what will happen
- ✓ You will know about the pros and cons of the options
- ✓ We will know what is important to you. We will then help you make a decision based on these things

I'm still not sure...

Don't worry, you're not alone. Some patients are not sure if they want to be more involved, maybe because it's not what they are used to. There may be things stopping you getting more involved - to help, here is what we say to patients who aren't sure...

Doctors know best, what do I know?
We know a lot about illnesses and how to treat them, but we don't know what matters most to you. Healthcare workers are experts in diagnosis & treatment, but patients are experts in their own lives.

I can't understand medical jargon!
Medical terms can be confusing, even the names of some drugs are difficult to say. However, we will try to explain your options in simple language so that you understand what is involved. If you don't understand, it's okay to say so, and we will go through things again.

I don't want to be a difficult patient
Don't worry, you won't. We want you to be involved - it's important that you speak up. Asking questions and sharing what's important means we can provide the best care for you. Think of it as working together as partners or a team.

I don't want to be responsible for a wrong decision
It's important to know there are no right or wrong decisions, just decisions that are right for you. What matters to someone else might not matter to you. Knowing your options means you know what to expect, and you can decide what is right for you.

3. Why should I get involved? (Page 4)

This section (see Figure 4.5) provides the rationale for SDM and patient involvement in healthcare decisions. It emphasises that there are two ‘experts’ and explains the different types of expertise that the patient and the clinician contribute to the decision-making process. This section challenges the common patient-perceived barrier that ‘doctor knows best’ and it explains why patients’ personal preferences are just as important as medical expertise. The right hand column highlights some of the benefits of participating in SDM, and the bottom paragraph highlights the potential downsides to not being involved i.e. receiving treatments the patient did not want, or outcomes that they did not expect.

4. I’m still not sure... (Page 5)

This section (see Figure 4.5) focuses on directly challenging the key patient-reported barriers that arose in Chapter 2. It presents four of the key barriers, framed from the patient perspective, and presents four responses to these barriers, framed from the clinician perspective. These four barriers include: ‘doctor knows best, what do I know?’ (Patients undervaluing the importance of their own expertise); ‘I can’t understand medical jargon!’ (Perceiving that patients are not capable of understanding information about options); ‘I don’t want to be a difficult patient’ (fear of the repercussions of being an active patient); ‘I don’t want to be responsible for a wrong decision’ (perceiving that there are right and wrong decisions, rather than equipoise). It emphasises that other patients often feel the same (social comparison). The clinicians’ responses provide reassurance to patients and attempt to change patients’ perceptions.

5. What will I have to do? (Page 6)

This section (see Figure 4.6) focuses on providing information to patients on how to perform the behaviour i.e. SDM. It outlines what to expect from a SDM consultation, or consultations. The section is formatted as a flowchart, which outlines three key stages of making a shared decision. Each heading is accompanied by a list of the key tasks that will be required during that stage. These headings relate to the three stages outlined in the SDM model for clinical practice.⁽¹⁾ This section is also written from the clinicians’ perspective, to provide confirmation that clinicians want patients to be

involved. It encourages patients to ask questions if they are not sure and to involve significant others in the decision-making process (social support).

6. What can help me get more involved? (Page 7)

This section (see Figure 4.6) focuses on enabling patients to become more involved in SDM by providing a tool to help prepare for the consultation and the decision-making process. This page provides a notepad that patients can write on. Patients are encouraged to use the notepad to write down their questions for the clinician. They are also encouraged to write what they think about their options, should they be told they have them. It also encourages patients to bring someone to their appointment if they wish (social support).

Figure 4.6 - Pages 6 & 7 of the ‘Your Health, Your Choice’ booklet



7. Your appointment checklist...(page 8)

The final page of the booklet (see Figure 4.7) includes an Appointment Checklist. Patients frequently report that they do not know what to expect from a SDM consultation, and this can act as a barrier to SDM. The aim of this page is to provide patients with a guide to the key features of an SDM consultation (picking up from the flowchart on page 6). The checklist acts as an aide memoire of the type of care patients should be receiving if they are faced with healthcare choices. The checklist

format allows patients to tick these off as and when they occur, if they so wish. Again, this page challenges attitudes that patients should not be involved; it ensures patients know that they can be actively involved and encourages them to check that they are.

Figure 4.7 - Page 8 of the ‘Your Health, Your Choice’ booklet



The colour scheme, layout, format and character design used throughout the booklet have been selected to ensure that the booklet is engaging and stands out from traditional patient information leaflets. It has also been designed in a way that will appeal to a variety of different age groups. Clear and concise language has been used throughout, and the content has a Flesch Reading Grade score of 5, making it accessible to a large number of people. In order to make sure that patients perceive that the booklet is from a credible source, organisational logos have been included. The text is also framed as if written from the local health board's and / or clinicians' perspective. This will help patients to feel that they have permission from their clinician to take part in SDM.

4.3.4.2 Behaviour Change Techniques Taxonomy coding exercise

The results of the Behaviour Change Techniques Taxonomy coding are reported in column E. Full definitions of the behaviour change techniques used are available in Additional Appendix 4.3 (on included CD). 16 different behaviour change techniques were used in the intervention. Techniques were used from the following groups (number of techniques from each grouping included in parentheses): 3. Social support (2); 6. Comparison of behaviour (2); 12. Antecedents (2); 1. Goals and planning (1); 2. Feedback and monitoring (1); 5. Natural consequences (1); 4. Shaping knowledge (1); 7. Associations (1); 9. Comparison of outcomes (1). The four most frequently selected techniques were: 9.1 Credible source (12); 6.3 Information about others' approval (11); 4.1 Instruction on how to perform the behaviour (6); and 6.2 Social comparison (5).

4.4 Discussion

This chapter described how the BCW Guide(166) was used to develop a theoretical patient-targeted intervention designed to prepare patients for a SDM clinical encounter. This guide offered a systematic approach to developing the resulting 8-page A5 booklet, 'Your Health, Your Choice'. The four-step approach has combined theory and empirical research to select intervention components, moving through a process of identifying target behaviours, mapping barriers / facilitators to theoretical domains, selecting behaviour change techniques, and developing the intervention. The benefit of developing a theory-based intervention is the potential to explore associations between intervention components and intervention effects. The integrated framework, which covers various behaviour change theories, also

allows for a more comprehensive evaluation of the possible determinants of behaviour. Further, use of the Behaviour Change Techniques Taxonomy helps to specify the active ingredients for evaluation planning, and assists with intervention replication.

It should be noted that this intervention focuses on the individual level i.e. the patient. Patient attitudinal factors are a significant barrier to increased involvement in SDM, as noted in Chapter 2. However, there are multiple other factors that will also need to be addressed in conjunction with patient-related attitudinal factors, if the intervention is to be successful (presented in Table 4.5). These include organisational factors (e.g. time in the consultation to do SDM; appropriate distribution models), clinician-related factors (e.g. displaying negative attitude towards patient involvement; encouraging patient passivity) and factors related to knowledge acquisition about options (e.g. provision of decision support tools). A single patient-targeted intervention such as the 'Your Health, Your Choice' booklet cannot address all of these factors. Therefore, the intervention will be implemented within a broader on-going SDM implementation programme called MAGIC (MAKING Good Decisions in Collaboration).

MAGIC is a large-scale implementation programme taking place in Cardiff and Newcastle, commissioned by The Health Foundation, designed to embed SDM into routine clinical settings.(33, 37) In Cardiff, there have been three distinct phases to the MAGIC programme. Phase One (August 2010 – January 2012) was led by researchers at Cardiff University, and aimed to work collaboratively with various primary and secondary care teams to develop and test interventions within an implementation setting. Phase Two (February 2012 – August 2013) was led by the Cardiff and Vale University Health Board, and focused on wider dissemination, implementation and sustainability of the successful interventions identified in Phase One. Phase Three began in December 2013, and is currently on going. This is an evaluation phase looking at three secondary care teams who have routinely embedded SDM into their clinical settings. These teams are the Breast Care Centre, Chronic Kidney Disease team, and the Paediatric Ears, Nose and Throat team.

In addition to my PhD work, I have also been employed to work on the MAGIC programme since 2010. I was project manager during Phase One, and I was responsible for coordinating the development and implementation of SDM across four secondary care teams and four primary care teams. I worked closely with the dedicated SDM facilitators, and was responsible for collating the key learning from the different clinical areas. I am also

involved in the SDM implementation evaluation for Phase Three of the programme. During Phase One, I took the lead on convening the Patient & Public Involvement panel for MAGIC; this involved meeting with the panel every other month to develop and refine SDM interventions, and making sure that they were consulted at all times when new developments arose. The ‘Ask 3 Questions’ campaign was developed with the panel (intervention included in Chapter 3 review), and this has helped with my understanding of patient perceived barriers and facilitators to SDM. This is one of the key reasons I decided not to conduct primary research with patients to explore barriers and facilitators; I was confident that the themes that emerged from the systematic review in Chapter 2 were reflective of the feedback I had heard from many patients throughout the MAGIC programme. The current intervention (‘Your Health, Your Choice’) was not developed as part of the MAGIC programme, but my work on MAGIC has ensured I have a sound understanding of SDM implementation, which will assist with the development and implementation of my PhD work.

The two key interventions that were most successful in Phase I were the advanced SDM skills workshops for clinicians and the brief in-consultation decision support tools (Option Grids):

- *SDM skills workshops*: 1-3 hour skills training workshops framed around the SDM model for clinical practice,⁽¹⁾ using role play. The aim of the workshops is to help teams to understand the key steps in SDM and differentiate it from current ways of working.
- *Option Grids*: brief one-page documents used within a consultation to facilitate discussion between patients and clinicians. They are designed to help people compare reasonable treatment or screening options for medical conditions. Using the grid, patients and clinicians can read and compare the answers to questions that patients frequently ask about each relevant option (see Figure 4.8)

Figure 4.8 - Option Grid for breast cancer surgery



Breast cancer surgery

Use this grid to help you and your healthcare professional talk about how best to treat breast cancer.

Frequently asked questions	Lumpectomy with radiotherapy	Mastectomy
What is removed?	The cancer lump is removed, with some surrounding tissue.	The whole breast is removed.
Which surgery is best for long-term survival?	Survival rates are the same for both options.	Survival rates are the same for both options.
What are the chances of cancer coming back in the breast?	Breast cancer will come back in the breast in about 10 in every 100 women (10%) in the 10 years after a lumpectomy. Recent improvements in treatment may have reduced this risk.	Breast cancer will come back in the area of the scar in about 5 in every 100 women (5%) in the 10 years after a mastectomy. Recent improvements in treatment may have reduced this risk.
Will I need more than one operation?	Possibly, if there are still cancer cells in the breast after the lumpectomy. This can occur in up to 20 in every 100 women (20%).	No, unless you choose breast reconstruction
How long will it take to recover?	Most women are home within 24 hours of surgery.	Most women are home within 48 hours of surgery.
Will I need radiotherapy?	Yes, for up to six weeks after surgery	Radiotherapy is not usually given after a mastectomy.
Will I need to have my lymph glands removed?	Yes, some or all of the lymph glands in the armpit are usually removed.	Yes, some or all of the lymph glands in the armpit are usually removed.
Will I need chemotherapy?	You may be offered chemotherapy, but this does not depend on the operation you choose.	You may be offered chemotherapy, but this does not depend on the operation you choose.
Will I lose my hair?	Hair loss is common after chemotherapy.	Hair loss is common after chemotherapy.

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These were implemented within the context of broader organisation and clinical team support, secured through various engagement activities with the Cardiff & Vale University Health Board members and clinicians. This included working directly with the Director of Patient Experience, securing support from the Chief Executive, and a dedicated SDM facilitator working directly with the clinical teams. This programme has ensured that the current intervention will be implemented in a supportive context, and that it can be delivered alongside complementary interventions that will address some of the barriers that could not

be addressed by the patient-targeted intervention alone. For example, several of the barriers related to clinicians' attitudes and behaviours (individualised approach, authoritarian clinicians, clinician does not explain the options) can be addressed by the SDM skills workshops, and also the team engagement activities that have taken place throughout MAGIC. Further, several of the barriers related to knowledge can be addressed by the provision of decision support tools, such as the Option Grids. The combination of different interventions and a supportive organisational context will maximise the impact of the 'Your Health, Your Choice' intervention, but it is proposed that this preparation is an essential component to promote SDM for the greatest number of patients.

The next chapter (Chapter 5) describes the pre-testing process, whereby the prototype booklet was tested with members of the public, and clinicians / organisational representatives who will be integrating the booklet into their clinical pathways.

Chapter 5

Pre-testing the prototype ‘Your Health, Your Choice’ intervention with users and clinicians: a qualitative study

5.1 Introduction

In relation to the MRC’s framework for the development and evaluation of complex interventions(45), Chapters 2 and 3 focused on the ‘theoretical phase’ of intervention development. That is, understanding the factors that will promote or inhibit patients becoming more involved in the healthcare decision-making process. The results from Chapters 2 and 3 formed the theoretical basis for the ‘Your Health, Your Choice’ prototype intervention. Chapter 4 reports how the BCW Guide(47) used the results from Chapters 2 and 3 to systematically develop the theoretically grounded intervention. The MRC stage of development used in the current chapter is known as ‘modelling’. This process involves delineating the actual intervention components, and examining how these active components may relate to outcomes. This stage also allows for refinements to be made to the design of the intervention, before embarking on a full-scale evaluation.

Using the BCW Guide,(47) the active ingredients of the intervention were specified in Chapter 4 (see Table 4.6). In particular, the Behaviour Change Techniques Taxonomy(170) was used to specify the exact intervention components. Using the mapping process, assumptions were made about the components of the booklet that could address the key barriers and facilitators, and thus potentially change patients’ attitudes and behaviours. An important stage in intervention development is ‘pre-testing’. This is the process of trying out the specific messages of the prototype intervention and the intervention materials with the intended participants before the final version is created.(175) This stage precedes the ‘field-testing’, or pilot-testing, phase where the intervention is trialled as it will be implemented, with both the implementers (i.e. clinicians) and the intended participants (i.e. patients), before actual implementation (see Chapter 6 for details of the intervention pilot-testing). Bartholomew and colleagues argue that the pre-testing phase is crucial to determine whether the planning up until this stage has resulted in an intervention that has

the potential to have the desired effect, is usable, and is likely to be implemented in the way intended.(175)

The pre-testing phase provides reassurance that the assumptions made during intervention development are correct, or it identifies if changes are needed to address these assumptions. Additionally, feedback from individuals who are involved in delivering the intervention and / or the broader organisational remit of patient-centred care, will allow us to make a judgement as to whether the intervention will fit with current practice.

The aim of this chapter was to conduct pre-testing of the prototype intervention agreed in Chapter 4. Specifically, the chapter aimed to assess public users' and clinicians' reactions to the booklet's content (or 'active ingredients'), design, readability, usability, and potential implementation.

5.2 Methods

Pre-testing was conducted with two key groups: the general public and clinicians/organisational representatives. For ease of describing the methods and results, these groups will be referred to as the user group and the clinician group, respectively. A qualitative approach was used whereby participants were asked to take part in a structured interview. The interviews took approximately 45 minutes each, and were audio recorded. The study protocol and materials were reviewed and approved by the Cardiff University School of Medicine Research Ethics Committee, and a favourable ethical opinion was given in August 2014.

5.2.1 User group – recruitment and analysis

I aimed to recruit approximately six users, depending on data saturation. Potential participants had to be 18 years and over, and be able to read and speak English, but were not required to be a patient currently receiving care. Users were recruited via various routes. Involving People is part of Health and Care Research Wales. They encourage and support the active involvement of patients, carers and service users in health and social care research. Involving People were contacted, and a study opportunity form was completed, which outlined the requirements of participants and formed the basis of an advert that was

sent to the Involving People network members. Opportunistic sampling was also used to recruit users via social media websites (e.g. Facebook) and word of mouth.

All individuals who indicated an interest in taking part in the study were sent the study information leaflet, a consent form and a study reply form, together with a self-addressed pre-paid envelope. Once the study reply form and consent form had been signed and returned, the individual was contacted in order to arrange a convenient time for the interview. When an interview had been arranged, participants were sent a copy of the intervention booklet and were encouraged to read the booklet before the interview, and to make notes if they wished.

During the interview, participants were asked about their views on the booklet. The interview schedule was organised into two distinct sections: 1) questions based on the TDF (and key drivers of behaviour identified in Chapter 4); and 2) questions based on the booklet's design elements, format and intended use (see Additional Appendix 5.1 on included CD for full interview schedule). The results of Chapter 4 indicated that certain pathways of change (TDF domains) were more significant, in terms of the frequency of barriers / facilitators being mapped to them. These key drivers of behaviour were: social influences; social and professional role and identity; beliefs about capabilities; beliefs about consequences; knowledge; and environmental context and resources.

The mapping exercise in Chapter 4 ensured that the booklet content addressed these key barriers, and thus the key pathways of change e.g. the barrier 'not knowing what to expect from a SDM consultation', which mapped to the TDF domain 'knowledge', was addressed by including a section in the booklet on what to expect ('What will I have to do?' section). A key task of the pre-testing is to determine whether these specific elements of the intervention could potentially have the desired effect on the key drivers of behaviour e.g. does the section 'What will I have to do?' make users feel that they know what to expect from consultations where they are offered treatment options?

All interviews were transcribed verbatim, and entered into NVivo qualitative analysis software.⁽⁷²⁾ Each transcript was thoroughly read, and the audio-recorded interview was re-listened to, to ensure familiarisation with the content of each interview. Using the key drivers of behaviour identified in Chapter 4 (see above), an initial set of codes were developed, each with a brief definition. This formed the initial analytical framework for the framework analysis,⁽¹⁷⁶⁾ which was used to code two of the transcripts. New codes that

did not fit with this initial framework were noted, and they were added to the revised framework. Codes that were redundant were removed or merged with other codes. The final framework was applied to each transcript using NVivo software (see Additional Appendix 5.2 on included CD for final analytical framework). Once all data had been coded using the analytical framework, the data were summarised in a separate matrix for each analytical theme (each matrix comprised one row per participant, and one column per code). Themes were generated from the data set by reviewing the matrices and making connections within and between participants and categories, influenced by the initial framework and new concepts that were generated inductively from the data.

Content analysis, completed by hand, was also conducted to summarise feedback regarding the design elements, format, and text/graphic content (see Interview guide section B, Additional Appendix 5.1 on included CD). All requested changes were recorded, and sent to the designer to incorporate into the final version of the booklet used during pilot-testing (see Chapter 6). This feedback is summarised with the clinicians' feedback in results section 5.3.4.

5.2.2 Clinicians – recruitment and analysis

I aimed to recruit around six clinicians, depending on data saturation during qualitative analysis. The clinician group was recruited via known contacts that worked at either Cardiff and Vale University Health Board or Abertawe Bro Morgannwg University Local Health Board. Participants could either be clinicians or Health Board employees who are involved in the areas of patient experience or quality and safety. Potential participants were contacted via email in the first instance to gauge interest in taking part in an interview. All individuals who expressed an interest in taking part were sent the participant information leaflet, a consent form, and a study reply form, together with a self-addressed pre-paid envelope. Once the study reply form and consent form had been returned, the participant was contacted to arrange a convenient time and date for interview. Before the interview, participants were sent a copy of the booklet, and a covering letter that encouraged them to read the booklet and make notes.

During the interview, the participants were asked about their views on the booklet. Specifically, they were asked about the following areas: overall purpose; format and design; views on the specific elements (see Additional Appendix 5.3 on included CD for full

interview schedule). Unlike the patient interview schedule, the focus was on the potential use of this booklet within a healthcare setting e.g. anticipated patients' reactions, how could this fit into existing clinical pathways, and how does it fit with the organisation's approach to patient-centred care? Using NVivo software, thematic analysis was conducted to analyse the feedback.⁽¹⁷⁷⁾ Framework analysis was not used for the clinician data; the framework was guided by the TDF (or the drivers of behaviour), and the focus of clinician interviews was on design / implementation feedback. Content analysis by hand was also conducted to summarise suggested changes to the booklet's design, format or text / graphic content. All requested changes were recorded, and sent to the designer to incorporate into the final version of the booklet used during pilot-testing (see Chapter 6). This feedback is summarised with the users' feedback in results section 5.3.4.

5.3 Results

Results have been organised into four key areas: (1) key themes emerging from the framework analysis of user data; (2) key themes emerging from the thematic analysis of clinician data; (3) implementation of the intervention (from user and clinician data); and (4) a summary of design and content changes (from user and clinician data).

5.3.1 Sample

Six participants (three male, three female) were recruited to the user group and interviewed. Two participants were recruited via the Involving People network (one male, one female). The four other participants included three females and one male. The age of the sample ranged from 21 – 74 years. Six participants were recruited to the clinician group (two male, four female), covering the following professions: Clinical Nurse Specialist (n=2), Patient Experience Facilitator (n=1), Investigation and Redress Manager (n=1), Senior Nurse in Quality and Safety (n=1), and People Centred Care Lead for Public Health Wales (n=1).

Interviews lasted between 17 and 44 minutes (29 minutes average). For the participants' convenience, two user participants were interviewed together (P9 and P10), and two clinician participants were interviewed together (C2 and C3). The transcripts for these two interviews were entered into NVivo twice, and each participant's feedback was coded separately.

5.3.2 Patient sample - framework analysis using the TDF

The initial analytical framework consisted of 23 codes, clustered across five categories. After coding two transcripts, one code was removed as it was not relevant to the interview transcripts ('poor articulation or ability to communicate preferences') and further codes were merged due to similarities in the coded content: 'changing attitudes that good patients are passive and active patients are difficult' was merged with 'changing views on perceived acceptability of being involved in healthcare decisions (social norms)'; 'overcoming perceived negative consequences' was merged with 'promoting perceived positive outcomes'; 'knowledge of existence of choice' was merged with 'knowledge about rationale'. Six new codes were added. The final analytical framework that was applied to the remainder of the transcripts consisted of 25 codes, clustered across six categories (see Appendix 5. 2)

Data were then summarised into a matrix for each category in the analytical framework, with one row per participant and one column per code. Verbatim quotes were abstracted and entered into the corresponding cell. The following key themes emerged from examination of the data matrices:

5.3.2.1 'This is the way that things are going to be' – a shift in attitudes regarding patient involvement in healthcare decisions

A key theme that emerged from the data related to social norms, or the perceived acceptability of patients' participating in the healthcare decision-making process. A key barrier identified in the systematic review in Chapter 2 was patients perceiving that they cannot, or should not, be involved in decisions. Significantly, the booklet appears to have resulted in a positive change of attitude amongst most of the user participants; after reading the booklet, the users accepted that it is 'okay' for them to be more actively involved:

'I wouldn't have even thought about it before to be honest with you...you go to the doctor...you're always mindful you're not going to be asking too much about the treatment or medication, but this message tells you now 'we're offering a shared decision-making appointment – I'm meant to be offered it.' [P6]

'Yeah definitely, I'd like to be more involved now after reading that...when going to the doctors, I know now I can have a choice in it, whereas before you'd go to the doctors for them to tell you what's wrong and how to make you feel better.' [P8]

The shift in attitudes towards active patient involvement in healthcare decisions was supported by personal stories from some of the participants, whereby they provided clear and detailed examples of situations where they had previously not been involved in SDM:

'You don't want your doctor making decisions for you, well I don't like it when I'm just told this is what's happening, because when I went to my last appointment they were like 'well you're having this cream' and I said 'well I've had it before, that's a really weak cream, you're just giving me something now that isn't going to work because I know it hasn't worked before'. They're not taking on board what's happened, so yes it's bad.' [P8]

'Well, when I went to have my knees done, he wanted to do both knees at once. But that would have immobilised me for eight weeks, and I was like 'I'm not having that', at some point I will have it done, but I was like 'no, you're not doing both knees'. So he was trying to get me to have two knees done, which would have been against me, which goes against what that [booklet] is sort of saying.' [P9]

The fact that the users discuss these situations in a negative light, in comparison to the SDM approach, suggests that they would have preferred to be more involved in the previous decisions, even if they did not realise this at the time of the original consultation.

After reading the booklet, one participant saw SDM as an entirely new way of conducting most healthcare consultations, referring to them as a 'new type of appointment', but also recognised that some areas of healthcare do already promote the SDM approach:

'This is what's going to be happening in the future...how this is going to evolve into these types of appointments. I think it would encourage you that this is the way that things are going to be, and that it's okay to do it.' [P6]

'I think already some departments have started encouraging people, as in maternity, you get asked what kind of birth plan you want, consultant led, or do you want the midwifery led unit?' [P6]

Interestingly, it seemed to be a case of participants not being able to know what they do not know; in other words, some felt that they had never been offered SDM before, or did not know what SDM was, but now that they know about it, they would want this type appointment:

'Probably because I didn't have any knowledge about it, I didn't know I could ask about it...but if they told me more, then I'd probably ask more questions and want to choose what cream I have.' [P8]

'Well it's changed my views because I didn't really know anything about it before, to be honest.' [P6]

Some users also believed that as other patients experience SDM, or become aware of SDM through the booklet, they would no longer wish to receive the 'old type of appointment':

'More people then will start expecting to have this, because once they know someone who has had a shared decision appointment, I suppose not many people would want the ordinary type of appointment. They would say 'why can't I have that appointment, my friend had an appointment where she was able to choose from the options...'.' [P6]

Generally, users felt that the elements of the booklet that made comparisons to other patients were helpful and reinforced positive social norms about SDM. This social comparison provided information about what other patients think about SDM, and it clarifies that others approve of it, thus providing reassurance about their own involvement in decision-making:

'It just showed how many actually want it, so it made me feel 'well I want that now 'cause 51 out of a 100 people like it, so it's obviously got to be good.' [P8]

'I like this bit, everyone else's opinion, it asks the opinions from characters, and it made me feel like I can ask questions...I think going in now I'd be reassured.' [P8]

Users also felt that if they, or another individual that they knew, were prompted to speak to other people about the decision, such as family and friends, this would also encourage and support them to participate in SDM:

'It says here that you can share this with you doctor, nurse, or family, so the family becomes part of your treatment, whatever you're going to do, the family become part of helping you to work together with your healthcare professional.' [P6]

5.3.2.2 'You know your life, better than the doctor knows your life' – recognising the importance of patients' contribution to decision-making

Another key theme that emerged was users acknowledging that there are two experts in the healthcare consultation. One of the key patient-reported barriers identified in the systematic review in Chapter 2 was 'doctor knows best'; in other words, patients placed a

significant emphasis on the medical knowledge from the clinician, and undervalued the importance of their own personal preferences in the decision-making process.

The user interview data suggest that the booklet had a positive impact on helping patients to recognise the importance of both the clinician's knowledge and the patient's knowledge. It helped patients to understand that whilst clinicians know a lot about the diagnosis and the evidenced-based options that might help the patient, they do not know about the things that matter most to patients, and that the best decision for them would be made in collaboration with the clinician:

'A healthcare professional doesn't know what would matter most to you and your family...[the booklet] would make you feel that it's okay to do that and say 'well actually I need to look after my mother, so I can't go into hospital just yet, can I go in 3 months time and have a watchful waiting period?''
[P6]

'I used to feel like they had to make a decision for me, so when I'd go to the doctors they'd prescribe the creams that they'd give me and the tablets, whereas now I'd probably feel like 'well is this strong enough?' [P8]

'...the two spectrums in a way, it's like you know your side, you know yourself, and then they know the medical side of it, so it's a joint effort. I want them there to be able to advise me on what's available, but ultimately it's me that it's affecting, so it should be the choice is there for the patient.'
[P10]

P6 saw patients as an extension of the clinical team that already work together:

'Already your healthcare professional would be working as part of a team at the hospital or surgery, so I think the patient would just become an extension of that team, and work together, it's all about working together.'
[P6]

In relation to the figure on page 2 of the booklet (See Appendix 4.2), which shows that 23% of patients would like to make a decision on their own, P6 commented how she did not agree with this. This shows that the patient recognises the importance of both the patient and clinician contributions:

'23% saying they wanted to make a decision on their own, but I can't see how that would ever be, because you need the information from the professional before, you can't just make your own decisions on your health, it's got to be a joint thing.' [P6]

At the beginning of the interview, P9 noted that he felt clinicians knew best because *'they are the ones with all the training'*. However, during the interview he also provided examples of previous care that he had received, during which he was not asked about his personal preferences. Interestingly, whilst reflecting on this story, his viewpoint shifted to *'you know your life, better than the doctor knows your life'*.

Several users referred to the 'I'm still not sure section' on Page 5 (see Appendix 4.2) of the booklet as being particularly helpful in addressing the issue of having two experts in the consultation, and challenging common barriers to involvement. All of the users could see the importance of their contribution to the decision-making process, and could understand the benefit to the patient of being involved, but some also viewed patient involvement as beneficial to clinicians too:

'I think it can only help the healthcare professional if the patient will engage properly in making these shared decisions...if they've got more than one option, it must be quite difficult for them to decide which is the best option for you, because they don't know you like you know yourself.' [P6]

'You can both say, 'look we've both got the same checklist, I think this has been covered, and you do', so I think that would help them from their side because they'd know you were happy with everything.' [P10]

5.3.2.3 'A standard appointment' – knowing what to expect from a SDM consultation

It is clear from the systematic review in Chapter 2 that many patients are not aware that they have options available to them, and many patients have had little previous experience of SDM. Not knowing what to expect, or knowledge about the existence of options, was a key barrier to patient participation in SDM. The patients' interview quotes above show that many patients did not know what SDM entailed before receiving the booklet; as such, it would be difficult for patients to actively participate or express a view in something that they do not know anything about.

The third theme emerging from the patient interview data was knowing what to expect from a SDM consultation. The users reported that the booklet made it clear that there are sometimes healthcare choices to make, and it provided a clear rationale for this, for example:

'I didn't know a lot about it, but I think if you were sent this booklet you might be a bit more proactive in saying to your GP 'I had a leaflet which said that I could take part in my appointment a bit more and help decide on my choices'.' [P6]

All users reported that the booklet provided clear guidance on what to expect if they were faced with healthcare options, and this prepared them to participate. The 'what will I have to do?' section on page 6 of the booklet and 'your appointment checklist' on page 8 were particularly helpful in outlining what to expect (see Appendix 4.2):

'Yeah, that was broken down quite well into 'Do I have a choice?', 'What are my options?', and 'What matters to me?' [P6]

'It [the flowchart on Page 6] shows you the steps you'd go through, like the process you'd go through, you have an option and talk about it, and then it tells you who you could talk to about it, like you doctor or family. I thought it was good.' [P8]

Users talked about using the checklist as a way of helping them know what to expect, and also as an in-consultation tool that helped them to make sure they received what they were expecting from an SDM appointment:

'If you took this with you then you can just check it off as you go, and let's say they didn't tell you about your possible outcomes, you've got that [the checklist] there with you and you can say 'well why haven't I been told the possible outcomes?' It's something you can refer back to and question your doctor or whoever.' [P8]

'You've got your checklist, a standard appointment.' [P9]

P9 referred to the checklist as an 'appointment control sheet'; this indicates that the user feels that they may have some control over how the consultation will go, and the checklist can help to ensure that it is a SDM appointment. As well as being used by the patient to make sure that the checklist items had been covered, some users viewed the checklist as (in effect) a dyadic tool that they could complete together with a clinician, during a consultation:

'...with the healthcare professional, we could go through that [checklist], and we could see that everything from both sides was covered, and everything was clear to both of us. That I was clear with what the healthcare professional was saying, and he was clear with what I was trying to say.' [P6]

'You can both say, 'look we've both got the same checklist, I think this has been covered, and you do', I think it would help from their side as well.' [P10]

The notepad on Page 7 of the booklet helped to prepare users for a SDM appointment in various ways. Users can write down their health problem, concerns, or questions that they wanted to ask before the appointment, and it can act as an *aide memoire* of things that they wanted to cover with the clinician:

'I think it can prepare you before you go to the doctors as well, so if you know what's wrong with you, you can write it down and say 'this is what's wrong, help me with my options', and then you can say what you think about your options.' [P8]

'I think it would help you, because sometimes you're so nervous in a consultation, you could just look at that and go 'oh hang on a minute', and then spark your memory of something, something that you wanted to ask.' [P8]

Users felt that the notepad helped them to prepare for SDM, but it also helped to support the decision-making process after they had been given the options. P1 and P8 felt that the checklist was a useful tool to help them remember what was said during a consultation:

'...there were some things that [husband] said 'oh he said this' and I said 'I didn't hear him say that' and it's probably because your emotions are so up there aren't they, and you don't always take it in.' [P1]

'If it was something about my skin, and I hadn't taken my parents to the doctor that day, because normally they'd come, I'd write notes down.' [P8]

P8 also saw the notepad as a useful tool for recording their options, and facilitating discussion of these options with other people, such as family members:

'it prepares you before you go to the doctors, or after, you can even take it home and talk to your family about it...you could take it to an appointment with you, you could write down what they said if you didn't want to make a decision there and then, and you can bring it home and say 'this is what they've said'.' [P8]

P10 felt that if they completed the notepad, it would help to identify any gaps and issues that they wanted to discuss in further detail at the next appointment.

'And the space to write them...and even if you didn't do it [make decision] there and then, if you took it home afterwards and had a little think about what you had, if there was a gap, whenever you were at your next appointment you could think 'I want to discuss this...'.' [P10]

Interestingly one user viewed the checklist as a monitoring tool that could be retained by the clinician, or a research team, and analysed to make sure that patients are receiving a SDM appointment.

'...it's going to be completed at the end of the appointment with your GP...and that could be fed back as valuable information for the researchers, so that they can monitor progress, and how successful or not the appointments are.' [P6]

Overall, the booklet appeared to prepare users for the possibility of participating in SDM, provided useful tools that could help to ensure that they received SDM when offered healthcare options, and also tools that could support the SDM process.

5.3.2.4 'It made me think it's not so scary to make the decision about your healthcare' - overcoming perceived negative outcomes

The fourth theme that emerged from the data was overcoming the perceived negative outcomes of being involved in SDM. The perception that active patients are difficult and the fear of the negative repercussions was a key patient-reported barrier identified in Chapter 2. The user interview data show that before reading the booklet, users felt that they would be classed as 'difficult' if they tried to be involved in the decision. However, now they feel that it is 'okay' to be involved, and there would not be negative repercussions, such as annoying the clinician or making a wrong decision.

'You would think prior to reading something like this that there could be negative repercussions if you went to your GP and started trying to have some involvement in the appointment, which has never been done before...this says it's okay to take part, you're not going to be penalised for trying to put your view over. Your health appointment isn't going to be compromised because the doctor thinks, 'I'm going to put them to the back of a list because they're difficult, they want to know everything...'' [P6]

'It sort of made me think it's not so scary to make the decision about your healthcare.' [P8]

'I don't want to be a difficult patient, you feel like you're nagging sometimes. Last time I went to the doctors I was asking and asking, and then you feel you better not ask again, I'll just take what I've got and go, but if they give you the option to be involved, you're not going to feel like a pain when you're asking questions.' [P8]

'Or I think the fears that you might have about making the wrong decision, this is quite informative that that can't happen.' [P1]

It was clear that the patients were able to focus on the benefits of being involved in the decision-making process, even if the diagnosis is not good:

‘With the pros and cons, it’s nice that you would get all of the information, because obviously you’re not always going to get good news, it’s not always going to be the news you want, but if you’re told the pros and cons...’ [P6]

5.3.2.5 ‘If you think I should have the treatment, I’ll have it’ - the challenges of reaching certain patient populations

The fifth theme that emerged related to the challenges of getting the key message of the booklet across to certain patient populations, such as the elderly. The users who were interviewed were largely supportive of the booklet’s concept and key messages, and indicated that they would now participate in SDM (age range 18-74 years). However, some users reported that they could foresee difficulties in patients of older age groups accepting that they should be involved in SDM. Sometimes this was anecdotal, based on the participant’s experiences with patients of this age group, and sometimes this was based on the general perceptions of this patient population.

P1 talked about her experience of working with elderly patients located in the Valleys region of South Wales. Her work involved speaking to patients about their rights as a patient and encouraging patients to make sure that they are treated with dignity and respect in hospital. In this age group, perceptions of being a difficult patient were an important factor in their involvement, or lack of it:

‘It says here, ‘I don’t want to be a difficult patient’, that’s a biggy, they all worry about that.’ [P1]

P1 suggests that the attitudes of patients in these areas might be due to their social circumstances and the culture that they were brought up in more broadly, notably relatively deprived areas where people perceive that they have little choice in anything, let alone healthcare decisions, and where their opinions are not valued:

‘...the older people up there, I don’t feel have ever had a choice. You know, they were brought up in the mining community, and the mines closed, poverty...I used to talk about human rights, if you go into hospital you should be treated with dignity and respect, and if you’re not, you must speak up. Maybe one in each group of forty would speak up...’

'...I could tell they didn't really understand, it wasn't for them, I said 'it is for you, we all got rights, our lives are important, we need to make choices', and they said 'oh what's the point, nobody listens'.' [P1]

At an individual level, P1 refers to her experiences with her elderly mother of 94. P1 reports that her mother was resistant to take part in decision-making or voice her opinion in hospital, mainly to avoid 'rocking the boat'.

'There was a questionnaire that came around the ward on dignity and respect, and she said 'oh don't put my name now I don't want any come backs!', I said 'mum I'm just giving my opinion, I'm not saying they're not treating you with dignity and respect, I'm saying my opinion is it's important to treat people with it...'. She said 'but I don't want to rock the boat', I mean most of them in the ward were like it.' [P1]

Sometimes, lack of involvement is due to the elderly patient's attitudes towards patient involvement, but sometimes lack of involvement is due to practical reasons:

'...my husband takes his mother, and she's very deaf...she wouldn't be able to cope without my husband being there, because she wouldn't understand what the doctor was saying, not just because of the language, but because of her hearing....she won't wear her hearing aid.' [P1]

P6 also noted that elderly patients might be less likely to participate in SDM as it is something that they are not familiar with. However, whilst it might be a challenge to change elderly patients' attitudes, both P1 and P6 believe it is not impossible, if the booklet is delivered in the right way.

'Expert in their own lives'[reading from booklet]... well they might not think that for a while, they might think 'well I've never had a decision to make', with low self-esteem, so it would be quite good for a healthcare worker to sit with them and go through that.' [P1]

'I think especially older people might be set in their ways about an appointment with their doctor, or somebody at the hospital, like a consultant, but I think it [the booklet] would encourage you that this is the way things are going to be, and that it's okay to do it.' [P6]

5.3.3 Clinician sample – key themes emerging from thematic analysis

5.3.3.1 ‘We want you to be part of this’ - changing patients’ expectations

The first key theme that emerged was changing patients’ expectations. The overarching feedback from the clinician sample was that the booklet gave a clear message that patients and clinicians should work together to make healthcare decisions, and that clinicians are supportive of this approach:

‘I think the message is simple it’s just letting people know that you do have a choice, you should be involved. If I had my appointment letter and that was in it, I would feel far more encouraged that the health board, or the primary care provider is actually asking me to engage.’ [C6]

‘What I like is the message that you can work as a team, or in conjunction with your clinician to try to make you better, it takes away the old ‘your life in their hands’ thing’ [C7]

Participants felt that the booklet had the potential to change patients’ attitudes and expectations about their involvement in healthcare decisions; if patients read the booklet, they might come to an appointment with a different mind-set, expecting to be involved in healthcare decisions:

‘Yeah, I think the first challenge is getting them to read it and understand it, and I think if they did and they do, then it would put them in a different place when they went to a consultation... if the reception was appropriate when they went to the consultation, then it would lead them to perhaps expect something different to happen.’ [C1]

‘It would probably give me, if I was unsure, a bit more confidence to say what I wanted to say, in the consultation, or whatever, I’m not just sitting there sitting on my hands.’ [C7]

C4 described the impact of the booklet when she gave it to a family member:

‘I also gave it to my husband, because I’ve been working in the ‘professional’ I might know, but I gave it to him and he said ‘oh I didn’t realise all of this’, ‘cause touch wood, as a family we don’t access health on a regular basis, and he found it really useful...he didn’t realise he had choices, now he knows from this booklet.’ [C4]

Another participant referred to family members who manage a long-term condition, and the potential impact that the booklet might have:

'There's a lot of COPD in my family, and the best person to judge their current condition was the person suffering with the COPD...and very often they'll go in and see a new clinician who would know nothing about their past medical history...it was very easy for their opinions', to be overridden by a clinician on what they saw being presented, rather than what [the patient] felt. So I think if I was a patient and I had this prior to going to a consultation I'd definitely feel a bit more empowered to take control, or to maintain control of my illness and my treatment.' [C7]

Participants felt that the booklet clearly explained the SDM process to patients, and this helps the patient to know what to expect, and thus prepare:

'Well, I thought it's been a long time coming...I've been doing my role now, patient experience, for fourteen years, and patients were saying about the lack of information on what they can do, and I thought it was really well explained, even from the first page, it gives the explanation on why you have choices, what you can expect, and how.' [C4]

'And it is around that why, what, how, because that's what people need to know... 'cause it's not always been joined up, people will say 'oh you got choices', but no explanation where they get the choices from, or who would give them the choices...but from the first page, it explains who, and why, and how it all works.' [C1]

Some of the participants felt that the comparison and references to other patients were useful and a familiar concept, and this would provide further reassurance to the patients reading it:

'Do you know, just thinking of our patients, they relate so well to other patients...there's a little quote here from an asthma patients which is nice, patients relate very well to that, from experience' [C2]

The clinicians felt that the 'I'm still not sure' section of the booklet on page 5 (see Additional Appendix 4.3, on included CD) was particularly effective at challenging some of the common patient barriers that they have experienced with their own patients:

'I like this page here [page 5], 'Doctors know best, what do I know', 'I don't understand the medical jargon'. I think it's very good, because I can just hear patients saying it, 'Doctor knows best, what do I know better?', and you can imagine them saying about the medical jargon, some patients are 'umm, am I being a bit awkward if I'm asking...'.' [C2]

'I like the bit about 'don't want to be responsible for a wrong decisions', 'cause patients do think, 'oh gosh, have I made the right decision now?' [C4]

'I don't want to be a difficult patient', yeah you know we're in an NHS, free care, and a lot of us don't, we think 'oh well, we should be happy with our lot and I don't want to cause problems', so that's definitely relevant.' [C6]

Although the clinician sample felt that the booklet would help to change patients' attitudes regarding their involvement in healthcare decisions, they also recognised the challenges that might exist with certain patient populations. Again these included the elderly, the very ill, vulnerable patients, and patients from poorer backgrounds:

Elderly:

'I felt that it's saying 'it's okay to ask', a lot of people don't like to ask...my auntie, she'll ring me up, and I'll say 'oh why didn't you ask when you were there?', 'oh, I didn't like to', and I mean that's a lot of the older people, and the majority of people we treat isn't it, and they don't ask.' [C4]

'...it's a generation thing as well...so I think that the older generation will probably say 'what do I know, well doctors know best'. I don't want to be too 'generalistic' about that, because obviously older patients question as well, but that's just from my experience, whereas you find the younger generation who are more aware will use social media and internet to research things, they may have researched what they actually think is best for them and they happen to raise that.' [C6]

Ill /vulnerable patients:

'I think particularly with our patients, they would be pre-dialysis patients, you know their kidney function would be below 20%, which means that they're fairly uremic, so their ability to take in and retain information is very poor at that stage...yes it's something that they could refer back to, but I don't know if they would sit there and read all of it straight away.' [C3]

'From a personal perspective, I know that some more vulnerable family members are really frightened of choices...' [C7]

Socioeconomic background:

'We do tend to see quite a lot of patients in sort of the Merthyr area, the Valleys area, and again, not to stigmatise people but I think of the case load that one of our colleagues has, you know, I don't know whether they would sit and read the booklet.' [C2]

However, whilst these patient groups might be difficult to reach, the clinicians did not feel it was impossible with the correct implementation approach e.g. distributing the booklet to patients with chronic kidney disease earlier in their care pathway (see section 5.3.4 for further details).

5.3.3.2 ‘Getting the most out of your consultation and treatment’ - benefits of SDM

The second key theme was the perceived benefits of SDM. The clinician sample perceived clear benefits to patients if they were involved in SDM. They felt that that the booklet would encourage and enable patients to make sure that they were getting the most out of their consultation, and care or treatment that was right for them:

‘...because it keeps things focused doesn’t it...people have written this at home, or maybe got a family member who will say ‘have you asked about such and such’, they can jot it all down there [notepad, page 7], so that when they’re in a consultation they’re getting the best out of it, from their perspective.’ [C4]

‘the overall message is getting the most out of your time with the clinician, getting the most out of the consultation and the treatment, so it’s taking more control of you’re care...’ [C7]

However, the participants also perceived that there were clear benefits to clinicians, or the organisation more broadly, if patients took part in SDM. Firstly, it helps the clinician to know what matters most to the patient:

‘...if they’ve got the questions ready for the clinicians, you know it benefits both, it’s a partnership isn’t it, and the clinicians can only work on what the patient has told them...’ [C4]

‘...but if the clinician’s had the same checklist as part of the consent form, or perhaps the documentation they use to write up the consultation, I think it would prompt them to ask the question, because I still don’t think the patient’s priorities are addressed.’ [C7]

Some clinicians referred to the time pressures that they face, and felt that if the booklet encouraged the SDM approach among patients, it would be helpful in utilising their time more effectively:

‘...from the clinical perspective, because the clinical person will know that they’ve covered everything that the patient wanted...it saves time, for the clinicians and the patients.’ [C4]

‘...with the way the NHS is at the moment and the issues that the wards are facing in terms of acuity and staffing, I think anything that can help that short amount of direct patient care that the clinicians’ have can only help...direct care time percentages at the moment are around 30%, if something could improve the interaction between me and a patient in the very short time I had to spend with them, I would be happy.’ [C7]

C6 highlighted the importance of SDM in terms of downstream events that may result from poor communication, such as litigation cases and complaints against the health board:

'I come from the perspective of dealing with concerns...I see where things go wrong, the number one failure in all concerns is communication, we didn't communicate well enough, we didn't make people understand the consequences, didn't really tell them what their options were, they didn't think they had the option to say 'no I don't want that, thanks for all your advice, but I'm actually going to live with this because it's my choice'.'
[C6]

On the other side, from a risk management perspective, participant C6 believed that a record of patient involvement might also help the health board in cases where the patient experienced negative outcomes or side effects of the treatment:

'...from a risk management perspective, we may look to say 'we really did make you fully aware of the potential consequences of something going wrong, or side effects, you told us you understood, and we've got documentation where you asked those questions, you were part of the decision...' [C6]

5.3.4 'How this is given out is key' - implementation of the intervention

Separate analysis of the user and clinician interview data found that implementation of the intervention was a key theme. Upon further analysis, feedback regarding intervention implementation was similar across the user and clinician sample. Therefore, both datasets are considered together for this theme.

A booklet format was used for the prototype intervention as this was the easiest way to convey the key messages to the target audience, but it was also partly due to feasibility and cost considerations. Overall, the participants felt that the booklet would provide the easiest way to digest the information, but it was also the most accessible mode of delivery for most patients:

'It could go in other formats, but I think this is what's easier to read for everyone...if you don't catch the poster on the ward, you've got that there in your hand and you can just look through it.' [P8]

'If it was virtual, those are the things people forget to look at, only those that really want it will go on there, a lot of this is about people who haven't

thought about the fact they have a choice before, so if you've got it in your hand you're more likely to look at it.' [P10]

'If you're going for the broadest penetration, given the age profile, the booklet is probably the lowest common denominator that would reach everybody...I think we're still at booklet level for most people, to get to everybody.' [C1]

'...a booklet format...I don't know if you can do it any other way, we haven't got enough people to do pre-appointment stuff...people haven't got time to do it, the only way you've got to do it really is in booklet format.' [C7]

One participant noted the potential problems certain patient populations might have accessing the materials if they were in an online or phone / tablet app format:

'I know a lot of older people are not on the internet...when I worked with the older people in the Valleys, possibly 1% were on the internet...maybe it's gone up since with the 50's and 50's [year olds] coming online more...it's the modern thing isn't it, you've got to modernise with the times, but I think the hard copy is excellent.' [P1]

During the interviews, participants' perceptions on alternative modes of delivery were explored e.g. mobile phone / tablet app, website, social media accounts etc. Participants were not against the use of alternative formats per se, but they felt these would be additional items that would complement the booklet, which should be the main intervention:

'There are other ways of sending messages...you could have this [booklet] as the primary means of information, but then you could have links via Facebook, or Twitter, or email, you know, this could be the first step, but it could encourage you to visit these places to get more information.' [C6]

'I'd say the booklet was the better option, but if I'd seen that on my phone, I'd probably download the app to have a quick nose at it...because you always have your phone on you...but I'd say the booklet is the way I'd look at it more.' [P8]

Participants also discussed how and when the booklet should be delivered to patients. Many participants felt that the main route of delivery should be via patient appointment letters. This will ensure that they receive the information before an appointment, and this would help patients to prepare for the possibility of being offered a choice:

'Before an appointment, yeah, 'cause you can have a quick look...I think in a way it can prepare you before you go to the doctors.' [P8]

'I think with an appointment letter this could go out, so they are informed that there will be choices, or maybe choices, so if they're faced with choices, they can already pre-empt... 'what are my choices?', and they can build their questions...' [C4]

Some of the responses addressed issues of permission, which is a key patient-reported barrier. The sense of ownership by the clinical team, or the organisation, was important; if the booklet went out with appointment letters then patients will feel that their clinical team, or the broader organisation, want them to be involved in SDM.

'One of the lessons we've learned along the way is ownership of a clinical team, it needs to be going from the surgeon or clinician or whoever, rather than the organisation...logistically that's difficult, but this would probably need to be seen coming from the team they are seeing.' [C1]

'You've almost missed the opportunity if you're picking it up once you're there, but if you want to get the message out there, the real message should be with your appointment letter... 'well they've sent it to me, they obviously want me to read it, and they want me to come and engage.' [C6]

P6 also felt that the booklet should be delivered with appointment letters, and they emphasised the importance of a covering letter, from the clinical team, which explained that they would be conducting a 'SDM appointment', and encouraging patients to read the booklet. Again, this covering letter might act as some sort of 'permission' and direct encouragement from the team to engage:

'I think the booklet is great, but a booklet couldn't explain that, I think an accompanying letter that explains that this type of appointment is now available at your GP practice, or hospital, is also needed.' [P6]

Interestingly, this participant talked about patients having to 'opt out' of receiving a SDM appointment, believing it would be easier for healthcare professionals to roll out this type of approach if patients had to consciously opt out. This indicates that they want to see SDM appointments as the norm that patients should expect.

Some user participants also felt that the booklet would be appropriate at the point at which a diagnosis is made, or a condition has been identified. The key in such situations was allowing time to digest the diagnosis before being asked to make a decision. As such, the booklet would still be delivered before patients are asked to participate in making a decision, or being offered concrete options:

'The worst thing is being told you've got cancer, your heads in a whirl...maybe they say 'I'll come to see you next week, in the meantime take this booklet, it might help you look at your health and your options, there's a place here you can write some questions and we'll talk next time.' [P1]

'...it should be, 'okay, I know you've just had this news, this probably isn't the time you want to think about it, but take this away so you know that you do have a choice, so if you have any questions the next time you see me, you have everything ready.' [P10]

Another idea that emerged from both datasets was the applicability of the booklet across primary and secondary care. Participants felt that it could be used either by primary care practices, or by hospital teams. Some emphasised the importance of using this booklet in primary care, as this is often the first port of call for many patients, and the place where most patients seek support most often:

'...the type of appointment [SDM] at either your GP or hospital...' [P6]

'...and that's where I think it starts really, in primary care, 'cause that's where you go before you start coming into secondary [care], so how would you want to be managed really...they've got a choice if they want to defer a bit, 'can it be managed in primary care.' [C4]

Overall, the participants felt that a targeted approach was important, whereby the booklet was delivered to people who had appointments, or who would be facing treatment decisions; this made sure that the key messages were relevant to the patients. However, many participants felt that there was also scope for a broader public health campaign approach, as long as this followed on from, and accompanied, the targeted approach:

'I think you could do both, but the approach public health wise would be different...because I think people find it easier to get fixed on something if it's got a purpose, as opposed to hypothetical 'I might go into hospital at some point', but some general awareness raising is good...in time it needs to be embedded into the organisation, and into the NHS in Wales, because that's probably the level that you could make it spread across Wales.' [C1]

'The more the better really, in case something slips through the net and they didn't get it in their letter, I would put it into the main information areas within a hospital...people are always looking for information to read...it might not be for themselves, it can be knowledge for their families then, isn't it?' [C4]

'Perhaps an advertising campaign on radio...I myself hear lots of adverts like 'have you been coughing for more than six weeks', a message doesn't have to be long, just hit you, like 'do you know you can have a shared decision-making appointment at your surgery now?'. ' [P6]

Overall, there was scope for a broader public health campaign, but it was felt important the booklet should be targeted at patients who had an appointment in the first instance. This would ensure that the messages were relevant to the patient:

'I don't think just sending it out is going to do anyone any good. 'Cause we're the worst for it, get a thing through the door and it goes straight in the bin, we don't read it.' [P10]

P6 felt that adolescents and children, or 'patients of the future' would be an ideal target audience for the booklet; it would be easier to shape peoples' perceptions about appropriate behaviour in a healthcare consultation before they had experience of them:

'...schools even, at that age they're going to start going to the GP without their mum...it could be covered in pastoral lessons maybe? Teenagers, sometimes they're a bit shy of going to the surgery, but there's got to come a time why they start going on their own without their mums...this would help them know how things should be.' [P6]

The participants report that the booklet will be useful as it opens the door for patient involvement, and provides initial 'permission' to participate. However, they also note that it must be delivered in a supportive environment and initiated by clinicians with positive attitudes towards the SDM approach, the necessary SDM skills, and who can support patients through the process:

'...if you're taking part in an appointment, the doctor would obviously speak to the person in a way they could understand exactly what was going on, pros, cons...' [P6]

'Obviously, the surgery or hospital would have to be on board with this before you start offering these sorts of appointments, you can only assume that's been discussed, and they're happy...' [P9]

'...if the reception was appropriate when they went to the consultation, then it would lead them to perhaps expect something different to happen.' [C1]

5.3.5 Design, format and content changes

Overall, both participant groups were positive about the booklet's design and format. They liked the A5 format, and felt that eight pages was an appropriate length for the booklet. All participants felt that the overall design, colour scheme, and character drawings were appealing, and it would encourage them to read the booklet:

'First impressions when I literally opened the envelope and took it out, it was something that interested me, it was fun...you get so much junk mail through the post and it can be quite boring format, and this was something that sort of took my interest straight away...it sort of enticed me to look at it then and read on' [P6]

'It's very accessible from a patient point of [view]...you know I want to pick it up, I want to read it...I don't normally look at literature you know...when I go for hospital appointments...but if that was sitting there, or if I had that prior to an appointment, I'd want to read it' [C7]

'I think if I was in a waiting room, I would pick it up, I'd think 'oh that's colourful, that looks good'' [P1]

'I mean, I thought it was really well laid out, I think it was about the right length that you could reasonably expect someone to look at and digest, although there is quite a lot of information in there, you know the design looked good. Easy to get through...space for people to make notes and things...so as a piece of work at that level I thought it was really good' [C1]

The booklet's design was well received by a range of age groups, as reflected by the age range of the user and clinician sample, and also by statements made by participants:

'I would pick that up and read that quite happily and I think my son would pick that up and read that quite happily and I think some of my elderly relatives would do the same, so it has broad appeal' [C7]

'Younger teenagers would look at this and think 'oh I can read this easy', and then older people as well would look at it and think the same' [P8]

'...my Aunt is elderly, and I think she would understand it...because she does access health now, she's of that age, she has a few health conditions, she wasn't aware [of choice], I've not seen anything as plain English as this, so I'm sure she'd find this useful.' [C4]

Using the feedback from users and clinicians, several changes were made to the booklet's design, format and text or graphic content. Feedback and associated changes are listed in Appendix 5.4 and are summarised below.

Key changes related to the notepad and checklist tools on pages 7 and 8 of the booklet, respectively. Both users and clinicians were positive about the inclusion of such tools, but felt that there were some improvements that could be made to make them more useful for patients. First, the notepad needed to be larger so that there was more room to write. Second, the notepad required further guidance on how to use it i.e. before an appointment, to write down questions for the clinician, and / or after the appointment, to write down what they think about the options in relation to what is important to them. Third, the notepad could benefit from some example questions that patients might ask. All of these changes are detailed in Appendix 5.4 (see also, Figure 5.1).

Figure 5.1 - Page 7 after design, format and content changes



Finally, it was suggested that the checklist on page 8 would be better framed as a tool for preparing patients for an appointment, rather than solely as a post-hoc tool. Some participants pointed out that it is not always easy to schedule another appointment with the same clinician, should you realise after the appointment that they had not covered some of the checklist items e.g. in a secondary care setting, after an appointment with a consultant (see Figure 5.2 for changes; see also Figure 5.2):

‘...so whilst there could be a checklist, you’ve almost, you’ve missed the boat to some degree, because if the answer to them is no...you’ve missed the opportunity really, because the consultation is gone...the reality is it doesn’t work like that and it could be months before you get to see the same person again...so maybe the checklist, maybe the questions could be in preparation for a consultation’ [C6]

Another participant felt that the checklist could be improved by prompting patients to make sure that they know what will happen next; this has now been included (see Figure 5.2). Several participants felt that pages 7 and 8 of the booklet could be perforated, so that they could tear off the notepad and the checklist and take it to a consultation; one patient referred to it as their ‘appointment control sheet’ [P9]. The updated version will incorporate this.

Figure 5.2 - Page 8 after design, format and content changes

It is really important that you are involved in decisions about **your healthcare**. If you are told you have choices in your next appointment, **make sure that the items in the checklist are covered...**

checklist

- Have I been told why I have a choice?
- Have I been told what the choices are?
- Have I been told the possible outcomes, positive or negative?
- Have I been told how likely these outcomes are?
- Have I been asked about what's important to me?
- Have I asked all the questions I wrote down?
- Do I have any other questions?
- Have I been told what will happen next?

If your healthcare worker does not cover any of the checklist items, or you have questions, it's okay to ask

Developed by Natalie Joseph-Williams, Cardiff University, 2015
Design and illustration by www.jessicadraws.com

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Other key changes were made to the terminology used throughout the booklet. It was suggested that some of the terms used were ‘medical’ and not patient-friendly. For example, one user felt that the term ‘healthcare workers’ needed to be clarified:

‘Healthcare workers, like again, is that nurses, doctors?...maybe say something like ‘your nurses, doctors and consultants are healthcare workers...a little example of who your healthcare worker is.’ [P1]

A ‘call-out’ with text has been added to page 3 of the booklet changed to clarify who healthcare workers are.

Several participants also did not like the use of the terms ‘pros, cons, and options’:

‘This is what I wasn’t happy with, we will tell you what your options are and what they involve, we will describe the likely outcomes, including the pros and cons, I didn’t like that...maybe you need to think of some other way of asking that...umm, negative and positives I suppose...I didn’t feel it [pros and cons] was user friendly at all.’ [P1]

‘Although I’m not an expert in terms of literacy levels, it was just occasionally I was reading it and thought outcomes, pros, cons, options, watchful waiting, still sounded a bit medical...we’ve used choice, so it could be choices...’ [C1]

As a result, the terms ‘pros and cons’ have been changed to ‘positive(s) and negative(s)’ and the term ‘option(s)’ has been changed to ‘choice(s)’, throughout the booklet.

Some participants felt that the booklet might only be applicable to secondary care, due to the use of the word ‘clinic’ on the front page of the booklet. It was also unclear whom the booklet was coming from, because the Cardiff and Vale University Health Board logo was on the back page of the booklet. To correct this, I have now used the terms ‘hospital’ and ‘surgery’ on the front cover, to indicate that the booklet is relevant across primary and secondary care, and the Health Board’s logo has been moved to the front page.

Feedback indicated that the booklet could benefit from providing some examples of healthcare decisions. These have now been included on page 3 of the booklet:

‘I think the key message that I get is that it’s an encouraging leaflet to want you to ask questions, or to have choice...I think it could go a little further to explain what perhaps those choices could be e.g. maybe if surgery is being considered’[C6]

Changes were also made to the design of the booklet. Some users associated the red used for the leaflet and the building on the front cover of the booklet with negative connotations, or a 'football red card'. These have now been changed to green (See Figure 5.3).

5.3.6 The pilot-testing version of 'Your Health, Your Choice'

The key changes to the booklet were presented in section 5.3.4 and in Appendix 5.4. There were no changes to key elements of the booklet in terms of additional or deleted sections / elements. As such, all of the booklet elements described in Table 4.6 (Chapter 4) stand for the latest version. Changes were only made to the design and / or content of these elements. This updated version of the booklet was used during pilot-testing, described in Chapter 6 (see Appendix 5.5 for full booklet).

5.4 Discussion

The aim of this chapter was to pre-test the 'Your Health, Your Choice' booklet with public users and clinicians to check reactions to the booklet's content (key messages), design, and implementation. The booklet appears to be addressing the key patient attitudinal barriers to participation in SDM, identified in Chapter 2. Further, both users and clinicians were positive about the booklet's design and format, and only minor changes were requested. A targeted approach to patients with upcoming appointments was suggested as the best distribution method, but this could be complemented over time by a larger scale public health campaign, delivered in various formats.

From the systematic review of patient reported barriers / facilitators (Chapter 2) and the mapping exercise conducted in Chapter 4 (to the COM-B model of behaviour / TDF), the key drivers of behaviour were identified as social influences, social and professional role and identity, beliefs about capabilities, beliefs about consequences, knowledge, and environmental context and resources. Many of these key barriers are attitudinal in nature, and focus on patients' perceptions of 'normal' patient behaviour in a consultation and perceived lack of influence over the SDM discussion (either due to lack of self-efficacy or fear of consequences).

From the framework analysis of user data, it appears that the booklet is addressing all of the key attitudinal factors identified, which might influence patients' participation (or lack of) in healthcare decisions; this is key if the booklet is to be successful in changing patients' attitudes, and their subsequent behaviour. A key barrier is patients' perceiving that they cannot, or should not, be involved in decisions because it is not part of the patient role, and it is not socially accepted to be active; it is thought part of the clinician's role to make a decision for the patient. Significantly, a key theme that emerged from the user interviews was a shift in users' attitudes from expecting to be told what to do by a clinician, to perceiving that SDM is the best way to approach situations where there are healthcare options. Users felt that this key message was conveyed throughout the booklet, but the 'I'm still not sure section' (Page 5, Appendix 5.5) was particularly useful, as were the comparisons to what other patients would do and the 'permission' from the clinical team, as this reinforced positive social norms about patient involvement.

Another key barrier to participation is patients failing to recognise their contribution to the decision-making process, and the importance of their own personal preferences. After reading the booklet, users recognised the importance of both the clinician and patient's contribution, stating things such as 'you know your life, better than the doctor knows your life'. This is in contrast to the prior belief that 'doctor knows best'. Again, the 'I'm still not sure section' (Page 5, Appendix 5.5) was cited as being particularly helpful in forming those views, and providing reassurance, but it was also a key message presented throughout the booklet.

Not knowing what to expect from SDM, or knowledge about SDM more broadly, is another key barrier to participation. The 'what will I have to do?' section (page 6), the notepad (page 7), and the appointment checklist (page 8), were all designed to help patients to know what to expect from a SDM consultation. They outline the process of being offered a choice, being told what the choices are, and being asked about what is important to the patient. They also encourage patients to prepare for this process by thinking about the choices in relation to their own personal preferences, and support patients to make a note of any questions / issues / concerns that they want to discuss. Users report that the booklet provided a clear rationale for healthcare options, and also provided clear guidance on what to expect if they were offered options. The checklist helped users to know what to expect, and it could also help users to make sure that they received a SDM appointment. The notepad could help patients to tailor the appointment to their concerns, facilitate

discussion of options with significant others, and also help to identify knowledge gaps that need further discussion with a clinician at a follow-up appointment. Patients used phrases such as 'standard appointment' and 'appointment control sheet', indicating that they would now expect this as part of a consultation, and that they felt they had some influence over the process. This suggests that the tools promote self-efficacy in these patients to become more involved in the process.

Fear of the perceived negative consequences of being involved is another key patient-reported barrier. However, the booklet appears to have challenged these perceptions by providing reassurance that patient involvement is expected and valued, and by promoting the positive aspects of being involved. Users report that whilst they previously felt they were being a difficult patient if they asked questions, they now felt that it was okay to be involved and that it was not 'so scary'. Again, the 'I'm still not sure' section (page 5, Appendix 5.5) was cited as being helpful in forming these views, specifically the quotes 'I don't want to be a difficult patient' and 'I don't want to be responsible for a wrong decision'.

From the thematic analysis of the clinician data, clinicians felt that the booklet's key message was 'we want you to be part of this'. They were positive about the booklet's remit, and were encouraged that the message was that patients and clinicians should work together to make healthcare decisions. In line with the users' responses to the key messages, the clinician group felt that the booklet had the potential to change patients' attitudes and their 'mind-set' towards being actively involved in healthcare decisions. The booklet provided the 'permission' to be involved, that they often witness their own patients needing. Clinicians also felt that the 'I'm still not sure' section (page 5, Appendix 5.5) was particularly useful in challenging common patient barriers to participation; many of the clinicians could relate to the quotes, stating that their own patients have said these things (e.g. 'doctor knows best', 'I can't understand medical jargon').

Significantly, both participant groups reported the benefits of SDM to both patients and clinicians. The primary intention of the booklet was to help patients to understand why they should be involved in decisions, and to help them perceive the positive benefits of being involved. All of the users could see the benefit to themselves and other patients, but some also recognised how this approach would help the clinicians to provide them with better care. They touched upon the difficulty that clinicians must face if they do not know what matters most to the patient, and were sympathetic to this. From the clinician

perspective, SDM was felt to have clear benefits to patients and the clinicians involved in their care, but the benefits of SDM to the organisation more broadly were also discussed in terms of risk management and reducing litigation. Clearly, SDM has numerous benefits to different people involved in the healthcare process, and how these are perceived will depend on the person; either way, the different benefits will provide motivation to the different agents involved in the healthcare process to participate in SDM.

With regards to the booklet's design, format, and content, users and clinicians were overall positive, and only minor changes were suggested. Both groups felt that the booklet was engaging, something that they would want to read, and that it would stand out from other materials. Key changes included replacing some of the 'medical' terminology (e.g. changing 'pros and cons' to 'positive and negative' outcomes), and making the notepad (page 7) and the checklist (page 8; Appendix 4.2 for original) more useful for appointment preparation e.g. giving example questions, and encouraging patients to consider the checklist items during their appointment.

It was agreed by both participant groups that a booklet format was the most accessible mode of delivery for most patients, and this would ensure the biggest reach. There was agreement between both groups that the booklet needed to be sent to patients ahead of their appointments. This would ensure that they had time to digest the information, and that they can also use the booklet to help them prepare. Importantly, all of the participants felt that the booklet needed to be sent to people who have a scheduled appointment with a clinician, or clinical team. Many saw scope for a broader public health campaign that built on the initial booklet, but, in the first instance, the booklet should be distributed as a targeted approach. This would ensure that the key messages of the booklet are relevant to the person it has been sent to, and it helps the individual to feel that they have 'permission' from the specific clinical team or clinician that they will be dealing with. Both of these were deemed very important for successful implementation.

Whilst both participant groups were generally positive about the booklet, and believed that it had scope to change patients' attitudes towards involvement, both groups also emphasised the potential difficulties of reaching certain patient populations. Sometimes this was based on the participants' perceptions of these groups, and sometimes it was based on the participants' own experiences of these groups. These hard-to-reach groups could include the elderly, the very ill, vulnerable patients, and patients from poorer

backgrounds. For example, the social norms about active patient involvement being unacceptable behaviour appear to be amplified in older patients. Further, for patients who are very ill or who have lower levels of educational attainment, it might be difficult for them to understand the information in the booklet. Whilst the participants did not feel these were an impossible group to target, they acknowledged the challenges it posed. However, implementation strategies could help to overcome some of these challenges e.g. a clinician going through the booklet with an elderly patient to provide additional encouragement, or delivering the booklet at an earlier point in the care pathway of a long-term patient, before the patient becomes acutely unwell.

5.4.1 Strengths and weaknesses

This iterative pre-testing approach included members of the general public, clinicians, and health board representatives; this ensured that feedback was sought from all parties who would be involved the implementation of the booklet. The pre-testing involved a small sample (six patients, six clinicians). However, this phase focused on initial testing of the key messages and design feedback, in order to refine the intervention, and implementation planning. The booklet will be tested with a larger number of real-life patients during the pilot-testing stage (see Chapter 6). The framework analysis conducted on the patient data enabled me to establish whether the booklet elements designed to address the key attitudinal barriers were likely to have the intended impact on patients' attitudes. A graphic designer was commissioned to develop the booklet, and this ensured that the product was produced to the highest standard.

The clinician sample consisted of clinicians who are currently involved in a large-scale SDM implementation programme, and individuals whose role focused on the improvement in patient care, whether that be from a patient experience, quality improvement, or investigation and redress perspective. Clearly these individuals are receptive to the idea of patient-centred care, and might be more responsive than individuals who are not directly involved in these areas of work. However, this booklet will be implemented in teams that practise SDM as part of everyday clinical practice, so I would expect the clinicians involved to be receptive to patient involvement; this will be discussed in further detail in Chapter 6 (Process evaluation) and Chapter 8 (Discussion).

The user group sample who volunteered to take part in the interviews are probably quite motivated individuals, who may be more likely to be actively involved in their care. This is particularly the case for the participants recruited via Involving People, who have a lot of experience of working on other research projects involving patient literature. Further, user participants recruited for pre-testing were not required to be patients currently receiving care, or currently faced with healthcare decisions. As such, their feedback is based on a hypothetical situation i.e. if they had treatment options. It is essential to know how this booklet will be received in a real-life clinical setting, where patients have received a diagnosis and are required to make a decision; this will be addressed during the process evaluation phase (Chapter 6).

5.4.2 Conclusion

Using a systematic and theoretically grounded development process (i.e. BCW),(47) I have been able to ensure that the intervention directly addresses some of the key attitudinal barriers and facilitators, which were identified in Chapter 2 of the thesis. This pre-testing process delineated the specific parts of the booklet that the participants found most useful, and it has provided reassurance that the booklet has the potential to change patients' attitudes towards SDM, and possibly their behaviour. The process has also led to various design improvements, and has identified the most appropriate implementation strategy for use during pilot-testing. Pre-testing has provided an overview of users' initial reactions to the booklet's key messages in an artificial setting. The next step will be to pilot-test the 'Your Health, Your Choice' booklet in a clinical team, using patients who are currently seeking healthcare, and who are likely to be faced with healthcare decisions (see Chapter 6). The pilot-testing will aim to further understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors.

Chapter 6

Pilot-testing the ‘Your Health, Your Choice’ booklet: a process evaluation

6.1 Introduction

The focus of Chapter 4 was the theoretical development of the prototype ‘Your Health, Your Choice’ intervention, using the Behaviour Change Wheel (BCW) approach.⁽⁴⁷⁾ The four key steps of the BCW Guide⁽⁴⁷⁾ used to develop the prototype intervention in Chapter 4 are listed in Table 6.1. In Chapter 5, the prototype version underwent pre-testing with lay members of the public, clinicians, and representatives from healthcare organisations. The focus of Chapter 5 was to pre-test the booklet’s key messages, to refine the design and content, and to determine possible implementation strategies; an updated version of the booklet was then produced (see Appendix 5.5). The fifth step in the BCW approach to intervention development and evaluation is to plan the intervention’s evaluation; this step involves planning and testing how the behaviour change can be measured and understood. The aim of the current chapter is to pilot-test the ‘Your Health, Your Choice’ booklet, using a process evaluation, with real patients to determine if the booklet has the potential to result in the desired behaviour change (i.e. active participation in SDM with a clinician), before planning a full-scale evaluation.

The target behaviours were specified in Chapter 4 as part of Step 1 (see Table 6.1 and Chapter 4). The aim of the intervention is to promote active patient participation in the decision-making process with a clinician. Step 2 identified various mediators of the target behaviour, and Steps 3 and 4 ensured that the intervention addressed these mediators. The fifth step of the BCW approach, addressed by this chapter, aligns with the feasibility and pilot-testing phase of the MRC framework for developing complex interventions.⁽⁴⁷⁾ According to the MRC framework, feasibility and pilot-testing should take place before a full-scale evaluation of intervention effectiveness. A full-scale evaluation (e.g. randomised controlled trial) would establish the booklet’s effectiveness, but testing feasibility before evaluation can provide important information about the design of the intervention and the proposed evaluation.⁽⁴⁵⁾ Specifically, it can identify weaknesses (intervention or process),

help to refine the intervention / implementation / evaluation plans, and determine if a full-scale evaluation is warranted.

Table 6.1 Steps used to develop and evaluate intervention content

STEP	KEY TASKS
STEP 1: Identifying the problem – what behaviour are you trying to change, and in what way?	<ul style="list-style-type: none"> • Identify the evidence-practice gap • Specify the behaviour change needed to reduce the evidence-practice gap • Specify the group whose behaviour needs changing
STEP 2: Assessing the problem – what are the barriers/facilitators, and what will it take to bring about the desired change?	<ul style="list-style-type: none"> • Review potential barriers and facilitators to the behaviour • Use the TDF and COM-B model to identify the pathway(s) of change to the behaviour
STEP 3: Forming possible solutions – what types of intervention are likely to bring about the desired change?	<ul style="list-style-type: none"> • Use the BCW to identify potential behaviour change techniques (intervention and policy level) to overcome the barriers and enhance the facilitators • Use the APEASE criteria to select those intervention functions and policies that are most appropriate
STEP 4: Deciding on specific intervention content – using a taxonomy of behaviour change techniques	<ul style="list-style-type: none"> • Use the Behaviour Change Techniques taxonomy to select specific intervention content and mode of delivery • Use the APEASE criteria to select those behaviour change techniques that are most appropriate
STEP 5: Planning the intervention evaluation - how can the behaviour change be measured and understood?	<ul style="list-style-type: none"> • Identify mediators of change to investigate the proposed pathways of change • Select appropriate outcome measures • Determine feasibility of outcomes to be measured in a trial

At the feasibility and pilot-testing phase, a process evaluation plays a vital role in understanding the feasibility of the intervention, assessing acceptance, and optimising intervention design and evaluation. A process evaluation is defined as a study that aims to understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors (See Figure 6.1).(46) The focus and depth of a process evaluation will vary according to the stage at which it is conducted (e.g. feasibility testing, evaluation of effectiveness etc.), but they assess three key areas:

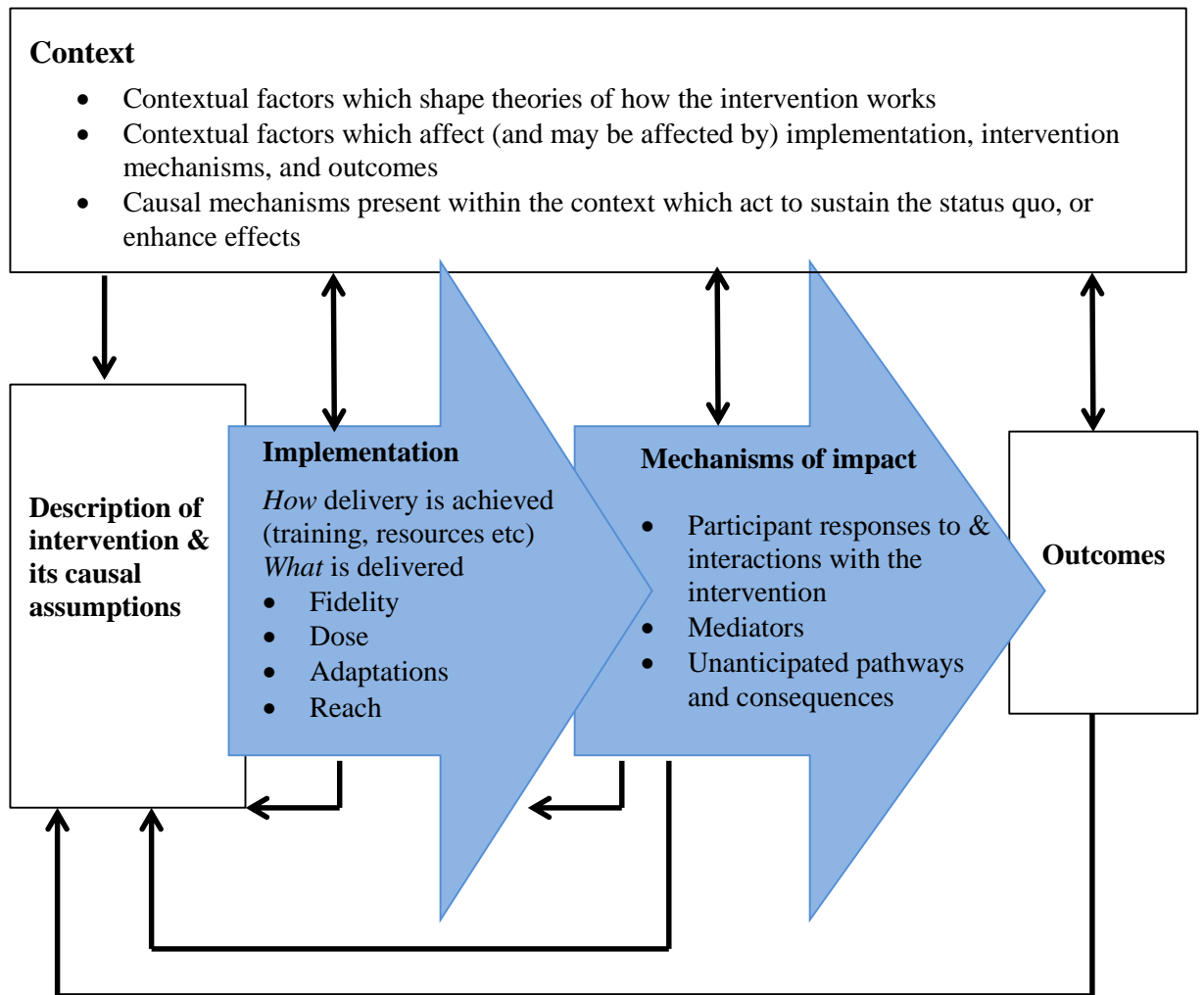
1. **Mechanisms of impact** – how intervention activities, and participants’ interactions with them, trigger change;
2. **Implementation** – the structures, resources and processes through which delivery is achieved, and the quantity and quality of what is delivered;

3. **Context** – how external factors influence the delivery and functioning of interventions

The overall aim of the current chapter is to pilot test the ‘Your Health, Your Choice’ booklet, using the MRC guidelines for process evaluations.(46) The key objectives include examining:

1. If the intervention produces change, and describe how it produces change;
2. How delivery of the ‘Your Health, Your Choice’ intervention is achieved, and what is delivered to patients;
3. Contextual factors that might affect process and outcomes.

Figure 6.1 Key functions of a process evaluation and relationships amongst them



Adapted from Moore et al(46)

6.2 Methods

6.2.1 Clinical team and sample recruitment

In Chapter 4, I stated that the ‘Your Health, Your Choice’ booklet forms part of a broader implementation strategy, and this is how it will be used during the pilot-testing phase. The booklet targets the individual level i.e. trying to change patients’ attitudes and behaviours. However, use of the intervention in isolation is unlikely to be effective, given the significance of clinician attitudinal barriers and the requirement of information about

treatment options. This means that the booklet needs to be implemented in a clinical team that is receptive and supportive of the SDM approach, and where clinicians have received SDM skills training. These teams might also routinely use patient decision support tools to assist with information exchange about the options, and to elicit patients' preferences. With this in mind, the Cardiff and Vale University Health Board Breast Care Centre was selected for the pilot-testing phase.

The Breast Care Centre has worked with the Institute of Primary Care and Public Health, Cardiff University, for five years on an on going SDM implementation programme (MAGIC), funded by The Health Foundation (see section 4.4, Chapter 4, for further details about this programme).(33, 37) During this implementation project, the Breast Care Centre has worked closely with researchers to design and test the best ways to embed SDM into their routine clinical practice. The team is supportive of the SDM approach, and also demonstrates senior level engagement in SDM (i.e. lead nurse, consultants/surgeons). During the period August 2010 – January 2012, the majority of the team (including nurses, clinical nurse specialists, and consultants), attended SDM skills training workshops. These skills workshops cover the model of SDM for clinical practice, developed by Elwyn and colleagues,(1) and use role-play scenarios to develop SDM skills. Learning reports from the MAGIC programme indicate that the skills workshops were effective in embedding SDM, and moved many of the clinicians from saying 'we do this already' to 'we could do this better'.(33, 35, 37)

The Breast Care Centre has also embedded a decision support tool (Option Grid) into routine clinical care (see Figure 4.8, Chapter 4). The Option Grid is designed to support women with early stage breast cancer to make a decision between lumpectomy with radiation or mastectomy.(178) It is used during the diagnostic consultation by the consultant, and sometimes the clinical nurse specialist, to outline the treatment options. It is then given to the patient to take home. The clinical nurse specialist also uses it during the follow-up home visit, approximately one week after diagnosis; it is used to describe the options in more detail and to elicit patients' preferences. When they are not using specific decision support tools, the team have the necessary skills and experience to describe treatment options, including possible outcomes, and to incorporate patient's preferences into the decision-making process.

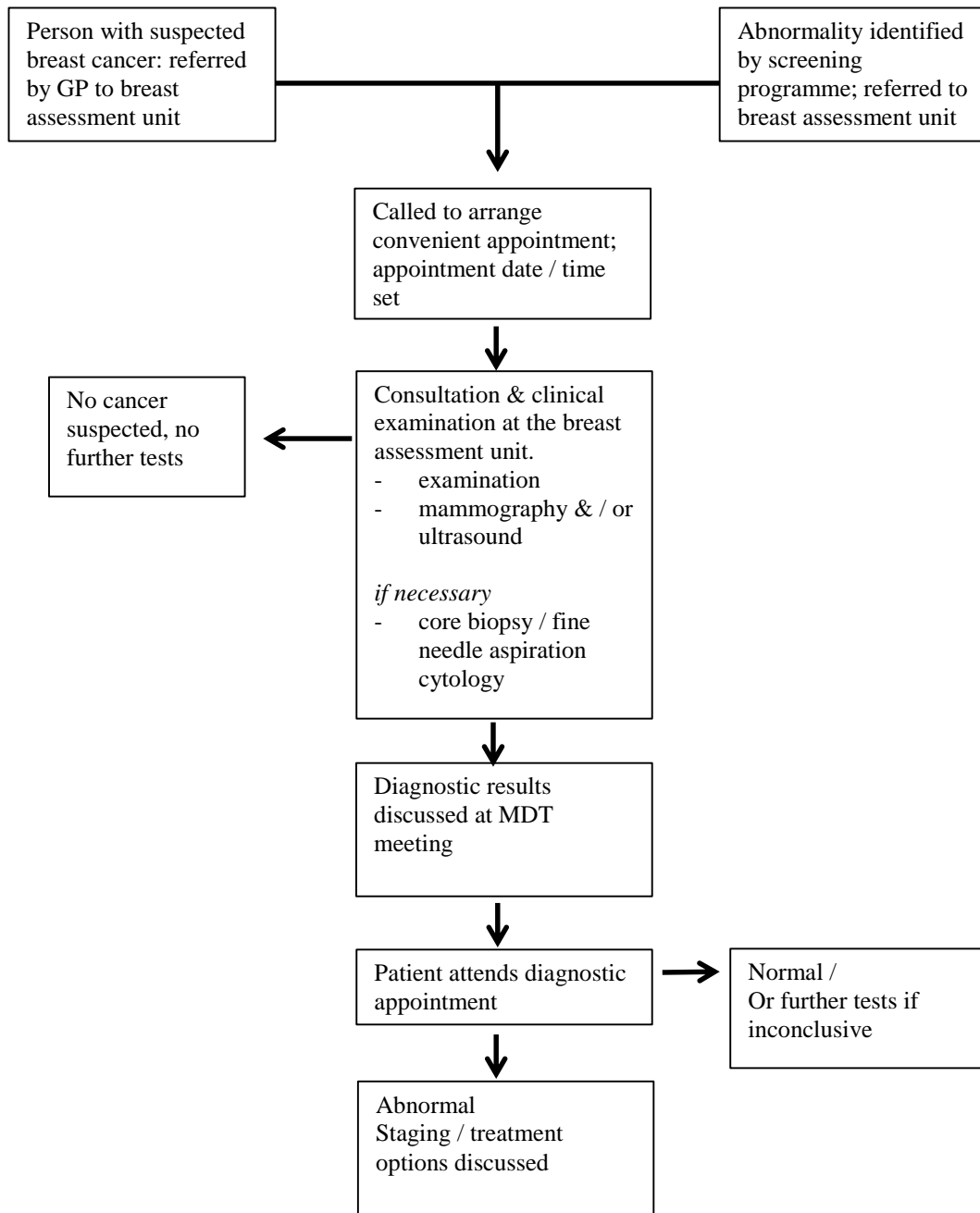
In addition, they have embedded a breast cancer decision quality measure (DQM) into their care pathway, and continue to collect routine data on patient decision quality to

inform their day-to-day care. Results from the DQM data indicate that patients' average knowledge scores improve between the diagnostic consultation and the follow-up home visit (from 63% to 93%; based on data from October 2013 - February 2015). This supports the view that the SDM process used by the clinical nurse specialists is effective in increasing patients' knowledge about the condition and the treatment options available. Further, since July 2011 (initiation of implementation programme, after SDM skills training), patients' average knowledge scores on the DQM after the follow-up home visits have increased from 83% correct responses to 93% correct responses, demonstrating an improvement over time. This indicates that the team are providing adequate information about the treatment options available, and thus address the essential knowledge component of SDM.

A brief outline of the Breast Care Centre referral and appointment process is provided in Figure 6.2. All new patients (males and females) referred to the Breast Care Centre between June 2015 and August 2015 were invited to take part in the study, to ensure a range of different decision-making circumstances. This includes: patients who are waiting for their initial appointment with the Breast Care Centre; patients not diagnosed with breast cancer at first visit who do not have current decisions, but who might have decisions to make in future; patients with a cancer diagnosis who have explicit treatment options available to them (e.g. early stage breast cancer); patients with a cancer diagnosis whose treatment options are less explicit (e.g. breast cancer recurrence that has spread).

For this pilot and feasibility-testing phase, it was felt that the value lay in in-depth qualitative feedback with patients. This would allow a detailed understanding of the intervention functioning on a small scale, and an in depth understanding of causal mechanisms. Therefore, patients were invited to take part in a semi-structured interview (approx. 1 hour) with a researcher. All new patients referred to the breast cancer clinic between May - August 2015 were sent the 'Your Health, Your Choice' booklet, a covering letter from the clinical team inviting them to take part in an interview with a researcher, a patient information sheet, a study reply form, a consent form, and a pre-paid return envelope. Interviews were audio recorded and transcribed verbatim. The interview content is described in the following sections. Ethical approval was sought as part of the broader MAGIC evaluation project, and a favourable ethical opinion was granted on 19.03.14 (14/WA/0036).

Figure 6.2 Referral and appointment process – Breast Care Centre



6.2.2 Assessing mechanisms of impact – does the intervention produce change, and how does it achieve this (objective 1)

A key requisite for a good quality process evaluation is a clear description of the intended intervention and how it will be implemented.(46) The systematic BCW approach that has been used to develop the intervention has ensured that there is a clear description of the ‘Your Health, Your Choice’ booklet content, and a description of how it is intended to work i.e. causal mechanisms.

A detailed mapping process of patient-perceived barriers / facilitators to components of the COM-B Model / Theoretical Domains Framework (TDF) was conducted during Step 3 and 4 of the BCW approach (see Chapter 4 for full details). Table 4.6 described how the barriers / facilitators map to the COM-B model / TDF, the selected intervention components, and the exact content of the intervention that has been designed to address the specified barrier / facilitator. The key barriers / facilitators were mapped to the following TDF domains: knowledge; professional role and identity; beliefs about capabilities; beliefs about consequences; and social influences. Table 6.2 provides a summary of the key mediators of behaviour change, as mapped to the COM-B model / TDF (Columns A-C).

Process evaluation outcome measures to assess mechanisms of impact were based on the TDF questionnaire developed by Huijg *et al.*(179) The questionnaire contains 32 items assessing 11 of the 14 TDF; it aims to measure TDF-based determinants of behaviours. Questions that related to the key domains were selected / adapted for use during one-to-one patient interviews. Additional questions were added to explore whether the booklet content was having the desired impact on patients’ intended future behaviours, and to assess perceived barriers / facilitators to involvement. The questions used for the current study, based on the TDF questionnaire, are listed in Table 6.2 (Column D). The full interview schedule, including intended future behaviour questions, can be found in Additional Appendix 6.1 (on included CD).

Table 6.2 Summary of the key mediators of behaviour, mapped to the COM-B Model / TDF and interview questions based on TDF questionnaire

A COM-B Component	B TDF Domain	C Mediators of behaviour (key barriers and facilitators)	D Interview guide, based on TDF questionnaire (questions used as a guide to facilitate discussion, and are adapted based on participants' responses)
Psychological capability	Knowledge	<p>Knowledge about the existence of healthcare choices (generally); knowledge of the rationale for patient involvement in healthcare choices; knowledge about what to expect from a SDM encounter / process (i.e. when healthcare choices are available and are offered by a clinician).</p> <p>Note: Knowledge as a key mediator in achieving SDM also refers to knowledge about the treatment options available to the patient more specifically (i.e. what choices are available, and their likely outcomes). Information provision about treatment options is beyond the remit of the 'Your Health, Your Choice' booklet (to be addressed by complementary interventions e.g. Option Grid). For the purposes of the interview, this domain focuses on knowledge of the existence of choice, rationale etc.</p>	<ol style="list-style-type: none"> 1. Did the booklet help you to understand what it means to be involved in making a decision with a clinician? <ol style="list-style-type: none"> a. Can you describe what this means to you? 2. Did the booklet explain <i>why</i> patients should become involved in healthcare decisions together with clinicians? <ol style="list-style-type: none"> a. Can you explain why you think it is important that patients are involved in their healthcare decisions? [What does the patient contribute?] 3. Did the booklet explain <i>what to expect</i> if a clinician asks you to be involved in a healthcare decision? <ol style="list-style-type: none"> a. Can you describe the key steps a clinician might go through if you have a healthcare decision to make together? [process] 4. Do you think the booklet enhanced your knowledge about shared decision-making, or was it something you already knew about?

			5. After reading the booklet, do you feel that you know enough about shared decision-making to take part in future decisions? If no, is there anything else you would like to know beforehand?
Reflective motivation	Professional / social role and identity	Patients' belief that they should not / cannot be involved in the decision-making process because it is not part of the patient role (it is part of the clinicians role to make decisions for the patient).	<ol style="list-style-type: none"> 1. Do you think it is part of the patient's role to take part in decision-making? Why? <ol style="list-style-type: none"> a. To what extent has your view changed since reading the booklet? 2. As a patient, do you feel that it is okay to ask the clinician questions? <ol style="list-style-type: none"> a. To what extent has your view changed since reading the booklet?
	Beliefs about capabilities	Patients' belief that they are not capable of being involved in the decision-making process (e.g. due to lack of self-efficacy in ability to understand the information about choices); patients' not recognising the value of their own expertise and capabilities (i.e. knowledge about their own personal preferences).	<ol style="list-style-type: none"> 1. For you personally, would you say it would be possible or impossible to make a decision together with a clinician? <ol style="list-style-type: none"> a. Did the booklet have any influence on how you feel? <p>Thinking ahead to your next appointment with a doctor or nurse, if you were told that you had healthcare choices;</p> <ol style="list-style-type: none"> 2. How confident are you that you would be able to understand the information that is given to you about the choices? 3. How confident are you that you can take part in the decision-making process with a clinician? 4. Has the booklet helped you to feel more confident in any way?

	Beliefs about consequences	Patients' perceiving that involvement in the decision-making process might have negative repercussions (fear of consequences)	<ol style="list-style-type: none"> 1. How did the booklet make you <i>feel</i> about patients being involved in healthcare decisions with their clinicians? 2. After reading the booklet, do you feel that there are benefits for patients who take part in their healthcare decisions? Can you describe these please? 3. After reading the booklet, do you think that there are disadvantages for patients becoming more involved? Can you describe these please? 4. After reading the booklet, do you feel that there are disadvantages for patients who do not take part in their healthcare decisions? Can you describe these please? 5. For you personally, do you think that being involved in your healthcare decisions: <ol style="list-style-type: none"> a) would be a good thing, or a bad thing? Why?
Social opportunity	Social influences	Patients' belief that the active patient role is not socially acceptable (it is not 'normal' behaviour among patients), and the belief that clinicians do not want patients involved in the decision-making process.	<ol style="list-style-type: none"> 1. Do you think that most other patients would want to take part in a shared decision? To what extent has this view changed since reading the booklet? 2. Do you think that most clinicians want patients to become more involved in decision-making? <ol style="list-style-type: none"> a. To what extent has the booklet influenced how you feel about this? How? 3. Do you think that the local health board more broadly wants patients to become more involved in decision-making? <ol style="list-style-type: none"> b. To what extent has the booklet influenced how you feel about this? How? 4. As a patient, are there any other people that you would involve in your decision-making? How would you involve them? How would this help you?

6.2.3 Assessing implementation, context & design issues (objectives 2 & 3)

In addition to assessing mechanisms of impact, the process evaluation aimed to assess implementation of the intervention and consider the contextual factors that might influence delivery of the intervention. Open-ended interview questions were included in the interview guide to address the following:

- **Reach**

Questions assessing whether the patient came into contact with the intervention, and how they are interacting with it e.g. did they receive the booklet before the appointment, did they read the booklet straight away, did they share the booklet with anyone else, how long did it take to read, etc.?

- **Dose**

Questions assessing the quantity of the intervention received e.g. did the patient read all / part of the booklet, which parts did they read, did they use the tools e.g. checklist, etc.?

- **Context**

Questions assessing the patients' context and the other external factors that might impede or strengthen the effects of the intervention e.g. stage in the care pathway, patient diagnosis, comorbidities, past experience (experiential or vicarious), the clinical care pathway and administrative processes of the Breast Care Centre.

As this study is part of the pilot and feasibility stage of evaluation, patients were asked for feedback regarding the booklet's design and future implementation. The full interview schedule including questions covering mechanisms of impact, implementation, and context can be found in Additional Appendix 6.1 (on included CD).

6.2.4 Analysis

6.2.4.1 Understanding mechanisms of change – framework analysis (Objective 1)

All interviews were transcribed verbatim, and entered into NVivo qualitative analysis software.(72) Each transcript was thoroughly read, and the audio-recorded interview was re-listened to, to ensure familiarisation with the content of each interview. In the first instance, a framework analysis method was used to analyse the interview data.(176) Using the TDF

questionnaire as a guide,(179) questions that related to the key drivers of behaviour were selected for use during the one-to-one interviews. This also formed the basis of an initial analytical framework, which was used to code two transcripts. New codes that did not fit with this initial analytical framework were noted, and they were added to the revised framework (See Additional Appendix 6.2 on included CD for the final analytical framework), and codes that were redundant were removed or merged with other codes. The final framework was applied to each transcript using NVivo software. Once all data had been coded using the analytical framework, the data were summarised in a separate matrix for each analytical theme (each matrix comprised one row per participant, and one column per code). Themes were generated from the data set by reviewing the matrices and making connections within and between participants and categories, influenced by the initial framework and new concepts that were generated inductively from the data.

6.2.4.2 Implementation, context and design issues – thematic analysis (Objectives 2 and 3)

Thematic analysis(177) was conducted on the transcripts to identify themes relating to the implementation of the intervention (e.g. reach, dose etc.), contextual factors that might affect delivery / effectiveness, and design issues. Feedback relating to design elements, format, and text / graphic content was recorded, assessed for feasibility, and summarised for further development.

6.3 Results

6.3.1 Sample

From 162 invitations, 8 female participants were recruited and interviewed. The age of the sample ranged from 21 – 62 years. Patients were at the following stage in the care-pathway (see Figure 6.2): waiting for initial appointment (n=1); attended appointment, no diagnosis (n=4); cancer diagnosis with no clear treatment options (n=1); cancer diagnosis with clear treatment options (n=1); cancer recurrence (n=1). Interviews lasted between 23 and 53 minutes (35 minutes average).

6.3.2 Mechanisms of impact – does the intervention produce change, and how does it achieve this?

The initial analytical framework consisted of 16 codes, clustered across six categories related to the TDF domains, intended future behaviour and barriers / facilitators. After coding two transcripts, two codes were removed as it was not relevant to the interview transcripts ('what to expect' and 'capability to be involved'), and some codes were merged due to similarities in the coded content: 'patient's or clinician's role to make decisions' was merged with 'acceptability of involvement'; 'rationale' was merged with 'existence of healthcare choices.' One code ('purpose of booklet') was grouped under 'knowledge' instead of 'other themes'. The final analytical framework that was applied to the remainder of the transcripts consisted of 12 codes, clustered across six categories (see Additional Appendix 6.2 on included CD). Data were then summarised into a matrix for each category in the analytical framework, with one row per participant and one column per code. Verbatim quotes were abstracted and entered into the corresponding cell. The following key themes emerged from examination of the data matrices:

6.3.2.1 Knowledge – awareness of the existence of SDM

Knowledge about the existence of healthcare treatment options was a key barrier to greater patient participation in SDM, identified in Chapter 2. Therefore, the 'Your Health, Your Choice' booklet content was designed to ensure that patients were made aware that healthcare options exist, as this is the first step in becoming more involved in healthcare decisions. The booklet appeared to increase knowledge about SDM among the patients that were interviewed. When the patients were asked what they felt the main purpose of the booklet was, they all believed that it was to explain that patients should and can be involved in healthcare decisions:

'I think it's been designed to give, well show people that they have choices that are to be made, and can be made depending on the circumstances, whatever that may be.' [P2]

'To try and make healthcare a little bit more accessible to the patient and to make us, you know, aware of what's going on, what's happening to us.' [P7]

'I think it gives you the alert to say you've got a choice. You've got the ability, you should ask the questions, you should have the answers back, and if they don't, you should seek the answers back...' [P4]

'Well, to give people the choice of treatment and to maybe don't always listen to 'you have to take this', you have choices and together you can find the right choice for yourself.' [P5]

One patient explained that they did not have treatment choices available after their initial breast cancer diagnosis, due to the stage of the cancer, but the booklet still reinforced the point that there will sometimes be choices available:

'There are several types of treatments...obviously in my particular case I don't think there was any other solution for me. But, every person, every case is a case, so there are different situations where they can have different types of treatment.' [P4]

For most patients, the availability of options and choice was not something that they were previously aware of, and thus the booklet had managed to change their perceptions about patients being involved in healthcare decisions:

[P4]: 'Because it gave me a perspective that I did not have.' [Interviewer]: 'So it's helped change your views on patient involvement?' [P4]: 'Yes.'

'For me [in the past] it would be the doctors telling me what to do, and fair enough. I would have my questions, but I never thought about me having a decision about it.' [P5]

'It made me think, yeah, there's not always the option that they tell you to do.' [P7]

For those patients who were previously aware that healthcare choices exist, they still felt the booklet would be useful to patients who are not aware, especially those in younger age groups:

'there were loads of young people there...if you've just turned eighteen...you don't realise that you can go and ask questions or if you're not sure how to go about it, you know the setting it out and the checklist or the 'what do you think', it's a really good way to explain that yes you can, and this is how you can do it.' [P3]

'I think if people knew they had a choice then they probably would want to be involved, it's their lives after all, they're the ones living with it so if they were more involved they'd be able to better manage some of their problems.' [P6]

'I think it's set out in a very good way so maybe if you weren't aware...it's a good prompt to get people to do that...' [P8]

6.3.2.2 Professional / social role and identity

A key barrier identified in Chapter 2 was patients perceiving that they cannot, or should not, be involved in decisions, because it is not ‘part of the patient’s role’. Therefore, the booklet was designed to reinforce the message that there are two experts in the healthcare decision making process, and to emphasise the importance of both the patient’s and clinician’s input. Feedback from patients indicates that the booklet gave a clear message that it is part of the patient role to be involved, and that they have a right to do this:

‘It’s not them and us, it’s together, so it’s your life and you should be able to take part.’ [P2]

‘The back page [the checklist], ‘do I have a choice?’, going through all that made it very obvious that you are allowed to have a say in the decision.’ [P3]

‘So this outlines what I always thought was important, we should have the opportunity to know our case and if the doctor is unsure or whatever...then give you the option to do something so that you both discuss it, and that’s what it’s saying in here.’ [P5]

‘It just gave me the open eye to say, no, hold on...if there are options, if there are choices, you can actually have an input. It’s not only up to them, it’s your life, it’s your body, it’s your input. That’s how it worked for me.’ [P7]

‘it makes you review yourself as well, and to the point that, it’s my health. Yes, it’s a high responsibility, but then I do have some input. It gives you a bit of control.’ [P8]

The feedback suggests that the booklet has moved beyond high level awareness of the existence of healthcare options, to helping these patients understand the rationale for their part in the decision making process:

‘I think it’s really important [to be involved] ...it gives you the chance as well to have some sort of feedback on your own treatment and your own life...you know, there are treatments that for the consultant they might be more suitable for you, but then if you had a choice, you might go for something else because of the outcome, the effect it will have in your life.’ [P4]

Some patients who were interviewed already believed that it was part of the patient role to be involved in healthcare decisions, and they were already comfortable taking an active role in consultations:

[Interviewer]: 'do you think it is part of the patient's role to become more involved?' [P2]: 'Yes, it's ignorant not to be isn't it, it's your health, so yes.'

However, P2 went on to explain that the booklet did give a clear message to other patients who might not already think in that way. Another patient, who also already believed that it was part of the patient role to be involved, discussed the difficulties of some patients becoming involved, even if they accept that it is part of their role:

'A lot of people, you're sat opposite somebody who's got a badge and a position and a label, and you know, there's obviously an imbalance of power isn't there...' [P1]

This perceived power imbalance is discussed further under the 'social influences' section below. Overall the feedback provides evidence that the booklet goes some way to helping patients recognise that it is part of their role to be involved in the decision making process, when healthcare choices exist.

6.3.2.3 Social influences

Another key barrier identified in Chapter 2 was the perception that clinicians do not want patients to become more involved in their healthcare. The booklet was designed to reinforce the message that clinicians, and the healthcare organisation more broadly, want patients involved; text content was framed from the clinician perspective, thus providing permission and encouragement to take part from an influential source. When asked, patients stated that it was clear that the booklet's messages were coming from clinicians, and it was clear that the local healthcare organisation had endorsed the booklet e.g. the logos. However, when patients were asked if they believe clinicians want patients to become more involved in healthcare decisions, most of the patients believed that clinicians do not really want patients to be more involved. They perceive that clinicians would become frustrated by patient involvement; clinicians might perceive that they are the ones with the knowledge and the training, and it might interfere with them being able to do their job:

'I think they want them [patients] involved in the way that they want them to...I mean, you don't question them, don't make them explain, they get slightly irritated by that.' [P1]

'By and large, most people are left to do their jobs, so it's probably quite frustrating that a doctor can and has to take on the opinion of the patient because it's them that's being treated.' [P3]

'Personally I don't think so...because if you've got a patient that is asking questions, and you're trying to do your job, from their perspective...they are the doctors, they are the health experts, they know best.' [P4]

'They don't like it if you're verbal, then it's another problem because sometimes people mistake forthrightness for confrontation and it's not the same thing...if you're asking too many questions they don't like it either.' [P6]

For some patients, they believe clinicians might not want patients involved because they do not have the time:

'I don't think so...I think it's so rushed, so there are so many patients to see, but if somebody is sort of saying 'oh I want to try this', and it's all the time, and I know they all need to get their numbers down.' [P5]

'When I was at the clinic, there were so many patients waiting, waiting a long time...I don't think they would want to make the wait any longer. Maybe they would want it if there was more time...' [P8]

Two patients believed the clinicians do want patients involved, and the booklet emphasised this:

'I would say the whole booklet to be honest...the fact that it says 'if you're still not sure', it gives you explanations of why they think it's best for you to make choices and ask questions.' [P2]

'I mean, it helps having something like that beforehand, it's like an open-door then that you can have a say...they are listening to what you want.' [P7]

When asked about whether the healthcare organisation more broadly wants patients to be more involved in their healthcare decisions, most patients believed that they did not want this:

'No, I don't think so...well people are awkward aren't they, and no two are alike and that's really annoying for a health board when you're providing a service, you want everybody to fit into that nice little box.' [P1]

'I personally think for them it's going to be a nightmare...GPs, they give you ten minutes of their life...and according to the health board that's the most they can spend with a patient...by the time you open your mouth and start explaining what is going on, the ten minutes are gone.' [P4]

Some patients perceived patient choice and individualised healthcare as an inconvenience to the healthcare organisation, and therefore they would not want to encourage patients to become more involved. Also, one patient commented on the potential danger if patients try to become more involved in the 'wrong' way:

'Probably not, because once you start listening to everyone, and then people meddle...it's a bit risky...there's always a couple of people that take something too far, kick up a fuss, rather than going and being appropriate about it and being involved.' [P3]

One patient believed that healthcare organisations are supportive of patient involvement, as there may be benefits for the organisation:

'I think it would be beneficial, in the way that maybe they wouldn't be prescribing so many drugs. I've had a condition, then given medication that made it worse, so that medication was no good, so maybe a bit more of a discussion about the problems you have.' [P5]

P1 agreed with the principle of patient involvement in healthcare decisions, and was a relatively 'activated patient' in terms of her own healthcare, but she believed the shared decision making approach was not realistic or attainable:

'It's a little bit of NHS propaganda to be honest with you...it's just fantastic that there is this thing patient choice and patient involvement; in reality it doesn't happen.' [P1]

P1 firmly believed that clinicians and the organisation do not want patient involvement, and whilst she felt that the booklet conveyed the message that patients should become more involved, and she believed this herself, she felt that the booklet only served to *'highlight the void between theory and practise.'* [P1] Analysing the data, it is likely that these views are based on negative past experiences with the healthcare system; this is discussed in more detail under 'contextual factors' section below.

6.3.2.4 Beliefs about consequences

A key barrier identified in Chapter 2 was fear of the negative consequences of being involved in SDM. Therefore, the booklet was designed to promote the advantages of patient involvement, and to reassure patients that there will not be negative consequences. Feedback indicated that patients felt the booklet conveyed the benefits of SDM, and these could be for patients or clinicians:

'Yeah, as a good thing yeah...I think if a person didn't have choices and something went wrong...it could literally go on from there.' [P2]

'I think it makes it easier for the doctor involved as well rather than having to sit and detail every single thing, somebody that's bothered to take an interest

in their own health and their own wellbeing, I think that probably makes life a bit easier for everybody involved.’ [P3]

‘You know, there are treatments that for the consultant they might be more suitable for you, but then if you had a choice, you might go for something else because of the outcome, the effect it will have in your life.’ [P4]

‘I don’t see disadvantages, only advantages...because if you know you’re going to a hospital or clinic or something, you will know that you have the choice to either say you want to be involved in the treatment, or no, you make the decision for me.’ [P5]

‘Basically it’s making sure you know what’s going to happen before you make a decision, you’re ready for the bad consequences, if they end up happening.’ [P7]

When asked, most patients did not perceive disadvantages of SDM after reading the booklet, or disadvantages of sending the booklet to patients. However, P3 noted that there is potentially a risk of patients ‘thinking they know too much’:

‘I think the only risk that people getting too involved is thinking they know too much really...gone away and researched it and practically diagnosed themselves with something much worse.’ [P3]

As discussed above, P1 believes that the SDM approach is ‘idealistic’ and ‘unattainable’. When asked if there are any potential disadvantages of promoting patient involvement, P1 responded:

‘I think it kind of lulls them into a false sense of security that you will be having a nice time.’ [P1]

6.3.3 Contextual factors

Contextual factors that might impede or strengthen the effects of the intervention were considered during the process evaluation. Key themes that emerged from thematic analysis of the patient interview data are as follows:

6.3.3.1 Negative past experiences

Some patients reported negative past experiences with the healthcare system, such as inadequate care processes and poor interactions with clinicians. These past experiences appear to have a significant impact on the patients’ beliefs that SDM is an approach that is

supported by clinicians and healthcare organisations, and on the feasibility of the approach. It is likely that it will also have an impact on how receptive patients are to the key messages of the 'Your Health, Your Choice' booklet. In relation to poor care processes, P4 describes the 'battle' that she went through trying to get her GP to listen to her, and to refer her to the breast care team in the first instance:

'They sent the GP a letter to say that I went through the first surgery, what they've done, and then what they were going to do, he rang me [GP]...he said 'oh you did have breast cancer' and really friendly...I'm like, well if I wasn't a pain you wouldn't have sent me to the breast cancer centre, and I wouldn't be here now.' [P4]

P1 describes a situation where information about a friend's health condition had been withheld:

'We requested all of her notes...I was in hospital every single day with her, I've asked all the questions, and only when we went through her notes you know, there was a perforated lung from the biopsy nobody told us about that...as soon as you get cancer, it just gazumps everything and nobody cares, nobody talks to you about it.' [P1]

Some patients describe the length of time that they had to wait for an appointment [P8's was for an unrelated health condition]. For these patients, the priority was to be seen by a clinician, rather than the ability to take part in their decisions:

'He was complaining because he'd been waiting thirty minutes, and I was like 'we've been here an hour and a half already', so there are other issues that's more important than, than your, I don't know, your dream about this patient form.' [P1]

'And you know, despite it being an urgent referral and NICE guidelines saying two weeks, it was almost four weeks...I would prefer leaflets that tell you where to complain about that, where the NICE guidelines are.' [P7]

'It's been so drawn out, it's upsetting that it took so long, I'd chase and chase but get nowhere. I mean most people, by the time you've waited and waited and waited to see consultant, you're just so bloody grateful you'd do anything.' [P8]

Poor past interpersonal interactions with clinicians have an impact on patient's views about the feasibility of SDM. One patient describes a situation when there were options available, but she was not told about them:

'No, they didn't explain I had options, just a prescription for something, and they irritated other symptoms, and when I look it up or whatever, or a

different GP, and they'll say 'oh well that can cause that', and you think 'if only I'd known that in the first place!' [P5]

Clinicians with poor interpersonal skills and a negative attitude towards patients are a key barrier to SDM, and are likely to have an impact on how receptive patients are to the message that clinicians want them to become more involved:

'Oh yeah, if they had a negative attitude, I wouldn't share it, I haven't before, it puts you off.' [P2]

'I was feeling really unwell and he comes in and goes 'so what's your problem?' [Laughs]. *I was a little bit taken aback to be honest, I thought surely there's better ways of putting it. And I'm not generally frightened to speak up for myself.* [P8]

For this reason, one patient believed that the focus should be on communication skills of clinicians, rather than on patients:

'Her [friend] oncologist, he's got the personality of a gnat! So even when you ask questions, and I'm not shy about asking questions...he just shuffles his feet and looks at the floor.' *So it's wonderful this might be applicable to some consultants, but I really do think you should be producing a leaflet for the consultants on skills, people skills and communication skills.'* [P1]

This patient, who is relatively 'activated', also reports being actively discouraged from becoming more involved:

'Yeah, and I mean I've sat there with my notebook and pen and I was told 'you don't need to write anything down because I will give you a leaflet'.' [P1]

As well as being diagnosed with metastatic breast cancer, P1 has a vast amount of experience of supporting friends and family through the healthcare process when they have been unwell. Therefore, this patient has had first-hand experience of interacting with clinicians, experience as a third-party, and she also has experience of various healthcare administration processes. It is clear from this patient's interview transcript that past experiences with clinicians and the organisational processes have had a significant impact on her views about patient involvement, and the effectiveness of the 'Your Health, Your Choice' booklet. As mentioned above, P1 agrees with the principle of patient involvement, and believes the booklet clearly conveys this message; however, her past experiences have impacted on her belief that SDM is attainable:

'I mean, I think if you'd asked me twenty years ago I would have said 'oh yes, it's a lovely idea, it's a lovely concept', I don't think it's very realistic.' [P1]

'I guess it just makes me feel disappointed really because I mean, wouldn't it be lovely if it was like this, the NHS was like this...but alas it's not, you know so it is a disappointment, you know, if this is the standard that the NHS is reaching for, it's not, it's not making it, it's really not.' [P1]

6.3.3.2 Emotional factors

Some patients discussed their emotional state when they were given their cancer diagnosis. For these patients, the shock of being told that they have bad news overrode their ability to think about being involved:

'He sat there and said well 'you've had the biopsy, you'll come back in a weeks time for the results, he said 'do you have any questions?' I said there isn't any questions I can ask really unless you've got a crystal ball because you don't know until you the biopsy results, and he just went 'oh but I think it's bad, it's very bad'; that was a shock.' [P1]

'Because it's frightening, going to hospital is quite frightening, nobody likes going to hospital do they?' [P3]

'When I went to see the consultant, obviously the first day I couldn't even hear what...what the heck she was on about...I wasn't expecting it, I thought it was just a routine thing, it would be just a lump, and they said 'no'.' [P4]

'They asked if I had questions, but to be honest with you, as soon as you hear the C word you don't really have any questions, you're just thinking, 'God, I'm doomed'.' [P8]

P4 went on to explain that if the booklet were given to her at that first diagnostic appointment, she would be unlikely to look at it due to how worried and how nervous she was:

'Personally, if I was given this on the first day I went, I wouldn't even look at it, not in the state of mind I was in. And the reason why, because you're in the Breast Care Centre, so you know, the chances of having something wrong with you are so high, you get so nervous.' [P4]

This suggests that emotional factors, such as the shock of diagnosis, might impede a patient's ability to get involved in SDM, regardless of whether the booklet helped to prepare them to take part beforehand.

6.3.3.3 Time

Most patients perceived that there is not enough time for clinicians to do SDM, even if they wanted to. This is another key barrier that leads patients to perceive that SDM might not be feasible in real-life clinical settings:

'You know they've waited months and months to go there [psychiatrist] and you get ten minutes with some bloke who's, you know, wanting you out the door and you know he's not there to listen to your story, he's just there to write you a prescription.' [P1]

'The patient care thing has disappeared because of the society we live in, everyone's in such a rush it's like they go to the doctors, they're under pressure obviously, it's going back to the time management thing, targets on them, then it sort of somehow gets trickled down to the patient.' [P6]

6.3.4 Implementation and use of the intervention

I analysed how delivery of the 'Your Health, Your Choice' intervention was achieved, and what was delivered to patients.

6.3.4.1 Reach

All patients received the booklet in the mail before their appointment at the Breast Care Centre, as intended. This varied from 4 days – 14 days before the appointment, depending on where the patients were placed in the appointment schedule. Almost all patients read the booklet straight away when they received it in the post. One patient put the booklet aside for a couple of days, as they realised they only needed to read it before the appointment, which was a week away. All patients reported that it took them less than ten minutes to read the booklet. Some patients spent a couple of minutes skimming through the information, and then went back through the booklet in more detail:

'About 10 minutes, because obviously you go back over and have a little look through something that maybe you've not taken in.' [P5]

Most patients did not share the booklet with anyone else (e.g. family members or friends). One patient [P1] shared the booklet on a professional basis with colleagues at her workplace, as they are involved in developing healthcare leaflets. One patient [P6] showed the booklet

to her teenage son. Both of these patients felt that the design was more suitable for a younger audience (see above).

6.3.4.2 Dose

Most patients reported that they read the entire booklet (8 pages). One patient [P1] only read the first three pages of the booklet, and then quickly glanced at the remaining five pages. However, this patient felt that the ‘patient-centred’ approach was ‘idealistic’ and was unlikely to be achieved in practice. Therefore, whilst she was not against the messages portrayed in the booklet, she felt that they would not come to fruition and decided not to read the booklet in detail (this is discussed in more detail in section 6.3.3 above). Another patient [P3] reported that she only ‘flicked’ through the booklet and quickly glanced at each page. However, this patient was not sure of the relevance of the booklet to her upcoming appointment due to implementation process issues. The covering letter that accompanied the booklet did not clearly indicate that it was sent from the Breast Care Centre. The letter for this pilot-testing stage was dual purpose, and this could have led to some confusion: it was used by the Breast Care Centre to encourage patients to read the booklet before their next appointment, and it was also used to recruit patients to the associated interview study. Further, it transpired after commencing the study that patients attending the Breast Care Centre do not receive paper appointment letters in the post. They receive a telephone call from the clinic coordinator to arrange the appointment. As such, the booklet and covering letter that encourages patients to read the booklet before their next appointment are sent independent of any appointment confirmation. Future implementation should make it clearer that the booklet is being sent on behalf of the clinical team that the patient is seeing:

‘In hindsight I think it’s very informative but it just, it seems silly saying it but I just didn’t make the link at all, I presumed it was something to do with the uni.’ [P3]

None of the patients used the notepad or the checklist at the back of the booklet ahead of, during, or after their appointment at the Breast Care Centre. When asked why they did not use the tools, the majority of patients reported that they did not have a decision to make at this time (e.g. no cancer identified, routine follow-up check after previous breast cancer diagnosis). Again, P1 did not read the entire booklet because she felt the approach was

idealistic, and P6 felt that there were other priorities than becoming more involved in decisions e.g. timely care.

However, most of the patients believed that the checklist and the notepad would be helpful in future appointments, and it was something that they intended to use, when appropriate:

'...it's a good tick list...because I suppose they are the things that I would never think of.' [P2]

'No, I didn't need to as I say this time but in future I would, yes, yeah that is something I would use.' [P8]

Some would use the checklist before, during and after the appointment as a way of checking that they received the appointment that they should have received, including a SDM process:

'I'd take it to the appointment with me and then as I go along I'd just do the checklist and then double check it coming back from the appointment and check again when I got home.' [P2]

'While I'm waiting I may actually have a look and see the questions...it might raise an idea of what I should be asking, and what should be my attitude, and then probably afterwards I would go through it and say, okay, I've done this, I've done that.' [P4]

Some patients would use the notepad before the appointment to write down questions that they have, and to act as an *aide memoire* whilst they were at the appointment, or suggest that it could be used during the appointment to note down what was said for future reference.

'Because you're so bombarded with different things and the hospital is so rushed so having somewhere you can put down your points you'd like to know is very good....often you go there and you think oh yeah I'll ask that and it goes around and you think oh I didn't ask.' [P5]

'It would make it easier, I think, if you took this and used it as a tool, but I didn't do that.' [P3]

'It was quite stressful, you're so emotional and there's so much going through your mind...maybe not the first consultation [diagnostic], but the one when they come to see you a week later to talk about the surgery.' [P7]

'I can see something like this helping my mum too...it's so easy to forget what is going on when you have all that information, and when we ask her what was said, she can't remember.' [P8]

6.3.4.3 Future implementation

Patients were asked for their opinion on how the booklet could be implemented in future, outside of the research study setting. All patients believed that it should be sent to patients ahead of their appointment, as it was implemented during the pilot-testing. Preferably, this should accompany an appointment letter and any other important information that is sent to patients regarding their appointment. :

'I think it would be better to be sent, because when you get your appointment you get all the jargon, what you have to do before you get there, what you have to take...so with that it would be very good because obviously that's making that [the booklet] important.' [P5].

However, some patients felt that the booklet should also be available at the place of the appointment (e.g. waiting area, consultation room), just in case they forgot about the booklet. Posters and additional booklets in the waiting area would prompt them to become more involved and ask questions:

'I'd say both [sent before appointment and handed out at appointment], just in case I forgot.' [P2]

'I think if there was information on the board, because every single appointment, I went to thousands of them, I tend to look around, and read the news and read this and that, while you're waiting.' [P3]

Patients typically have to wait in a waiting area for their appointment, so the clinic receptionist could hand out the booklet, and patients could read it during that time:

'It depends what kind of appointment you've got. If I go to the GP and that's given to my hand before my appointment, I've got enough time, because I'm waiting, I will read it and I'll go through it and yes, do you know, open my eyes to what I should be asking.' [P4]

6.3.5 Design and format feedback

Overall, the patients were positive about the general design of the booklet. This included the colour scheme, graphics, size of booklet, the font used, and the layout of the text and graphics. Patients felt that the inclusion of cartoon characters made it approachable, they covered a broad spectrum of the population, and they made the booklet different to the usual text-heavy leaflets that can be found in waiting areas. However, two patients did feel

that the character design would appeal more to a younger audience (e.g. children and teenagers), and that adults might be put off by the design:

'I have to say I was a bit put off by the cartoon characters...if I was handing it to a child I probably would, but I'm not sure I'm the target audience.' [P1]

'Because if you're giving that to a kid, fair enough, but as a grown up I think grown-ups prefer photographic imagery, if you know what I mean.' [P6]

The intervention is currently in booklet format; patients were asked if they saw scope for the booklet to be created into alternative formats (e.g. website, iPhone app, tablet app). Overall, most patients felt that a booklet was the most suitable format for the intervention. Whilst positive about the possibility of electronic versions of the intervention for other patients, they did not believe that it was something that they either could or would use. This was reflected across the different age groups:

'I would use it if I knew how to use it!' [P2, age 26]

'It's not something I'd use no...I think people always want things like that don't they because we use phones now more than paper, so it would probably be a good idea.' [P3, age 21]

'I'm going to be honest with you, I don't have the time, I really don't...I wish I could, but I think I turn on my computer or my tablet about once or twice a week, if that much.' [P4, age 40]

'Probably not, I mean I've only just got into an iPhone...I think in leaflet form even youngsters would read that more than an app.' [P5, age 59]

However, P6 felt that an electronic version of the booklet would be more appealing to patients, especially those of a younger age group, and a short film in patient waiting areas could convey the messages more efficiently. All patients felt that the booklet was easy to read, that they could understand the information, and that the text size was appropriate; this included one patient with dyslexia [P2]. However, P1 did suggest that some of the sentences could be condensed so that shorter and simpler key messages are portrayed:

'I think short and sweet with bold questions, just key points is of more use when somebody is sat in front of a consultant.' [P1]

6.4 Discussion

The aim of this chapter was to pilot-test the ‘Your Health, Your Choice’ intervention with breast care patients, using a process evaluation method. Overall, the intervention shows potential to prepare patients for involvement in healthcare decisions, in the way that it was intended: increasing knowledge about what SDM involves, moving patients from thinking that they should not be involved to recognising the importance of the patient contribution, and patients stating that they want to be involved in future. The intervention was well received by a range of patients, with evidence of high levels of reach, dose and fidelity. However, important contextual factors, such as negative past experiences, can have a significant impact on the overall efficacy of the booklet, and this will be discussed below.

From ‘doctor knows best’ to ‘doctor doesn’t want me involved’?

Chapter 2 showed that many patients do not perceive that they have choices available in the healthcare setting. Clearly, if patients do not know that they have choices available in their healthcare, they will be unlikely to participate in the decision-making process. The booklet aimed to address this key barrier by explaining when healthcare choices exist and why, and describing what is involved in the SDM process. Another key barrier that the booklet addressed was patients perceiving that it is not part of their role to be involved in the decision making process; for example, ‘doctor knows best, they should make the decision for me’. The booklet reinforced that there are two experts in healthcare, the patient and the clinician, and explained the importance of the complementary expertise that each brings.

The results of the pilot-testing suggest that the booklet is addressing these two key barriers. When patients were asked about the purpose of the booklet, they all identified that it was to let patients know that they have choices available in their healthcare, and that patient preferences are important. Therefore, a clear message was reaching the target audience. There was some evidence that the booklet raised awareness of healthcare choices, and knowledge about why they exist, and it also influenced some patients’ perceptions about their role in the consultation. For patients who were not previously aware that they had choices, the booklet helped these patients to understand and accept that it is part of the patient role to be involved in healthcare decisions, and they subsequently intended to do so in future.

However, results show that changing patients' attitudes about what *should* be the norm, and what *can* be the norm, are very different tasks. Despite patients stating that the booklet has reinforced their belief that they should be part of the decision-making process, they still believe that clinicians and healthcare organisations more broadly do not want patients involved. Patients cite various reasons for this belief, including: clinicians perceiving that they are the experts; patient involvement interfering with the clinician's ability to do their job; lack of time to do SDM; the inconvenience of individualised care for the healthcare organisation; and the danger of patients becoming involved in the 'wrong way'. When examining the broader contextual factors that might influence outcomes, negative past experiences were a significant contributing factor to this belief that clinicians and the organisation do not want patients involved.

For some patients, negative past experiences with the care process dominated their views of what might be attainable in future healthcare consultations. Some patients had experience of negative interactions with clinicians (e.g. rude / dismissive clinicians), some had received inadequate care (e.g. delays in diagnosis, inappropriate medication), and some had experience of poor administrative processes (e.g. long delays for referral). When patients had experienced delays in treatment, their priority was to receive timely care, not involvement in their decisions. Past experiences led some patients to adopt a 'defensive' approach to consultations, where they expect the worst and feel that they have to 'fight their corner'. Interestingly, the more 'activated' patients reported more experiences of poor care and the booklet seemed to have less of an impact among these more 'activated' patients; these patients had positive views about patient involvement, but were the most pessimistic about it taking place routinely (e.g. 'it's a little bit of NHS propaganda really... it's great to think there's such a things as patient choice, but in reality it just won't happen' [p1]). Interestingly, the pilot-testing patients appeared to be more pessimistic about the feasibility of the approach than the lay-users interviewed during the pre-testing phase (Chapter 5). However, most of the lay-users were not currently receiving care, and were asked to consider hypothetical situations. In contrast, the patients who participated in pilot-testing are currently receiving care, have recent experience of busy clinical environments and interactions with clinicians, some are unwell or have experienced a negative emotional response, and some have been in and out of the care system for many years.

The results suggest that there are two significant types of social norm to be addressed by a patient activation intervention: norms about the perceived acceptability of patient

involvement (*should* patients be involved), and norms about perceived clinicians attitudes towards patient involvement (*would* patients *actually* be involved). Clearly, encouraging patients to want SDM and encouraging them to believe and expect that it can be a reality are distinct tasks. The booklet attempted to address both of these, but from preliminary small-scale pilot-testing it appears to have had more influence on the former. Therefore, preparation (i.e. changing patients attitudes towards patient involvement / allowing patients to make an informed decision to be involved) must be followed by more substantial effort and progress towards enablement (i.e. encouraging and supporting patients to become involved in SDM). Receptive clinicians who fully endorse principles of person-centred healthcare will play a key part in moving those patients who think they *should* be involved, to be those patients who also think that they *would* be involved. An internally driven approach to the ‘Your Health, Your Choice’ intervention is also critical, as it will show patients that the clinical team and the healthcare organisation endorse the key messages.

Overall, the pilot-testing highlights the importance of implementing the ‘Your Health, Your Choice’ intervention as part of a multi-faceted SDM intervention, or ‘SDM bundle’: this ‘bundle’ must address patients’ attitudes, but also clinicians’ attitudes (e.g. skills training), and organisational factors (e.g. time for SDM during care pathway). I attempted to achieve this during pilot-testing, by implementing the booklet in a team that is receptive to SDM, with clinical team members who had received SDM skills training and who use SDM tools, within the context of an organisation and team that has supported SDM implementation.(35). However, the fidelity of the breast care team’s broader SDM approach is not clear, and this may impact on the efficacy of the ‘Your Health, Your Choice’ intervention (e.g. not all clinicians had received SDM skills training): this is discussed further in the strengths and weaknesses section below. Overall, unless a holistic approach is used, we are in danger of preparing patients to want and expect something that they do not feel is attainable.

Use, design, and implementation of the intervention

Overall, the results show that a booklet format is a feasible and effective way to deliver the ‘Your Health, Your Choice’ intervention. The booklet had high levels of reach (all of the intended target audience came into contact with it before their appointment), relatively high levels of fidelity (used as intended, by patients), and relatively high levels of dose (the quantity of the booklet that was read by the patients), especially among the less ‘activated’

patients. Regarding fidelity, the patients did not use key aspects of the booklet, such as the notepad and checklist. However, most patients did not have a treatment decision to make at this time, and most reported that it would be something that they would use in future situations when there are decisions. This suggests that the booklet would be useful, and possibly more effective, if targeted at patients who had imminent healthcare decisions to make. However, it is often difficult to establish this up-front in many settings e.g. general practice. The fact that patients without current decisions display positive intentions to use the tools and try SDM in the future indicates that there is still potential value in sending the booklet to a broad spectrum of patients.

There was little demand for alternative formats (e.g. electronic versions, phone apps), and all but one patient felt that the booklet was the most accessible and usable format that should be distributed to patients. This view was shared across the different age groups (21 – 62 years). It was suggested that the additional work that is involved in accessing online formats or downloading a phone app might impact on the reach of the intervention, and the dose (quantity of intervention used). In a previous study of a web-based decision support intervention for prostate specific antigen testing, participants accessed less than half of the available content and did not use the interactive features.⁽¹⁸⁰⁾ This previous study included an older male population, but it highlights the importance of developing an intervention that is likely to be accessed by all patient groups, especially as perceived power imbalances are more pronounced in the older age group.

In terms of the implementation process, the booklet was meant to be easily integrated into the clinical care pathway, as it only needed to be posted to patients by the administrative team. However, the Breast Care Centre appointment process was changed after initial study plans, and was not ideal for the distribution of the booklet. Patients do not receive an appointment letter for their upcoming appointment; they receive a telephone call from a clinic coordinator to arrange the appointment, meaning the booklet had to be sent independently. Some participants noted that they did not understand that the booklet was being sent on behalf of the Breast Care Centre in relation to their upcoming appointment. This was probably confounded by the fact that Cardiff University was mentioned in the dual-purpose covering letter, which was also trying to recruit patients for pilot-testing interviews. In Chapter 5, lay users believed that the way in which the booklet was distributed to patients was key: the booklet should be sent directly from the clinical team together with the appointment letters. If it is clear that the clinical team you would be seeing

have endorsed and sent the booklet, it provides patients with permission and reassurance to take part. As discussed above, many patients believe that clinicians do not want patients involved, and this can have a significant impact on how receptive people are to the feasibility and expectations of the SDM approach. Future implementation attempts should establish a clear link between the booklet and the clinical team, which could be supported by conjoint branding and a tailored booklet for each clinical area.

6.4.1 Strengths and weaknesses

The pilot-testing phase built on the work conducted in Chapter 5 by testing the intervention with real-life patients, currently accessing care. The use of real-life patients in routine clinical settings meant that the results of the pilot-testing were more ecologically valid, and that they considered a broader range of contextual factors that might influence implementation and / or outcomes of the intervention. The framework analysis method enabled me to determine whether the theoretically developed booklet has the potential to produce the desired change: i.e. promoting positive patient attitudes towards SDM.

One of the most significant weaknesses of the pilot-testing is the sample size (n=8). Experience on parallel SDM research programmes has shown that this patient population is particularly difficult to recruit.⁽¹⁸¹⁾ Many of the patients are extremely emotional and worried about a cancer diagnosis after initial referral, and for those who are diagnosed, they receive surgery and follow-up treatment within two weeks, and thus they are recovering both physically and psychologically. The number of parallel projects taking place at the Breast Care Centre, which includes the ongoing MAGIC programme, also impairs recruitment. The research nurses are sensitive to demands on the patients, and are keen not to over burden them with requests for research participation. As discussed in the methods section, the ‘Your Health, Your Choice’ intervention is part of a complex intervention that needs to be implemented in a clinical team that is receptive and supportive of the SDM approach, and where clinicians have received SDM skills training (where they might also use decision support tools for patients to assist with information exchange and preference elicitation).

There are clear benefits to using such a team, and it is important to the success of the patient activation intervention, but it does also present problems. This team has worked closely with researchers for five years, developing and testing SDM interventions, and their team has undergone some level of cultural change regarding their approach to patient decision-

making. This is on top of their day-to-day clinical demands, targets and organisational restructuring at the local health board level. We have begun to witness ‘research fatigue’ and sustainability issues in this team, where some clinical team members have disengaged from the research elements of the broader programme of work (e.g. audio-recording of consultations for SDM analysis). This must be considered during future testing of the booklet (e.g. by considering a new clinical area / team), regardless of the additional background work that will be needed to engage and train a new team. Working with additional teams is also crucial for knowledge-transfer, and wider rollout of the intervention.

The sample composition is also a potential weakness. The sample frame for this study included all patients referred to the Breast Care Centre over a 16-week period, and could have included males or females. Approximately 90% of the patients referred and invited to participate were female; unfortunately, only female patients responded to the study request and agreed to take part in the study. It is important to consider this when making judgements about the feasibility and future implementation of the booklet. Further work should test the booklet in a setting that includes a higher proportion of male patients (e.g. osteoarthritis orthopaedic / urology setting) to determine if there are important differences in the way that male patients interact with the intervention, or if there are unique contextual factors that are specific to this population.

Whilst I can be fairly confident about the fidelity of the ‘Your Health, Your Choice’ intervention, I cannot be sure about the fidelity of the broader SDM approach that is used at the Breast Care Centre. Most of the clinical team received SDM skills training as part of the MAGIC programme. However, some clinicians were unable to attend this session, and new team members have also not received this training. Therefore, it is likely that some of the patients were not seen by a clinician who had received SDM skills training, or worse, were seen by a clinician who was not receptive to the SDM approach. As we have seen from the pilot-testing, follow-up from a clinician who outwardly supports and encourages patient involvement is important. Future testing of this intervention will also need to ensure fidelity of what the clinicians are delivering to patients; a controlled trial setting with a parallel process evaluation can support this. A controlled trial would also allow me to determine if clinicians with SDM skills, who might also use decision support tools, is sufficient to encourage SDM among patients, or if the ‘Your Health, Your Choice’ intervention is a necessary (additional) component that would result in greater benefits (this is discussed further in Chapter 7).

The pilot-testing interviews were based on self-reported use of the intervention. First, we cannot guarantee that patients read the content / amount that they reported to read. Some patients might also experience social conformity due to the interviewer being present, feeling that they have to report a positive outcome and reaction to the booklet. A think-aloud technique might have been more useful in this scenario, where patients would be asked to say whatever comes into their mind as they read the booklet. This would ensure that they have read the booklet, would identify any areas where they encountered difficulties, and it would also give an insight into the patient's cognitive processes as they read the key messages. Clearly, the pilot-testing stage was not a before and after trial. It is therefore difficult to know what patients thought beforehand, and whether the booklet did change patients' attitudes. Self-reports from patients are a useful indicator of change, but future testing would need to consider patients' beliefs before and after exposure to the intervention, in order to make more concrete judgments about the booklet's effectiveness.

6.4.2 Conclusion

Preliminary pilot-testing has shown that the 'Your Health, Your Choice' booklet has potential to change patients' attitudes towards involvement in healthcare decisions, and thus prepare them for SDM. However, the intervention had more impact on patients' beliefs that SDM *should* happen, and less impact on their beliefs that it *would* happen. Contextual factors, such as past negative experiences with healthcare and organisational constraints (e.g. time in consultations), play an important role in the potential effectiveness of the messages conveyed in the intervention. The results highlight the importance of different SDM component interventions working together; a patient activation measure will not work on its own. Ultimately, actions will speak louder than words for patients. Preparation needs to be followed by enablement from willing and skilled clinicians, who can reinforce the message that they want patients to become equal partners, as it is difficult to convey this message in a booklet alone. If preparation is not followed by enablement, we are in danger of creating activated patients whose care does not meet their expectations, and exaggerating the void between theory (or ideal care) and practise. A holistic approach will ensure that we do not only move patients from thinking 'doctor knows best' to 'doctor doesn't want me involved': it will encourage them to believe that clinicians and healthcare organisations are driving forward the principles of person-centred care, and that patients' input is expected and valued.

Chapter 7

Further research plans

This thesis presents the development and initial pilot-testing of the ‘Your Health, Your Choice’ booklet. This chapter will present further research proposals that have arisen from the work that has been completed to date, which are beyond the remit of this thesis. Several proposals are presented relating to the further development and evaluation of the ‘Your Health, Your Choice’ intervention. This culminates with the key research proposal; a cluster-randomised controlled trial and process evaluation of the ‘Your Health, Your Choice’ intervention, embedded in a SDM clinical pathway.

7.1 Integrated taxonomy of patient reported barriers and facilitators, and cultural adaptation

Chapter 2 resulted in a taxonomy of patient reported barriers and facilitators to involvement in SDM. This is the first review, to my knowledge, to focus exclusively on patient-reported data. The results of this review have been published in two journal articles: the Patient Education and Counselling article (Appendix 2.2)(182) presents the results of the systematic review; the BMJ article (Appendix 2.3)(172) is a discussion piece highlighting the key themes that emerged from the review and practice implications. As with the preceding review published by Legare et al,(57)which focuses on healthcare professional-perceived barriers, this review has the potential to inform researchers, implementers, educators, and clinicians interested in implementing SDM. Specifically, it highlights the factors that need to be considered when trying to engage patients in a SDM process. The taxonomy should be considered during SDM intervention development, implementation planning, and SDM training and education.

The taxonomy produced in Chapter 2 focuses exclusively on patient-reported factors, but, as discussed, this cannot be considered in isolation. The field of SDM, and patient-centred care more broadly, has expanded exponentially over the last decade, evidenced in part by the increase in the number of RCTs included in the Cochrane Review of patient decision aids,(16) and a move towards implementation learning programmes based in real-life clinical

settings.(33) The factors identified in my review need to be considered in conjunction with healthcare professional-reported barriers literature,(57) and learning from SDM implementation programmes that are taking place internationally. There is scope to build on the patient-reported barriers review to produce an integrated taxonomy of factors influencing successful SDM implementation; this taxonomy would draw on the existing literature around barriers and facilitators, and the learning from implementation programmes. This comprehensive integrated framework would better guide researchers, implementers, educators, and clinicians attempting to embed SDM into routine care.

The growth in the number of publications in the area of patient-centred care also means that the review should be updated to incorporate new literature published since 2012. Most studies included in the review were conducted in Europe (24/44) and North America (18/44). This area of research is not well indexed, so it would be important to see if further work has been conducted in lower income countries. This would allow us to investigate if the barriers and facilitators are culturally specific to those countries included in the review, or if they are exacerbated / minimised by different cultural factors.

7.2 Further development and testing of the ‘Your Health, Your Choice’ intervention

Further pilot-testing

The pilot-testing in the breast care team (Chapter 6) was significantly limited by the sample size and sample composition, and this impacts on the generalisability of the results. Before proceeding to a full-scale trial, I would recommend conducting further pilot-testing of the ‘Your Health, Your Choice’ intervention to broaden understanding of the intervention’s acceptability, mechanisms of impact, and implementation. Pilot-testing with eight patients indicated that the intervention has relatively high reach, dose and fidelity. However, the very low response rate in the breast care team indicates that these eight patients might have been more ‘motivated’ patients, and they might not be representative of the broader group of patients. Therefore, it is important to test the booklet with a larger group of patients to see if the findings are replicated. It would also be important to establish if the pilot-testing patients’ attitudes towards the intervention are representative of a larger patient group i.e. believing that it is part of the patient’s role to take part in SDM, but also believing that

clinicians do not want patients involved in SDM. The pilot-testing in the breast care team also identified implementation process issues (the appointment confirmation process) and further pilot-testing could be used to progressively refine and establish the most effective implementation process, prior to full-scale evaluation. Further pilot-testing could be conducted in a breast care setting with more patients, but it would also be useful to conduct pilot-testing in other clinical areas with different patients compositions, as this would give a better indication of how the intervention might work in other settings.

Speciality specific

Currently, the booklet is generic and could be used for any health condition, across primary and secondary care. Feedback indicated that there is scope to develop condition specific versions of the booklet. To achieve this, we would have to work closely with patient representatives from the specific clinical area, and also with clinicians who deliver the care to patients. Most of the text content would remain standardised, but the messages could be framed from the specific clinical team that is delivering the booklet e.g. 'your chronic kidney disease team want to know what's important to you.' Further, it was suggested that the inclusion of brief patient stories / quotes might be beneficial to other patients. Patients from the relevant clinical area could be interviewed about their experiences of SDM, and these stories could be included in the decision specific versions of the booklet.

Different formats

There is also scope to develop the booklet into other formats. The overarching view from the pre-testing (clinicians and patients) and pilot-testing feedback was that a booklet was the preferred, and most accessible, format. If the booklet were created on online / application platforms, certain people might not have access to these formats, and it is possible that only motivated patients would access these. However, feedback did indicate that the development of the booklet in different formats would be useful, if they supplemented rather than replaced the booklet. For instance, the booklet could be linked with: a website that could provide more detailed information that does not fit within an eight-page booklet (e.g. further patient stories, video clips); with tablet / phone applications that include the interactive features (e.g. notepad / checklist); various social media accounts (e.g. Twitter, Facebook), which might promote engagement. The results of the pilot-testing (Chapter 6) suggest that online / virtual formats might be increasingly appropriate for clinical settings. The breast care team that were involved in the pilot-testing no longer send out appointment letters to

their new patients (i.e. patients who have received a referral from a general practitioner / identified via the national cancer screening programme); a call is made to the patient to arrange the appointment. Further, several other teams in the Cardiff and Vale University Health Board send appointments to existing patients via short messaging services. This move to paperless appointment management signals a move towards more cost-effective and efficient online formats. However, any further development of the booklet should involve patient and public representatives to ensure that the products created are accessible, useable, and that they address patients' needs.

Pre-testing with hard to reach groups

Clinician and patient feedback from the pre-testing (Chapter 5) indicated that certain patient groups might be harder to engage than others. This might include the elderly, ill or vulnerable patients, and patients from poorer backgrounds. It was acknowledged in the discussion section of Chapter 5 that the pre-testing sample might be biased to include more motivated and engaged patients. As such, there is scope to conduct further pre-testing with individuals who represent the groups above. This would allow us to determine if the booklet has the same impact on these groups as it did with the sample of patients included in the pre-testing, or whether there are specific factors that need to be considered. This could then be used to refine / re-develop the booklet, and it would provide specific insight into the barriers / facilitators that are most significant within these patient populations, which could also contribute to and validate the taxonomy of patient-reported barriers.

Public health campaign

Pre-testing feedback established that a targeted approach was essential, whereby the booklet was delivered to people who had healthcare appointments, or who would be facing treatment decisions. This ensured that the messages conveyed in the booklet were relevant to patients. However, many participants (public users and professionals) felt that there was scope to complement the targeted approach with a broader public health campaign. The focus for a broader campaign should be on developing interactional health literacy;(44) this would encourage the development of advanced cognitive and literacy skills so that people can use the knowledge acquired to actively participate in the SDM process. This is opposed to functional health literacy, where the focus is on transmission of factual information e.g. about choices and outcomes.

A public health campaign would have broader reach than the targeted approach, as it would be delivered to patients attending clinical appointments and to the general public. There is scope to work with organisations such as Public Health Wales or the 1000 Lives Plus National Improvement Programme (Wales), to develop a ‘Your Health, Your Choice’ campaign. Again, an advisory panel, consisting of patient / public representatives, clinicians, and organisational representatives, would be essential to guide the development and implementation of this campaign. Further, Health Literacy models, such the Optimising Health Literacy (Ophelia) Process, should be considered during development to ensure that the health literacy strengths and weaknesses of the target population are understood.(183)

Targeting children and young people

One of the key patient-perceived barriers to involvement in SDM, identified in Chapter 2, is perceived norms about the patient role. Many patients feel that they cannot, or should not, be involved in decision-making, and that they should be passive recipients of care. These beliefs are long engrained in many patients, especially those of older age groups. They are likely to be the result of many years of interactions with paternalistic orientated clinicians, and the belief that ‘doctor knows best’. It was suggested during the pre-testing interviews (Chapter 5) that children might be an appropriate target group for the ‘Your Health, Your Choice’ intervention. These ‘patients of the future’ could be targeted before they transition as independent adult patients into the healthcare system. It would be easier to shape peoples’ perceptions about the ‘normal’ patient role, than to change attitudes once they are formed. The intervention could be developed as part of a school-based programme and developed as a broader health literacy intervention e.g. integrated into the Personal, Social, Health and Economic (PSHE) Education component of the UK National Curriculum.

7.3 Evaluation Proposal – cluster randomised controlled trial and process evaluation of the ‘Your Health, Your Choice’ intervention

7.3.1 Evaluating complex interventions

The MRC framework⁽⁴⁵⁾ that has been used to guide the development of the ‘Your Health, Your Choice’ booklet has four key stages: development (Chapters 2, 3, 4, and 5), feasibility / piloting (Chapter 6), evaluation, and implementation. The results of Chapter 6 indicate that the intervention has relatively high levels of reach, dose and fidelity, and has the potential to change patients’ attitudes towards involvement in healthcare decisions, and thus prepare them for SDM. However, pilot-testing could not determine effectiveness of the intervention as a before-and-after design was not used, and randomisation did not occur. It is not in the scope of this thesis to conduct a full-scale evaluation, but this chapter concludes by presenting a detailed study protocol for the evaluation of the ‘Your Health, Your Choice’ intervention.

Chapter 6 described the feasibility / pilot-testing stage of the ‘Your Health, Your Choice’ booklet. As discussed above, the further pilot testing is recommended due to the low sample achieved. The next stage in the MRC complex intervention framework is the evaluation phase.⁽⁴⁵⁾ RCTs are the gold standard for establishing effectiveness of interventions, when randomisation is feasible. However, effect sizes do not provide researchers with information about the mechanisms of change, or policy makers with information on how an intervention might be replicated in their specific context, or whether trial outcomes can be reproduced. As such, the study protocol that will be presented will incorporate an evaluation of effectiveness and a parallel (further) process evaluation (see Figure 6.1, Chapter 6).⁽⁴⁶⁾ The process evaluation will build on the one conducted as part of the feasibility testing (Chapter 6), and will aim to assess fidelity and quality of implementation, explore causal mechanisms, and identify contextual factors associated with variation in clinical outcomes.

In addition to evaluating effectiveness and process, it is important for evaluations to examine cost-effectiveness and resource use implications. To date, very few trials of decision support interventions or SDM implementation programmes have considered system level savings.⁽¹⁸⁴⁾ Some studies have shown that SDM leads to a reduction in uptake of elective

procedures,(16) so potential cost savings will be important to consider in an evaluation of the intervention. An economic evaluation will be of interest to policy makers and to health service decision makers; however, improvements in system efficiency (e.g. reduced waiting times for surgery and faster access to alternative therapies) will also be of benefit to patients.

In summary, the evaluation should address several key issues. First, it should examine if the complex intervention results in improved quality of care (i.e. providing the right care for the patient) and outcomes (e.g. quality of life) for patients. Second, it should examine the mechanisms of change, the quality and fidelity of intervention implementation, and the contextual factors that might influence outcomes. Third, it should consider the cost-effectiveness of the intervention, and examine the impact on system efficiency. Essentially, the evaluation should consider whether the complex intervention has the potential to provide 'prudent healthcare' to patients; that is effective, efficient, and patient-centred.(185) The full-study protocol is outlined below.

7.3.2 Setting and context

Several factors need to be considered when selecting a setting for the evaluation of the 'Your Health, Your Choice' intervention. First, the clinical area and the specific decision point chosen need to be preference sensitive i.e. decisions which are appropriate for the SDM approach, where there is clinical equipoise over treatment options. Ideally, the evaluation setting selected should ensure that there are a large number of patients who are eligible for the decision point, and thus the sample. During the pilot-testing phase (Chapter 6), the intervention was delivered to women with early stage breast cancer, who were eligible to choose mastectomy or lumpectomy with radiation. This yielded a relatively small sample of women, as many of the women did not have this choice (e.g. those with breast cancer recurrence, co-morbidities). Further, breast cancer treatment decisions tend to be time-sensitive, and surgical decisions are irreversible. It would be valuable to evaluate the intervention in a setting where patients have more time to make decisions, and where they can revisit the decision point if necessary e.g. long term conditions.

Osteoarthritis of the knee affects almost 20% of the UK population aged 45 and over (4.7 million), with over 90,000 knee replacements carried out in 2012 (an increase of 7.5% from 2011).(186) Faced with an aging population, this is expected to rise considerably in future, reaching 6.4 million people by 2035.(187) Therefore, this patient group is relatively large, and

has the potential to yield a large sample. Further, treatment options for joint arthritis are preference sensitive,(188) they come with substantial trade-offs between benefits and risks to the patient, and a person-centred approach is advocated. Results shows that 20% of knee replacement patients are not satisfied, and 10% do not get significant pain relief.(189, 190) As such, this would provide an ideal setting to conduct an evaluation of the ‘Your Health, Your Choice’ intervention, embedded in a SDM care pathway.

As discussed previously, many SDM interventions are tested in controlled trial settings, rather than real-life settings. Healthcare service designers are keen to involve knee osteoarthritis patients in the preference sensitive decision-making process to improve patient outcomes. The Aneurin Bevan University Health Board (ABUHB), South East Wales, is currently redesigning the orthopaedic care pathway for patients with osteoarthritis of the knee. The redesigned pathway is based on the principle of person-centred healthcare, a cornerstone of NHS care across the UK and the focus of various government publications regarding the NHS.(25, 191, 192) The changes also reflect the policy in Wales to achieve ‘prudent healthcare’; that is to deliver effective, efficient, patient-centred healthcare.(191) With increasing pressures on NHS resources, there are calls for health organisations to consider how care can be delivered more cost-effectively, whilst maintaining quality; orthopaedics is a key priority area due to the number of patients referred to services annually.(187) The ABUHB alone deals with approximately 2,000 new referrals for knee surgery every year, and around 50% of these patients undergo knee replacement surgery. The ABUHB hope to achieve prudent healthcare, in part, by re-designing services around SDM.

This proposal aims to capitalise on planned service changes within an organisation that is committed to the SDM approach using interventions known to be effective for patient-based outcomes, and based on learning from large-scale implementation programmes on how to implement SDM.(33) The proposed redesign of the orthopaedic knee surgery services will change the way in which the service is delivered, and the way in which patients interact with the service. This provides an opportunity to evaluate the intervention in real-life clinical settings.

In summary, orthopaedic knee arthritis is an ideal setting for the evaluation for several reasons: the scale and impact of the healthcare issues (e.g. number of patients using services); the preference sensitive nature of knee arthritis decisions; the broader policy drive to deliver

‘prudent healthcare’; the supportive and receptive context; and the ability to capitalise on planned service changes, thus providing a more ecologically valid evaluation setting.

7.3.3 Aims and objectives

The aims of the study will be to evaluate:

1. Effects of a SDM pathway for osteoarthritis of the knee on patient outcomes, system efficiency, and costs; and
2. Whether an enhanced SDM pathway (with patient activation element i.e. ‘Your Health, Your Choice’ booklet) results in greater benefits

Based on the work conducted as part of thesis, I proposed that the ‘Your Health, Your Choice’ patient activation intervention cannot be used in isolation. The booklet needs to be implemented as part of a broader complex intervention, and embedded in a SDM implementation pathway. This would also include clinician-targeted interventions (e.g. skills training, engagement activities) and information provision interventions that provide patients with information about the options available (e.g. patient decision support interventions, such as Option Grids).(178) The second aim of the proposed study aims to determine if the ‘Your Health, Your Choice’ booklet is a necessary (additional) component to result in greater benefits. To examine this, we would compare an enhanced SDM pathway (which includes the patient activation element), with a standard SDM pathway.

Principal Outcomes

- a) Quality of life
- b) Conversion to knee surgery for patients presenting to GP with osteoarthritis of the knee within one year of referral

By comparing enhanced SDM with usual care, we aim to establish whether SDM leads to improved patient outcomes, including quality of life, improved system efficiency and cost savings. To date, RCTs of patient decision support tools have focused on patient reported outcomes, such as satisfaction, decisional conflict, and decisional regret.(16) Few trials have focused on health and resource outcomes, such as quality of life, or cost-effectiveness.(184) As above, I would not expect the patient activation intervention to work in isolation, and it should form part of a broader programme of SDM implementation. As such, the principal

outcome measures were selected on the basis of the whole intervention, rather than patient activation component alone.

Secondary Outcomes

Quantitative patient reported outcomes:

- Patient activation
- Knowledge of treatment options
- Patient-reported experience of SDM
- Decisional regret

Process evaluation

- *Implementation* – the structures, resources and processes through which delivery is achieved, and the quantity and quality of what is delivered;
- *Mechanisms of impact* – how intervention activities, and participants’ interactions with them, trigger change (including patients/clinicians attitudes and perceptions towards SDM pathways);
- *Context* – consider external factors that might influence the delivery and functioning of the intervention

Economic analysis

- Of non-surgical health services (e.g. GP visits, physiotherapy, weight loss management, joint injections) & surgical appointments

7.3.4 Study design

A randomised stepped wedge design will be used to examine the impact of the Enhanced SDM pathway. The stepped wedge randomised cluster trial is a novel research study design that involves random and sequential crossover of clusters from control to intervention phases, until all clusters are exposed. It is a pragmatic design suited to the evaluation of service redesign, and associated interventions.(193)

Key comparisons will be:

- Enhanced SDM pathway (Group 2b) versus usual care (Group 1) (see Figure 7.1)
- Enhanced SDM (Group 2b) versus standard SDM (Group 2a) (see Figure 7.2)

Usual Care (Group 1)

The usual care pathway (Group 1 i.e. control) is by/with referral direct from a general practitioner (GP) to a consultant orthopaedic surgeon, requesting an opinion about suitability for surgery. The ABUHB orthopaedic surgeons do not currently use SDM tools and have not undergone SDM training; patients do not currently receive a 'patient activation' intervention, such as the 'Your Health, Your Choice' booklet. Typical waiting times in ABUHB are about 6-9 months from referral, and a further 6-9 months on waiting lists if surgery is recommended (approximately 50% of patients convert to surgery).

SDM Care Pathway (Group 2a)

The standard SDM (redesigned) pathway includes 'therapy-led education' clinics led by nurses and physiotherapists in the community, instead of the consultant orthopaedic appointment:

- Led by clinical nurse specialists and physiotherapists who have received SDM skills training – general skills and how to deliver the educational / SDM interventions
- Group session for approximately 12 patients
- Patients given educational materials and the Option Grid(178) for osteoarthritis of the knee to facilitate discussion of the different management options, e.g. physiotherapy, joint injection, and weight management, and discussion of patients' preferences
- Opportunity for individual discussion and questions; clinics will be supported by 'expert patients' or representatives from Arthritis UK
- Outcome of this clinic will be the patient choosing self-management or direct access to physiotherapy, joint therapy, or weight management
- Following the 'therapy-led education' clinic, patients can also ask their GPs for a referral to an orthopaedic specialist
- Patients can re-access the clinic if needed to review options and choices.

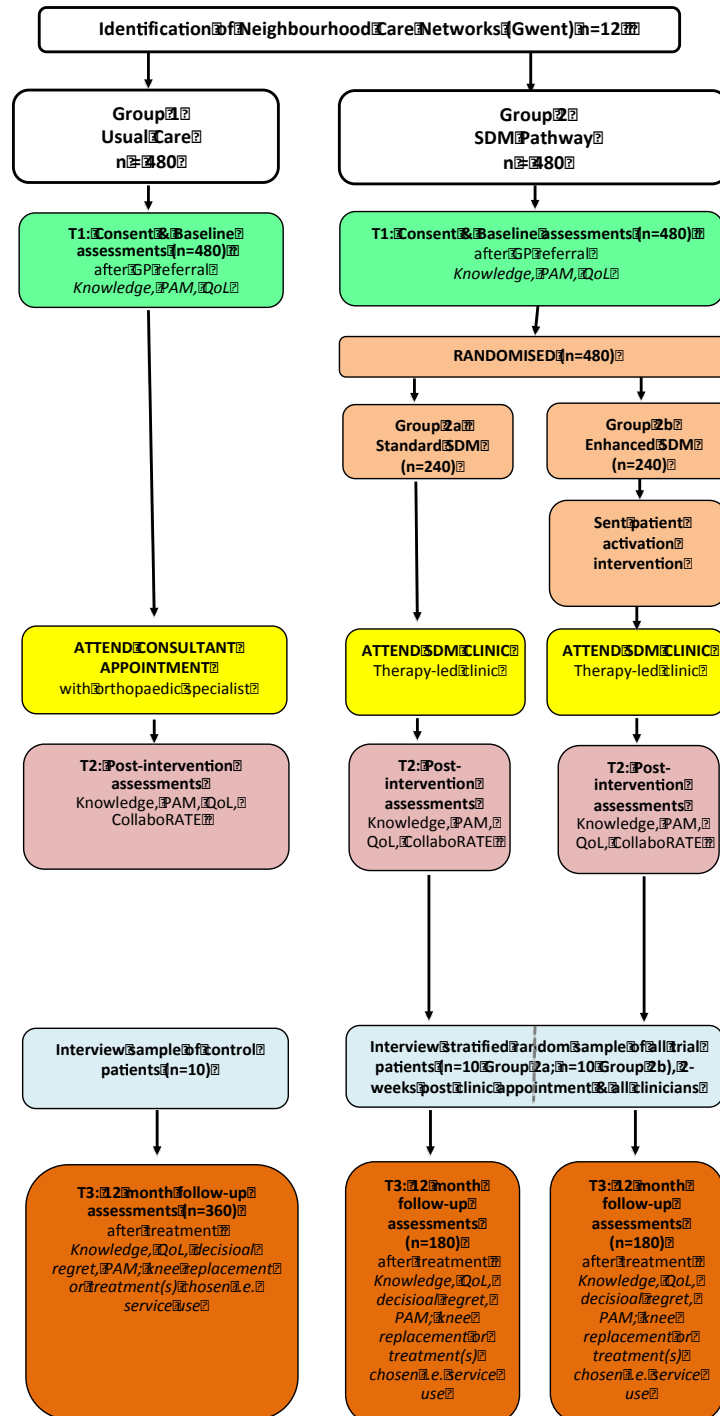
Enhanced SDM Pathway (Group 2b)

The enhanced SDM pathway is the same as the standard SDM pathway, with the addition of the ‘Your Health, Your Choice’ booklet (patient activation intervention). The booklet will be sent to patients ahead of their appointment at the ‘therapy-led education’ clinics.

The first comparison will be the redesigned enhanced SDM pathway (Group 2b), against usual care (Group 1). This evaluation will take place in the context of service redesign within the ABUHB Neighbourhood Care Networks (NCNs), whereby the new enhanced SDM pathway will be rolled out to NCNs sequentially. NCNs are described as collaborative networks comprising all Primary Care, health, and social care community providers operating within the boundaries of the neighbourhood, who plan and deliver services to districts of around 50,000 people- typically six-seven general practices and connected providers.⁽¹⁹⁴⁾ As these service changes are already planned and will take place in line with the ABUHB’s roll-out strategy, a traditional RCT is not feasible. However, a cluster trial and stepped-wedge design is suitable (see Figure 7.1), and offers a fair and randomized evaluation. NCNs act as a form of a cluster; the stepped-wedge design will roll out the enhanced SDM pathway across NCNs in a random order, with a before and after analysis conducted within NCNs. Patients in NCNs that are not ‘live’ will be in the control group (Group 1), and will act as comparators for those in ‘live’ NCNs.

The second comparison will be enhanced SDM (Group 2b) and standard SDM (Group 2a). This comparison will be at the individual patient level; therefore, a RCT will be embedded within the cluster trial (see Figure 7.1). Unlike the ‘therapy-led’ education sessions, which are being rolled out across the entire NCN as part of routine service change, it is possible to direct the additional patient activation intervention (‘Your Health, Your Choice’) booklet in the enhanced SDM arm to individual patients. Therefore, patients in ‘live’ NCNs (i.e. the SDM arm of the trial) will be randomized to receive either the enhanced SDM (Group 2b) or the standard SDM (Group 2a) pathway (see Figure 7.1 and 7.2). This embedded RCT will allow us to examine the potential additional impact (or necessity in order to achieve best outcomes) of the patient activation element of the enhanced pathway (i.e. the ‘Your Health, Your Choice’ booklet).

Figure 7.1 Flowchart of study progress



Control NCN patients will receive usual care (appointment with orthopaedic specialist), but will be contacted to consent to provide data to the study.

7.3.6 Outcome measures

The outcome measures that will be used are outlined below. Three key time points will be used during the evaluation: T1 = baseline; T2 = Post-intervention; T3 = 12-month follow-up.

Principal outcome measures

a) *Quality of Life (QoL)*

Specific QoL measured using the Oxford Knee Score(196) and generic QoL measured using EQ-5D-5L health index.(197)

T1/2/3

b) *Conversion to knee surgery for patients with osteoarthritis of the knee within one year of referral*

Available from routinely collected data – Secure Anonymised Information Linkage (SAIL) Databank(198)

Secondary Outcome Measures

Quantitative

- *Patient activation*

Measured using the 13-item Patient Activation Measure (PAM)(199)

T1/2/3

- *Knowledge*

Assessed by knowledge of treatment options questionnaire (based on information provided by the Option Grid)(178) Questionnaire available from previous study(200)

T1/2/3

- *Patient reported experience of SDM*

Measured using a short 3-item post intervention CollaboRATE questionnaire(174)

T2

- *Decisional regret*

Measured using the 5-item Decisional Regret Scale(201)

T3

Process Evaluation

- *Implementation*

Clinicians delivering the redesigned pathway will be trained in SDM and they will receive training on how. A researcher will observe a limited number of selected sessions using a fidelity checklist to assess if the intervention was delivered as planned, the clinician's SDM communication skills, whether patients' preferences are considered during the clinics, and process issues. We will also examine reach (whether the intended audience came into contact with the intervention and how) and dose (the quantity of the intervention implemented e.g. whether patients read the entire booklet).

- *Mechanisms of impact*

Patients' perceptions and attitudes towards the different care pathways

Interviews will be conducted with patients in the intervention groups as part of a process evaluation (approximately 20 interviews). These will take place in the patients' homes, within 2 weeks of them attending the clinic. These audio-recorded interviews will explore participants' perceptions of the SDM pathway e.g. informed decision-making, level of involvement, whether preferences were explored, expectations of care, attitudes towards healthcare professional conducting appointment, experience of intervention. We will also interview some patients from the control groups to understand and describe usual care. Data will be thematically analysed to identify emerging themes.(177)

Clinicians' attitudes towards the SDM pathways

Interviews will be conducted with all of the clinicians who deliver the intervention pathway (enhanced and standard). This will include clinicians who deliver the intervention clinics, and the consultants who deal with referrals from the intervention clinics (expected to be between eight-12 clinicians). We will explore perceptions of the redesigned pathway, strengths and weakness of the intervention, and process / delivery issues. Data will be thematically analysed to identify emerging themes.(177)

- *Context*

Throughout the process evaluation, any external factors that might impede or strengthen the effects of the intervention, or the way in which it is implemented, will be considered. Factors might include readiness or ability to change, organisational

norms, or the fact that the intervention is being delivered as part of planned, and resourced, service changes, which reflect the organisation's remit and targets. It will be important to consider if any external factors might have an impact on the replication of the intervention (process and outcomes). An understanding of the planned service change protocol will be key, and all documents (e.g. protocols, meeting minutes, project reports) will be examined. Interviews will also be conducted with clinicians who deliver the intervention, administrative teams involved in the implementation of the redesigned pathway, and with other key stakeholders (e.g. ABUHB service planners). Framework analysis(176) will be conducted using core constructs of the Normalization Process Theory (NPT).(202) NPT proposes that 'complex interventions become routinely embedded (implemented and integrated) as the result of people working, individually and collectively, to implement them'.(35, 203) This theory provides an ideal frame for understanding contextual factors.

Economic analysis

The economic analysis will include two separate components, it will determine the cost of delivering and implementing the intervention pathways and it will assess the NHS resource use (or savings) of patients in the intervention and control arms of the study. These will be combined and measured against the primary outcome measure to a) inform a cost-effectiveness analysis and b) against Quality –Adjusted Life Years to inform a cost utility analysis. An experienced health economist with experience in evaluation of complex interventions would be required to advise and support this economic analysis.

7.3.7 Sample size

Group 2 vs. Group 1

The study is based in the ABUHB NCNs. To my knowledge there are no data on intra-NCN correlation coefficients for the proportion of knee surgery referrals who receive surgery. As few such intra-cluster correlation coefficients (ICCCs) exceed 0.02, I conservatively base the estimated power on an ICCC of 0.02. To yield 80% power to detect differences of 15% in surgery rates between post-intervention and pre-intervention NCNs with a significance level of 5% requires an effective sample of 366. Hence I need to recruit a total sample of 920 [366 multiplied by 2.513, namely $1 + (920 / 12 - 1) \times 0.02$] to allow for clustering. To allow for

losses to follow-up by routine data, the target sample is 80 participants per NCN (960). As we shall analyse the stepped wedge design by time series analysis, effectively treating each cluster as its own control, this estimate is even more conservative. Allowing for losses to follow-up by participant-reported questionnaires of 25%, we estimate that this design will have 80% power to detect a 'small' effect size of 0.31 in Oxford Knee Score or EQ-5D-5L; because an ICC of 0.02 is even less likely for participant-reported outcomes than for surgery rates, this is also conservative.

Group 2b vs. Group 2a

We shall randomise individual patients between enhanced and standard SDM. As this will reduce ICCs to zero, the sample of 480 participants so randomised will yield analysable samples of 460 for surgery rates and 360 for patient-reported outcomes; and thus more than 80% power to detect differences between enhanced and standard groups of 15% in surgery rates and effect sizes of 0.3 in participant-reported outcomes.

7.3.8 Proposed study team

To ensure that the study is effectively managed and conducted, the correct team needs to be in place, covering the key areas of expertise. The proposed study is a cluster randomised controlled trial and a process evaluation. Therefore, a clinical trials unit should be involved to support trial methodology, and to manage, monitor, and analyse trial data. The trial includes an economic evaluation; therefore the trial team should include an experienced health economist, ideally with experience of evaluating complex interventions. An experienced qualitative researcher should be consulted for the qualitative elements of the study e.g. patient / clinician interviews analysis, NPT framework analysis, observations. Researchers with experience of implementation research and methodology should guide the process evaluation elements of the study. Patient and public representatives should form part of the core study team, and should also be involved in the early study design phase. Key ABUHB stakeholders involved in the service redesign should be consulted during the study design phase, and included in the core study team. Currently, this would include the Assistant Medical Director, the Primary Care Clinical Director, who is coordinating the planned services changes to the orthopaedic pathway, and clinical team members who will be delivering the new service.

7.3.9 Expected outputs and next steps

This research aims to assess whether a SDM pathway can improve patient-reported and also health outcomes, and service efficiency. I would expect the findings of the evaluation to show that SDM results in improved outcomes for patients including, quality of life, knowledge about condition and treatments, experience of decision-making, increased activation, and reduced decisional regret. It is hypothesised that the patient activation intervention is a necessary component for additional benefits.

Currently, there is little evidence regarding the impact of SDM on health outcomes and cost-effectiveness, the effects of SDM in routine healthcare settings, or the added value of patient activation interventions (Group 2b) in achieving greater benefits from SDM interventions. It is likely that the results of this process evaluation could influence how SDM programmes are implemented and evaluated in future. More broadly, I could expect the results of this study to benefit planners of services for knee arthritis across Wales and the UK. Findings will be shared with the ABUHB and the Planned Care Strategy Group (Welsh Government), who are initiating the planned service changes to the orthopaedic pathway, so they can extend the SDM intervention to other services. I expect the SDM pathway to result in fewer but more appropriate patients being referred to consultants, thus fewer undergoing surgery but sooner; and to enable patients who do not choose surgery to receive alternative treatments sooner. If the SDM intervention is effective, similar interventions should be implemented and evaluated for other preference-sensitive conditions, especially surgical.

Chapter 8

General Discussion

The studies described in this thesis aimed to assess patient-reported barriers and facilitators to SDM in order to develop and pilot-test a theory-based intervention, which aims to prepare patients to participate in SDM. This final chapter of the thesis presents an overview of the principal findings, discusses the strengths and weakness of the methodological approach, and considers implications for future implementation of SDM.

8.1 Knowledge is *not* power for patients – the importance of patient-reported barriers to SDM implementation

Recent efforts to implement SDM into routine clinical settings have tended to neglect patient-reported barriers and facilitators to participation. The focus has been on designing decision support tools for knowledge transfer, understanding and overcoming clinician-perceived barriers to implementation, and achieving clinician and healthcare organisation engagement. This oversight could be due to researchers and implementation scientists underestimating the importance of patient-reported factors, but it is more likely that this knowledge was not easily accessible and synthesised in a way that could usefully guide implementation attempts. In contrast, two iterations of a systematic review of clinician-reported barriers have been available to guide implementation programmes since 2006.^(57, 204) The aim of Chapter 2 was to systematically review the literature to identify patient-reported barriers and facilitators to SDM, and to synthesise these data into a practical taxonomy that could be used to guide intervention development and implementation.

My results showed that patients need knowledge *and* power to participate in SDM, and they highlight the significance of perceived power imbalances in the clinical encounter. The old adage that ‘doctor knows best’ is still very much prevalent and engrained in the minds of current patients, old and young. To date, researchers have focused on addressing part of the knowledge barrier (i.e. adequate information provision). However, my results show that knowledge provision alone is unlikely to encourage SDM for the majority of patients: perceived power imbalances and perceived acceptability of patient involvement in healthcare

decisions must also be addressed. Significantly, the patient-reported barriers identified in Chapter 2 contrast with existing literature on clinician-reported barriers, whereby clinicians perceive patients not wanting SDM as a key barrier.(57) The results of this thesis have shown that most patients feel that they *cannot* participate, rather than the more common view among clinicians that patients *won't* participate because they *don't want* to. Again, this demonstrates the importance of also considering patient-reported barriers during SDM implementation, and the significance of clinicians' attitudes. 'Collaborative deliberation' between patients and clinicians will rest upon a foundation of constructive interpersonal engagement, an invitation from the clinician to participate, and the support to do so.(205) Referring back to the 'activated' cancer patient in Chapter 2, Mr Schneider, he felt that 'medicine could tell us the numbers – probabilities – but to make the choice is the patient's right.' To achieve SDM in routine clinical practice, we need to develop interventions that help patients believe that they *can, should and would* be involved; that it is their right to be involved in decisions about their healthcare.

Chapter 3 found that existing interventions designed to prepare patients for SDM do not comprehensively address the key patient-reported attitudinal barriers to participation, and the majority were not theoretically grounded, thus making it difficult to understand mechanisms of change. Overall, the theoretical work of this thesis found that overcoming 'white coat silence' is one of the key challenges to successful SDM implementation, and that there was scope to develop an intervention that more comprehensively addressed patient-reported barriers to SDM. The systematic review conducted during Chapter 2 advances the field by describing a taxonomy of key patient-reported barriers and facilitators that need to be considered during SDM intervention design and implementation, in conjunction with clinician-reported barriers and organisational factors.

8.2 'Actions speak louder than words' - the significance of past experiences

The theory-guided process outlined in Chapter 4 led to the development of the 'Your Health, Your Choice' intervention. The systematic four-step BCW approach combined theory and empirical research to ensure that the key barriers and drivers of behaviour identified in Chapter 2 were addressed by the intervention, those being: knowledge;

professional role and identity; beliefs about capabilities; beliefs about consequences; and social influences. Chapter 5 focused on pre-testing the prototype intervention with lay users, clinicians, and local healthcare organisation representatives, using a qualitative interview method. Respondents were positive about the booklet's design and format, and the booklet appeared to be addressing key patient attitudinal barriers to participating in SDM, identified in Chapter 2. Chapter 6 built on the work of the pre-testing phase by pilot-testing the intervention using a process evaluation method, with real patients in a routine NHS setting. This allowed for a more ecologically valid view of how this intervention might translate into real practice. Patients who were referred to the Cardiff and Vale University Health Board Breast Care Centre were sent the intervention prior to their initial appointment, and a sample was also recruited for qualitative interviews. The patient group was also generally positive about the booklet's design and format, and the results indicate relatively high levels of reach (all of the intended target audience came into contact with it before their appointment), dose (the quantity of the booklet that was read by the patients), and fidelity (used as intended, by patients), especially among the less 'activated' patients.

The preliminary pilot-testing also found that the 'Your Health, Your Choice' booklet has potential to change patients' attitudes towards involvement in healthcare decisions, and thus prepare them for SDM. However, the results also highlighted the significance of contextual factors, such as patients' negative past experiences, and the impact this can have on the potential effectiveness of the booklet. Compared to the lay user and clinician / organisation representative groups, the patient group was far more pessimistic about SDM becoming a reality. The booklet helped these patients to know that they had choices available and to believe and accept that it is part of the patient role to take part in healthcare decision-making, but it had less impact on helping these patients to believe that clinicians actually want this. It appears that the booklet has adequately addressed the 'knowledge of choice' 'acceptability of patient involvement' barrier frequently cited by patients, but it has not adequately addressed 'social influences', such as perceived social norms about clinicians' attitudes towards patient involvement.

Fundamentally, negative past experiences with clinicians and the care system stick, and they trump the booklet's message that clinicians value patients' input. The pilot-testing patients reported various accounts of previous inappropriate care (e.g. wrong diagnosis), inadequate care processes (e.g. very long delays to see a specialist), and poor interactions with negative clinicians, and these experiences were only from a very small sample of eight patients. They

are also very aware of the time pressures faced by the clinicians, and the NHS more broadly, and this pressure translates to their own behaviour in a consultation e.g. not asking questions because of the amount of people in the waiting room. One patient, with vast experience of healthcare interactions, even went as far to say that the booklet was ‘NHS propaganda that just won’t happen in reality’, and it just served to ‘highlight the void between theory and practice’. When patients do have accounts of negative experiences, it is unsurprising that they have priorities other than becoming more involved in their healthcare decisions. In the list of top ten patient complaints published by the Patients Association, they broadly relate to problems with access, waiting times, and clinicians’ attitudes.(206) The cost of healthcare, or lack of resources to provide the NHS, waiting times, and patient safety errors dominate the media messages portrayed to patients. A quick scan of the UK online health news for one specific day identified the following headlines:

*‘Health Board vows immediate action after **waiting time targets missed**’*

*‘Care Quality Commission: three in four **hospitals failing**’*

*‘Overseas NHS nurses: restrictions lifted amid **widespread shortages**’*

*‘NHS faces biggest **financial crisis** in decades’*

*‘**Waiting times** hit new high’*

*‘Action demanded on **weekend NHS risk**’*

*‘**Safety is ‘big concern’** in NHS and care’*

*‘7-day GP opening **unachievable**’*

*‘Doctor’s Chief warns of **NHS collapse** this winter’*

When patients are presented with these messages on a day-to-day basis, it is unsurprising that their safety (which includes staying alive), waiting times, and access to clinicians who are not ‘rude’ is much more important than greater engagement with clinicians; as discussed in the pilot-testing chapter, *any* engagement is perceived as better than *no* engagement for those patients who have waited a considerable amount of time to see a specialist. Face-to-face communication in healthcare, and other sectors, is at a premium, and patients are acutely aware of this. There is a constant drive to move away from these types of interactions towards systems that can save time and resources e.g. online repeat prescriptions, self-service check-in at GP surgeries, and telephone consultations. When patients are faced with systems that discourage interaction and dialogue, it is difficult to also convey the message that

healthcare organisations want to encourage dialogue between clinicians and patients about healthcare choices. Patients are overwhelmed with the message that the NHS does not have enough money, staff or resources to provide safe and / or timely care. Rarely are patients presented with the message that the NHS would like them to become more involved in a discussion with their GP / nurse / consultant etc.

If we consider access to medical records, this is also an area where patients might be receiving mixed messages. Patient access to medical records remains, on the whole, a limited, complex, and sometimes costly process in the UK, although there is some indication of change in the US with innovations such as the OpenNotes initiative.(207) On the one hand we are trying to reassure patients that clinicians want them to be involved, they are the ‘experts in their own lives’, and patients should be involved in important decisions about their healthcare, which could include surgical and medical treatments. On the other hand, information about their eventual choices and outcomes is extremely limited and difficult to access. A recent survey on SERMO (a social networking site for doctors) asked members ‘should patients have access to their entire medical record – including notes, any recordings, etc.?’ Two thirds of the respondents were reluctant to share health data with their patients, and 17% were completely opposed to the idea. One doctor from the United States stated *‘the records remain private property of the physician who generated it for the care of the patient. If the patient doesn’t like that fact then they can go elsewhere.’*(208) Similar debates have arisen regarding patients’ rights to audio-record their consultations;(209, 210) the negative response from some doctors suggests that information exchanged within the clinical encounter is somehow *owned* by the clinician, and such requests question the clinician’s integrity. Considering all of the above, it is not surprising that the patients interviewed during pilot-testing are sceptical about the feasibility of SDM in routine care, and it is likely that other patients will also feel the same. That said, it does not mean that these priorities are not changeable; a discrete choice experience found that patients who are exposed to SDM place a higher valuation on it than those who are not (by randomisation).(124) The challenge is making sure that patients experience SDM in the first place.

Again, referring back to Mr Schneider the cancer patient, I stated he could be the ‘ideal’ SDM patient, as he believes that it is a patient’s right to be involved, and understands the importance of patients’ personal preferences in the decision–making process. However, the fact that he refers to himself as the ‘Patient from Hell’ in his book title also suggests that he believes that he is going ‘against the grain’, in some way, and that his behaviour is not

supported by some clinicians. If an activation intervention is used in isolation, it is likely that we will only change patients' expectations of what they *should* receive, but we will leave more patients perceiving that they are 'patients from hell' for wanting to become more involved. Of course, the potential negative implications of patients using the 'Your Health, Your Choice' intervention must be considered. Whilst the aim is to promote positive attitudes towards SDM and to encourage patients to become more engaged, in situations where patients are faced with disempowering clinicians, they might believe that the intervention 'falsely' reassured them in some way, which in turn might have a detrimental impact on their future beliefs and feelings of self-efficacy. I recommend that the booklet be used in conjunction with supportive clinicians with the appropriate skills, and in a receptive and supportive healthcare environment. However, even in this setting, there is no way to guarantee the receptiveness of every clinician. As such, in future iterations of the intervention, it might be more appropriate, and honest, to soften some of the key messages presented in the intervention e.g. by using sentences such as 'most' healthcare professionals welcome patients' involvement.

8.3 A 'SDM bundle' – patient activation will not work alone

It was clear from Chapter 2 that social influences and the perceived power imbalance between patient and clinician were significant factors affecting participation in SDM, and the pilot-testing with patients in Chapter 6 highlighted just how significant these barriers are, although this was a small sample. These barriers especially pronounced when the patient has experience of inadequate care, poor care processes, and negative interactions with clinicians. Pilot-testing revealed that the 'Your Health, Your Choice' booklet is a good place to start preparing and activating patients, but preparation to participate must be followed by enablement, and delivered as one component intervention as part of a broader 'SDM bundle': several interventions / practices that when performed collectively and reliably, have the potential to improve SDM outcomes for patients. Preliminary results indicate that 'Your Health, Your Choice' could be useful for signalling that healthcare choices do exist, providing a rationale for patient choice, and changing patients' attitudes towards the perceived acceptability of the active patient role in healthcare decision-making. However, it might have less impact on changing patients' attitudes about whether clinicians and healthcare organisations want them to become more involved (or social influences). For

patients, especially those with negative past experiences, actions will speak louder than words. Positive attitudes towards SDM and evidence of SDM behaviours amongst clinicians delivering patients' care will be key to reinforcing the messages delivered in the booklet: that patients *should* be involved, they *can* be involved, and clinicians *want* them involved. I acknowledge that clinicians will not be able to change the experience of every patient, especially those who still believe it is not part of the patients' role, but they should try to make it easier and safer for patients to feel included and respected when they want to be involved.

More broadly, preparation for and enablement to do SDM needs to be delivered in an organisational culture that overtly supports the approach. Contextual factors that support successful improvement and sustainability of quality in healthcare organisations have been synthesised in a recent review published by The Health Foundation.(211) 'Quality and coherence of policy' and 'supportive organisational culture' are two of the most important contextual factors at the meso level. This would include, for example, aligning the organisational objectives of delivering SDM with SDM human resource and training strategies that ensure the workforce is skilled, and the degree to which SDM is viewed and emphasised (possibly rewarded) as an organisational priority. It should be acknowledged that structural change, such as introducing patient choice and SDM, also requires psychological change (cultural change among patients, clinicians and the organisation). The Model for Understanding Success in Quality (MUSIC) also proposes that senior management support and organisational culture (i.e. values, beliefs and norms present in the microsystem) are key aspects of context that can influence successful quality improvement.(212) Fundamentally, if attempts to prepare and enable patients to do SDM are not embedded in a supportive organisation, they are unlikely to be successful.

This thesis has highlighted the significance of patients' perceptions about clinicians' beliefs and healthcare organisations' practices. If we want every patient to feel that they want to become more involved and that they are able to become more involved, implementation scientists will need to think more broadly than local clinical team and hospital level, and drive these messages from a public health angle using mass media. The '#hello my name is' campaign is one example of a successful mass social media campaign.(40) The campaign was started by a clinician with terminal cancer, who made the stark observation that most staff looking after her did not introduce themselves before delivering care. It aims to improve the relationship and human connection between clinician and patient, build trust, and promote

passionate care. Raising awareness that patient involvement is supported by the healthcare organisation is key for successful SDM, and mass media (including social media) campaigns have wide exposure and can increase awareness quickly and effectively. This might go some way to counteracting the negative mass media messages that patients are more familiar with.

Fundamentally, successful and sustainable implementation of routine SDM in healthcare rests upon two types of cultural change, which is a momentous challenge: cultural change amongst many clinicians and the healthcare organisation, and cultural change amongst patients, whereby both groups have their own values, goals, perceived roles, experiences, attitudes and assumptions. Given the challenges of cultural change, implementation researchers may want to focus their attention on ‘moulding’ attitudes and behaviours at the ‘grass roots’ level, rather than ‘changing’ them: it is difficult to turn a big ship, but it can be set on a different course for future generations. Embedding SDM into the undergraduate medical and nursing curriculum, and junior doctor and inter-professional training is essential. A receptive culture will only truly exist if clinicians see SDM as usual practice and as a fundamental component of safe and effective healthcare for patients, not as an optional style of communication if they have the time. A number of successful local improvement initiatives have been targeted at and driven by junior doctors, including the ‘Ask 1 Question’ campaign. It simply involves asking a patient ‘what can I do for you today’, with the goal of improving care at the bedside and understanding the patient’s daily goals.(213) Adolescents, children, and pregnant women, or ‘patients of the future’, would also be an ideal target audience for SDM interventions, as they are learning to interact with and navigate the healthcare system. It might be easier to shape perceptions about appropriate behaviour in a healthcare consultation before they have had experience of them, especially negative experiences.

8.4 Methodological strengths and weaknesses

8.4.1 Patient-reported taxonomy and review of interventions

The first key step in developing a complex intervention is to understand the existing evidence base. Two comprehensive literature reviews were conducted as part of this thesis, which provide a sound evidence base for intervention development: a systematic review and a literature review. The systematic review identified and described patient-reported barriers

and facilitators to patient involvement in healthcare decisions. To my knowledge, this is the first systematic review to focus exclusively on patient-reported barriers and facilitators to SDM, and direct enquiry with patients in the primary studies is a significant strength of this study. The results from 44 studies were synthesised to produce a taxonomy that guided the development of the intervention, ensuring it was based on empirical evidence. The literature review identified and critically evaluated existing interventions that aim to prepare patients to participate in SDM. The identified interventions were evaluated against the patient-reported barriers and facilitators identified in Chapter 2, thus allowing me to make a reasonable judgment about the need for a new intervention. I have acknowledged that new interventions were identified after the review was conducted (August 2013), but examination of these found that they would not change the results of the literature review, and there was still scope to develop a more comprehensive intervention that addressed the key barriers identified in Chapter 2.

8.4.2 MRC framework and BCW approach to intervention design and testing

The ‘Your Health, Your Choice’ intervention was developed using an accepted and robust framework for developing complex interventions.⁽⁴⁵⁾ The MRC framework ensured that the intervention was developed systematically, using the best available evidence, and appropriate theory. Behaviour change interventions tend to be more effective if they are based on evidence-based principles of behaviour change (theoretically grounded).⁽¹⁶¹⁾ With this in mind, a theory-based intervention was developed using the Behaviour Change Wheel (BCW) Guide⁽⁴⁷⁾ To my knowledge, this theory has not previously been used to develop SDM interventions, and thus offers a novel approach in this field of research. Various alternative behaviour change theories exist, and could have been used for the development of the intervention. For instance, the Health Belief Model⁽²¹⁴⁾ could have provided some insight into the peoples’ beliefs about active patient involvement, their perceived benefits of this approach, their perceived barriers to involvement, and the impact of self-efficacy on their ability to enact the behaviour. However, the danger of selecting one or two theoretical approaches to guide intervention development is the possibility of missing the full range of possible influences, and key determinants of behaviour not being addressed by the intervention. This is especially important given the different barriers reported by patients in Chapter 2, and the significance of social influences. Therefore, the BCW guide was chosen

to guide the theoretical development of the intervention. The BCW is an integrated behaviour change framework, which combined 33 different behaviour change theories, and 128 theoretical constructs of behaviour change. The origins of the framework are in clinical implementation settings, which is also suitable for this thesis as the intervention was pilot-tested in a routine breast care setting. The systematic four-step approach combined theory and empirical research to select intervention components, moving through a process of identifying target behaviours, mapping barriers / facilitators to theoretical domains, selecting behaviour change techniques, and developing the intervention. The BCW allowed me to design an intervention that addressed the key barriers identified, and it also provided a framework for understanding potential mechanisms of change during the pilot-testing.

8.4.3 Intervention testing methods

The pre-testing process (Chapter 5) included members of the general public, clinicians, and health board representatives; this ensured that feedback was sought from all parties who would eventually be involved the implementation of the booklet. The clinician sample consisted of nurses who are currently involved in a large-scale SDM implementation programme, and individuals whose role focused on the improvement in patient care. The user group who volunteered to take part in the interviews (convenience sample) are probably quite motivated individuals. Therefore, it is important to consider that the pre-testing was conducted with individuals who are likely to be more receptive to the SDM approach, and the user-group may be more 'activated' than the general population.

Qualitative interviews were chosen for pre-testing and pilot-testing, and this allowed for detailed understanding of causal mechanisms and the potential impact of the booklet on patients' attitudes. However, this method also relied on self-reported use of the intervention, which may not provide an accurate representation of reach, dose, fidelity, or respondents' actual beliefs. In the one-to-one interview setting, respondents might have provided socially acceptable answers that did not represent how they felt about the booklet, or the true impact of the booklet on their attitudes, especially if they knew what the purpose of the booklet was and if they perceived that the interviewer developed the booklet. They might have wanted to appear engaged in the booklet, and reported that they read more than they did. Further, whilst every effort was made to remain neutral and to use the semi-structured interview questions to guide discussions, that fact that I have been heavily involved in the development of the booklet might have led to some moderator bias.

Think-aloud techniques might be more useful in future work as it will guarantee that the patients have used the booklet in the way that is intended, and it would help to understand patients' cognitive processes as they read the key messages. The 'think-aloud' method is commonly used for usability testing, and involves participants thinking aloud as they perform a task. This approach would allow better insight into how users of the booklet interpret and respond to it, and analysis of this data could feed into iterative development of the intervention. An independent researcher who makes it clear that they have not been involved in the development of the booklet would also be beneficial for future testing. Clearly, the pilot-testing stage was not a before and after trial. It is therefore difficult to know what patients thought beforehand, and whether the booklet did change patients' attitudes. Self-reports from patients are a useful indicator of change, but future testing would need to consider patients' beliefs before and after exposure to the intervention, in order to make more concrete judgments about the booklet's effectiveness. It should be noted that the sample consists only of females, which might limit the generalizability of the findings; further work must test the booklet in settings with higher proportions of male patients to determine if there are unique contextual factors that might influence booklet implementation and effectiveness. It was not feasible to conduct a full-scale evaluation of the 'Your Health, Your Choice' booklet as part of this thesis, which would address some of the weaknesses listed above. However, clear plans for further work, including a cluster-randomised trial and process evaluation, are detailed in Chapter 7.

8.4.4 Implementation setting – 'research fatigue'

The 'Your Health, Your Choice' intervention is based on a clear analysis of need, it has a strong theoretical basis, and the development and testing process was guided by well-established methods. However, a significant weakness of this thesis has been the ability to effectively pilot-test the intervention in a real-life clinical setting with a sufficient sample of patients. As discussed throughout the thesis, I would not expect the 'Your Health, Your Choice' intervention to work in isolation, it would only work in combination with complementary SDM processes. It needed to be embedded within a team that agreed with the principle of SDM, who were receptive to their patients becoming more involved, and who had the necessary SDM skills to support the patient through the decision making process. The team might also use decision support interventions to assist with knowledge transfer of treatment options, and to support the deliberation process. Fortunately, the

research team where I am based in Cardiff University have worked very closely with the Cardiff and Vale Breast Care Centre over the last five years on an ongoing SDM implementation programme. The Breast Care Centre is supportive of SDM, team members have attended skills training workshops, they were involved in the development and testing of SDM interventions, and they have embedded a decision support tool(178) and routine decision quality measurement into their care pathway. On paper, this team offered an ideal scenario for embedding a new SDM intervention, which complemented the wider SDM practices. However, a number of factors might have impacted on the ability to obtain a reasonable sample of patients in this team, and on the overall effectiveness of the pilot-testing.

Experience on parallel SDM research programmes has shown that this patient population is particularly difficult to recruit.(181) Many of the patients are extremely emotional and worried about a cancer diagnosis after initial referral, and for those who are diagnosed, they receive surgery and follow-up treatment within two weeks, and thus they are recovering both physically and psychologically. The number of parallel research projects taking place at the Breast Care Centre also impaired recruitment; this includes the ongoing MAGIC programme, but also other clinical and non-clinical research. The research nurses are sensitive to demands on the patients, especially when many of them are dealing with a cancer diagnosis, and they are keen not to over burden them with requests for research participation. Therefore, when recruitment was low during pilot-testing, it was a difficult task to ask the research nurses to send more invitations to an already 'over-researched' population. In less emotional settings, it might be feasible to follow-up invited patients more closely in order to achieve a higher sample; however, it was not deemed acceptable in this setting.

Additional team factors might have also impacted on the effectiveness of the pilot-testing more broadly, regardless of the sample size. Whilst I can be fairly confident about the fidelity of the 'Your Health, Your Choice' intervention, I cannot be sure about the fidelity of the broader SDM approach that is used at the Breast Care Centre. Most of the clinical team received SDM skills training as part of the MAGIC programme. However, some clinicians (mainly consultants / surgeons) were unable to attend this session, and new team members who have been recruited since the last training session in 2013 will not have received this training. Therefore, it is likely that some of the patients were not seen by a clinician who had received SDM skills training, or worse, they were seen by a clinician who was not receptive

to the SDM approach. As we have seen from the pilot-testing, follow-up from a clinician who outwardly supports and encourages patient involvement is important. Work by Lloyd et al(35) has shown just how difficult it is to engage some clinicians, and the challenge of 'building coherence', or a shared understanding of the SDM approach amongst different team members. Some clinicians are outwardly against the approach (e.g. seeing their role as decision maker to 'protect' their patients), and some clinicians cannot see how SDM differs to their current care (e.g. 'we do this already'). The SDM skills workshops were key in building coherence and shared values about SDM amongst team members, and this is the first step in embedding new interventions into routine clinical care.(202) If some team members did not attend the SDM workshops, it is likely that they view SDM differently from their colleagues who did attend, and who have been involved in the SDM implementation programme from inception.

The importance of a local clinical champion leading change was a key learning point from the first phase of the MAGIC implementation programme;(33) a factor that has been identified as important to success across other improvement programmes(211) Throughout the MAGIC implementation programme, the project was driven by a motivated clinical nurse specialist. This person was the key contact with the research team, they played a significant role in engaging other clinical team members in the work, and they took responsibility for the overseeing the development, testing, and delivery of the different SDM initiatives (e.g. making sure that all clinicians used the Option Grid). This same clinical nurse specialist also agreed to act as lead for the pilot-testing phase of the thesis, and I worked closely with her to develop the protocol. However, this nurse has since retired from her role, and her leave coincided with the recruitment of patients for the pilot-testing. Subsequently, this led to some implementation process issues that could not have been foreseen during the planning phase. After the pilot-testing protocol had been developed, and the booklet / recruitment documents had been sent to patients in the post, it transpired that the Breast Care Centre do not send appointment letters to patients; they telephone each patient who has been referred to arrange an appointment, with no confirmation letter. The disconnect between the telephone appointment confirmation process used by the Breast Care Centre and the intervention being sent via post meant that some patients did not make the link between the two. It is likely that this caused problems for recruitment; some of the patients who agreed to take part in the pilot-testing stated that they were not aware that it had anything to do with the Breast Care Centre, and they perceived it as a Cardiff University project. Feedback from Chapter 5 indicated that the booklet should be sent directly from the

team that patients would be seeing, as this provides ‘permission’ to take part; this seems especially important given patients’ views in Chapter 6 that clinicians do not want patients involved. Therefore, this process issue caused problems for recruitment, and it might also impact on the effectiveness of the booklet.

As discussed above, an engaged team that is routinely using SDM interventions was deemed important for the successful implementation of the ‘Your Health, Your Choice’ intervention. There are clear benefits to using such a team, and it is important to the success of the patient activation intervention, but it does also present problems. I have begun to witness ‘research fatigue’ in this team, with some team members disengaging from the broader SDM work. They have worked closely with researchers for five years, developing and testing SDM interventions. This team has also undergone some level of cultural change regarding their approach to patient decision-making, and to some extent, they have embedded SDM interventions into their routine clinical practice. Sustainability and maintaining motivation in implementation teams is a key challenge, and this was not facilitated by the departure of the key clinical champion for this work. Also, it might be the case that the clinicians perceive that they are already delivering a SDM approach, and there is little need for any further interventions. Their patients receive a decision support tool (when relevant), most of the team have received SDM training, and routine data collection has shown an improvement in patients’ knowledge about their treatment options over time. In terms of building coherence about the SDM approach,(35, 202) we might have reached a point where these clinicians again view that they ‘do this already’, and they do not perceive any value in further interventions. Clearer attempts should have been made to highlight the key patient-reported barriers to SDM, and to explain that their efforts as clinicians alone are not sufficient to actively engage most patients in a SDM dialogue. Fundamentally, further attempts should have been made to explain how all of the different parts of the ‘SDM intervention bundle’ might work together to achieve better results and greater patient engagement.

Overall, the sample limitation should be carefully considered when discussing the applicability and generalisability of the results in Chapter 6. This thesis has developed a theoretically sound intervention, and provided preliminary results about the potential effectiveness and feasibility of the intervention; but, further pilot-testing and a follow-up trial are essential to address some of the weaknesses identified above. Suggestions for further

research are presented in Chapter 7, but in short, further pilot-testing with a larger group of patients will establish if the pilot-testing patients' attitudes towards the intervention are representative of a larger patient group i.e. believing that it is part of the patient's role to take part in SDM, but also believing that clinicians do not want patients involved in SDM. Pilot-testing in other clinical areas with different patients compositions would give a better indication of how the intervention might work in other settings. Future testing of this intervention will also need to ensure fidelity of what the clinicians are delivering to patients, or the broader SDM approach; a controlled trial setting with a parallel process evaluation can support this. A controlled trial would also allow me to determine if clinicians with SDM skills, who might also use decision support tools, is sufficient to encourage SDM among patients, or if the 'Your Health, Your Choice' intervention is a necessary (additional) component that would result in greater benefits (this is discussed further in Chapter 7).

8.5 Conclusion

The work in this thesis has highlighted the significance of patient-reported barriers in the development and implementation of SDM interventions. Preparing patients for SDM is an important part of making sure that it becomes embedded into routine clinical practice. However, one of the biggest challenges will be to change patients' perceptions that clinicians do not want them to become more involved in their healthcare decisions. Implementation researchers are not only dealing with behaviour and attitudinal change at an individual patient level; they are faced with the considerable task of changing cultural norms amongst patients, clinicians *and* organisations. Therefore, preparation followed by enablement in a receptive organisation is essential. Fundamentally, we must be careful not to activate patients so that they perceive themselves as '*the patient from hell*' for wanting to take part in their healthcare decisions. Unfortunately, researchers are tasked with embedding patient and clinician-targeted SDM interventions in a healthcare culture characterised by scarcity and time pressures, and patients seem to be acutely aware to this: patients might suppress their desire to be informed and involved as it could be a recipe for conflict and burnout. We need to reassure patients and public that their input is encouraged, valued, and feasible, but organisational culture might be one of the biggest barriers to reassuring patients that SDM can be a reality.

Reference List

1. Elwyn G, Frosch D, Thomson R, Joseph-Williams N, Lloyd A, Kinnersley P, Cording E, Tomson D, Dodd C, Rollnick S, Edwards A, Barry M. Shared decision making: a model for clinical practice. *J Gen Intern Med.* 2012;27(10):1361-7.
2. Mulley AG, Trimble C, Elwyn G. Stop the silent misdiagnosis: patients' preferences matter. *BMJ.* 2012;345:e6572.
3. Parsons T. *The Social System.* New York: Free Press; 1951.
4. Kaba R, Sooriakumaran P. The evolution of the doctor-patient relationship. *Int J Surg.* 2007;5(1):57-65.
5. Roter D. The enduring and evolving nature of the patient-physician relationship. *Patient Educ Couns.* 2000;39(1):5-15.
6. Emanuel EJ, Emanuel LL. Four models of the physician-patient relationship. *JAMA.* 1992;267(16):2221-6.
7. Armstrong D. The emancipation of biographical medicine. *Soc Sci Med.* 1979;13A:1-8.
8. Lown BA, Hanson JL, Clark WD. Mutual influence in shared decision making: a collaborative study of patients and physicians. *Health Expectations.* 2009;12(2):160-74.
9. Rothman DJ. The origins and consequences of patient autonomy: a 25-year retrospective. *Health Care Anal.* 2001;9(3):255-64.
10. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics.* 4th ed. New York: Oxford University Press; 1994.
11. Department of Health. *The patient's charter.* London: HMSO; 1991.
12. Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango). *Soc Sci Med.* 1997;44(5):681-92.
13. Towle A, Godolphin W. Framework for teaching and learning informed shared decision making. *BMJ.* 1999;319(7212):766-71.
14. Elwyn G, Edwards A, Kinnersley P, Grol R. Shared decision making and the concept of equipoise: the competences of involving patients in healthcare choices. *Br J Gen Pract.* 2000;50(460):892-9.
15. Elwyn G, Lloyd A, May C, van der Weijden T, Stiggelbout A, Edwards A, et al. Collaborative deliberation: A model for patient care. *Patient Educ Couns.* 2014.

16. Stacey D, Legare F, Col N, Bennett CL, Barry MJ, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev*. 2014(10):CD001431.
17. Greenfield S, Kaplan S, Ware JE, Jr. Expanding patient involvement in care. Effects on patient outcomes. *Ann Intern Med*. 1985;102(4):520-8.
18. O'Connor AM, Boyd NF, Tritchler DL, Kriukov Y, Sutherland H, Till JE. Eliciting preferences for alternative cancer drug treatments. The influence of framing, medium, and rater variables. *Med Decis Making*. 1985;5(4):453-63.
19. Kasper JF, Mulley AG, Jr., Wennberg JE. Developing shared decision-making programs to improve the quality of health care. *QRB Quality review bulletin*. 1992;18(6):183-90.
20. Health Dialog. Shared decision making [Internet]. 2015 [cited 2015 Oct 26]. Available from: <http://www.healthdialog.com/solutions/shared-decision-making>
21. NHS Right Care Programme. Shared decision making [Internet]. 2012 [cited 2015 Oct 26]. Available from: <http://sdm.rightcare.nhs.uk/>
22. Secretary of State for Health. *Equity and Excellence: Liberating the NHS*. London: The Stationary Office; 2010.
23. Department of Health. *Health and Social Care Bill 2010-2011*. London: House of Commons; 2011.
24. Welsh Government. *Together for health: a five year vision for the NHS in Wales*. London: HMSO; 2011.
25. The Scottish Government. *The healthcare quality strategy for NHSScotland*. Edinburgh: The Scottish Government; 2010.
26. Department of Health Social Services and Public Safety. *Quality 2020: A 10-year strategy to protect and improve quality in health and social care in Northern Ireland*. London: HMSO; 2011.
27. Frosch DL, Moulton BW, Wexler RM, Holmes-Rovner M, Volk RJ, Levin CA. Shared decision making in the United States: policy and implementation activity on multiple fronts. *Z Evid Fortbild Qual Gesundheitswes*. 2011;105(4):305-12.
28. Legare F, Stacey D, Forest PG, Coutu MF. Moving SDM forward in Canada: milestones, public involvement, and barriers that remain. *Z Evid Fortbild Qual Gesundheitswes*. 2011;105(4):245-53.
29. Department of Health. *The NHS Constitution*. London: Department of Health; 2009.
30. General Medical Council. *Good Medical Practice* [Internet]. 2013 [cited 2015 Oct 26]. Available from: http://www.gmc-uk.org/guidance/good_medical_practice.asp
31. National Institute for Health and Care Excellence. *Quality statement 6: shared decision making* [Internet]. 2013 [cited 2015 Oct 26]. Available from:

<https://www.nice.org.uk/guidance/qs15/chapter/quality-statement-6-shared-decision-making>

32. Mulley AG. The Role of Shared Decision Making in Achieving Allocative Efficiency in Health Systems. In: Edwards A, Thomson R, Elwyn G, editors. *Shared Decision Making in Healthcare*. 3rd ed. Oxford: Oxford University Press; In Press.
33. The Health Foundation. *The MAGIC programme: Evaluation*. London: The Health Foundation; 2013.
34. Langley GL, Moen R, Nolan KM, Nolan TW, Normal CL, Provost LP. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance*. 2nd ed. San Francisco: Jossey-Bass Publishers; 2009.
35. Lloyd A, Joseph-Williams N, Edwards A, Rix A, Elwyn G. Patchy 'coherence': using normalization process theory to evaluate a multi-faceted shared decision making implementation program (MAGIC). *Implement Sci*. 2013;8(1):102.
36. Elwyn G, Lloyd A, Joseph-Williams N, Cording E, Thomson R, Durand MA, Edwards A. Option Grids: Shared decision making made easier. *Patient Educ Couns*. 2012;90(2):207-12.
37. The Health Foundation. *Implementing shared decision making: clinical teams' experiences of implementing shared decision making as part of the MAGIC programme*. London: The Health Foundation; 2013.
38. Frosch DL, May SG, Rendle KA, Tietbohl C, Elwyn G. Authoritarian physicians and patients' fear of being labeled 'difficult' among key obstacles to shared decision making. *Health Aff (Millwood)*. 2012;31(5):1030-8.
39. Francis RQC. *Report of the Mid Staffordshire NHS foundation trust public enquiry*. London: HMSO; 2013.
40. Granger K. *The Other Side* [monograph online]. Kindle edition; 2012.
41. Aronson L. "Good" patients and "difficult" patients: rethinking our definitions. *N Engl J Med*. 2013;369:796-7.
42. Tomlinson J. *A Better NHS: Exploring the relationships between doctors and patients and health policy* [Internet]. 2014 [cited 2015 Oct 26]. Available from: <http://abetternhs.wordpress.com/>.
43. Edwards M, Wood F, Davies M, Edwards A. The development of health literacy in patients with a long-term health condition: the health literacy pathway model. *BMC Public Health*. 2012;12:130.
44. Nutbeam D. Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century. *Health Promot Int*. 2000;15(3):259-67.
45. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*. 2008;337:a1655.

46. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, Moore L, O’Cathain A, Tinati T, Wright D, Baird J. Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*. 2015;350:h1258.
47. Michie S, Atkins L, West R. *The Behaviour Change Wheel: A guide to designing interventions*. Great Britain: Silverback Publishing; 2014.
48. Coulter A, Collins A. *Making shared decision making a reality: no decision about me without me*. London: The Kings Fund; 2011.
49. Department of Health. *Liberating the NHS: No decision about me without me*. London: Crown; 2010.
50. Department of Health. *The Operating Framework for the NHS in England 2011/12*. London: NHS Finance, Performance & Operations Directorate; 2011.
51. Government of Saskatchewan. *Government Goal-Security: Plan for 2010-2011*. Saskatchewan; 2009.
52. Saskatchewan Ministry of Health. *For Patients' sake: Patient first review commissioner's report to the Saskatchewan Minister of Health*. Regina, Saskatchewan; 2009.
53. Patient protection and affordable care act, HR 3590: 11th Congress. 2010. Available from: <https://www.govtrack.us/congress/bills/111/hr3590/text>
54. Washington State. *Blue ribbon commission on health care costs and access, E2S S.B. 5930*. 2007. Available from: <http://www.ofm.wa.gov/healthcare/planning/finalreport.pdf>
55. Coulter A, Edwards A, Elwyn G, Thomson R. Implementing shared decision making in the UK. *Z Evid Fortbild Qual Gesundheitswes*. 2011;105(4):300-4.
56. Holmes-Rovner M, Valade D, Orlowski C, Draus C, Nabozny-Valerio B, Keiser S. Implementing shared decision-making in routine practice: barriers and opportunities. *Health Expect*. 2000;3(3):182-91.
57. Legare F, Ratté S, Gravel K, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions. *Patient Educ Couns*. 2008;73(3):526-35.
58. Lake Research Partners for the Informed Medical Decision Making Foundation. *Informing and involving patients in medical decisions: The primary care physicians' perspective*. Boston: Informed Medical Decisions Foundation; 2009.
59. Elwyn G, Scholl I, Tietbohl C, Mann M, Edwards A, Clay K. "Many miles to go..." A systematic review of the implementation of patient decision support interventions into routine clinical practice. *BMC Med Inform Decis Mak*. 2013; 13 (Supplement 2): S14.

60. Belkora JK, Volz S, Teng AE, Moore DH, Loth MK, Sepucha KR. Impact of decision aids in a sustained implementation at a breast care center. *Patient Educ Couns.* 2012;86(2):195-204.
61. Frosch DL, Singer KJ, Timmermans S. Conducting implementation research in community-based primary care: a qualitative study on integrating patient decision support interventions for cancer screening into routine practice. *Health Expect.* 2011;14 Suppl 1:73-84.
62. O'Connor AM, Graham ID, Visser A. Implementing shared decision making in diverse health care systems: the role of patient decision aids. *Patient Educ Couns.* 2005;57(3):247-9.
63. Uy V, May SG, Tietbohl C, Frosch DL. Barriers and facilitators to routine distribution of patient decision support interventions: a preliminary study in community-based primary care settings. *Health Expect.* 2014;17(3):353-64.
64. Elwyn G, Laitner S, Coulter A, Walker E, Watson P, Thomson R. Implementing shared decision making in the NHS. *BMJ.* 2010;341:c5146.
65. Caldon LJ, Collins KA, Reed MW, Sivell S, Austoker J, Clements AM, Patnick J, Elwyn G. Clinicians' concerns about decision support interventions for patients facing breast cancer surgery options: understanding the challenge of implementing shared decision-making. *Health Expect.* 2011;14(2):133-46.
66. Legare F, Stacey D, Turcotte S, Cossi MJ, Kryworuchko J, Graham ID, Lyddiatt A, Politi MC, Thomson R, Elwyn G, Donner-Banzhoff N. Interventions for improving the adoption of shared decision making by healthcare professionals (Review). *Cochrane Database Syst Rev.* 2014;9:CD006732.
67. Fraenkel L, McGraw S. What are the essential elements to enable patient participation in medical decision making? *J Gen Intern Med.* 2007;22(5):614-9.
68. Bhavnani V, Fisher B. Patient factors in the implementation of decision aids in general practice: a qualitative study. *Health Expect.* 2010;13(1):45-54.
69. Eldh AC, Ekman I, Ehnfors M. Conditions for patient participation and non-participation in health care. *Nurs Ethics.* 2006;13(5):503-14.
70. Say R, Murtagh M, Thomson R. Patients' preference for involvement in medical decision making: a narrative review. *Patient Educ Couns.* 2006;60(2):102-14.
71. Benbassat J, Pilpel D, Tidhar M. Patients' preferences for participation in clinical decision making: a review of published surveys. *Behav Med.* 1998;24(2):81-8.
72. QSR International Pty Ltd. NVivo qualitative data analysis software. Version 11. 2014.
73. Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic reviews. *BMC Med Res Methodol.* 2008;8(45). DOI: 10.1186/1471-2288-8-45.

74. Peek ME, Odoms-Young A, Quinn MT, Gorawara-Bhat R, Wilson SC, Chin MH. Race and shared decision-making: perspectives of African-Americans with diabetes. *Soc Sci Med.* 2010;71(1):1-9.
75. Peek ME, Wilson SC, Gorawara-Bhat R, Odoms-Young A, Quinn MT, Chin MH. Barriers and facilitators to shared decision-making among African-Americans with diabetes. *J Gen Intern Med.* 2009;24(10):1135-9.
76. Avis M. Choice cuts: An exploratory study of patients' views about participation in decision-making in a day surgery unit. *Int J Nurs Stud.* 1994;31(3):289-98.
77. Barnard KD, Cradock S, Parkin T, Skinner TC. Effectiveness of a computerised assessment tool to prompt individuals with diabetes to be more active in consultations. *Practical Diabetes International.* 2007;24(1):36-41.
78. Caress AL, Beaver K, Luker K, Campbell M, Woodcock A. Involvement in treatment decisions: what do adults with asthma want and what do they get? Results of a cross sectional survey. *Thorax.* 2005;60(3):199-205.
79. Caress AL, Luker K, Woodcock A, Beaver K. A qualitative exploration of treatment decision-making role preference in adult asthma patients. *Health Expect.* 2002;5(3):223-35.
80. Cohen H, Britten N. Who decides about prostate cancer treatment? A qualitative study. *Fam Pract.* 2003;20(6):724-9.
81. Doherty C, Doherty W. Patients' preferences for involvement in clinical decision-making within secondary care and the factors that influence their preferences. *J Nurs Manage.* 2005;13(2):119-27.
82. Kelsey J, Abelson-Mitchell N, Skirton H. Perceptions of young people about decision making in the acute healthcare environment. *Pediatr Nurs.* 2007;19(6):14-8.
83. Skea Z, Harry V, Bhattacharya S. Women's perceptions of decision-making about hysterectomy. *BJOG.* 2004;111(2):133-42.
84. Thompson AG. The meaning of patient involvement and participation in health care consultations: a taxonomy. *Soc Sci Med.* 2007;64(6):1297-310.
85. Beaver K, Campbell M, Craven O. Colorectal cancer patients' attitudes towards involvement in decision making. *Health Expect.* 2009;12(1):27-37.
86. Entwistle V, Prior M, Skea ZC, Francis JJ. Involvement in treatment decision-making: its meaning to people with diabetes and implications for conceptualisation. *Soc Sci Med.* 2008;66(2):362-75.
87. Beaver K, Jones D, Susnerwala S, Craven O, Tomlinson M, Witham G, et al. Exploring the decision-making preferences of people with colorectal cancer. *Health Expect.* 2005;8(2):103-13.
88. Adler SR, McGraw SA, McKinlay JB. Patient assertiveness in ethnically diverse older women with breast cancer: Challenging stereotypes of the elderly. *J Aging Stud.* 1998;12(4):331-50.

89. Belcher VN, Fried TR, Agostini JV, Tinetti ME. Views of older adults on patient participation in medication-related decision making. *J Gen Intern Med.* 2006;21(4):298-303.
90. Curtis JR, Patrick DL. Barriers to communication about end-of-life care in AIDS patients. *J Gen Intern Med.* 1997;12(12):736-41.
91. Decker C, Garavalia L, Chen C, Buchanan DM, Nugent K, Shipman A, Spertus JA. Acute myocardial infarction patients' information needs over the course of treatment and recovery. *J Cardiovasc Nurs.* 2007;22(6):459-65.
92. Janssen DJA, Curtis JR, Au DH, Spruit MA, Downey L, Schols JM, Wouters EF, Engelberg RA. Patient-clinician communication about end-of-life care for Dutch and US patients with COPD. *Eur Respir J.* 2011;38(2):268-76.
93. Newsome A, Sieber W, Smith M, Lillie D. If you build it, will they come? A qualitative evaluation of the use of video-based decision aids in primary care. *Fam Med.* 2012;44(1):26-31.
94. Agard A, Hermeren G, Herlitz J. When is a patient with heart failure adequately informed? A study of patients' knowledge of and attitudes toward medical information. *Heart Lung.* 2004;33(4):219-26.
95. Ekdahl AW, Andersson L, Friedrichsen M. 'They do what they think is the best for me.' Frail elderly patients' preferences for participation in their care during hospitalization. *Patient Educ Couns.* 2010;80(2):233-40.
96. Ekdahl AW, Andersson L, Wirehn AB, Friedrichsen M. Are elderly people with comorbidities involved adequately in medical decision making when hospitalised? A cross-sectional survey. *BMC Geriatr.* 2011;11. DOI: 10.1186/1471-2318-11-46.
97. Larsson IE, Sahlsten MJM, Segesten K, Plos KAE. Patients' perceptions of barriers for participation in nursing care. *Scand J Caring Sci.* 2011;25(3):575-82.
98. Nordgren S, Fridlund B. Patients' perceptions of self-determination as expressed in the context of care. *J Adv Nurs.* 2001;35(1):117-25.
99. Charles C, Whelan T, Gafni A, Reyno L, Redko C. Doing Nothing is No Choice: Lay Constructions of treatment decision-making among women with early-stage breast cancer. *Soc Health Ill.* 1998;20(1):71-95.
100. O'Brien MA, Ellis PM, Whelan TJ, Charles C, Gafni A, Lovrics P, et al. Physician-related facilitators and barriers to patient involvement in treatment decision making in early stage breast cancer: perspectives of physicians and patients. *Health Expect.* 2011;16(4): 373-84.
101. Thorne S, Oliffe JL, Stajduhar KI. Communicating shared decision-making: Cancer patient perspectives. *Patient Educ Couns.* 2012; 90(3): 291-6.
102. Clover A, Browne J, McErlain P, Vandenberg B. Patient approaches to clinical conversations in the palliative care setting. *J Adv Nurs.* 2004;48(4):333-41.

103. Henderson S. Influences on patient participation and decision-making in care. *Prof Nurse*. 2002;17(9):521-5.
104. Anoosheh M, Zarkhah S, Faghihzadeh S. Nurse-patient communication barriers in Iranian nursing. *Int Nurs Rev*. 2009;56(2):243-9.
105. Farahani MA, Sahragard R, Carroll JK, Mohammadi E. Communication barriers to patient education in cardiac inpatient care: A qualitative study of multiple perspectives. *Int J Nurs Pract*. 2011;17(3):322-8.
106. Bastiaens H, Van Royen P, Pavlic DR, Raposo V, Baker R. Older people's preferences for involvement in their own care: A qualitative study in primary health care in 11 European countries. *Patient Educ Couns*. 2007;68(1):33-42.
107. Ruan J, Lambert V. Differences in perceived communication barriers among nurses and elderly patients in China. *Nurs Health Sci*. 2008;10(2):110-6.
108. Sainio C, Lauri S, Eriksson E. Cancer patients' views and experiences of participation in care and decision making. *Nurs Ethics*. 2001;8(2):97-113.
109. Simon D, Loh A, Wills CE, Harter M. Depressed patients' perceptions of depression treatment decision-making. *Health Expect*. 2007;10(1):62-74.
110. Claramita M, Utarini A, Soebono H, Van Dalen J, Van der Vleuten C. Doctor-patient communication in a Southeast Asian setting: The conflict between ideal and reality. *Adv Health Sci Educ Theory Pract*. 2011;16(1):69-80.
111. Kawabata H, Konishi K, Murakami M, Kisa K, Maezawa M. Factors affecting the physician-patient relationship regarding patient participation in medical encounters in primary care. *Hokkaido Igaku Zasshi - Hokkaido Journal of Medical Science*. 2009;84(3):171-5.
112. Aasen EM, Kvangarsnes M, Heggen Kr. Perceptions of patient participation amongst elderly patients with end-stage renal disease in a dialysis unit. *Scand J Caring Sci*. 2012;26(1):61-9.
113. Park EK, Song M. Communication barriers perceived by older patients and nurses. *Int J Nurs Stud*. 2005;42(2):159-66.
114. van Staa A. Unraveling triadic communication in hospital consultations with adolescents with chronic conditions: The added value of mixed methods research. *Patient Educ Couns*. 2011;82(3):455-64.
115. Fishbein M. The role of theory in HIV prevention. *AIDS Care*. 2000;12(3):273-8.
116. Fishbein M, Ajzen I. *Predicting and changing behavior: the reasoned action approach*. New York: Psychology Press; 2010.
117. Ajzen I. The theory of planned behavior. *Org Behav Human Decis Process*. 1991;50:179-211.

118. Charles C, Gafni A, Whelan T. Decision-making in the physician-patient encounter: revisiting the shared treatment decision-making model. *Soc Sci Med*. 1999;49(5):651-61.
119. McLeroy KR, Bibeau D, Steckler A, Glanz K. An ecological perspective on health promotion programs. *Health Educ Q*. 1988;15(4):351-77.
119. Shaffer VA, Probst CA, Merkle EC, Arkes HR, Medow MA. Why do patients derogate physicians who use a computer-based diagnostic support system? *Med Decis Making*. 2013;33(1):108-18.
121. Edwards M, Davies M, Edwards A. What are the external influences on information exchange and shared decision-making in healthcare consultations: a meta-synthesis of the literature. *Patient Educ Couns*. 2009;75(1):37-52.
122. Foucault M. *The Birth of the Clinic: An Archaeology of Medical Perception*. 3rd ed. Oxford: Routledge; 2003.
123. Higgins JPT, Green S, editors. *Cochrane Handbook for Systematic Reviews of Interventions*. Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from: www.cochrane-handbook.org
124. Longo MF, Cohen DR, Hood K, Edwards A, Robling M, Elwyn G, Russel IT. Involving patients in primary care consultations: assessing preferences using discrete choice experiments. *Br J Gen Pract*. 2006;56(522):35-42.
125. Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, Thompson R, Barratt A, Barry M, Bernstein S, Butow P, Clarke A, Entwistle V, Feldman-Stewart D, Holmes-Rovner M, Llewellyn-Thomas H, Moumjid N, Mullley A, Ruland C, Sepucha K, Sykes A, Whelan T. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ*. 2006;333(7565):417.
126. Elwyn G, O'Connor AM, Bennett C, Newcombe RG, Politi M, Durand MA, Drake E, Joseph-Williams N, Khangura S, Saarimaki A, Sivell S, Stiel M, Bernstein SJ, Col N, Coulter A, Eden K, Harter M, Rovner MH, Moumjid N, Stacey D, Thomson R, Whelan T, van der Weijden T, Edwards A. Assessing the quality of decision support technologies using the International Patient Decision Aid Standards instrument (IPDASi). *PLoS One*. 2009;4(3):e4705.
127. Joseph-Williams N, Elwyn G, Edwards A. Knowledge is not power for patients: A systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making. *Patient Educ Couns*. 2014; 94(3); 291-309.
128. Kinnersley P, Edwards A, Hood K, Cadbury N, Ryan R, Prout H, Owen D, Macbeth F, Butow P, Butler C. Interventions before consultations for helping patients address their information needs. *Cochrane Database Syst Rev*. 2007(3):CD004565.
129. Duncan E, Best C, Hagen S. Shared decision making interventions for people with mental health conditions. *Cochrane Database Syst Rev*. 2010(1):CD007297.

130. Wetzels R, Harmsen M, Van Weel C, Grol R, Wensing M. Interventions for improving older patients' involvement in primary care episodes. *Cochrane Database Syst Rev.* 2007(1):CD004273.
131. Higgins J, Green S, editors. *Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]* The Cochrane Collaboration, 2011.
132. Edwards A, Elwyn G, editors. *Shared Decision-Making in Health Care: Achieving Evidence Based Patient Choice.* 2nd ed. Oxford: Oxford University Press; 2009.
133. Brown RF, Butow PN, Sharrock MA, Henman M, Boyle F, Goldstein D, Tattersall MH. Education and role modelling for clinical decisions with female cancer patients. *Health Expect.* 2004;7(4):303-16.
134. Butow P, Devine R, Boyer M, Pendlebury S, Jackson M, Tattersall MH. Cancer consultation preparation package: changing patients but not physicians is not enough. *J Clin Oncol.* 2004;22(21):4401-9.
135. Greenfield S, Kaplan SH, Ware JE, Jr., Yano EM, Frank HJ. Patients' participation in medical care: effects on blood sugar control and quality of life in diabetes. *J Gen Intern Med.* 1988;3(5):448-57.
136. Rost KM, Flavin KS, Cole K, McGill JB. Change in metabolic control and functional status after hospitalization. Impact of patient activation intervention in diabetic patients. *Diabetes Care.* 1991;14(10):881-9.
137. Sepucha KR, Belkora JK, Aviv C, Mutchnick S, Esserman LJ. Improving the quality of decision making in breast cancer: consultation planning template and consultation recording template. *Oncol Nurs Forum.* 2003;30(1):99-106.
138. CemPED Sydney University & Family Planning NSW. Ask Share Know [Internet] 2012 [cited 2013 19 Aug]. Available from: <http://www.askshareknow.com.au/index.html>.
139. Belkora J, Katapodi M, Moore D, Franklin L, Hopper K, Esserman L. Evaluation of a visit preparation intervention implemented in two rural, underserved counties of Northern California. *Patient Educ Couns.* 2006;64(1-3):350-9.
140. Sepucha KR, Belkora JK, Mutchnick S, Esserman LJ. Consultation planning to help breast cancer patients prepare for medical consultations: effect on communication and satisfaction for patients and physicians. *J Clin Oncol.* 2002;20(11):2695-700.
141. Sepucha KR, Belkora JK, Tripathy D, Esserman LJ. Building bridges between physicians and patients: results of a pilot study examining new tools for collaborative decision making in breast cancer. *J Clin Oncol.* 2000;18(6):1230-8.
142. The Health Foundation. Person-centred care resource centre [Internet]. 2014 [cited 2015 26 Oct]. Available from: <http://personcentredcare.health.org.uk/>
143. Shepherd HL, Barratt A, Trevena LJ, McGeechan K, Carey K, Epstein RM, Butow PN, Del Mar CB, Entwistle V, Tattersall MH. Three questions that patients can ask

- to improve the quality of information physicians give about treatment options: a cross-over trial. *Patient Educ Couns*. 2011;84(3):379-85.
144. Advancing Quality Alliance. Your health - your decision: evaluation and output report of the AQUA workstream within the national shared decision making programme. Cambridge: Right Care Shared Decision Making Programme; 2013.
 145. Advancing Quality Alliance. Shared decision making [Internet]. 2013 [cited 2013 19 Aug]. Available from: <http://www.advancingqualityalliance.nhs.uk/sdm/>
 146. Cardiff & Vale University Health Board. Ask 3 Questions [Internet]. 2011 [cited 2013 19 Aug]. Available from: <http://www.cardiffandvaleuhb.wales.nhs.uk/the3questions>.
 147. Von Winterfeldt D, Edwards A. Decision analysis and behavioural research. USA: Cambridge University Press; 1993.
 148. Irwig L, Irwig J, Trevena L, Sweet M. Smart health choices. London: Hammersmith Press; 2008.
 149. Barratt A. Evidence based medicine and shared decision making: the challenge of getting both evidence and preferences into health care. *Patient Educ Couns*. 2008;73(3):407-12.
 150. Brown R, Butow PN, Boyer MJ, Tattersall MH. Promoting patient participation in the cancer consultation: evaluation of a prompt sheet and coaching in question-asking. *Br J Cancer*. 1999;80(1-2):242-8.
 151. Patel V, Groen G. Knowledge based solution strategies in medical reasoning. *Cog Sci*. 1986;10(1):91-116.
 152. Doyle M, Straus D. How to Make Meetings Work. New York: Jove Books; 1982.
 153. Hammond J, Keeney R, Raiffa H. Smart Choices: A Guide to Making Better Decisions. Cambridge, MA: Harvard University Press; 1998.
 154. Argyris C. Knowledge for Action: A Guide to Overcoming Barriers to Organisational Change. San Francisco: Jossey-Bass Inc; 1993.
 155. Argyris C, Putnam R, Smith D. Concepts, Methods, and Skills for Research and Intervention. San Francisco: Jossey-Bass Inc; 1985.
 156. Berwick D, Godfrey A, Roessner J. A New Strategy for Quality Improvement. San Francisco: Jossey-Bass Inc; 1990.
 157. Berwick DM. Continuous Improvement as an Ideal in Health Care. *N Engl J Med*. 1989;320(1):53-6.
 158. Howard R, Matheson J, editors. The Principles and Applications of Decision Analysis. Menlo Park, CA: Strategic Decisions Group; 1989.
 159. Rapley T. Distributed decision making: the anatomy of decisions-in-action. *Sociol Health Illn*. 2008;30(3):429-44.

160. Shepherd H, Barratt A, Jones A, Bateson D, Carey K, Trevena L, et al., editors. Can consumers learn to ask three questions to improve shared decision-making?: A feasibility study of the ASK (AskShareKnow) patient-clinician communication model intervention in a primary health care setting. Proceedings of the International Shared Decision Making Conference: Pacientes @ the Centre of Healthcare; 2013; Lima, Peru.
161. Abraham C, Kelly MP, West R, Michie S. The UK National Institute for Health and Clinical Excellence public health guidance on behaviour change: a brief introduction. *Psychol Health Med*. 2009;14(1):1-8.
162. Coulter A, Entwistle VA, Eccles A, Ryan S, Shepperd S, Perera R. Personalised care planning for adults with chronic or long-term health conditions. *Cochrane Database Syst Rev*. 2015;3:Cd010523.
163. Legare F, Stacey D, Turcotte S, Cossi MJ, Kryworuchko J, Graham ID, Lyddiatt A, Politi MC, Thomson R, Elwyn G, Donner-Banzhoff N. Interventions for improving the adoption of shared decision making by healthcare professionals. *Cochrane Database Syst Rev*. 2014;9:Cd006732.
164. Deen D, Lu WH, Weintraub MR, Maranda MJ, Elshafey S, Gold MR. The impact of different modalities for activating patients in a community health center setting. *Patient Educ Couns*. 2012;89(1):178-83.
165. Joseph-Williams N, Newcombe R, Politi M, Durand MA, Sivell S, Stacey D, O'Connor A, Volk RJ, Edwards A, Bennett C, Pignone M, Thomson R, Elwyn G. Toward Minimum Standards for Certifying Patient Decision Aids: A Modified Delphi Consensus Process. *Med Decis Making*. 2013;34(6):699-710.
166. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci*. 2011;6:42.
167. Rosenstock I. Historical origins of the Health Belief Model. *Health Education Monographs*. 1974;2(4).
168. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. *Implement Sci*. 2012;7:37.
169. Michie S, Johnston M, Abraham C, Lawton R, Parker D, Walker A. Making psychological theory useful for implementing evidence based practice: a consensus approach. *Quality & safety in health care*. 2005;14(1):26-33.
170. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, Eccles MP, Cane J, Wood CE. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Annals Behav Med*. 2013;46(1):81-95.
171. Hobbs L, Campbell R, Hildon Z, Michie S, editors. Behaviour change theories across Psychology, Sociology, Anthropology and Economics: A systematic review. Proceedings of the 25th Annual Conference of the European Health Psychology Society; 2011; Crete.

172. Joseph-Williams N, Edwards A, Elwyn G. Power imbalance prevents shared decision making. *BMJ*. 2014;348 g3178.
173. Barr PJ, Thompson R, Walsh T, Grande SW, Ozanne EM, Elwyn G. The psychometric properties of CollaboRATE: a fast and frugal patient-reported measure of the shared decision-making process. *J Med Internet Res*. 2014;16(1):e2.
174. Elwyn G, Barr PJ, Grande SW, Thompson R, Walsh T, Ozanne EM. Developing CollaboRATE: a fast and frugal patient-reported measure of shared decision making in clinical encounters. *Patient Educ Couns*. 2013;93(1):102-7.
175. Bartholomew L, Parcel GS, Kok G, Gottlieb NH, Fernandez M. Planning health promotion programs: An intervention mapping approach. 3rd ed: Jossey Bass; 2011.
176. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol*. 2013;13:117.
177. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol*. 2006;3(2):77-101.
178. Option Grid Collaborative. Option Grid [Internet]. 2014 [cited 2015 26 Oct]. Available from: <http://www.optiongrid.org/>
179. Huijg JM, Gebhardt WA, Dusseldorp E, Verheijden MW, van der Zouwe N, Middelkoop BJ, Crone MR. Measuring determinants of implementation behavior: psychometric properties of a questionnaire based on the theoretical domains framework. *Implement Sci*. 2014;9:33.
180. Joseph-Williams N, Evans R, Edwards A, Newcombe RG, Wright P, Grol R, Elwyn G. Supporting informed decision making online in 20 minutes: an observational web-log study of a PSA test decision aid. *J Med Internet Res*. 2010;12(2):e15.
181. Sivell S, Marsh W, Edwards A, Manstead AS, Clements A, Elwyn G. Theory-based design and field-testing of an intervention to support women choosing surgery for breast cancer: BresDex. *Patient Educ Couns*. 2012;86(2):179-88.
182. Joseph-Williams N, Elwyn G, Edwards A. Knowledge is not power for patients: a systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making. *Patient Educ Couns*. 2014;94(3):291-309.
183. Batterham RW, Buchbinder R, Beauchamp A, Dodson S, Elsworth GR, Osborne RH. The OPTimising HEalth LIterAcy (Ophelia) process: study protocol for using health literacy profiling and community engagement to create and implement health reform. *BMC Public Health*. 2014;14:694.
184. Walsh T, Barr PJ, Thompson R, Ozanne E, O'Neill C, Elwyn G. Undetermined impact of patient decision support interventions on healthcare costs and savings: systematic review. *BMJ*. 2014;348:g188.
185. Bradley P, Wilson A, Buss P, Harrhy S, Laing H, Shortland G, et al. Achieving prudent healthcare in NHS Wales. Cardiff: Public Health Wales; 2014.

186. National Joint Registry. NJR 10th Annual Report: NJR for England, Wales, and Northern Ireland. Hemel Hempstead: NJR; 2013.
187. Arthritis Research UK. Osteoarthritis in general practice: data and perspectives Chesterfield: Arthritis Research UK; 2013.
188. Wennberg JE, Fisher ES, Skinner JS. Geography and debate of Medicare reform. *Health Aff (Millwood)*. 2002;23:96-114.
189. HES Online. Finalised Patient Reported Outcome Measures (PROMs) in England April 2009 - March 2010. Pre- and Post- operative data. Experimental statistics. Leeds: Health and Social Care Information Centre; 2010.
190. National Collaborating Centre for Chronic Conditions. Osteoarthritis: National clinical guidelines for care and management in adults. London: Royal College of Physicians, 2008.
191. Williams A. The listening organisation: Ensuring care is person-centered in NHS Wales. Cardiff: 1000 Lives Plus; 2013.
192. Department of Health. Equity and Excellence: Liberating the NHS. London: Crown; 2010.
193. Hemming K, Haines TP, Chilton PJ, Girling AJ, Lilford RJ. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *BMJ*. 2015;350:h391.
194. Welsh Assembly Government. Setting the Direction: Primary & Community Services Strategic Delivery Programme. Cardiff: Crown Publisher; 2010.
195. Welsh Government. Welsh Index of Multiple Deprivation. Norwich: HMSO, 2014.
196. Dawson J, Fitzpatrick R, Murray D, Carr A. Questionnaire on the perceptions of patients about total knee replacement. *J Bone Joint Surg Br*. 1998;80(1):63-9.
197. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, Bonsel G, Badia X. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res*. 2011;20(10):1727-36.
198. Lyons RA, Jones KH, John G, Brooks CJ, Verplancke JP, Ford DV, Brown G, Leake K. The SAIL databank: linking multiple health and social care datasets. *BMC Med Inform Decis Mak*. 2009;9:3.
199. Hibbard JH, Stockard J, Mahoney ER, Tusler M. Development of the Patient Activation Measure (PAM): conceptualizing and measuring activation in patients and consumers. *Health Serv Res*. 2004;39(4 Pt 1):1005-26.
200. Marrin K, Wood F, Firth J, Kinsey K, Edwards A, Brain KE, Newcombe RG, Nye A, Pickles T, Hawthorne K, Elwyn G. Option Grids to facilitate shared decision making for patients with Osteoarthritis of the knee: protocol for a single site, efficacy trial. *BMC Health Serv Res*. 2014;14:160.

201. Brehaut JC, O'Connor AM, Wood TJ, Hack TF, Siminoff L, Gordon E, Feldman-Stewart. Validation of a decision regret scale. *Med Decis Making*. 2003;23(4):281-92.
202. May C, Finch T. Implementing, embedding, and integrating practices: an outline of Normalization Process Theory. *Sociology* 2009;43(535-554).
203. Elwyn G, Legare F, van der Weijden T, Edwards A, May C. Arduous implementation: does the Normalisation Process Model explain why it's so difficult to embed decision support technologies for patients in routine clinical practice. *Implement Sci*. 2008;3:57.
204. Gravel K, Legare F, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: a systematic review of health professionals' perceptions. *Implement Sci*. 2006;1:16.
205. Elwyn G, Lloyd A, May C, van der Weijden T, Stiggelbout A, Edwards A, Frosch DL, Rapley T, Barr P, Walsh T, Grande SW, Montori V, Epstein R. Collaborative deliberation: a model for patient care. *Patient Educ Couns*. 2014;97(2):158-64.
206. The Patients Association. Common complaints [Internet]. 2015 [cited 2015 14 Oct]. Available from: <http://www.patients-association.org.uk/helpline/common-complaints/>
207. Delbanco T, Walker J. OpenNotes: patients and clinicians on the same page [Internet] 2015 [cited 2015 26 Oct]. Available from: <http://www.myopennotes.org/about-opennotes/>
208. Munro D. New poll shows two-thirds of doctors reluctant to share health data with patients. *Forbes* [online]. 2015 June 8 2015 [cited 2015 26 Oct]. Available from: <http://www.forbes.com/sites/danmunro/2015/06/08/two%E2%80%92thirds-of-doctors-are-reluctant-to-share-health-data-with-patients/>
209. Elwyn G. "Patientgate"--digital recordings change everything. *BMJ*. 2014;348:g2078.
210. Elwyn G, Buckman L. Should doctors encourage patients to record consultations? *BMJ*. 2015;350:g7645.
211. Fulop N, Robert G. Context for successful quality improvement. London: The Health Foundation, 2015.
212. Kaplan HC, Provost LP, Froehle CM, Margolis PA. The Model for Understanding Success in Quality (MUSIQ): building a theory of context in healthcare quality improvement. *BMJ Qual Saf*. 2012;21(1):13-20.
213. Ward HO, Kibble S, Mehta G, Franklin M, Koo J, Jones A, Panesar S, Carson-Stevens A. How asking patients a simple question enhances care at the bedside: medical students as agents of quality improvement. *Perm J*. 2013;17(4):27-31.
214. Stretcher VJ, Rosenstock IM. The Health Belief Model. In: Baum A, editor. *Cambridge Handbook of Psychology, Health and Medicine*. Cambridge: Cambridge University Press; 1997. p. 113–7.

Appendix 2.2 – Patient Education and Counseling publication

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Review

Knowledge is *not* power for patients: A systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making



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ABSTRACT

Objective: To systematically review patient-reported barriers and facilitators to shared decision making (SDM) and develop a taxonomy of patient-reported barriers.

Methods: Systematic review and thematic synthesis. Study findings/results for each included paper were extracted verbatim and entered into qualitative software for inductive analysis.

Results: Electronic and follow-up searches yielded 2956 unique references; 289 full-text articles were retrieved, of which 45 articles from 44 unique studies met inclusion criteria. Key descriptive themes were grouped under two broad analytical themes: how the healthcare system is organized (4 descriptive themes) and what happens during the decision-making interaction (4 descriptive themes, 10 sub-themes). Predominant emergent themes related to patients' knowledge and the power imbalance in the doctor–patient relationship. Patients need knowledge *and* power to participate in SDM – knowledge alone is insufficient and power is more difficult to attain.

Conclusion: Many barriers are potentially modifiable, and can be addressed by attitudinal changes at the levels of patient, clinician/healthcare team, and the organization. The results support the view that many patients currently *can't* participate in SDM, rather than they *won't* participate because they do not want to.

Practice implications: Future implementation efforts should address patient-reported factors together with known clinician-reported barriers and the wider organizational context.

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1. Introduction

Shared decision making (SDM) is viewed as fundamental to safe and effective healthcare when there are legitimate options available to patients [1]. "No decision about me without me" [2,3] encapsulates the ambition of a more patient-centered healthcare system that promotes SDM, but this ambition is yet to be realized routinely. Despite some successes with SDM implementation (mainly concerning embedding decision support tools, securing policy support, training clinicians, and organizational buy-in) [4–9], implementation efforts still face considerable difficulties [9–11]. It is also not clear what role decision support tools play in preparing and enabling patients to engage in a decision-making discussion with a clinician [12]. Implementation researchers well recognize the clinician-perceived barriers and facilitators [4,6,13–16]. Surprisingly, implementation work has not considered the patient perspective in detail. This review examines what patients think helps or hinders them from being involved in making healthcare decisions.

An initial literature search identified several studies seeking to understand patients' perceptions of the factors promoting or hindering their involvement [17–20]. A comprehensive synthesis of data from these studies could complement the well-cited taxonomy of clinician barriers and facilitators [13]. Previous work identified factors influencing patients' preferences for involvement in medical decision-making [21], but most studies examined associations between patient characteristics (e.g. age, coping style) and desired levels of involvement, not actual patients' views. Whilst we acknowledge that factors affecting patient involvement in decision-making can also be identified through observational methods, which rely on a third party observer, only direct enquiry with patients will afford opportunities to understand *why* they view particular factors as barriers or facilitators.

One of the earliest papers in this field described what SDM involves: at least two participants, a clinician and patient [22]. However, implementation researchers seem to have overlooked that "it takes at least two to tango" when conducting implementation work. Previous work has identified the powerful influence of long-standing normative beliefs, such as patients being passive and not "rocking the boat" [20,23]. Implementation researchers need to address these attitudinal issues if other efforts on embedding decision support tools and addressing clinician- and organizational-level barriers are to be more effective. Clinician and organizational perspectives are critically important for implementation efforts, but SDM will not become the "norm" in healthcare, without simultaneously addressing patient-reported barriers. We aimed to systematically review and thematically synthesize patient-reported barriers and facilitators to SDM, seeking to

develop a taxonomy to inform implementation work alongside efforts to address clinician and organizational aspects of SDM.

2. Methods

2.1. Search strategies & selection criteria

We searched nine electronic databases: (from database inception, no language restrictions): ASSIA (1987>); CINAHL (1982>); BNI (1985>); Embase (1947>); Medline (1946>); Medline in Process; PsycINFO (1806>); Scopus (1966>); Web of Knowledge (1981>). Search strategies combined free-text words and MeSH, or database equivalent, derived from the following broad topic areas: decision-making, barriers/facilitators, and patient-reported (see Appendix A for Medline search strategy). Follow-up searches were conducted to determine if any additional references could be identified. These included scanning reference lists of papers that underwent full-text analysis and the contents lists of the top three most frequently cited journals, from journal inception (Health Expectations, Journal of General Internal Medicine, Patient Education & Counseling). Relevant researchers were contacted via known interest groups and email to identify ongoing work.

Key inclusion criteria were: (i) participants were patients; (ii) study based on direct enquiry with patients; (iii) reported patients' perceptions of their involvement in decision-making about their healthcare. Due to differences in authors' definitions, we used a broad definition whereby we considered barriers/facilitators to involvement in the decision-making process, although we use this interchangeably with the term SDM. However, when we refer to 'involvement', it is always in relation to a decision-making process, not healthcare more generally. The term 'patient' refers to anyone who is a potential user of healthcare. When complementary data from a single study were described in more than one article, all articles were included. Review articles were included as additional resources, and were scanned to determine if any additional references could be identified. For full inclusion/exclusion criteria, see Box 1.

2.2. Study identification & data extraction

Title and abstracts were screened for relevance to the inclusion criteria. Full-texts of potentially relevant studies were evaluated. Data were extracted about: study characteristics, participant characteristics, study context, operationalization of healthcare involvement, theoretical base/conceptual framework used, and the authors' main findings. Full study results/findings sections for included articles were extracted verbatim and entered into QSR International's NVivo 10 software [24]. As there is no prior

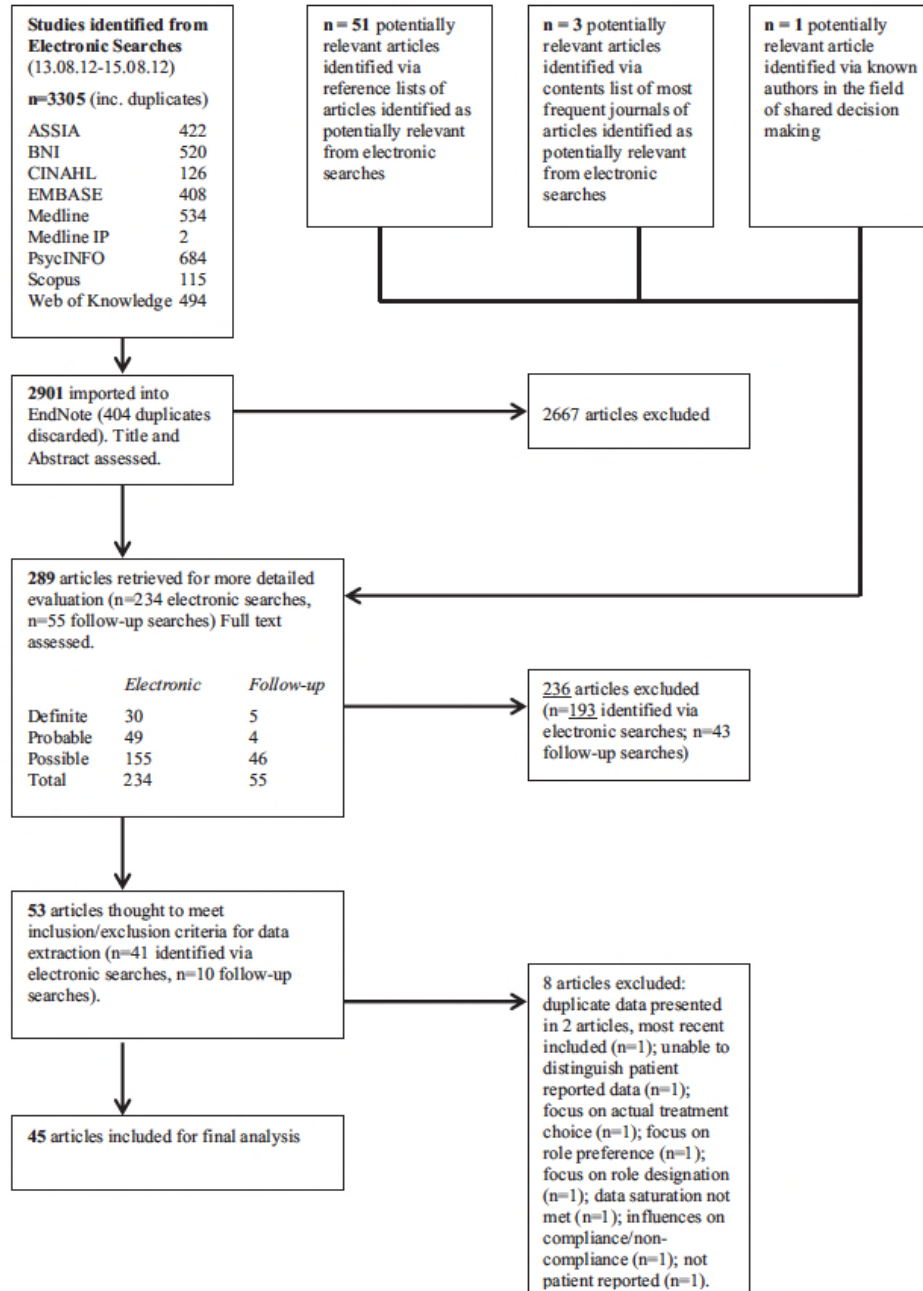


Fig. 1. A flowchart of progress through the systematic review.

address attitudinal change at the levels of patient, clinician and organization.

3.4.1.2. *Decision characteristics (19/44)*. Several decision characteristics were identified as barriers to SDM. Patients use different

approaches depending on the decision being made [28,40] and involvement can depend on timing along the illness trajectory [35,43]. Significant decisions (e.g. cancer treatment) were identified as both a barrier and facilitator to SDM [44]. Most decision characteristics identified as barriers are potentially amenable to

Table 1
Description of included articles that identified barriers/facilitators (*n* = 45).

First author, year of publication, country of origin, citation	Principal objective of the study	Reporting focus (barriers and/or facilitators)	Operationalization of involvement	Conceptual framework for barriers/facilitators assessment	Design/methods of study within which barriers and facilitators elicited	Setting(s) Health condition(s)	Participant characteristics
Aasen, 2011, Norway [27]	To explore how elderly patients with end-stage renal disease who are undergoing treatment with hemodialysis perceive patient participation in a dialysis unit	Facilitators	Participation in the healthcare decision making process	Yes [28]	Cross-sectional. Qualitative. Semi-structured interviews	Secondary care, outpatient. End stage renal disease	11 patients. 64% male, 36% female. Age range 74–90
Adler, 1998, USA [29]	To focus on aspects of patient behavior, specifically assertiveness, to examine how they influence patient–physician communication	Barriers & facilitators	Patient–physician communication and patient activation	No	Cross-sectional, qualitative, focus groups (<i>n</i> = 4)	Secondary care, outpatient. Breast cancer	29 female patients. Age range 63–85
Agard, 2004, Sweden [30]	Explore patients' knowledge of heart failure and their attitudes toward medical information (prognostic information in particular) and to assess different patient-related factors that might hamper the improvement of patient's knowledge	Barriers	Information disclosure to patients	No	Cross-sectional. Qualitative. Semi-structured interviews	Secondary care, outpatient. Chronic heart failure	40 patients. 62% male, 38% female. Age range 60–80 (75 mean)
Anoosheh, 2009, Iran [31]	To investigate nurse–patient and environment-related communication barriers perceived by patients and nurses in Iranian nursing	Barriers	Communication between nurses and patients. Communication is the application of words and conduct for making, transmitting and interpreting messages. Communication involves an interaction between the speaker and subject, and the environment influences this process. These three factors co-influence the communication outcome, and any barriers to them can result in ineffective communication	Pos	Cross-sectional. Quantitative. Self-administered questionnaire/investigator administered questionnaire	Secondary care, inpatient. No specific health condition	61 patients. 48% male, 52% female. Age not reported
Avis, 1994, UK [32]	Examine the patients' perspective on making choices about treatment in a day surgical unit through the use of qualitative methods	Barriers	Patient participation and making choices about treatment	No	Cross-sectional. Qualitative. Observations (b) Interviews	Secondary care, inpatient & outpatient. Hernia repair	20 patients overall. Age range 15–70. 12 male patients (b) 10 patients. 90% male, 10% female
Barnard, 2007, UK [33]	To assess whether using a computerized touch screen assessment tool prior to outpatient consultation makes patients more active in consultations	Barriers & facilitators	Patient centered care: eliciting the patients' concerns and activating the patient to contribute more to the consultation [using interactive education]	No	Cross-sectional. Qualitative. Self-administered questionnaire (open-ended questions)	Secondary care, outpatient. Diabetes	53 patients. No further details reported for sub-set of patients who completed open-ended questions

Table 1 (Continued)

First author, year of publication, country of origin, citation	Principal objective of the study	Reporting focus (barriers and/or facilitators)	Operationalization of involvement	Conceptual framework for barriers/facilitators assessment	Design/methods of study within which barriers and facilitators elicited	Setting(s) Health condition(s)	Participant characteristics
Bastiaens, 2007, Belgium* [34]	Explore the views of people aged over 70 years on involvement in their primary health care in 11 different European countries	Barriers & facilitators	Patient involvement: enabling people to take an active role in deciding about and planning their care	No	Cross-sectional. Qualitative. Semi-structured interviews	Primary care. No specific health condition	406 patients. 45% male, 55% female. Age range 70–96 (79 mean)
Beaver, 2005, UK [35]	To explore patient views on participation in treatment, physical care and psychological care decisions and factors that facilitate and hinder patients from making decisions	Barriers & facilitators	Shared decision making – participation in treatment decisions and care decisions	No	Cross-sectional. Qualitative. Semi-structured interviews	Secondary care. Colorectal cancer	41 patients. 46% male, 54% female. Age range 37–84 years (62 mean)
Belcher, 2005, USA [36]	To explore views of older adults regarding participation in medication decision-making	Barriers & facilitators	Shared decision making is a model for the way in which the physician and patient participate in treatment decision-making. One of the core assumptions of this model is that the patient brings to the decision information that the physician cannot know without engaging the patient in the decision making process. In this model, the physician and patient share information with each other. The physician provides information, or acknowledges uncertainty, regarding the harms and benefits of available treatment options and the patient provides information regarding beliefs and preferences; both participate in the decision-making process, although in different aspects ^a	Pos	Cross-sectional. Qualitative. Semi-structured interviews	Primary & community care. Multiple chronic conditions	51 patients. 37% male, 63% female. Age range 65–89
Bhavani, 2009, UK [18]	To examine patients' views about a variety of decision aids for different conditions (heart disease, osteoporosis, osteoarthritis and breast cancer) in order to inform a strategy to introduce them into general practice	Barriers	Patient decision aids are interventions designed to help those people facing treatment or screening decisions make choices by providing information on the management options available and the possible health outcomes	No	Cross-sectional. Qualitative. Focus groups (n = 12)	Primary care. Heart disease and stroke, osteoarthritis, osteoporosis & breast cancer	77 patients. 19% male, 81% female. Age range 42–83 (66 mean)

Caress, 2002, UK [37]	To explore preferred treatment decision-making roles, and rationales for role preference, and to identify perceived facilitators and barriers to attaining preferred role.	Barriers & facilitators	Participation in treatment decision-making.	No	Cross-sectional. Qualitative. Semi-structured interviews.	Primary & secondary care. Asthma.	32 patients. 53% male, 47% female. Age range 18–84 (47 mean).
Caress, 2005, UK [38]	Explore preferred and perceived levels of involvement in treatment decisions, rationales for role preference, perceived facilitators/barriers to involvement and the interrelationship of role preference and demographic variables in a sample of patients with asthma	Barriers & facilitators	Participation in treatment decision-making	No	Cross-sectional. Qualitative. Structured interviews	Primary care & secondary care. Asthma	230 patients. 42% male, 58% female. Age range 19–94 (52 mean)
Charles, 1998, Canada [22]	Exploratory study focusing on three related issues: (1) the extent to which women with early stage breast cancer perceived they had treatment options; (2) their understanding of the risks and benefits associated with different treatment options, and (3) the role they wanted for themselves and for their oncologists in the treatment decision-making process	Barriers & facilitators	Patient participation in treatment decision-making: patients' being provided with information about their disease and treatment options, as well as opportunities to actively participate in treatment decision-making	No	Cross-sectional case study. Qualitative. Interviews	Secondary care. Early stage breast cancer	20 female patients. Age range 42–78 (56 mean)
Claramita, 2011, Indonesia [39]	Explore the perceived ideal communication style for doctor–patient consultations and the reality of actual practice in a Southeast Asian context	Barriers	The informed and shared decision making between doctors and patients is the substantial issue in the ideal style	No	Cross-sectional. Qualitative. Interviews	Primary, secondary and community care. Various medical conditions	16 patients. No further details reported
Clover, 2004, Australia [40]	Explore patients' understanding of their discussions about end-of-life care with nurses in a palliative care setting	Barriers & facilitators	Patient participation in discussions about end of life care and negotiation of preferences	No	Cross-sectional. Qualitative. Interviews	Secondary care, inpatient. Terminal illness	11 patients. 64% male, 36% female. Age range 57–85 (74 mean)
Cohen, 2003, UK [41]	To gain an in depth understanding of the perspectives of men recently diagnosed with localized prostate cancer, and to explore the value of decision-making models in the setting of NHS practice	Barriers	Shared decision-making: interchange of both information and attitudes between both parties	No	Before and after. Qualitative. Semi-structured interviews	Primary & secondary care. Localized prostate cancer	19 male patients. Age range 58–88
Curtis, 1997, USA [42]	Identify barriers and facilitators to communication about end-of-life care for patients with AIDS and their physicians	Barriers & facilitators	Patient–physician communication about end-of-life care	No	Cross-sectional. Qualitative. Focus groups (n=6)	Community care. AIDS	47 patients. 66% male, 34% female. Age range 23–58 (38 median)

Table 1 (Continued)

First author, year of publication, country of origin, citation	Principal objective of the study	Reporting focus (barriers and/or facilitators)	Operationalization of involvement	Conceptual framework for barriers/facilitators assessment	Design/methods of study within which barriers and facilitators elicited	Setting(s) Health condition(s)	Participant characteristics
Decker, 2007, USA [43]	Describe cardiac patients' preferences for involvement in decision making, and their informational needs, in the context of the myocardial infarction event continuum	Barriers & facilitators	Two theories prevail in the patient involvement literature – shared decision-making and informed choice. Shared decision making is the more popular model and involves the patient and clinician “sharing” in the decision-making process as opposed to decisions being made by the clinician only (paternalistic model) or the patient only (informed patient model)	Pos	Cross-sectional. Qualitative. Focus groups	Secondary care. Myocardial infarction	19 patients. 79% male, 21% female. Age range 38–70 (61 mean males; 44.5 mean females)
Doherty, 2005, UK [44]	To identify what involvement patients want in clinical decision making and explore the underlying factors influencing that choice, thus identifying aids and barriers to increasing patients' involvement in decision making	Barriers & facilitators	Preferences for involvement in clinical decision-making. Three models described: the paternalistic model where the clinician decides what treatment to implement with the patient being given the amount of information that the clinician considers the require; the shared model where the patient and clinician share decision making throughout the process with a two-way exchange of information, and the informed model where the clinician's role is to provide the patient with enough information in order that the patient can make his own choice of treatment option	No	Cross-sectional. Qualitative. Semi-structured interviews	Secondary care. Various medical/surgical conditions	20 patients. 55% males, 45% female. Age range 18–79 (66 mean)
Ekdahl, 2010, Sweden [45]	To deepen the knowledge of frail elderly patients' preferences for participation in medical decision making during acute hospitalization	Barriers & facilitators	Patient participation in decision-making: MeSH defines patient participation as “involvement in the decision making process in matters pertaining to health”	No	Cross-sectional. Qualitative. Semi-structured interviews	Secondary care. No specific health condition	15 patients. 34% male, 66% female. Age range 75–96 (84 mean)

Ekdahl, 2011, Sweden [46]	To investigate the preferred and actual degree of control i.e. the role elderly people with comorbidities wish to assume and actually had with regard to information and participation in medical decision making during their stay in hospital	Barriers	Patient participation in decision-making	No	Cross-sectional. Quantitative. Telephone administered questionnaire	Secondary care. No specific health condition	156 patients. 49% males, 51% female. Age range 76–98 (83 mean)
Eldh, 2006, Sweden [19]	To explore conditions for patients' experiences of participation and non-participation in their health care	Barriers & facilitators	Patient participation and non-participation in health care: the foremost perspective of patient participation is that it represents taking part in decision-making. Note that patients' notion of participation is closer to dictionary definition 'whereby, patients contribute by sharing their unique knowledge'	No	Cross-sectional. Qualitative. Self-administered questionnaire (open-ended questions)	Secondary care, inpatients and outpatients. No specific health condition	212 patients. 40% males, 60% females. Age not reported
Entwistle, 2008, UK [47]	To investigate the meaning of involvement in treatment decision-making for people with diabetes	Barriers & facilitators	Patient involvement in treatment decision-making	No	Cross-sectional. Qualitative. Semi-structured interviews	Primary & secondary care. Diabetes	18 patients. 55% male, 45% female. Age range 20–79
Farahani, 2011, Iran [48]	Explore communication barriers [health care] from perspectives of nurses, physicians and patients who were hospitalized, in cardiac care settings with either unstable angina or for evaluation of suspected acute myocardial infarction and their family members	Barriers	Nurse–patient communication, for the purpose of patient education	No	Cross-sectional. Qualitative. Semi-structured interviews	Secondary care, inpatient. Cardiac disease	9 patients and 4 family members. 64% male, 36% female (58.7 mean)
Fraenkel, 2007, USA [17]	To gain a more complete understanding of the essential elements, or the prerequisites, critical to active patient participation in medical decision making from the patients' perspective	Barriers & facilitators	Shared decision-making: where patients play an active role in decisions related to their health care	No	Cross-sectional. Qualitative. Semi-structured interviews	Secondary care, outpatient. Osteoporosis	26 patients. 4% male, 96% female. Age range 49–76 (61 mean)
Frosch, 2012, USA [20]	To arrive at a better understanding of how patients perceive these communication tasks, specifically when considering clinical decisions that are sensitive to patients' preferences	Barriers & facilitators	Shared decision-making	Yes [49,50]	Cross-sectional. Qualitative. Focus groups (n=6)	Primary care. No specific health condition	48 patients. 38% male, 62% female (65 mean age)

Table 1 (Continued)

First author, year of publication, country of origin, citation	Principal objective of the study	Reporting focus (barriers and/or facilitators)	Operationalization of involvement	Conceptual framework for barriers/facilitators assessment	Design/methods of study within which barriers and facilitators elicited	Setting(s) Health condition(s)	Participant characteristics
Henderson, 2002, Australia [51]	To explore and describe the phenomenon of patient participation within the context of hospital nursing in Western Australia	Barriers & facilitators	Patient participation: being allowed to become involved in a decision-making process or in the delivery and evaluation of a service, or even simply being consulted on an issues of care such as activities of daily living, pain management or treatment options	No	Cross-sectional. Qualitative. Semi-structured interviews & observations	Secondary care, inpatient (after discharge). Various acute medical, surgical, extended care	32 patients, 44% male, 56% female. (59 mean age)
Janssen, 2011, The Netherlands & USA [52]	To compare quality of patient–clinician communication about end-of-life care, and endorsement of barriers and facilitators to this communication in the Netherlands and the USA	Barriers & facilitators	Patient–clinician communication about end-of-life care	No	Cross-sectional (baseline data from 3 datasets ^b). Quantitative. Self-administered questionnaire	Secondary care. Chronic Obstructive Pulmonary Disease (COPD)	122 Dutch patients (62% males, 38% females, 67 mean age) and 391 USA patients (92% males, 8% females; 68 mean age)
Kawabata, 2009, Japan [53]	To reveal factors affecting the physician–patient relationship regarding patient participation in medical encounters in primary care	Barriers & facilitators	Patient participation in medical encounters	No	Cross-sectional. Qualitative. Focus group (n=1)	Primary care. No specific health condition	5 female participants (patient representatives). Age range 45–59 (53 mean)
Kelsey, 2007, UK [54]	To explore young people's perceptions of their involvement in healthcare decisions affecting their management of care	Barriers & facilitators	Involvement in healthcare decisions affecting the management of care	No	Cross-sectional. Qualitative. Interviews & patient audio diaries	Secondary care, inpatient. Various medical/surgical conditions	10 patients. 60% male, 40% female. Age range 13–16
Larsson, 2011, Sweden [55]	To explore barriers for patient participation in nursing care with a special focus on adult patients with experience of inpatient physical care	Barriers	Participation in nursing care: active patient involvement in all aspects of own care	No	Cross-sectional. Qualitative. Focus groups (n=6)	Secondary & community care. No specific health condition	26 patients, 69% male, 31% female. Age range 32–87
Lown, 2009, USA [56]	To explore how patients and physicians describe attitudes and behaviors that facilitate shared decision-making	Facilitators	Shared decision making: interaction between patients and physicians when both parties wish to participate in making a decision about health care tests or treatments, and in which both physician and patient are both involved in the process, both shared information and express preferences, and both agree about the decision plans	Pos	Cross-sectional. Qualitative. Research work groups (n=4)	Primary care. Various chronic conditions	44 patients, 32% male, 68% female. Age not reported

Newsome, 2012, USA [57]	To examine the use of decision aids and uncover barriers to greater decision aid utilization in primary care	Barriers	Shared decision making: involvement of both the patient and the doctor, a sharing of information by both parties, both parties taking steps to build a consensus about the preferred treatment, and reaching an agreement about which treatment to implement	No	Cross-sectional. Qualitative. Focus groups	Primary care. Various conditions	37 patients. Gender & age not reported
Nordgren, 2001, Sweden [58]	To describe patients' perceptions of how self-determination finds expression in the context of care	Barriers & facilitators	Self determination: within health care, self determination has been described in terms of patient participation in decisions concerning their own lives without a controlling involvement from others	No	Cross-sectional. Qualitative. Semi-structured interviews	Secondary care, inpatient. Various surgical/medical conditions	17 patients. 65% male, 35% female. Age range & mean not reported
O'Brien, 2011, Canada [59]	To identify patients' and physicians' perceptions of physician-related verbal and nonverbal facilitators and barriers to patient involvement in treatment decision-making, during encounters for women with early stage breast cancer	Barriers & facilitators	Involvement in treatment decision-making	Pos	Cross-sectional. Qualitative. Semi-structured interviews	Secondary care. Early stage breast cancer	40 female patients. Phase 1: Age range 40-70 (62 mean). Phase 2: Age range 48-79 (61 mean)
Park, 2005, South Korea [60]	Investigate the communication barriers perceived by older hospitalized patients and nurses in Korea, with the aim of identifying disparities between the two parties	Barriers	Communication between patients and nurses: Communication involves an interaction between the speaker and the subject and the environment influences this process	No	Cross-sectional. Quantitative. Self-administered questionnaire	Secondary care, inpatient. Various medical/surgical/ ophthalmology conditions	100 patients. 59% male, 41% female (68 mean age)
Peek, 2009, USA [61]	To explore barriers and facilitators to SDM among African-Americans with diabetes	Barriers & facilitators	Shared decision-making: a process where both patients and physicians share information, express treatment preferences and agree on a treatment plan	Yes [22,62-64]	Cross-sectional. Qualitative. Focus groups (n=5) (b) Semi-structured interviews	Primary care. Diabetes	51 patients overall. 18% male, 82% female (62 mean age). 27 patients (b) 24 patients
Peek, 2010, ^c USA [65]	To explore barriers and facilitators to SDM among African-Americans with diabetes	Barriers & facilitators	Shared decision making models contain three domains: information sharing, deliberation/ physician recommendation, decision making	Yes [22,62-64]	Cross-sectional. Qualitative. Focus groups (n=5) (b) Semi-structured interviews	Primary care. Diabetes	51 patients overall. 18% male, 82% female (62 mean age). 27 patients (b) 24 patients

Table 1 (Continued)

First author, year of publication, country of origin, citation	Principal objective of the study	Reporting focus (barriers and/or facilitators)	Operationalization of involvement	Conceptual framework for barriers/facilitators assessment	Design/methods of study within which barriers and facilitators elicited	Setting(s) Health condition(s)	Participant characteristics
Ruan, 2008, China [66]	Identify the major communication barriers (nurse-related, patient-related, environment-related) perceived by both nurses and elderly patients and to determine the perceived differences in the level of importance of the communication barriers between nurses and elderly patients	Barriers	Nurse patient communication: communication is the use of words and behaviors to construct, send and interpret messages. It is a process by which one individual may affect another through written, verbal and non-verbal means	No	Cross-sectional. Quantitative. Investigator administered questionnaire	Secondary care, inpatient. Various conditions	56 patients. 64% male, 36% female. Age range 69–88 (79 mean)
Sainio, 2001, Finland [67]	Explore the views and experiences of adult cancer patients about patient participation in care and decision-making and the preconditions for this participation	Barriers & facilitators	Active patient participation in decision-making and care	No	Cross-sectional. Qualitative. Semi-structured interviews	Secondary care, inpatient. Various cancer diagnoses	34 patients. 53% male, 47% female. Age range 24–54 (44 mean)
Simon, 2006, Germany [68]	Investigate depressed patients' perceptions of the treatment decision process with general practitioners	Barriers	Involvement in the treatment decision-making process. In shared decision making at least two individuals are involved in partnership to share the process of making a treatment decision	No	Cross-sectional. Qualitative. Semi-structured interviews	Inpatient and outpatient. Depression	40 patients. 40% male, 60% female. Age range 18–70 (43 mean)
Skea, 2004, UK [69]	To explore women's views of decision-making relating to hysterectomy	Barriers & facilitators	Various aspects of decision-making relating to hysterectomy	No	Cross-sectional. Qualitative. Semi-structured interviews	Secondary care. Hysterectomy	20 female patients. Age range 36–53
Thompson, 2007, UK [28]	Examine the views and preferences of citizens, as patients, members of voluntary groups, or neither, on involvement in health care delivery (role they wish to play and their conceptual meanings behind them). Develop a taxonomy based on this	Barriers & facilitators	Patient involvement and participation in health care consultations	No	Cross-sectional. Qualitative. Semi-structured interviews (b) Focus groups (n=36) (c) Workshops (n=12)	Primary and community care. Various health conditions, including chronic conditions	355 patients overall. 44 patients (b) 190 patients (c) 121 patients Gender & age not reported
Thorne, 2012, Canada [70]	To contribute to the evolving dialog on optimizing cancer care communication through systematic analyses of patients' perspectives	Barriers & facilitators	Shared decision-making	No	Longitudinal. Qualitative. Interviews	Secondary care. Various cancer diagnoses	100 patients. 28% male, 72% female. Age range 23–83 (65% between 50–69)

<p>Van Staa, 2011, The Netherlands⁵ [71]</p>	<p>To integrate findings of mixed methods research (MMR) into preferences and competencies for communication during consultations of adolescents with chronic conditions, in order to demonstrate the added value of MMR for health communication research</p>	<p>Barriers & facilitators</p>	<p>Triadic communication during healthcare consultations</p>	<p>No</p>	<p>Cross-sectional. Qualitative. Semi-structured interviews</p>	<p>Secondary care. Various chronic conditions</p>	<p>31 patients, 52% males, 48% females. Age range 12–19 (15 mean)</p>
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^a Lead author from Belgium. Study recruited participants from 11 countries: Austria, Belgium, Denmark, France, Germany, Israel, The Netherlands, Portugal, Slovenia, Switzerland, UK.

^b Baseline data analyzed included data from one longitudinal study. However, only baseline data considered, so overall design cross-sectional.

^c Peek 2010 and Peek 2009 use same sample, but Peek 2010 reports additional data obtained from additional questions/prompts used during focus groups and semi-structured interviews.

^d Mixed methods study – reported barriers and facilitators derived from one method only so logged as qualitative/quantitative (as appropriate) for the purposes of this review.

change. Modifiable barriers include embarrassing topics (e.g. not receiving information about sexual-related side effects due to cultural stigma) [48] and sensitive topics (e.g. end-of-life discussions) [52]. Again, the focus could be on attitudinal change, either at the individual belief or subjective norm level [62]. Not having time to come to adjust to a diagnosis is a barrier to SDM as the consultation can be “overshadowed” by the shock of receiving threatening news, whilst having time to come to terms with the diagnosis and consider the decision facilitates involvement [35,59,69]. However, sometimes the time between diagnosis and treatment commencing is too short and hinders SDM [18]. Timing barriers are potentially modifiable for most situations, if we can reconsider where SDM fits in the clinical pathway or patient’s disease trajectory, and provide time before considering options after a diagnosis, if feasible.

3.4.2. Interactional context factors (39/44)

3.4.2.1. Power imbalance in the patient–clinician relationship (36/44).

• Presumptions about the patient role

Several modifiable barriers relating to patients’ presumptions of the “normal”, expected patient role were identified: that “normal” patients are passive and expect clinicians to make decisions [27,32,38,44,45,58], fearing bad consequences if one were labeled as inflexible or troublesome [20,40]. Fear of being described as a difficult patient is often accompanied by a fear of retribution: many patients felt it might lead to poorer quality care or to less attention [17,20,51]. The desire to be a “good” patient is also driven by the perceived benefits that might arise e.g. lack of conflict in the encounter [20,51] and having the clinician “on your side” [29].

Perceived unacceptability of asking the clinician questions and raising options can act as a barrier to SDM. Some patients believe that hospital is somewhere where you do not ask questions [18,32], that clinicians do not want patient involvement or to be questioned [27,36,45,47,53], and asking questions would undermine the status of the professional [20,32,47], and indicate distrust [20,22], or a lack of respect [29,38,41]. Conversely, patients’ feeling that it is acceptable to ask questions acts as a facilitator [17,36,39,54,65]. Sometimes, passive behavior is directly reinforced by clinicians e.g. where compliant, non-questioning individuals are called “easy” or “best” patients [29]. Explicit encouragement to be involved in SDM is an effective facilitator to involvement [34,36,47,51,65,67], whereas lack of explicit “permission” or encouragement is a barrier to involvement. Some patients feel that they do not have “the right” to be involved in healthcare decisions [65] and do not initiate dialog unless the clinician encourages this [20,71].

• Patients undervalue their expertise relative to clinicians

Many patients believe “doctor knows best”, and that their own knowledge is superfluous to the decision-making process, being trumped by medical expertise and experience. These patients rely on clinicians to make decisions because they are the “experts” and “skilled technicians” [27–30,32,34,35,37,38,22,40,41,44,51,58,65], and patients are not educated in the field of medicine e.g. “I am an engineer and I know my area of work, the nurses and doctors know theirs” [51]. When patients discuss their knowledge relative to clinicians, they often talk about themselves, or their knowledge, as inferior to the “gods in white” [34,36] and frequently undervalue their contribution (e.g. “the average lay person knows nothing you know”) [17]. Some patients also feel they are incapable of

Table 2
Patient-reported barriers and facilitators to shared decision making^a: overview of analytical, descriptive & sub-themes (no. of studies/44 identified as factor) [references identified as a factor].

3.3 How the healthcare system organized (27)			
Analytical theme			
Descriptive themes			
3.3.1 Time (20) [17,18,20,27,34–39,44,45,47,53,58–60,65,67,69]	3.3.2 Continuity of care (15) [31,34–38,44,45,47,52,55,65,67,69,70]	3.3.3 Workflow (9) [17,18,37,44,47,53,57,59,67]	3.3.4 Characteristics of the healthcare setting (7) [17,19,36,44,60,66,69]
<ul style="list-style-type: none"> • Clinicians are too busy [17,20,27,34–36,39,44,45,47,53,58,60,67,69] • Lack of time during consultation [17,20,34,36–38,53,58,67,69] • Adequate time in the consultation (fac) [27,34,36,38,59,65,69] 	<ul style="list-style-type: none"> • Inability to choose clinician to do SDM with [36] • Too many clinicians involved in care [31,34–36,44,45,47,52,55,67] • Lack of continuity in the informational flow between clinicians [55] • Clinician does not know the patient [34,47,69] • Being known by the clinician (fac) [34,36–38,70] 	<ul style="list-style-type: none"> • Distributing SDM among different clinicians e.g. nurse takes part in SDM with patient (fac) [37,44,53,67] • System does not offer multiple-consultation model that may be needed for SDM [18,57,59] • Appropriate consultations for SDM (fac) [17] 	<ul style="list-style-type: none"> • Inadequate environmental conditions e.g. noisy, lack of privacy [44,60,66,69] • Not paying for healthcare (bar)/paying for healthcare (fac) [17] • Overspecialization of doctors [36] • Lack of reimbursement for clinicians undertaking SDM [19,36]
3.4 What happens during the healthcare consultation (44)			
Analytical theme			
Descriptive themes			
3.4.1 Predisposing factors (33) [27–32,34–48,51–55,59,60,65–68,71]	3.4.2 Interactional context factors (39) [17–20,27,29–32,34–38,22,39–41,44,45,47,48,51–60,65–67]	3.4.3 Preparation for a SDM encounter (32) [17–20,27–29,32,34–38,22,40,41,44,45,47,51,52,54–56,58,59,65,67–71]	3.4.4 Preparation for the SDM process (36) [17–19,27–29,32–38,22,40,41,44–48,51,53–61,66–70]
<p>Patient characteristics (29)</p> <p>[27–32,34–39,42,44–48,51–55,60,65–68,71]</p> <ul style="list-style-type: none"> • Being in poor [34,36–38,44–46,54,55,60,67,68] • Being in good health (fac) [67] • Cognitive/physical impairments [34,37,38,55,60,66] • Prior exposure to illness/decision-making point (fac) [52,65] • Age (older/younger) [29,34,37,38,45,51,53,67,71] • Ethnicity [29,65] • Lower level of Education [30,34,37,39] • Poor articulation [32,34,38,44,66] • Difference in personal characteristics [31,45,46,48,55] • Health condition–stigma/discrimination [28,31,42,47] • Long term patient (bar) [27] & fac [37,38] <p>Decision characteristics (18)</p> <p>[28,34,35,38,40–44,47,48,51–54,59,67,68,71]</p> <ul style="list-style-type: none"> • Timing along the illness trajectory (bar & fac) [28,35,40,43,51,53] • Major decisions (bar) [38,44] & fac [38,44,67] • Minor decisions (bar) [44] & fac [38,44] • Embarrassing or sensitive topics [34,42,48] • Shock of receiving diagnosis [28,41,47] • Time to come to terms with diagnosis (fac) [41,59] 	<p>Power imbalance in the patient–clinician relationship (36)</p> <p>[17–20,27–30,32,34–38,22,39–41,44,45,47,51,53–60,65–67,69–71]</p> <p>Presumptions about the patient role</p> <ul style="list-style-type: none"> • Expectation of the clinician making the decisions [17,18,27–30,32,36–38,40,41,44,46,51,58,65] • Desire to act like a “good” patient driven by a fear of consequences [17,18,20,27,29,32,34,40,41,51,55,58,65,67,70] • Perceived acceptability of asking the clinician questions (bar) [20,29,32,36,38,22,40,41,45,47,51,53,54,65] & fac [17,28,29,34,36,39,45,47,51,53,54,56,58,59,65,67,69] • Belief that clinicians do not want patients involved [17,18,20,27,29,34–36,45,47,53,58,60,70] • Clinician reinforces passivity by rewarding this behavior [34,40,41,66] • Not having explicit “permission” to participate in SDM [17,20,36,38,51,54,57–59,65,69,71] • Having explicit “permission” to participate in SDM (fac) [17,19,34,36,38,47,51,56,59,65,67,70] <p>Patients undervalue their expertise relative to clinicians</p> <ul style="list-style-type: none"> • “Doctors know best” and patients’ have “inferior” knowledge [17–20,27–30,32,34–38,22,39–41,44,45,51,53–55,58,65,67,69,71] <p>Patients are not capable of understanding medical/technical information [30,32,35,55,71]</p> <ul style="list-style-type: none"> • Recognize that there are two experts in the medical encounter (fac) [17,28,29,36–38,22,39,40,44,47,54,56,65,70] <p>Interpersonal characteristics of the clinician(s) (35)</p> <p>[17,19,20,27–29,31,32,34,36–38,22,39–41,44,45,47,48,51–56,58–60,65–67,69–71]</p> <ul style="list-style-type: none"> • Authoritarian HCPs [20,27,34,36,51,55,58,60,65,69] • Equal relationship (fac) [19,20,28,29,36–38,22,39,47,56,58,65,70] • Clinician does not listen to patient’s concerns [19,20,27,28,34,36–40,44,47,51,54,55,58–60,65,66] • Clinician listens to patient’s concerns (fac) [19,34,36–38,47,56,58,65,70] • Clinician with poor interpersonal skills [20,31,34,36–38,40,44,47,48,55,60,65–67,69,7] • Clinician with positive interpersonal skills (fac) [34,37,47,59,65,67,69,70] • Good relationship with clinician (fac) [17,28,37,38,44,47,52,56,58,65,67,70] • Poor relationship with clinician [67] • Lack of individualized approach and not asked about preferences [19,20,27,36,41,44,47,53,55,67] • Individualized approach where clinician seeks patient’s preferences (fac) [19,28,34,36,38,47,52,56,58,59,70] • Clinician does not address patient directly [54,55,71] <p>Trust (24) [17,18,27–30,32,34–38,22,40,41,44,45,47,52,55,56,58,65,66]</p> <ul style="list-style-type: none"> • Trust in clinician (bar) [17,18,27–30,35–38,40,41,44,45,55,58] & fac [17,34,36,47,52,55,56,66] • Lack of trust in clinician (bar) [36,65,66] & fac [17,28,38] 	<p>Perceived need for preparation (30)</p> <p>[17–20,27–29,32,34–38,22,40,41,44,45,47,52,54,56,58,59,65,67–71]</p> <ul style="list-style-type: none"> • Patient is not entitled to a choice [17,29,32,35,38,40,52,54,58,59,69] • Patient is not explicitly offered a choice or it is presented in a biased way [27,35,40,41,47,69,70] • “Doing nothing” is not an option [35,22,41,69] • Patient does not want to or need to participate in SDM [18,19,28,29,32,34,36,41,44,45,52,54,58,70,71] • Accepting responsibility to be involved in decision-making (fac) [17,20,28,29,34–38,22,47,54,56,67,70,71] • Not knowing what to expect from the SDM consultation [44,52,65,69] <p>Expectations of the outcome of being involved in SDM (21)</p> <p>[17,18,28,32,34–36,22,40,41,45,47,51,52,55,65,67–71]</p> <ul style="list-style-type: none"> • Perceiving that there are “right” and “wrong” decisions (not wanting responsibility for wrong decision) [18,28,32,34–36,22,40,41,45,51,55,71] • Recognizing equipoise and uncertainty (fac) [17,34,36,67,69,70] • Fear of accepting reality of diagnosis [18,28,34–36,40,52,55,65,67,68] 	<p>Providing information about options (27) [17,19,27–29,32,34–38,22,40,41,44,45,47,51,53–55,58,59,65,67,69,70]</p> <ul style="list-style-type: none"> • Insufficient information about condition, options and outcomes [19,27,32,35,36,38,40,41,44,45,47,51,53,55,58,59,65,69,70] • Sufficient information about condition, options and outcomes (fac) [17,19,28,29,34,35,37,38,44,45,47,54,59,65,67,70] • Clinician does not explain the options and outcomes [17,19,35,41,47,54,65,69] • Clinician explains the options and outcomes (fac) [17,28,34–36,38,22,47,54,59,69,70] <p>Terminology used by HCPs (17)</p> <p>[17,19,28,32,35,36,38,44,45,48,54,55,58,60,65,66,68]</p> <ul style="list-style-type: none"> • Clinician uses medical terminology [17,28,32,36,38,44,46,48,55,58,60,65,66,68] • Clinician uses simple terminology (fac) [19,28,35,36,54,65] <p>Decision support (8)</p> <p>[18,33,36,53,56,57,59,69]</p> <ul style="list-style-type: none"> • Lack of written decision support (bar) [53,59,69] • Lack of written decision support (fac) [18,33,59] • Purpose of the decision support tool is unclear [57] • Decision support from others e.g. family, other clinicians (fac) [56,69]

^a Unless otherwise stated, all sub-themes were reported as barriers to participating in SDM. When a factor was reported as a facilitator or both a barrier & facilitator to SDM, this is indicated: Fac=Facilitator; Bar=Barrier.

understanding the “complex and technical” information needed to make a decision [30,32]. However, when patients recognize the contribution and importance of their own personal preferences, rather than that of technical knowledge, this facilitates SDM [17,36–38,22,40,44,47,54,65,70]. Many of these barriers are potentially modifiable as they could be addressed through attitudinal change at the levels of patient and the clinician, possibly at the organizational level, and complemented by promoting self-efficacy in patients.

3.4.2.2. Interpersonal characteristics of the clinician(s) (35/44). Authoritarian or dismissive clinicians who dominate decision-making encounters, do not listen to or respect patients’ concerns, or use negative verbal or non-verbal behavior, are a barrier to SDM for many patients [19,20,36–39,47,51,54,55,58,60,65–67]. However, clinicians who do not dominate the consultation [28,39,65] and who do listen to patients and respect their concerns [19,34,36–38,47,58], facilitate SDM, also creating a sense of partnership [65], a positive environment where patients feel comfortable participating in the decision-making dialog, and a good relationship with the patient [17,37,38,44,56,67].

Clinicians who seek to understand individual needs and preferences can facilitate involvement [19,34,38,47,52,70]. Not acknowledging that for some people quality of life is more important than life span [27] or focusing merely on treating a “disease” [19,36,67], acts as a barrier [19,27,36,41,47,53,55]. Inability to address the patient directly also compromises SDM, such as in a triadic consultation with young people and their parents or when nurses discuss the patient’s issues with relatives “behind their back” [54,71]. The presence of an advocate in the consultation can support involvement in decision-making (practical and social support) [20,34,36,44,56,65,67], whilst not having a family member present can act as a barrier [60,66]. Again, most factors related to interpersonal characteristics of the clinician are potentially modifiable, because, in theory, clinician attitudes are changeable.

3.4.2.3. Trust (24/44). Both the presence and absence of trust was identified as a facilitator or a barrier to participation, depending on the individual. Trust can act as a barrier because it can lead patients to be passive in consultations (e.g. “leave their lives in the hands of the professional”) [29,30]. Trust might be based on the following: the clinician’s knowledge and length of training [28,30,37,38,40]; positive past experiences with the clinician or good reputation [17,29,37]; a “blind” or unconditional trust, having faith the clinician will act in the patient’s best interests [18,36,37,41,45]; and a “need” to trust the clinician as a way of coping [35,22]. Trust can also facilitate SDM. A trusting relationship makes patients more willing to ask questions, share personal information and discuss concerns [17,36,47,56,65]. Similarly, some patients have cited lack of trust as a barrier to involvement [36,65,66], but it can sometimes encourage SDM: some patients ask more questions if they do not trust their doctor [17]. Whilst question asking does not equate to SDM, questioning patients are carefully considering possible actions, an essential element of SDM. Issues related to trust are potentially modifiable, but cannot be addressed in isolation due to the inherent complexity described above e.g. we would not advocate for distrusting relationships, but for promotion of both trusting relationships and positive attitudes toward involvement among both patients and clinicians.

3.4.3. Preparation for a SDM encounter (32/44)

This theme differs from the next (“preparation for a SDM process”), as it identifies the preparation needed for a patient to have *opportunity to participate* in SDM, rather than participation in the *actual SDM process*.

3.4.3.1. Perceived need for preparation (30/44). Perceiving there is no decision to be made is a barrier to SDM and can arise for several reasons: patients believe they are not entitled to or offered a choice [17,32,35,40,54,58]; the clinician may present the options in a biased way [27,35,40,41,47,69]; or the actual options available e.g. some patients believe that “doing nothing” is not an option and is not of equal value to other options [35,22]. When patient do not know what to expect from a SDM consultation, or what they should be involved in, this limits involvement [44,65].

Perceiving that you do not want to be involved in SDM is an important barrier, potentially due to various reasons, including: general preference for passivity and wanting to be told what to do [28,32,36,45]; not wanting to receive or understand information [18,34,70]; finding medical information too distasteful [29,32,44]; feeling SDM may delay treatment [18]; preference for “happy talk” or being “kept in the dark” [70]. Perceiving that you do not need to be involved is another, related barrier e.g. some patients presume that everything will get done for them, and thus they do not need to be prepared to play an active role in decision-making [29,71]. Conversely, recognizing the SDM patient role and accepting responsibility for one’s own healthcare decision-making facilitates involvement [17,28,29,34–38,47].

3.4.3.2. Expectations of the outcome of being involved in SDM (21/44). The perception that there are “right” and “wrong” decisions is a barrier to SDM; patients do not want to be responsible for a “wrong” decision [32,35,22,41,51], wanting to avoid potential regret. Some patients use the term “right” to describe decisions that are made by their doctor [34,22,41,51], and talk about being able to “blame” clinicians for “bad” outcomes if they are not active participants in the decision-making process [22]. When patients recognize that there are no right or wrong decisions in situations of equipoise, just “the right decisions for me” based on personal values [17,36,69,70], this facilitates involvement.

Most of these factors appear modifiable, and could be addressed by changing attitudes or subjective norm beliefs e.g. emphasizing patients’ roles/responsibilities in SDM, outlining what is involved in the SDM process.

3.4.4. Preparation for a SDM process (36/44)

3.4.4.1. Providing information about options (27/44). Many patients feel they cannot be involved in decisions when they do not have information about their specific condition, when they are unaware of the options and what these entail, or do not know the possible outcomes [58,69]. Unsurprisingly, providing sufficient information to address individual information needs facilitates SDM [19,70], and can promote participation and question asking about treatment options [65]. When the clinician clearly explains the available options and what they entail (e.g. procedure, possible outcomes), patients feel much better prepared for SDM [28,38,59]. Earlier provision of information, e.g. before consultations, was also reported by some patients as an important for being prepared for a SDM process [69].

3.4.4.2. Terminology used by clinicians (17/44). The use of medical terminology by clinicians is a barrier to SDM [35,44]. Patients feel that clinicians are “talking another language” [58] or “talk so far over patients’ heads” [17], sometimes leading patients to misinterpret the procedures being offered [48]. Conversely, simple, non-medical or “layman terms” facilitate involvement in the decision-making process [19,65], and enhances perceived, and possibly real, power and autonomy in young people [54].

3.4.4.3. Decision support (8/44). Lack of written decision support can act as a barrier to involvement, because it is difficult to

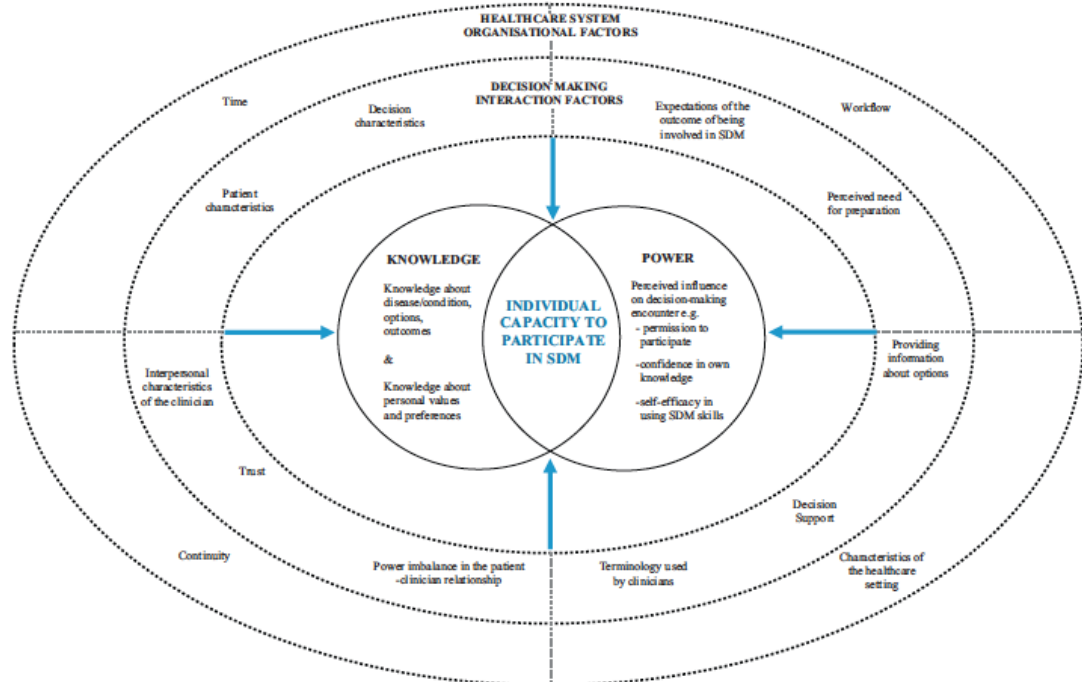


Fig. 2. Knowledge and power: patient-reported influences on individual capacity to participate in shared decision making.

remember the information presented [53,59]. Using decision support helps patients to remember information, focus on points of concern, think about issues they wish to discuss in the consultation [33], and is a good starting point to promote discussion with clinician [18], although some feel that it makes the consultation feel impersonal and false, favoring direct information provision by the clinician [18,33]. The facilitative potential of decision support is also reduced if the purpose of the tool is unclear to the patient [57], and patients also commented on the difficulty of “keeping up” with rapidly evolving medical information [36]. Decision support also refers to the support that the patient is offered from alternative sources e.g. family, other patients, non-doctors; this support can facilitate involvement [56,69].

Many of these factors are potentially modifiable as they could be addressed through adequate information provision about the options available (whether this be decision aids or from the clinician), a balanced presentation of options, and use of non-medical terminology by clinicians.

3.5. Synthesis of results

A taxonomy of patient-reported influences on individual capacity to participate in SDM was developed by synthesizing the identified barriers and facilitators (see Fig. 2). It demonstrates that individual capacity to participate in SDM depends on two key factors: knowledge and power. Knowledge refers to both knowledge about the treatment options available and of personal preferences and goals. Power refers to the patients' perceived capacity to influence the decision-making encounter, including factors such as: having permission to participate, confidence in the value of own knowledge and ability to acquire medical knowledge, necessary skills to participate, and self-efficacy to use these skills

[73,74]. All other factors identified as barriers and facilitators (e.g. interpersonal characteristics of the clinician, patient characteristics, time) will promote or inhibit this capacity depending on their presence or absence. Importantly, some of the barriers and facilitators reported will only be relevant to specific situations, and will not always be applicable (e.g. requirement to undergo physical examination, health insurance contexts). It should also be noted that this taxonomy is based on patient-identified factors: it will need to be considered within the wider organizational context and situated alongside clinician-reported factors [6,9,13] during implementation attempts.

4. Discussion & conclusion

4.1. Discussion

The results suggest that a large number of patients currently *can't* participate in healthcare, due to various structural, predisposing, interactional, and preparatory factors, rather than the more common view among clinicians that patients *won't* participate because they *don't want* to. Patient-reported barriers and facilitators to SDM relate to how the healthcare system is organized (i.e. time available, continuity of care, organization of workflow and the setting itself) and to what happens in the consultation (i.e. predisposing factors such as patient characteristics, interactional influences including the power imbalance between patient and clinician, and preparation for the SDM encounter and the process itself, including knowledge gain). These need to be considered alongside clinician-reported factors [6,13] during intervention development and implementation. Predominant themes were patients' knowledge and the power imbalance in the clinician-patient relationship. Significantly, most patient-reported barriers

and facilitators are potentially modifiable, and many could be addressed by attitudinal changes at the levels of patient, clinician/healthcare team, or organizational change.

4.1.1. An 'informational paradox'

An important 'informational paradox' has been identified. Unsurprisingly, the principal enabler to SDM is having informational needs met at an appropriate level for the individual, but we cannot consider this in isolation from other relevant factors because of their complex interactions. Due to the prevailing view that "doctor knows best", patients undervalue their ability to acquire the "complex" knowledge that clinicians "own", and undervalue any knowledge gain relative to that of clinicians. A contributing factor is that patients also place much emphasis on the medical information provided, but do not recognize, or undervalue, the complementary expertise that they can bring to the SDM encounter i.e. personal preferences and circumstances. Therefore, information provision alone appears insufficient for SDM; patients need to be supported so they feel capable of acquiring and understanding knowledge about the available options, and so that they value their personal knowledge contribution to SDM.

4.1.2. 'Covert contracts' in the patient–clinician relationship

Interacting with this informational paradox are the 'covert contracts' that patients develop with clinicians, typically physicians, which are not usually acknowledged. Many patients enter into an unspoken contract with the clinicians, adopting the role of a "good patient", characterized by passivity and compliance. This study does not elucidate the reasons why these contracts exist (e.g. socialization to patient role, previous experience, social/cultural norms, the media) [72]. Nonetheless, presumptions about the "normal" patient role emerged as an important barrier, with many patients believing that they should not or cannot be involved. In Foucauldian terms [73], we may be able to change discursive practices regarding expected patient roles if patients experience discursive practices where they are encouraged to avert the traditional "clinical gaze", by considering their own preferences and developing skills of self-representation. Therefore, implementation attempts should also focus on providing patients with explicit permission to change these 'contracts' [23], and promote their self-efficacy, or confidence, in achieving this.

4.1.3. Knowledge does not equal power

As we have seen, knowledge provision, acquisition, and expectation to contribute personal preferences are done in the context of a power imbalance between clinicians and patients. Therefore, information provision and encouragement to value personal contribution alone are unlikely to promote SDM for most patients. We must also address the power imbalance that exists so that people feel that they can and want to use this knowledge. Contrasting the well-known phrase, it would appear that knowledge is *not* power (*Sir Francis Bacon, 1597*), at least in the discourse of medical decision making: patients need knowledge *and* power to participate in SDM. Individual capacity to participate is linked to how much knowledge a patient has *and* how much power they have, or their perceived capacity to influence the decision-making encounter [74,75] (see Fig. 2). Some pre-consultation interventions have been developed that attempt to redress perceived, or real, power imbalances (e.g. coaching sessions, patient activation [76–78]). However, they are difficult to integrate into routine healthcare settings because of the additional time required ahead of scheduled appointments, so researchers need to investigate alternative methods to address this issue.

4.1.4. Comparison with clinician barriers

The three most commonly cited clinician-reported barriers are time, lack of agreement with the applicability of SDM to the patient, and lack of agreement with the applicability of SDM to the clinical situation [13], suggesting clinicians presume that many patients will not benefit from SDM, or do not wish to take part. Whilst patient characteristics, such as desire to participate, were identified in this review, factors other than desire were much more prominent (e.g. knowledge, power imbalance, interpersonal characteristics of the clinician). This highlights the importance of understanding patient-reported barriers, as they are distinct from those of clinicians.

4.1.5. Strengths and weaknesses

To our knowledge, this is the first systematic review to focus exclusively on patient-reported barriers and facilitators to SDM, and direct enquiry with patients in the primary studies is a significant strength of this study. Direct enquiry might miss more subtle barriers and facilitators that are not so apparent to patients (e.g. coping style), but we are confident that the key factors influencing participation have been identified, supported by their consistency across numerous studies with varied designs. Although we conducted systematic searches, this is not a well-indexed field and researchers have varying interpretations of SDM: therefore some articles might have been missed in this review. Synthesizing qualitative data from systematic reviews is also an emerging field of research, in which methods are not as well defined as for other reviews, but we chose a well-documented approach developed for analyzing qualitative data [25]. The inductive approach ensured key themes were derived directly from the data, and the resultant taxonomy of patient-reported barriers and facilitators complements the clinician taxonomy [13]. We acknowledge that we still have little understanding of patients who say that they do not want to be involved in SDM, and whether this decision is informed; further research is needed to delineate the 'cannot' participate patients from the definitely 'do not' want to participate.

4.2. Conclusion

We found that patients need knowledge *and* power to participate in SDM. One of the most significant barriers to SDM was inadequate information provision. To date, researchers appear to have 'picked off' this most prominent patient-reported barrier ("treated" by decision aids), and have perhaps wrongly assumed that they can address this barrier in isolation from the many other interacting factors: as demonstrated by a focus on developing patient decision aids [79]. Decision aids are successful at supporting patients in the SDM *process*, but they fail to address the essential first step of 'preparing for the SDM encounter', including perceiving the opportunity and personal ability to be involved. Knowledge provision and encouragement to think about personal values alone are unlikely to support actual involvement in SDM for a large number of people. Power imbalance in the doctor–patient relationship and perceived acceptability of patient involvement are also key barriers. These must be addressed too if patients are to change their long-established behaviors and actively engage in decision-making discussions.

4.3. Practice implications

To ensure that we do not ineffectually 'cherry-pick' the most prominent barriers, intervention development could be structured around the taxonomy proposed. Interventions should take account of the relationships between factors (Fig. 2) and address the 'entry level' factors to SDM, such as changing subjective norms and

redefining patients' roles [49,62], before secondary process factors, such as information provision and values clarification. However, we cannot address the patient-reported factors by focusing on patients alone: significant structural and attitudinal changes at the organizational and clinician level are also still needed [11], and clinicians will have a valuable contribution to changing the subjective norms of patients. Future implementation attempts should consider these patient-reported factors alongside known clinician-reported barriers and the wider organizational context.

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Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.pec.2013.10.031>.

References

- Mulley AG, Trimble C, Elwyn G. Stop the silent misdiagnosis: patients' preferences matter. *Brit Med J* 2012;345:e6572.
- Coulter A, Collins A. Making shared decision making a reality: no decision about me without me. London: The King's Fund; 2011.
- Department of Health. Liberating the NHS: no decision about me without me. London: Crown; 2010.
- Belkora JK, Loth MK, Volz S, Rugo HS. Implementing decision and communication aids to facilitate patient-centered care in breast cancer: a case study. *Patient Educ Couns* 2009;77:360–8.
- Frosch DL, Singer KJ, Timmermans S. Conducting implementation research in community-based primary care: a qualitative study on integrating patient decision support interventions for cancer screening into routine practice. *Health Expect* 2011;14(Suppl. 1):73–84.
- Legare F, Ratté S, Stacey D, Kryworuchko J, Gravel K, Graham ID, et al. Interventions for improving the adoption of shared decision making by healthcare professionals (Review). *Cochrane Database Syst Rev* 2010;5:CD006732.
- Elwyn G, Scholl I, Tietohl C, Mann M, Edwards A, Clay K, et al. The implementation of patient decision support interventions into routine clinical practice: a systematic review. In: Volk R, Llewellyn-Thomas H (Eds.), *Update of the International Patient Decision Aids Standards (IPDAS) collaboration's background document*; 2012. <http://ipdas.ohri.ca/resources.html>.
- The Health Foundation. The Health Foundation Implementing shared decision making: clinical teams' experiences of implementing shared decision making as part of the MAGIC programme. London; 2013.
- The Health Foundation. The MAGIC programme: evaluation. London; 2013.
- Elwyn G, Scholl I, Tietohl C, Mann M, Edwards A, Clay K. Many miles to go... A systematic review of the implementation of patient decision support interventions into routine clinical practice. *BMC Med Inform Decis Mak* 2013 [in press].
- Lloyd A, Joseph-Williams N, Edwards A, Rix A, Elwyn G. Patchy 'coherence': using normalization process theory to evaluate a multi-faceted shared decision making implementation program (MAGIC). *Implement Sci* 2013;8:102.
- Fagerlin A, Pignone M, Abhyankar P, Col N, Feldman-Stewart D, Gavaruzzi T, et al. Clarifying and expressing values. In: Volk R, Llewellyn-Thomas H (Eds.), *Update of the International Patient Decision Aids Standards (IPDAS) collaboration's background document Chapter D*; 2012. <http://ipdas.ohri.ca/resources.html>.
- Legare F, Ratté S, Gravel K, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions. *Patient Educ Couns* 2008;73:526–35.
- Coulter A, Edwards A, Elwyn G, Thomson R. Implementing shared decision making in the UK. *Z Evid Fortbild Qual Gesundhwes [German J Evid Qual Healthcare]* 2011;105:300–4.
- Holmes-Rovner M, Valade D, Orlowski C, Draus C, Nabozny-Valerio B, Keiser S. Implementing shared decision-making in routine practice: barriers and opportunities. *Health Expect* 2000;3:182–91.
- Lake Research Partners for the Informed Medical Decision Making Foundation. Informing and involving patients in medical decisions: the primary care physicians' perspective. Massachusetts; 2009.
- Fraenkel I, McGraw S. What are the essential elements to enable patient participation in medical decision making. *J Gen Intern Med* 2007;22:614–9.
- Bhavnani V, Fisher B. Patient factors in the implementation of decision aids in general practice: a qualitative study. *Health Expect* 2010;13:45–54.
- Eldh AC, Ekman I, Ehnfors M. Conditions for patient participation and non-participation in health care. *Nurs Ethics* 2006;13:503–14.
- Frosch DL, May SG, Rendle KA, Tietohl C, Elwyn G. Authoritarian physicians and patients' fear of being labeled 'difficult' among key obstacles to shared decision making. *Health Aff (Millwood)* 2012;31:1030–8.
- Say R, Murtagh M, Thomson R. Patients' preference for involvement in medical decision making: a narrative review. *Patient Educ Couns* 2006;60:102–14.
- Charles C, Whelan T, Gafni A, Reyno I, Redko C. Doing Nothing is No Choice: lay constructions of treatment decision-making among women with early-stage breast cancer. *Social Health Ill* 1998;20:71–95.
- Prothome J, Brooks H, Chew-Graham C, Gardner C, Rogers A. 'Permission to participate?' A qualitative study of participation in patients from differing socio-economic backgrounds. *J Health Psychol* 2013;18:1046–55.
- QSR International Pty Ltd. NVivo qualitative data analysis software. Version 10; 2012.
- Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic reviews. *BMC Med Res Methodol* 2008;8.
- Kmet L, Lee R, Cook L. Standard quality assessment criteria for evaluating primary research papers from a variety of fields. HTA Initiative #13. Edmonton: Alberta Heritage Foundation for Medical Research (AHFMR); 2004.
- Aasen EM, Kvangarsnes M, Heggen Kr. Perceptions of patient participation amongst elderly patients with end-stage renal disease in a dialysis unit. *Scand J Caring Sci* 2012;26:61–9.
- Thompson AG. The meaning of patient involvement and participation in health care consultations: a taxonomy. *Soc Sci Med* 2007;64:1297–310.
- Adler SR, McGraw SA, McKinlay JB. Patient assertiveness in ethnically diverse older women with breast cancer: challenging stereotypes of the elderly. *J Aging Stud* 1998;12:331–50.
- Agard A, Hemmeren G, Herlitz J. When is a patient with heart failure adequately informed? A study of patients' knowledge of and attitudes toward medical information. *Heart Lung* 2004;33:219–26.
- Anoosheh M, Zarkhah S, Faghizadeh S. Nurse-patient communication barriers in Iranian nursing. *Int Nurs Rev* 2009;56:243–9.
- Avis M. Choice cuts: an exploratory study of patients' views about participation in decision-making in a day surgery unit. *Int J Nurs Stud* 1994;31:289–98.
- Barnard KD, Craddock S, Parkin T, Skinner TC. Effectiveness of a computerised assessment tool to prompt individuals with diabetes to be more active in consultations. *Practical Diabetes Int* 2007;24:36–41.
- Bastiaens H, Van Royen P, Pavlic DR, Raposo V, Baker R. Older people's preferences for involvement in their own care: a qualitative study in primary health care in 11 European countries. *Patient Educ Couns* 2007;68:33–42.
- Beaver K, Jones D, Susnerwala S, Craven O, Tomlinson M, Witham G, et al. Exploring the decision-making preferences of people with colorectal cancer. *Health Expect* 2005;8:103–13.
- Belcher VN, Fried TR, Agostini JV, Tinetti ME. Views of older adults on patient participation in medication-related decision making. *J Gen Intern Med* 2006;21:298–303.
- Caress AL, Luker K, Woodcock A, Beaver K. A qualitative exploration of treatment decision-making role preference in adult asthma patients. *Health Expect* 2002;5:223–35.
- Caress AL, Beaver K, Luker K, Campbell M, Woodcock A. Involvement in treatment decisions: what do adults with asthma want and what do they get? Results of a cross sectional survey. *Thorax* 2005;60:199–205.
- Claramita M, Utarini A, Soebono H, Van Dalen J, Van der Vleuten C. Doctor-patient communication in a Southeast Asian setting: the conflict between ideal and reality. *Adv Health Sci Educ Theory Pract* 2011;16:69–80.
- Clover A, Browne J, McErlain P, Vandenberg B. Patient approaches to clinical conversations in the palliative care setting. *J Adv Nurs* 2004;48:333–41.
- Cohen H, Britten N. Who decides about prostate cancer treatment? A qualitative study. *Fam Pract* 2003;20:724–9.
- Curtis JR, Patrick DL. Barriers to communication about end-of-life care in AIDS patients. *J Gen Intern Med* 1997;12:736–41.
- Decker C, Garavalia L, Chen C, Buchanan DM, Nugent K, Shipman A, et al. Acute myocardial infarction patients' information needs over the course of treatment and recovery. *J Cardiovasc Nurs* 2007;22:459–65.
- Doherty C, Doherty W. Patients' preferences for involvement in clinical decision-making within secondary care and the factors that influence their preferences. *J Nurs Manage* 2005;13:119–27.
- Ekdahl AW, Andersson L, Friedrichsen M. They do what they think is the best for me: Frail elderly patients' preferences for participation in their care during hospitalization. *Patient Educ Couns* 2010;80:233–40.
- Ekdahl AW, Andersson L, Wiréhn AB, Friedrichsen M. Are elderly people with co-morbidities involved adequately in medical decision making when hospitalised? A cross-sectional survey. *BMC Geriatr* 2011;11.
- Entwistle V, Prior M, Skea ZC, Francis JJ. Involvement in treatment decision-making: its meaning to people with diabetes and implications for conceptualisation. *Soc Sci Med* 2008;66:362–75.
- Farahani MA, Sahragard R, Carroll JK, Mohammadi E. Communication barriers to patient education in cardiac inpatient care: a qualitative study of multiple perspectives. *Int J Nurs Pract* 2011;17:322–8.
- Fishbein M. The role of theory in HIV prevention. *AIDS Care* 2000;12:273–8.
- Fishbein M, Ajzen I. Predicting and changing behavior: the reasoned action approach. New York: Psychology Press; 2010.
- Henderson S. Influences on patient participation and decision-making in care. *Prof Nurse* 2002;17:521–5.

- [52] Janssen DJA, Curtis JR, Au DH, Spruit MA, Downey L, Schols JM, et al. Patient-clinician communication about end-of-life care for Dutch and US patients with COPD. *Eur Respir J* 2011;38:268–76.
- [53] Kawabata H, Konishi K, Murakami M, Kisa K, Maezawa M. Factors affecting the physician–patient relationship regarding patient participation in medical encounters in primary care. *Hokkaido Igaku Zasshi [Hokkaido J Med Sci]* 2009;84:171–5.
- [54] Kelsey J, Abelson-Mitchell N, Skirton H. Perceptions of young people about decision making in the acute healthcare environment. *Paediatr Nurs* 2007;19:14–8.
- [55] Larsson IE, Sahlsten MJM, Segesten K, Plos KAE. Patients' perceptions of barriers for participation in nursing care. *Scand J Caring Sci* 2011;25:575–82.
- [56] Lown BA, Hanson JL, Clark WD. Mutual influence in shared decision making: a collaborative study of patients and physicians. *Health Expect* 2009;12:160–74.
- [57] Newsome A, Sieber W, Smith M, Lillie D. If you build it, will they come? A qualitative evaluation of the use of video-based decision aids in primary care. *Fam Med* 2012;44:26–31.
- [58] Nordgren S, Fridlund B. Patients' perceptions of self-determination as expressed in the context of care. *J Adv Nurs* 2001;35:117–25.
- [59] O'Brien MA, Ellis PM, Whelan TJ, Charles C, Gafni A, Lovrics P, et al. Physician-related facilitators and barriers to patient involvement in treatment decision making in early stage breast cancer: perspectives of physicians and patients. *Health Expect* 2011.
- [60] Park EK, Song M. Communication barriers perceived by older patients and nurses. *Int J Nurs Stud* 2005;42:159–66.
- [61] Peek ME, Wilson SC, Gorawara-Bhat R, Odoms-Young A, Quinn MT, Chin MH. Barriers and facilitators to shared decision-making among African-Americans with diabetes. *J Gen Intern Med* 2009;24:1135–9.
- [62] Ajzen I. The theory of planned behavior. *Org Behav Hum Decis Process* 1991;50:179–211.
- [63] Charles C, Gafni A, Whelan T. Decision-making in the physician–patient encounter: revisiting the shared treatment decision-making model. *Soc Sci Med* 1999;49:651–61.
- [64] McLeroy KR, Bibeau D, Steckler A, Glanz K. An ecological perspective on health promotion programs. *Health Educ Quart* 1988;15:351–77.
- [65] Peek ME, Odoms-Young A, Quinn MT, Gorawara-Bhat R, Wilson SC, Chin MH. Race and shared decision-making: perspectives of African-Americans with diabetes. *Soc Sci Med* 2010;7:1–9.
- [66] Ruan J, Lambert V. Differences in perceived communication barriers among nurses and elderly patients in China. *Nurs Health Sci* 2008;10:110–6.
- [67] Sainio C, Lauri S, Eriksson E. Cancer patients' views and experiences of participation in care and decision making. *Nurs Ethics* 2001;8:97–113.
- [68] Simon D, Loh A, Wills CE, Harter M. Depressed patients' perceptions of depression treatment decision-making. *Health Expect* 2007;10:62–74.
- [69] Skea Z, Harry V, Bhattacharya S. Women's perceptions of decision-making about hysterectomy. *Br J Obstet Gynaecol* 2004;111:133–42.
- [70] Thorne S, Olfie JL, Stajduhar KI. Communicating shared decision-making: cancer patient perspectives. *Patient Educ Couns* 2012.
- [71] van Staa A. Unraveling triadic communication in hospital consultations with adolescents with chronic conditions: the added value of mixed methods research. *Patient Educ Couns* 2011;82:455–64.
- [72] Edwards M, Davies M, Edwards A. What are the external influences on information exchange and shared decision-making in healthcare consultations: a meta-synthesis of the literature. *Patient Educ Couns* 2009;75:37–52.
- [73] Foucault M. The birth of the clinic: an archaeology of medical perception. 3rd ed. Oxford: Routledge; 2003.
- [74] Edwards M, Wood F, Davies M, Edwards A. The development of health literacy in patients with a long-term health condition: the health literacy pathway model. *BMC Public Health* 2012;12:130.
- [75] Nutbeam D. Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century. *Health Promot Int* 2000;15:259–67.
- [76] Brown RF, Butow PN, Sharrock MA, Henman M, Boyle F, Tattersall D, et al. Education and role modelling for clinical decisions with female cancer patients. *Health Expect* 2004;7:303–16.
- [77] Greenfield S, Kaplan SH, Ware JE, Vano EM, Frank HJ. Patients' participation in medical care: effects on blood sugar control and quality of life in diabetes. *J Gen Intern Med* 1988;3:448–57.
- [78] Shepherd HL, Barratt A, Trevena LJ, McGeechan K, Carey K, Epstein RM, et al. Three questions that patients can ask to improve the quality of information physicians give about treatment options: a cross-over trial. *Patient Educ Couns* 2011;84:379–85.
- [79] Stacey D, Bennett CL, Barry MJ, Col NF, Eden KB, Holmes-Rovner M, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2011;10:CD001431.

Appendix 2.3 – BMJ publication

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Page 1 of 3

ANALYSIS

Power imbalance prevents shared decision making

Providing information is not enough to enable shared decision making, argue **Natalie Joseph-Williams and colleagues**. Action is required to change the attitudes of both patients and doctors

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Adoption of shared decision making into routine clinical settings has been slow.¹ Large scale implementation programmes in the UK have delivered valuable lessons on how best to embed shared decision making,^{2,3} but few programmes have actually considered what helps or stops patients from being involved in healthcare decisions. Organisational and clinician perceived barriers are important,^{1,3,6} but shared decision making is unlikely to become the norm if we do not also deal with the barriers that patients perceive. Our recent systematic review of patients' perceptions highlighted deeper rooted attitudes that need to be changed in order to prepare patients for a new type of clinical encounter.⁷ Here we highlight the main findings and discuss how to prepare patients for shared decision making.

Patients find it hard to speak up

There is good evidence that attitudinal barriers are hindering progress in implementing shared decision making.^{1,7} Even when patients are well educated and well informed, many still find it difficult to use this knowledge to participate meaningfully in decisions about their healthcare.⁸ The Francis report into failings at Mid Staffordshire trust revealed that patients often feel prohibited from speaking up, even when they are extremely concerned about safety or the quality of care they are receiving.⁹ Online blogs, publications, and social media campaigns (such as #hellomynameis)¹⁰ show that even doctors are not immune to the power imbalance when they become patients, feeling that they represent a disease rather than that they are an individual and aware of a pressure to be compliant and passive.¹⁰⁻¹² How then can we expect people to express their preferences about treatment options—especially when they often observe doctors assuming that they can act in their best interests, displaying unquestioned confidence in being able to make the best decision on their behalf?

Knowledge is not enough

The 44 studies in our review of patient barriers suggest that many patients currently feel that they can't participate in shared decision making rather than that they don't want to, as many clinicians believe. Unsurprisingly, having information needs met in an appropriate way was a key facilitator for many patients. If patients do not know about their condition, and they do not know or understand their available options, they cannot take part in decision making. However, many patients also undervalue their ability to understand the information given to them and underplay their knowledge gain relative to that of the clinician. Therefore, they tend to defer the decision to the expert who "owns" the knowledge.

Many patients also do not recognise the unique expertise that they bring to the clinical encounter—that is, knowledge about their personal preferences. Until patients believe that they are capable of understanding the information provided to them and believe that personal expertise and medical expertise are equally important, they are unlikely to become actively engaged.

Alongside this problem are the covert contracts that some patients develop with clinicians in which they feel compelled to adopt the role of a "good" patient. This role is characterised by passivity and compliance. Many patients believe that they cannot or should not be involved in decisions, often out of fear of annoying the clinician and the potential repercussions it might have, such as being labelled difficult or receiving less or lower quality care.⁸ Such views and beliefs are long engrained in many patients, especially older people and those with lower educational attainments.

Fundamentally, knowledge provision, knowledge acquisition, and expectation to contribute personal preferences occur in the context of a power imbalance between the clinician and the patient. Therefore, a patient's capacity to participate seems to be linked not only to how much knowledge she has but also to

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how much power or influence she feels she has in the decision making encounter (that is, her perceived ability to use this knowledge).

How to overcome passivity

Although great strides have been made to ensure that patients are informed about their treatment options,^{15–17} patient passivity has been neglected; the focus has been on supporting the process if and when a patient becomes engaged, rather than working out how to engage patients. A shared decision making encounter is considerably different from the appointments that many patients are used to, and may even be comfortable with. We cannot expect patients to change their long established behaviours just because they are given an opportunity to participate in decision making. Both implementation researchers and healthcare systems have invested substantial efforts in trying to shift the attitudes of clinicians but have not invested the same efforts in preparing patients for these new types of social interaction.

Some researchers have, however, recognised the importance of preparing patients for a shared decision making clinical encounter, partly by changing attitudes towards participation.^{4 16–20} There are relatively few evaluated interventions, and their use tends to be restricted to decision specific research settings (such as preparation for a cancer consultation), but they offer a platform for designing further interventions. The earliest example was developed in 1985 and aimed to alter the traditional patient role through decision coaching before the appointment.²¹ Other coaching interventions have since been developed,^{18–20 22} and most report some success at increasing patient engagement in trial settings (as measured by, for example, asking questions, seeking information, and taking an active role in decision making). However, decision coaching is both time and resource intensive—typically comprising a 20–45 minute session with a trained research nurse or counsellor before a clinical appointment—and is unlikely to be sustained in already pressurised healthcare systems.

Other campaigns, such as Ask Share Know (<http://askshareknow.com.au>) and Ask 3 Questions (<http://personcentredcare.health.org.uk>),⁴ try to increase participation by encouraging patients to ask: what are my treatment options, what are their benefits and harms, and how likely are they to happen to me? They use brochures and other media (videos, websites, etc) to explain why this is important. Although these campaigns show promise,^{3 23} patients are often not aware of them until they are given leaflets in waiting rooms. This does not provide sufficient time for patients to change attitudes and beliefs, especially when they are so deeply entrenched.

Better preparation

Another problem with current interventions aimed at patients is that they do not do enough to overcome two important barriers to participation—patients' perception that their knowledge is inferior to medical knowledge and desires to act like a good patient out of fear that they will receive worse care otherwise. Interventions aimed at changing long established behaviours are most likely to be effective if they are based on evidence from patients rather than what researchers or clinicians think is likely to work.^{24 25} Early work suggests that interventions should be delivered in two stages: preparation, followed by enablement. Patients should be sent a preparation intervention, such as a booklet with an accompanying website link, with their appointment letter. In primary care the intervention could be posted to all registered patients. At a minimum it should

- Inform patients about shared decision making—what it is, what to expect, and why it is appropriate
- Explain that there are two experts in the clinical encounter—describe the different but complementary knowledge
- Challenge attitudes that there are right and wrong decisions
- Redefine perceptions of a good patient and reassure patients that participation will not result in retribution
- Promote social acceptability of this role—confirm that clinicians want patient participation
- Build patients' belief in their ability to take part.

Once the patient has made an informed decision to be involved, the focus moves on to enablement. This is helping patients to take part in the shared decision making process by offering appropriate decision support tools¹³ and question prompt lists (pre-populated or for self completion).²² Importantly, the interventions need to be promoted from within the organisation—for example, by framing messages as “your local health board/doctors/nurses want(s) to know what is important to you”; this indicates to patients that the local health organisation and the clinicians are giving them permission to participate.^{1 4} Experts in shared learning recently remarked that skills training trumps tools for clinicians, and attitudes trump skills. The same can be said for patients. This is why attitudinal change is important before we make attempts to support the decision making process.

Achieving shared decision making in routine practice will require interventions targeted at both clinicians and patients. We acknowledge that clinicians will not be able to change the experience of every patient, but we should try to make it easier and safer for them to feel included and respected.²⁶ Patients need to believe that they can and should be involved, and clinicians need to ensure that they make efforts to understand what matters most to patients.²⁷ Tackling structural and process barriers, such as time to do shared decision making and tools to do it, is important, but unless we address deep rooted “white coat silence”²⁸ through appropriate interventions, routine shared decision making in healthcare is unlikely to become a reality.

Contributors and sources: This paper originated from discussion around the results of a systematic review of patient reported barriers and facilitators to shared decision making (Joseph-Williams et al, 2014). NJW is a research associate conducting patient centred care implementation research at Cardiff University. AE is professor of general practice with research and teaching interests in healthcare communication and quality improvement. GE is a physician-researcher and professor and senior scientist at the Dartmouth Health Care Delivery Science Center and the Dartmouth Institute for Health Policy and Clinical Practice, Dartmouth College, USA. NJW drafted the manuscript, and all authors worked collaboratively to contribute to the content, and to edit and agree the final version.

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- 1 Lloyd A, Joseph-Williams N, Edwards A, Rix A, Elwyn G. Patchy “coherence”: using normalization process theory to evaluate a multi-faceted shared decision making implementation program (MAGIC). *Implement Sci* 2013;8:102.
- 2 Health Foundation. Implementing shared decision making: clinical teams' experiences of implementing shared decision making as part of the MAGIC programme. Health Foundation, 2013.
- 3 Health Foundation. The MAGIC programme: evaluation. Health Foundation, 2013.
- 4 Health Foundation. Person-centred care resource centre. 2014. <http://personcentredcare.health.org.uk/>.
- 5 Advancing Quality Alliance. Your health, your decision: evaluation and output report of the AQUA workstream within the national shared decision making programme. 2013. <http://www.aquaalliance.org.uk/>.

Key messages

- Many patients currently feel they can't participate in shared decision making
- Power imbalances in the clinical encounter are a key barrier even if patients have the required knowledge
- Patients need to know that their input is valued and won't damage their care
- The attitudes of both patients and clinicians need to change to enable shared decision making

- //arma.uk.net/wp-content/uploads/2013/05/Your-Health-Your-Decision-Evaluation-Report.pdf.
- Legare F, Ratto S, Gravel K, Graham ID. Barriers and facilitators to implementing shared decision-making in clinical practice: update of a systematic review of health professionals' perceptions. *Patient Educ Couns* 2008;73:525-35.
 - Joseph-Williams N, Elwyn G, Edwards A. Knowledge is not power for patients: a systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making. *Patient Educ Couns* 2014;94:291-309.
 - Frosch DL, May SG, Randle KA, Tietzohl C, Elwyn G. Authoritarian physicians and patients' fear of being labelled "difficult" among key obstacles to shared decision making. *Health Aff (Millwood)* 2012;31:1030-8.
 - Francis R. Report of the Mid Staffordshire NHS foundation trust public inquiry. 2013. www.midstaffpublicinquiry.com/report.
 - Granger K. *The other side*. [Kindle Ebook.] Amazon, 2012.
 - Tominson J. When doctors become patients. A better NHS: exploring the relationships between doctors and patients and health policy. 2014. <http://abetternhs.wordpress.com/2014/01/27/dr-patients/>.
 - Aronson L. "Good" patients and "difficult" patients: rethinking our definitions. *N Engl J Med* 2013;369:796-7.
 - Stacey D, Legare F, Col N, Col NF, Eden KB, Holmes-Rovner M, et al. Decision aids for people facing health treatment or screening decisions. *Cochrane Database Syst Rev* 2014;10:CD001431.
 - Stacey D, Krywonuchko J, Bennett C, Murray MA, Mullan S, Legare F. Decision coaching to prepare patients for making health decisions: a systematic review of decision coaching in trials of patient decision aids. *Med Decis Making* 2012;32:E22-33.
 - Option Grid Collaborative. Option grid. 2014. www.optiongrid.org/.
 - Brown RF, Butow PN, Sharrock MA, Henman M, Boyle F, Goldstein D, et al. Education and role modelling for clinical decisions with female cancer patients. *Health Expect* 2004;7:303-16.
 - Butow P, Devine R, Boyer M, Pendlebury S, Jackson M, Tattersall MH. Cancer consultation preparation package: changing patients but not physicians is not enough. *J Clin Oncol* 2004;22:4401-9.
 - Rost KM, Flavin KS, Cole K, McGill JB. Change in metabolic control and functional status after hospitalization. Impact of patient activation intervention in diabetic patients. *Diabetes Care* 1991;14:881-9.
 - Belkora J, Katapodi M, Moore D, Franklin L, Hopper K, Esserman L. Evaluation of a pre-visit preparation intervention implemented in two rural, underserved counties of Northern California. *Patient Educ Couns* 2006;64:350-9.
 - Sapucha KR, Belkora JK, Aviv C, Mutchnik S, Esserman LJ. Improving the quality of decision making in breast cancer: consultation planning template and consultation recording template. *Oncol Nurs Forum* 2003;30:99-106.
 - Greenfield S, Kaplan S, Ware JE Jr. Expanding patient involvement in care. Effects on patient outcomes. *Ann Intern Med* 1995;102:520-8.
 - Kinnersley P, Edwards A, Hood K, Cadbury N, Ryan R, Prout H, et al. Interventions before consultations for helping patients address their information needs. *Cochrane Database Syst Rev* 2007;3:CD004565.
 - Shepherd HL, Barratt A, Trevena LJ, McGeechan K, Carey K, Epstein RM, et al. Three questions that patients can ask to improve the quality of information physicians give about treatment options: a cross-over trial. *Patient Educ Couns* 2011;84:379-85.
 - Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci* 2011;6:42.
 - Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* 2008;337:a1655.
 - Edwards A, Elwyn G, Smith C, Williams S, Thornton H. Consumers' views of quality in the consultation and their relevance to "shared decision-making" approaches. *Health Expect* 2001;4:151-61.
 - Elwyn G, Frosch D, Thomson R, Joseph-Williams N, Lloyd A, Kinnersley P, et al. Shared decision making: a model for clinical practice. *J Gen Intern Med* 2012;27:1361-7.
 - Judson TJ, Detsky AS, Press MJ. Encouraging patients to ask questions: how to overcome "white-coat silence". *JAMA* 2013;309:2325-6.

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Appendix 4.2

Prototype version of the 'Your Health, Your Choice Booklet'





Find your appointment checklist on the back!

This leaflet explains...

- ? **why** you sometimes have choices to make about your health
- ? **what** you can expect from your appointment if you have choices, and
- ? **how** you can work as part of a team with us, your healthcare workers

It doesn't matter if you have a long-term condition, if you are making an important decision for the first time, or if you are simply deciding which medicine to take - **everyone** can be more involved when they have healthcare choices.

? **When** we asked 100 other people like you about decision making...

51

said they wanted to share decision making with a healthcare worker

23

said they wanted to make the decision on their own

26

said they wanted a healthcare worker to make the decision



Let's work together...

so we can provide care that's right for you

People make hundreds of decisions every day... what to eat for lunch, where to go on holiday, tea or coffee? Sometimes, you will be asked to **be involved in decisions about your healthcare.**

"We want to get the message out there that it's okay to interact differently with healthcare workers...we can work together with them as part of a team"
- Asthma patient

Sometimes, doctors, nurses and other healthcare workers have to make quick decisions to help you - like when you are taken to A&E in an emergency.

But, most of the time **you will have choices.**

It doesn't mean that the people looking after you don't know what to do - it means that there is more than one way they can help you, and you can choose the option that fits best with what you prefer.





Why should I get involved?

There are **two experts** in health-care appointments.

As healthcare workers, we know a lot about treatments and tests that can help you, and we know a lot about your illness or condition. But, we don't know about the things that **matter most to you and your family**.

Some patients are surprised when they have a choice, but the fact is, nobody knows you better than you, so...

“we need you to share, so we can provide better care!”

Other patients tell us that when they were not involved in decisions about their care, they sometimes ended up receiving treatments they didn't want, or outcomes they didn't expect.

Some benefits of being involved:

- ✓ You will know about your options and what will happen
- ✓ You will know about the pros and cons of the options
- ✓ We will know what is important to you. We will then help you make a decision based on these things

I'm still not sure...

Don't worry, you're not alone. Some patients are not sure if they want to be more involved, maybe because it's not what they are used to. There may be things stopping you getting more involved - to help, here is what we say to patients who aren't sure...

Doctors know best, what do I know?

We know a lot about illnesses and how to treat them, but we don't know what matters most to you. Healthcare workers are experts in diagnosis & treatment, but patients are experts in their own lives.



Medical terms can be confusing, even the names of some drugs are difficult to say. However, we will try to explain your options in simple language so that you understand what is involved. If you don't understand, it's okay to say so, and we will go through things again.

I can't understand medical jargon!

I don't want to be a difficult patient

Don't worry, you won't. We want you to be involved - it's important that you speak up. Asking questions and sharing what's important means we can provide the best care for you. Think of it as working together as partners or a team.



It's important to know there are no right or wrong decisions, just decisions that are right for you. What matters to someone else might not matter to you. Knowing your options means you know what to expect, and you can decide what is right for you.

I don't want to be responsible for a wrong decision



What will I have to do?

Every appointment is different, but this guide might help you be more prepared if you're asked to get involved in making a decision.



Do I have a choice?

We will let you know if you have a choice and we will explain why

This can sometimes include doing nothing - or 'watchful waiting'

If you're not sure why you have a choice, just ask

Most decisions can be revisited at a later date



What are my options?

We will tell you what your options are & what they involve

We will describe the likely outcomes, including the pros & cons

We might give you more information to look at e.g. booklet or website link

If you don't understand the options, just ask



What matters to me?

Share what is important to you - Which outcomes would you accept?

It can help to discuss this with people who are close to you

Weigh up the pros and cons of each option by thinking about what matters to you

Share this with your doctor, nurse or family



What can help me get more involved?

There are lots of ways you can get more involved in decisions about your healthcare - here are some things other patients have found helpful - use them before, during, or after your next appointment. They might help you remember what you wanted to ask and what you wanted to say.

Make sure you:

- 1 ask what your options are, and
- 2 tell us what's important to you.

Some patients find it helpful to write down their questions and what's important to them. It might help you remember what you wanted to ask and what you wanted to say. Don't forget, you can always bring someone along to your appointment with you.



What do I think about the options?

Your appointment checklist

If you were given a choice, were you involved? Ask yourself...

checklist

- Was I told why I had a choice?
- Was I told what my options are?
- Was I told the possible outcomes?
- Was I told how likely they are?
- Was I asked about what's important to me?



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Appendix 5.4 – List of design, format and content changes to the ‘Your Health, Your Choice’ booklet

Category	Issue identified	Page	Section	Participant(s) quote(s)	Change(s) made
Terminology	Patients may not understand the term <i>interact</i> used in the quote ‘we want to get the message out there that it’s okay to <i>interact</i> differently with healthcare workers...’	3	Let’s work together...	‘How’d you mean <i>interact</i> ? I’m just being devil’s advocate here...do people know what <i>interact</i> means?’ [P1]	Term <i>interact</i> removed. Replaced with sentence: ‘ <i>We want to get the message out there that it’s okay to change the way we talk with healthcare workers...we can work together with them as part of a team</i> ’
	Patients may not know who <i>healthcare workers</i> are. This term needs to be more clearly defined or a different term used.	Throughout	Throughout	‘ <i>Healthcare workers</i> , like again, is that nurses, doctors?...maybe say something like ‘your nurses, doctors and consultants are healthcare workers, because they would think that somebody in green [uniform] was their healthcare worker...so maybe...a little example of who your healthcare worker is.’ [P1]	The following text has been added to page 3 of the booklet to clarify the term healthcare workers <i>‘Healthcare workers include doctors, nurses, consultants, surgeons, dentists, midwives, physiotherapists...basically anyone who is involved in your care’</i>
	Some of the terms used are not user-friendly and some patients might not know what they mean e.g. ‘ <i>pros and cons</i> ’, ‘ <i>options</i> ’, ‘ <i>outcomes</i> ’, ‘ <i>watchful waiting</i> ’. Consider using alternative terminology.	Throughout	Throughout	‘Umm, no this is what I wasn’t happy with, <i>we will tell you what your options are and what they involve, we will describe the likely outcomes, including the pros and cons</i> , I didn’t like that...maybe you need to think of some other way of asking that...umm, negative and positives I suppose...I didn’t feel it [pros and cons] was user friendly at all’. [P1] ‘Although I’m not an expert in terms of literacy levels, it was just occasionally I was reading it and though oh	The term ‘pros and cons’ has been changed to ‘positive and negative outcomes’, throughout the booklet. The term ‘option(s)’ has been changed to ‘choice(s)’, throughout the booklet.

				<i>outcomes, pros, cons, options, watchful waiting</i> , still sounded a bit medical...we've used <i>choice</i> , so it could be <i>choices</i> , and was I told <i>what might happen</i> or <i>what the effects might be</i> ' [C1]	
	In the checklist, the item 'was I told how likely they are?' needs to make reference to <i>outcomes</i> so it is clear what the item relates to.	8	Your appointment checklist	'I was just thinking... <i>was I told the possible outcomes?...so tick yes, was I told how likely they are...how likely are the outcomes?...I'm just thinking that could be worded differently, but I'm just not sure how at this stage...</i> ' [P1] 'You know the only one I was a bit confused about was, it might be obvious when you read it, but it could be a bit more explicit...the third box, <i>was I told the possible outcomes?</i> , and then there's <i>was I told how likely they are?</i> , maybe you could say <i>was I told how likely the possible outcomes are?...'</i> [P6]	Checklist item has been changed to include reference to outcomes: 'Have I been told how likely these outcomes are?'
	Some participants felt that the term 'like you' used for the percentages was too familiar and personalised; indicated that every patient is the same with the same condition etc.	2	Statistics	'it's just implying that everyone's like you, everyone's got your same condition, everyone's got your same issues...it just has to be <i>when we asked 100 other people</i> ' [P9]	Removed 'like you' from the sentence on page 2.
	Remove the word 'next' from the statement 'please read me before your <i>next</i> healthcare appointment'.	1	Front Cover	'...perhaps it should say <i>please read me before your healthcare appointment</i> not <i>next...</i> ' [C4]	Removed the term 'next', from the sentence on Page 1.
	The term 'clinic' on the right hand side of the front page looks like 'nic' – consider removing (see comment below of	1	Front Cover	'...her head there obviously covers the word 'clinic' so all you get left with it 'nic'...rather than just have her head partially covering some of the sign, do we need to have a sign on both sides?' [C6]	The term 'clinic' has been removed (see below for further changes)

	alternative term suggestion)				
	By using the term ‘clinic’ on the front cover, some patients might think that there are only choices at a clinic. It doesn’t refer to hospitals, GP surgeries etc. (other secondary, primary, community settings)	1	Front Cover	‘...you know, are we only saying that there are choices available at a clinic?...I don’t know if this is aimed at more primary care, or whether it’s something that we should be incorporating in secondary care, community setting, perhaps just not narrowing it down at all’ [C6]	One building has been changed to ‘hospital’ and the other building has been changed to ‘surgery’ (to represent primary and secondary care.
General Design (colour scheme, font style, font size)	The use of the colour red for the leaflet held by the clinician on the front of the booklet might be perceived as negative e.g. danger, bad. Also the use of green and red for the different clinics might indicate good and bad clinics / decisions.	1	Front Cover	‘It’s got a red card like being sent off though...well, it is, when you use colours, like green’s good for clinic, but red’s bad clinic there isn’t it, so do you want to go to the good clinic or the bad clinic?’ [P9] ‘I mean the red, well it looks like, it does look like he’s holding a red card, which I suppose...in sporting you know, she’s come to ask a question and he’s sent her off [laughs]’ [C6]	The leaflet colour has been changed to green. The buildings have been changed to green.
	Some of the letters may be difficult for people with visual impairments to interpret e.g. the ‘g’ in the body of the text. Change these to basic san-serif font types	Throughout	Throughout	‘...see the g’s there, you know they’re not...they’re fancy, and I think people with visual impairments ...see the g...it’s not clear, there’s a word for it but I can’t think’ [C4]	The main body font has been changed to a basic sans serif font.
	Patients might perceive that ‘health’ is more significant than ‘choice’ due to the font sizes in the title. Consider changing these around?	1	Front Cover	‘maybe if anything your choice is, if I was going to do anything I would reverse it, maybe just balancing out the size so it’s, it’s more equal’ [C6]	Colour emphasis has changed to make ‘your choice’ more prominent than previously.

	The 'please read me before your next healthcare appointment' call out could be made more prominent. Some patients' focused on the red call-out below.	1	Front Cover	'Mind you I've looked through this now several times as you can tell, and that's the first time I've seen that' [C7]	The 'please read me before your [next] healthcare appointment' call out has been made more prominent.
Character design	Some participants felt there could be a better mix of patient & clinician characters in the booklet. All clinicians appear to be young, and most patients are older.	Throughout	Throughout	'All the patients appear to be old as well...' [P9] 'Yeah I suppose there is a bit more older people...it would seem that the professionals look younger'[P10]	The clinician on page 5 ('Doctor knows best, what do I know?' section) has been changed to an older male character.
	Some patients wondered about the relevance of the background images on page 3 e.g. coffee cup, apple. This might distract patients / they might misinterpret their meaning.	3	Let's work together	'the apple, is it an apple a day keeps the doctor away, is that what I means...do they really need to be there?' [C6] 'Is that a coffee cup? Why is there a coffee cup on there?... Oh yeah, it says about coffee, that's why' [P10]	These background images have been removed from page 3.
Format, Layout, & Specific Design Elements	Some participants felt that the notepad could be larger to provide more space for questions and / or more clear guidance on how to use the notepad e.g. what it is for, when, what types of questions, example questions, prompts to consider what's important to me.	7	What can help me get more involved?	'Yeah, I thought that was helpful, but it's not a great amount of space, I would have saved that for the appointment, but would have liked perhaps a little bit more space to write down...it says you can ask questions, and yes I could have written them there, but then if I'd used that space, I wouldn't have had any room to write anything at the appointment maybe, so maybe just a little more room...[and] maybe like a little notepad above saying <i>questions I want to ask</i> , and then they're all on the same page then, you can write down your answers as well...' [P6] '...if there was any fault at all, I would have liked another notepad to write questions prior to the	The notepad on page 7 is larger, allowing more space for writing. Clearer guidance has been provided to patients about how to use the notepad i.e. to write down questions before the appointment, and to write down how they feel about the choices offered: 'If you have an appointment, you probably have lots of questions you would like to ask, but it can

				<p>appointment, on top of the one, then I could write my answers...’ [P6]</p> <p>‘...the one inside, which is free for you [to write], I don’t really know what sort of questions you want to ask there...’ [P9]</p> <p>‘What did I think of the options, and I’m just wondering if there’s scope for encouraging people to think more about this, what’s important to me end of it...if one of the key things around choosing the right option is around knowing what’s important’ [C1]</p> <p>‘...yeah you know, maybe giving again, giving some suggestions about the type of questions that you might want to ask, just examples again...because there’s a chance then that you lead people into narrowing down the questions, when in reality you want them to ask whatever they want to ask’ [C6]</p> <p>‘You’ve got some prompts you know – ask us about what your options are, and tell us what’s important to you, but you might, if you’re going to make some more space, perhaps you need some more prompts about what they need, the sort of things, the sort of questions they can ask, and how they can frame that...’ [C7]</p>	<p>sometimes be difficult to remember them – <i>use this notepad to write down your questions before your appointment...</i> If you have choices, you can use the notepad to write down <i>what you think about them</i> – what do they mean to you personally?’</p> <p>Some examples of questions and things that might be important to patients have also been included as prompts:</p> <p>‘e.g. What are my choices? What will they involve? Will I have to take time off work?... e.g. I am a full-time carer, a hospital stay would be difficult for me’</p>
	The checklist might be more useful if framed as a preparation tool for use before the appointment, and possibly during. Due to	8	Checklist	<p>‘...so whilst there could be a checklist, you’ve almost, you’ve missed the boat to some degree, because if the answer to them is no...you’ve missed the opportunity really, because the consultation is gone, so whilst in theory yes, okay well I didn’t get the answers so I’d</p>	The guidance for using the checklist has been changed to preparation for the appointment (rather than solely as a post-hoc tool). For example, it now encourages patients to think

	<p>structure of appointments, it might not be useful to complete the checklist after an appointment e.g. unlikely to see that same consultant for some time afterwards. Also prompt patients to ask if the clinician has not answered their questions or covered any of the checklist items. Consider splitting the checklist into two parts – one part for appointment preparation and one part for during the appointment.</p>			<p>like to ring up and make another appointment, the reality is it doesn't work like that and it could be months before you get to see the same person again...so maybe the checklist, maybe the questions could be in preparation for a consultation' [C6]</p> <p>'...so have I done this? Have I done that? Have I got my questions listed down?' [C6]</p>	<p>about these questions during their upcoming appointment.</p> <p>'It is really important that you are involved in decisions about your healthcare. If you are told you have choices in your next appointment, make sure that the items in the checklist are covered...'</p>
	<p>Possibility of having a tear-off (perforated) page for the notepad and checklist</p>	<p>7/8</p>	<p>Checklist / Notepad</p>	<p>'...you know that page could be kept, ripped off and kept, so you'd obviously want your notepads on a separate page...then the checklist could be kept by the surgery...[as a research tool collecting data]' [P6]</p> <p>'Oh, that would be good actually, 'cause the checklist are on both sides...It's almost like an appointment control sheet' [P9]</p> <p>'Yeah definitely, 'cause that's the little bit you can take then...' [P10]</p>	<p>The booklet will be printed with a tear-off perforated back page, and a prompt to tear off and take to appointment will be included.</p>
	<p>The checklist and notepad would benefit from a prompt to bring to the next appointment</p>	<p>7</p>	<p>Notepad / Checklist</p>	<p>'Does it say bring it with you? I can't remember now...particularly with that bit [points to notepad]...the checklist, yeah' [C1]</p>	<p>A prompt has been added to the notepad page to bring to the next appointment:</p> <p>'Bring me to your next appointment' (in a call out)</p>

	The checklist could benefit from an additional item e.g. 'was I told what would happen next'. Currently, the booklet does not cover this or prompt patients to make sure that they know.	8	Checklist	'...there's an issue about what happens next...if there's room, another checklist issue is <i>was I told what would happen next?</i> or <i>do I understand what's going to happen next?</i> 'Cause then it leads into what does happen next...and do I get the chance to revisit...is this the final chance. I think that would then just lead into a process, or a flow, rather than a single event' [C1]	The following has been added to the checklist on page 8: 'Have I been told what will happen next?'
	The arrows on the 'What will I have to do?' flowchart might be misleading. Some patients read the content from left to right, rather than downwards in the columns.	6	What will I have to do?	'but I didn't really know how to read the end bit by here, do I read all of them at once, then all of them, then all of them, or do I work my way across each one? I don't know which way to go...'cause obviously I was reading it that way, where the arrows told me to go' [P9]	Arrows removed from the flowchart on page 6
	Some participants felt that the statistics on the bottom of page 2 could benefit from a prompt e.g. 'what do you think?' This would make it more relevant and useful to the person reading it.	2	This leaflet explains... (percentages section)	'...the bit at the bottom with the percentages, which is fine, but I just wondered, it just sort of stopped there, you know in terms of...well should there be something there that says <i>what do you think?</i> Even if it's a <i>when we asked 100 other people...what do you think...or we will now explain what getting involved really means, or something like that</i> ' [C1]	The following prompt has been added to the bottom of page 2, to accompany the statistics: 'most people would rather share a decision - what do you think?'
	It could be made clearer who the booklet is from e.g. the local health board. Consider moving the logo to the front of the booklet. Might also benefit from a broader organisation logo e.g. NHS Wales	1	Front cover	'...if it's under public health, it should be up there, I think it's on the back, well Cardiff University, but I think it's public health information...so maybe, [people] will think <i>well I can use that in my hospital</i> ' [C4] 'The one thing I note is that you've got the NHS Wales [logo] which is obviously quite an identifiable logo on the back, um, and I just wondered whether that would be better on the front so that people would identify that	The Cardiff & Vale University Health Board logo has been included on the front page of the booklet (in addition to the Cardiff University logo on page 8)

				this is information relevant to the NHS, rather than a booklet about something else in an NHS setting' [C6]	
	The booklet would benefit from examples of the types of decision that might be made in healthcare, at a general / broad level (e.g. surgery may be an option for you, or you may be offered different types of tablet) This would complement the examples of decisions that people make in everyday life (i.e. holiday, lunch).	3	Let's work together	'I think the key message that I get is that it's an encouraging leaflet to want you to ask questions, or to have choice...I think it could go a little further to explain what perhaps those choices could be e.g. maybe if surgery is being considered....what we're saying is explore all the options, and give them some scenarios' [C6]	Some examples of healthcare choices have been provided on page 3 of the booklet: <i>'Some examples of healthcare choices</i> <ul style="list-style-type: none"> • Surgery or physiotherapy to manage your condition • Different types of tablets for your illness • Hospital or home birth for your baby'

Appendix 5.5

Pilot-testing version of the 'Your Health, Your Choice' booklet



This leaflet explains...

Find your appointment checklist on the back!



- ? why you sometimes have choices to make about your health
- ? what you can expect from your appointment if you have choices, and
- ? how you can work as part of a team with us, your healthcare workers

People make hundreds of decisions every day...what to eat for lunch, where to go on holiday, tea or coffee? Sometimes you will be asked to be involved in decisions about your healthcare.

? When we asked 100 other people about decision making...

51

said they wanted to share decision making with a healthcare worker

23

said they wanted to make the decision on their own

26

said they wanted a healthcare worker to make the decision

most people would rather share a decision - what do you think?



Let's work together...

so we can provide care that's right for you

Sometimes, doctors, nurses and other healthcare workers have to make quick decisions to help you – like when you are taken to A&E in an emergency.

But, most of the time **you will have choices.**

It doesn't mean that the people looking after you don't know what to do, it means that there is more than one way they can help you - **you can choose what fits best with you.**

"We want to get the message out there that it's okay to change the way we talk with healthcare workers...we can work together with them as part of a team"
- Asthma patient

Some examples of healthcare choices include surgery or physiotherapy to manage your condition, different types of tablets for your illness, and hospital or home birth for your baby.

It doesn't matter if you have a long term condition, or if you are making a healthcare decision for the first time – **everyone** can be more involved when they have healthcare choices.



Healthcare workers include doctors, nurses, consultants, surgeons, dentists, midwives, physiotherapists... basically anyone who is involved in your care



Why should I get involved?

There are two experts in healthcare appointments.

As healthcare experts, we know a lot about treatments and tests that can help you, and we know a lot about your illness or condition. But, we don't know about the things that **matter most to you and your family – you are the expert in your own life.**

Some patients are surprised when they have a choice, but the fact is, nobody knows you better than you, so...

“we need you to share, so we can provide better care!”

Other patients tell us that when they were not involved in decisions about their care, they sometimes ended up receiving treatments they didn't want, or outcomes they didn't expect.

Some benefits of being involved:

- ✓ You will know about your choices and what will happen
- ✓ You will know about the positive and negative outcomes you can expect
- ✓ We will know what is important to you. We will then help you make a decision based on these things

I'm still not sure...

Don't worry, you're not alone. Some patients are not sure if they want to be more involved, maybe because it's not what they are used to. There may be things stopping you getting more involved – to help, here is what we say to patients who aren't sure...

Doctors know best, what do I know?

We know a lot about illnesses and how to treat them, but we don't know what matters most to you. Healthcare workers are experts in diagnosis & treatment, but patients are experts in their own lives.



Medical terms can be confusing, even the names of some tablets are difficult to say. However, we will try to explain your choices in simple language so that you understand what is involved. If you don't understand, it's okay to say so, and we will go through things again.

I can't understand medical jargon!

I don't want to be a difficult patient

Don't worry, you won't. We want you to be involved – it's important that you speak up. Asking questions and sharing what's important means we can provide the best care for you. Think of it as working together as partners or a team.



It's important to know there are no right or wrong decisions, just decisions that are right for you. What matters to someone else might not matter to you. Knowing your choices means you know what to expect, and you can decide what is right for you.

I don't want to be responsible for a wrong decision



What will I have to do?

Every appointment is different, but this guide might help you be more prepared if you're asked to get involved in making a decision.



Do I have a choice?

We will let you know if you have a choice and we will explain why

This can sometimes include doing nothing - or 'watchful waiting'

If you're not sure why you have a choice, just ask

Most decisions can be revisited at a later date



What are my choices?

We will tell you what your choices are & what they involve

We will describe the positive and negative outcomes that you can expect

We might give you more information to look at e.g. booklet or website link

If you don't understand the choices, just ask



What matters to me?

Share what is important to you - Which outcomes would you accept?

It can help to discuss this with people who are close to you

Weigh up the positive and negative features of each option - what matters most to you?

Share this with your healthcare worker, your family or friends

Getting ready for your appointment

Bring me to your next appointment

If you have an appointment, you probably have lots of questions, but it can sometimes be difficult to remember them - use this notepad to write down your questions before your appointment.

If you have choices, you can also use this notepad to write down what you think about them - what do they mean to you personally?

My questions

e.g. What are my choices? What will they involve? Will I need to take time off work?

What do I think about my choices?

e.g. I am a full time carer, a hospital stay could be difficult for me.

Don't forget, you can always bring someone along to your appointment with you

It is really important that you are involved in decisions about **your healthcare**. If you are told you have choices in your next appointment, **make sure that the items in the checklist are covered...**

checklist

- Have I been told why I have a choice?
- Have I been told what the choices are?
- Have I been told the possible outcomes, positive or negative?
- Have I been told how likely these outcomes are?
- Have I been asked about what's important to me?
- Have I asked all the questions I wrote down?
- Do I have any other questions?
- Have I been told what will happen next?

If your healthcare worker does not cover any of the checklist items, or you have questions, it's okay to ask



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