

**An exploration and comparison of Shared Decision Making  
and Informed Consent in different clinical settings**

**Thesis submitted for the degree of  
Master of Philosophy**

**By Alastair Bradley  
MB ChB LLB(Hons) MRCP**

**Academic Unit of Primary Medical Care  
University of Sheffield  
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## Summary

This research project explores the theoretical concept that, in certain situations, Shared Decision Making and Informed consent can be concordant, by comparing patient decision-making in different clinical settings.

Shared Decision-making (SDM) and Informed Consent (IC) purport to promote patient engagement in health care decisions. SDM has developed from patient engagement in medical research whilst IC has developed from case law in routine medical practice. It has been suggested that the paradigms are concordant, particularly in cases of elective surgery where risks may be high and there is more than one choice.

Unilateral hip arthroplasty for osteoarthritis is one such case where potential adverse consequences can be severe, yet patients have the choice of not having surgery but continuing or increasing their analgesia.

Patient decision aids have been developed as a tool to promote SDM and engage patients in decision-making. They are developed to cover medical decisions where there is more than one choice and the evidence is equivocal. These are described as preference sensitive decisions as they are dependent on patient values and choice. One example is the consideration of insulin therapy in patients with Type 2 diabetes mellitus (T2DM) whose HbA1c is not controlled on maximum tolerated oral therapy.

What has not been explored is whether these decision-making paradigms are actually concordant and whether techniques from each can inform improved implementation of the other.

Qualitative and quantitative methodologies were employed in both clinical settings to examine factors that influence patient decision making in SDM and IC.

One study (study 1) explored the implementation of SDM and a Patient Decision Aid (PDA) in a primary care setting by recruiting patients with T2DM who were considering insulin therapy and their corresponding health care professional (HCP). A second study (Study 2) explored the implementation of IC in relation to unilateral hip arthroplasty for osteoarthritis by recruiting patients undergoing the procedure and orthopaedic surgeons who regularly obtained consent for this operation.

Participants from study 1 were recruited purposively from the intervention arm of The Patient AND Decision Aid trial (PANDAs study), a cluster Randomised Control trial in primary care. The PANDAs study was exploring the outcomes of using a PDA for patients with T2DM considering insulin therapy. Patients and their corresponding HCPs took part in semi-structured in-depth interviews after a consultation in which they had used the PDA. The consultation was audio-recorded and analysed, using the OPTION instrument, to assess the HCPs skill at engaging the patient in the decision-making process. Qualitative data from the interviews were triangulated with quantitative data from the consultation analysis.

Patient participants for study 2 were recruited by two methods. Patients for semi-structured in-depth interviews were recruited prospectively from the list of one orthopaedic surgeon and interviewed once before surgery and once three months after surgery. A second cohort of patients

were recruited retrospectively from the list of two different surgeons, having had surgery within the last six months. These patients participated in two focus groups to discuss their different experiences of the consenting process.

Patient reported outcome measures (PROMs) in the form of the Oxford Hip Score were collected before surgery and 3 months after surgery. This quantitative data was used to inform the post-operative interview and triangulate patients expressed satisfaction with the surgery.

Orthopaedic surgeons were recruited from one Orthopaedic Department and participated in semi-structured in-depth interviews on their techniques for obtaining IC.

Interview and focus group were analysed using Thematic Framework Analysis, employing an iterative approach until data saturation was achieved. The main themes from each study were compared and synthesised into frameworks that could be used to encourage improved patient engagement in the decision-making process of either paradigm.

### **Study 1.**

8 patient- HCP dyads were recruited resulting in 8 audiotaped consultations, 8 patient interviews and 8 HCP interviews. Data analysis revealed several main themes relevant to how patients make healthcare decisions. Some of these factors were specific to the patient such as their pre-conceived ideas about T2DM complications and insulin; some were HCP specific such as the importance of discussion with a trusted professional; some patients found the information contained in the PDA influenced their decisions and in some cases greater knowledge about complications and outcomes altered patient decisions.

### **Study 2.**

16 patients were recruited for the before and after interviews and 8 patients were recruited for the two focus groups. 4 out of 7 orthopaedic surgeons who regularly took consent for hip arthroplasty at one department were interviewed. Patient and surgeon data were analysed separately but had common themes developed from different perspectives. Themes relating to the consultation included surgeon assumptions about patient understanding and patients feeling overwhelmed by information, but relief at being offered an operation. Patients valued many sources of information whilst surgeons accepted they were not the sole source of information but considered theirs was the most important for consent signing. Patients often appreciated the hospital process of information provision, although this was often dissociated from the consent obtaining process.

Results from the two studies were synthesized in relation to “How do patients make healthcare decisions?” and four meta-themes were identified relevant to the comparison of SDM and IC: doctor-patient interactions, the presentation of information, external factors such as friends and family opinions and, the concepts and tools of Shared Decision Making. The doctor-patient interactions relate to the interpersonal skills of both participants in a consultation and skills and emotions in promoting decision-making. The presentation of information describes how different formats and combinations of information provision influence patient decisions. External factors can influence decision making and values attached to external influences such as friends or websites vary between patients and clinicians. The final meta-theme illustrates the extent to which the practical implementation of SDM techniques are used in each setting

Themes from SDM and IC are concordant when considering factors that influence how patients make healthcare decisions and, therefore, techniques from each paradigm are appropriate to consider in relation to the other.

The novel findings from this thesis indicate that patient healthcare decision-making can be influenced by many factors including who initiates the process, emotions, interactions with the HCP, sources and presentation of information and hospital pathways. SDM and PDAs are one approach to engaging patients in preference-sensitive decisions which also have the potential to improve patient engagement in IC. However IC techniques also use multiple patient contacts with different clinicians which is often recommended in SDM theory but rarely implemented.



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The Department(AUPMC)

The Academic Unit of Primary Medical Care

AB The researcher

AW Alex Ward, BMedSci medical student supervised by AB

BC Brigitte Colwell, Research Associate AUPMC

CJN Chirk Jenn Ng, Professor of Primary Care Kuala Lumpur, Malaysia

HT Helen Twohig, NIHR In-practice Fellow, AUPMC

IB Ian Brown, Lecturer, School of Nursery, Midwifery and Social Work, University of Manchester

LW Liz Walton, Academic Training Fellow, PhD student, AUPMC

MJ Maxine Johnson, Qualitative Research Specialist, School of Health and Related Research, University of Sheffield.

NM Nigel Mathers, Professor and Head of Department, AUPMC, University of Sheffield

# An exploration and comparison of Shared Decision Making and Informed Consent in different clinical settings

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## A personal introduction to Shared Decision Making and Informed Consent

This personal introduction explains how the topic for this thesis has been formulated over 25 years of personal experiences in health care provision. My reflection on experiences start as a Surgical House Officer in 1990 and progress through my Law degree (2001-2005) to my current position of General Practitioner and Academic. It is taken chronologically so, for the only time in this thesis, Informed consent is discussed prior to Shared Decision Making.

### Informed Consent

My earliest recollections regarding concerns about patient information giving and obtaining consent was as a House Officer in 1990 working in an Ear Nose and Throat Department. Part of my duties was to admit patients to the ward for theatre, often on the same day. Although patients had been seen in clinic and (presumably) had their operation explained to them, one of my duties on admission was to “obtain” consent from the patient- that is to say to get the patient to sign the consent form. Whilst this was relatively straightforward in tonsillectomies or insertion of grommets, it was much more testing for me and the patient when it came to “tympanoplasty” or some of the head and neck cancer surgery. Questions like “Where will the scar be and how big will it be?” had me scurrying for my textbooks. There was no readily available internet then.

Such questions also had me asking “Surely the person doing the operation is best placed to answer these questions?” However, the system required rapid clerking of patients to maintain a steady stream of “prepared” candidates in theatre, and the surgeons were too busy to answer simple questions other than in the most complex laryngeal tumours.

After a further brief stint as a Senior House Officer in ENT surgery, when I knew a lot more, my surgical career was over and informed consent did not particularly cross my mind until studying for a law degree at Sheffield Hallam University in 2001. Whilst studying the Medical Law module it became apparent that not only did academic lawyers have concerns about the way doctors dealt with informed consent issues, but the influence they had on the court rulings relating to IC as well. These considerations were prior to the decision in Chester (1) and it was impressed upon me that the courts showed too much deference to doctor opinions:

“Surely it is for the courts to make the law, not to ask the doctors what level of evidence should be considered appropriate.” Lecture on Medical law 2003 SHU

Prior to 2004 and the case of Chester the main level of evidence was the Bolam test:

“...the court held that there is no breach of standard of care if a responsible body of similar professionals supports the practice that caused the injury, even if the practice was not the standard of care. The ruling meant that the accused doctor need only to find an expert who would testify to having done the same thing.” (2)

Academic lawyers considered this was tantamount to doctors creating the standard of care to be judged by, rather than the courts. The deference to doctors reached a pinnacle in the case of Bolitho (3):

Facts of the case: A two year old child was admitted to hospital suffering from breathing difficulties. A doctor was summoned but did not attend as her bleep was not working due to low battery. The

child died. The child's mother brought an action claiming that the doctor should have attended and intubated the child which would have saved the child's life. The doctor gave evidence that had she attended she would not have intubated. Another doctor gave evidence that they would not have intubated. The trial judge applied the Bolam test and held that there was no breach of duty. The trial judge was most impressed by one of the medical experts, a Doctor Dinwiddie from Great Ormond Street Hospital, who agreed that he would not have intubated the child. The judge commented:

"...it will very seldom be right for a judge to reach the conclusion that views genuinely held by a competent medical expert are unreasonable. The assessment of medical risks and benefits is a matter of clinical judgement which a judge would not normally be able to make without expert evidence."

From the perspective of practising medicine this viewpoint appeared quite comforting, but it raised several legal and ethical issues. Was justice actually being done in these cases? What exactly was obtaining informed consent from a patient? Why was informed consent, an integral part of the patient pathway to surgery, being directed by the courts rather than the medical profession?

Perhaps through the opinions of the lecturers on the course we were directed to read articles such as Informed Consent and other Fairy Stories (4), academic essays on how the medical profession paid scant regard to this topic and judges should be more pro-active in deciding the law.

As I was taking my exams in this topic one of the lecturers commented on how there was an upcoming case in the House of Lords that would alter IC for ever and make Bolam obsolete. That case was Chester v Afshar (1) which led to the concept of negligence in taking IC by not revealing all relevant facts to the patient regardless of outcome. The General Medical Council (GMC) used this and other cases to develop their guidelines for doctors, Consent guidance: patients and doctors making decisions together (5).

Although this guidance for doctors does make their duties clearer with reference to obtaining consent from patients, it is still very much founded on legal doctrine. Whilst this may be no bad thing, creating uniformity of duty across the United Kingdom, it remains clear that the medical profession is not taking an active role in developing the direction of IC. There is no primary legislation defining IC and duty of care, whilst reference to the case law merely highlights duties of disclosure rather than an encompassing package of what good IC should look like.

## Shared Decision Making

My introduction to SDM as a concept came much later in 2009. I was appointed to an Academic Training Fellow post at Sheffield University's Academic Unit of Primary Medical Care. This was a one year tenure to assist with an on-going trial in primary care exploring the effects of a Patient Decision Aid (PDA) on patients with type 2 diabetes mellitus (T2DM) when considering insulin therapy (6). The trial was being conducted in Sheffield and required extra staff to extend the practice recruitment to Rotherham and Doncaster. During work on the main trial I recognised the need to explore with patients and Health Care Professionals (HCPs) their experiences of using a PDA and which elements of the tool or consultation influenced the patient decision. This is a recommended step when evaluating a complex intervention such as a PDA (7).

I started to explore the theory behind in-depth interviews as a research technique and developing topic guides for both patients and HCPs. During this process the parallels with IC became apparent in terms of exploring issues surrounding information gathering to make informed choices and how that is supported by the attending HCP. What also became apparent was the dichotomy between the

SDM model of supporting patients in terms of information needs and ensuring their own values were congruent with any decision that was made, and my experience of obtaining a signature on a consent form just before the patient was taken down to theatre. Processes of consent taking have altered significantly since I was last actively involved but how far had this improved the patient's position?

What was required was a systematic and thorough search of the medical, legal and ethical literature to identify what was known about patient opinions of consent taking, to identify how the process of consent taking had altered and whether surgeon and patient values were concordant with the common goal of obtaining *Informed* consent prior to surgery. This evaluation could be compared and contrasted with the doctrine of SDM which appears to have similar goals of patients making a preference sensitive decision on investigations or treatment options once being informed of the risks and options.

The topic for my PhD was, therefore set; Exploring experiences of patients and attending healthcare professionals in the settings of IC in secondary care and SDM in primary care, identifying frameworks appropriate to each, where these frameworks were concordant and consider whether results from investigating one paradigm could be used to inform the other.

## Introduction to Shared Decision making and Informed Consent

Both of these paradigms of patient involvement in healthcare decision making have arisen from different origins, as will be discussed more fully in the introduction. However, one of the main tenets of each is to engage patients more fully in discussion about their treatment and to ensure that they understand and accept their chosen option prior to implementation.

In terms of implementation we usually associate Shared Decision Making (SDM) in a medical setting with treatment or investigation options where the evidence may be equivocal (8). Informed Consent (IC) is more usually associated with considerations surrounding elective surgery. These may seem separate and disparate considerations but several commentators (9-12) have considered the concordance of the two paradigms in certain situations.

Whitney and colleagues (12), in particular, explored the different types of consent, from simple consent in situations such as blood test monitoring of medications, to emergency consent in the example of abdominal gunshot wounds. What they did conclude though was that in terms of consent for elective surgery where they classified risk of intervention high and certainty of outcome low, SDM and IC became concordant.

In theoretical terms then, when considering IC for elective surgery it should be appropriate to consider SDM techniques.

The research reported in this thesis progresses this theoretical approach to consider several important considerations potentially linking SDM and IC. These broadly relate to:

- If it is appropriate to consider SDM techniques in IC is it appropriate to consider IC techniques in SDM situations?
- Can SDM processes and IC processes be compared in real life situations?
- Do patients and health care professionals (HCPs) consider that the implementation of either process could be improved upon?
- If patients and HCPs have opinions on how either process could be improved upon, would these be achieved by synthesizing an exemplar of a patient journey by comparing results from each paradigm?

In order to explore these issues it was necessary to interview patients and HCPs in two separate settings; one where SDM was being implemented and one where IC was being considered in an elective surgery setting. Two separate studies were, therefore, established to explore these issues with separate analysis of results initially, followed by a comparison and synthesis of these results.

HCPs have often considered they are using SDM techniques in clinical settings when, on specialist assessment, they are not (13). To ensure that SDM techniques were being used in an appropriate manner, patients enrolled into the SDM study were purposively selected from a cluster randomised control trial exploring the implementation of a patient decision aid (PDA) (6). PDAs are tools specifically developed to encourage SDM.

In terms of explore IC issues it was important to consider Whitney and colleagues decision plane that proposed where SDM and IC were concordant. It was also important to consider elective surgery situations where patients would have opportunities to receive information from several different sources, not just the surgeon, and to have time to search for information themselves. A reasonable

time gap between initial consultation and surgery was important, not only to permit information gathering, but also to allow the researcher time to recruit patients.

For the reasons mentioned above it was proposed that the comparison of SDM and IC should be explored through the clinical scenarios of:

- Study 1. Patients with type 2 diabetes mellitus (T2DM) sub-optimally controlled on maximally tolerated oral therapy who are considering insulin as the next step. Hereafter referred to as **The T2DM study**.
- Study 2. Patients with unilateral osteoarthritis of the hip considering hip arthroplasty. Hereafter referred to as **The Informed Consent study**.

Critical appraisal might argue that exploring these two conditions could be inappropriate, not least because they are totally different conditions but also because Study 1 was conducted in primary care whilst study 2 was conducted in secondary care. However, exploiting the differences between the two studies can illuminate discussion about the paradigms more than considering either in isolation.

Evaluation of these two studies throughout this thesis will underline the fact that it is not the clinical condition or setting that is important but the way patients make decisions about treatment options and what influences their decision. The thesis will, therefore concentrate on the overarching concept of **“How patients make healthcare decisions.”**

Through discussion of the literature review it will become apparent that there are many factors that might influence this process, but they can be condensed into four main themes which will become the meta-themes for results analysis, comparison and synthesis. These meta-themes are:

- Doctor-patient interactions
- How the presentation of information can influence decisions
- External factors that might influence decision making such as family or friendship influence on patients, or hospital policy on the HCP.
- The concepts and tools of SDM.

The literature review has explored, systematically, the topics highlighted above, namely:

- Shared Decision Making, Informed Decision Making and decision making
- Informed Consent
- Patient decision aids
- Type 2 diabetes mellitus
- Osteoarthritis
- Hip arthroplasty
- How patients make healthcare decisions

References have been searched both through medical on-line resources such as Medline and PubMed as well as legal resources such as LexisNexis. Sources were searched using the above terms and appropriate references from identified articles were also followed-up.

The literature review identified several issues under the separate themes of SDM and IC with occasional attempts to amalgamate the two (14) but with little reference to the underlying theories of either paradigm (15).

What is clear, in terms of SDM, is that this is a relatively new concept in medicine (16) but has already generated vast quantities of medical research (17). Despite this there are still significant gaps in our understanding of how best to implement SDM with patients (18-28) and significant barriers on how to implement and reward the use of SDM by healthcare organisations (18, 29). A recent Cochrane review on PDAs (30) recognises the fact that many of these tools are introduced without evaluation and even when they are evaluated we still know little about their long-term impact.

Some have argued that the implementation of SDM may reduce healthcare costs (31) whilst others suggest this effect may be neutral or delaying decisions until more expensive intervention is required (32). Other critics have argued that most PDAs are developed in North America and are of little relevance in the UK.

The relevance of SDM and PDAs to the UK National Health Service (NHS) at the individual level and at policy and implementation level is still uncertain.

Although this thesis does not propose to answer all these questions it is important to ensure that implementation of SDM is thoroughly explored to create the most valid model for the NHS. Consequently this thesis will explore patient and HCP opinions on the implementation of SDM currently and whether improvements can be made by comparison with IC.

Resources relevant to IC have come from a number of different sources. Whilst there are many medical research studies relating to IC they tend to be very narrow in focus, either concentrating on one disease or issues surrounding signing the consent form. A broader picture of IC becomes apparent when reviewing non-medical sources such as case law, academic legal opinion, regulatory body guidance and litigation evidence.

A picture emerges of a paradigm that has evolved slowly over a century, with most guidance provided by the courts and adapted by regulatory bodies. Academic legal opinion (4) has been somewhat exasperated by the fact that courts of law will often defer to medical “expert” opinion to establish the legal standard of care. Very little of the literature explores how the medical profession could proactively improve the provision of IC, but most often reflects the medical profession concentrating on the legal aspects of risk disclosure whilst patients are concerned about post-operative recovery and resuming normal activities.

This dichotomy may not seem important if there was evidence of patient satisfaction with the consent process. The NHS Litigation Authority is an organisation that deals with negligence claims against the NHS in England and has a category specifically relating to “Failure to warn: Informed Consent”. As will be discussed in more detail figures from this organisation indicate an increasing tendency for patients to resort to litigation, with pay-outs and legal costs increasing year-on-year.

Such evidence indicates a dissatisfaction by increasing numbers of patients with the IC process. It is, therefore important to explore patient and HCP attitudes to and experiences of the IC process and if shortcomings are identified, whether the use of SDM techniques might improve patient experiences.

Many studies, including the main PANDAs trial, have used questionnaires to evaluate interventions in SDM and the Cochrane Review identifies the lack of qualitative work in evaluating the impact of SDM and PDAs. Much of the IC research also includes evaluation by questionnaire with little qualitative work exploring patient and surgeon attitudes and values. It was considered important to

fill our knowledge gaps in these areas by conducting semi-structured in-depth interviews with patients and HCPs in both settings, evaluating both separately with reference to the overarching concept of how patients make healthcare decisions, but then comparing and synthesizing the results to establish proposed exemplars for each setting.

Throughout this thesis the two paradigms will be considered separately in terms of background information and the two studies. Consideration will be given to the appropriateness of comparing the two paradigms and then results will be synthesized and discussed through this comparison.

## Chapter 1: Shared Decision Making.

As we have already seen some commentators consider Informed Consent and Shared Decision Making to be concordant (9, 11) whilst others would argue that the two are separate paradigms that can be concordant in certain situations (12).

Both paradigms are based on the premise that informed patients make better decisions and that patients need to be appropriately informed on procedures, alternatives and risks of each option (PARQ) before they can truly be said to make an informed choice (33). The physician should ensure the patient has the opportunity to ask questions until they are satisfied. Although the PARQ process is often applied to IC it can equally apply to treatment decisions in an SDM setting. However, the author argues that following such a process is too narrow and inappropriate for either SDM or IC.

PARQ does not promote either the assessment of patient understanding of information provided, or the eliciting and evaluation of patient values; core principles that have been promoted by the development of SDM. Some would argue that these are core principles of patient autonomy, an ethical concept that has risen in prominence in many healthcare systems during the 20<sup>th</sup> Century.

A gradual move away from doctor beneficence towards patient autonomy has to be a welcomed step, yet there is no generalized agreement in the literature as to what patient autonomy in healthcare is, or whether it is actually achievable. This review of the literature on SDM will explore the origins and development of key concepts of the paradigm with reference to practical and ethical considerations.

### 1.1 The Development of Shared Decision Making

Although ethical debate around patient involvement in medical decisions has been considered for most of the last century it was galvanised particularly during the Nuremburg Trials and the subsequent codes (34), developed to protect participants in medical research. Considerations prior to this tended to focus on legal cases of informed consent to treatment, with little consideration for general medical encounters. Indeed the first reference to Shared Decision Making appears to occur in the first chapter of a President's Commission report on biomedical research in 1982 (16) entitled "Informed Consent as Active, Shared Decisionmaking" it states that:

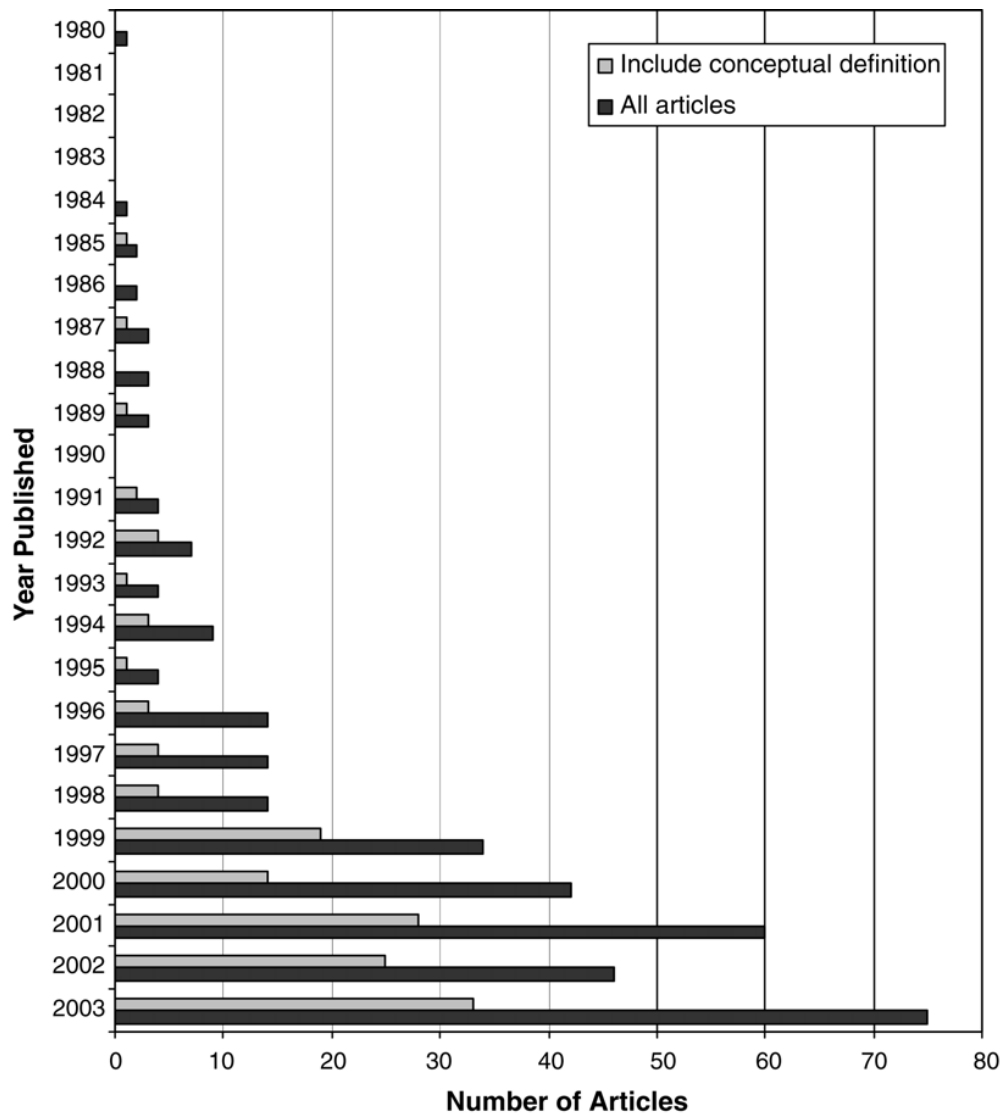
"Ethically valid consent is a process of shared decisionmaking based upon mutual respect and participation, not a ritual to be equated with reciting the contents of a form that details the risks of particular treatments."

This concept of mutual respect and participation has gradually developed into a patient-centred model of health care discussions(35) which has become known as Shared Decision Making(36).

The term has gradually become associated with an approach to patient involvement in general medical encounters. Makoul et al (17) reviewed the number of papers published in peer reviewed journals and registered in PubMed relating to Shared Decision Making and identified an almost exponential growth between 1980 and 2003. This is shown in the graph below.



Table 1 Growth in PubMed indexed articles on Shared Decision Making 1980 -



*All articles\** = results of the primary search strategy, which captured articles that were indexed in Pubmed (Medline) through 31 December 2003, included the words *shared decision making* in the title or abstract, and met the following two inclusion criteria: (1) in the context of patient-provider encounters; (2) published in English. N = 342.

This review is supported by evidence from 2002 to 2012 that the number of articles indexed under “shared decision making” grew from 105 to 428 per year (37).

Closer inspection of Makoul’s data reveals one of the enduring problems of Shared Decision Making, which is a conceptual definition of the term. Of 418 articles reviewed they found that only 38.5% had a conceptual definition of Shared Decision Making, but even then there was no consensus as to what this might be. In fact they only found two statements present in more than half of the articles:

“patient values/preferences” (67.1%) and “options” (50.9%).

The table below gives a list of the concepts associated with SDM in the articles Makoul reviewed and the frequency with which they occurred.

*Table 2 Concepts used in the definition of Shared Decision Making (17)*

Articles containing concept	Concepts used in definitions of SDMaking
67.10%	Patient values/preferences
50.90%	Options
46.00%	Partnership
37.30%	Patient participation
36.60%	Patient education
35.40%	Benefits/risks (pros/cons)
31.70%	Deliberation/negotiation
30.40%	Doctor knowledge/recommendations
29.20%	Mutual agreement
26.70%	Process/stages
23.60%	Middle ground
23.00%	Information exchange
18.00%	Make or explicitly defer decision
16.80%	Present evidence
13.00%	Define/explain problem
13.00%	Define roles (desire for involvement)
11.80%	Unbiased information
11.80%	Check/clarify understanding
11.20%	Flexibility/individualized approach
10.60%	Mutual respect

Makoul and colleagues also looked at the most frequent citing as a definition for Shared Decision Making and again there was no consensus on the best defining article, although the most quoted was Charles et al (38) which used a practical application definition rather than conceptual ideas. They compared models of patient-clinician encounter including the paternalistic model, the informed decision-making model and the professional-as-agent model to provide conceptual clarity to the Shared Decision Making model.

They identified that there are four main requirements for an SDM model of consultation, namely:

- (1) That at least two participants--physician and patient be involved;
- (2) That both parties share information;
- (3) That both parties take steps to build a consensus about the preferred treatment; and
- (4) That an agreement is reached on the treatment to implement

The authors along with Elizabeth Murray (39) updated this guidance in 2006 taking into account primary care consultations and also recommended:

“...sharing the decision-making around agreeing on an agenda for each consultation; and adapting the information transfer component of the model to acknowledge that doctors may not be the only, or even the main, source of technical information for patients”

One of the more recent attempts to define the concept of Shared Decision Making come from The Health Foundation, an independent organisation in the UK funded by endowments from the sale of their original backers, Private Patients Plan Limited in 1998 (40). It has a history of supporting programmes in Shared Decision Making such as The MAGIC programme (13) and promotes a working definition:

“Shared decision making is a process in which clinicians and patients work together to select tests, treatments, management, or support packages, based on clinical evidence and patients’ informed preferences. It involves the provision of evidence-based information about options, outcomes and uncertainties, together with decision support counselling and systems for recording and implementing patients’ treatment preferences.” (41)

This definition encompasses the fact that decisions about healthcare cover a broad spectrum of scenarios, not just the treatment options as espoused by informed consent.

The whole purpose of SDM is health care professionals working with patients to reach a decision that is most appropriate for the patient. The starting point has to be that each side of the consultation holds specialist information that is important to the eventual decision.

The clinician has specialist knowledge on disease symptoms and signs, the available treatment or investigation options and potential complications of the disease or individual treatments. Patients, on the other hand will have preferences on how decisions are made that may vary with disease severity or age. Each individual patient will have their own values dependant on many socio-economic and cultural beliefs (42) that require clarification during the consultation before patient-centred decisions can be made (43). Patient preferences and values are very individual and need to be elicited by the physician on each occasion to achieve the best outcome for every patient.

## 1.2 Preference-sensitive Decisions

One of the current themes for SDM is, therefore, “preference-sensitive” decisions to be considered in situations where there are no guidelines to direct doctors in treatment or investigation recommendations. This is apparent where there is no evidence to promote one option over another. This does not mean there is no evidence, but that any evidence indicates that one option is not superior in outcome to another. This may also be the case where evidence of benefit and harm are similar (44). Current examples of this in UK medical practice would include treatment for in-situ carcinoma of the prostate which include watchful waiting (doing nothing), radical prostatectomy, trans-urethral prostatectomy or radiotherapy (45). Another example would be the consideration of

anticoagulation for patients with non-valvular atrial fibrillation who have had their stroke risk stratified by the CHA<sub>2</sub>DS<sub>2</sub>-Vasc score (46, 47) with a resultant score of 1. The evidence is that such patients should not necessarily be recommended to take anticoagulant tablets but an informed discussion should be had, after which some patients might choose this option over doing nothing (48).

The suggestion with both these examples is that there is no evidence to recommend one treatment or investigation over doing nothing, although the patient still needs to be made aware of the evidence and options even if one of the options is to do nothing. On discussion of patient values in the light of this evidence some patients may choose treatment over non-treatment; that is to say it is their preference rather than evidence-based recommendation. However, to ensure that such decisions are made without clinical bias or coercion the presentation of evidence for and against each option must be done with equipoise (49).

### 1.3 Equipoise

From Elwyn et al's (49) qualitative interviews with general practitioners they identified the portrayal of equipoise and options as "the pivotal stage in shared decision making". They did, however, recognise the importance of the way information is portrayed. They identified that where there was no clear preference about the treatment choice it could be seen as presenting uncertainty but the participants viewed equipoise "to be different and seen as the skill of portraying options in an open, non-directive manner that did not lead to patient confusion, anxiety or lack of confidence in a professional's ability".

Elwyn went on to refine the concept of equipoise into dual equipoise (50), a situation where both health care professionals and the patient agree that equipoise exists. Both parties agree that the evidence does not promote one option over another and that taking no action is one choice. Elwyn discusses that in these situations decision support is more beneficial than behaviour support and such interventions can "help people to deliberate, independently or in collaboration with others, about options by considering relevant attributes".

In order to promote the concept of equipoise, clinicians will require a certain skill set to enable them to engage patients in meaningful dialogue. In considering the competences required by health care professionals of involving patients in healthcare choices Elwyn et al (49) identify several requirements essential within the medical encounter to ensure shared decision making can occur. These competences are outlined below.

## 1.4 Core competences within the consultation to promote Shared Decision Making

From their interviews with six experienced general practitioners Elwyn et al identified seven competences required in a consultation to permit shared decision making:

1. Implicit or explicit involvement of patients in decision-making process.
2. Explore ideas fears and expectations of the problem and possible treatments.
3. Portrayal of equipoise and options.
4. Identify preferred format and provide tailor-made information.
5. Checking process: understanding of information and reactions.
6. Checking process: acceptance of process and decision-making role preferences.
7. Make, discuss or defer decisions involving patients to the extent they desire to be involved.

They argue that this work builds on and expands Towle's framework for teaching and learning shared decision making (51). They also identified that preference was expressed to identify options before checking whether the patient wishes to be actively involved in the decision. Even by following these competences, clinicians will have a range of interpersonal skills and attitudes towards the concept of shared decision making. Earlier evidence from routine patient contacts with primary care physicians (52, 53) reveal that many of these competences are rarely portrayed. They explored consultations by primary care physicians as well as more complex consultations in surgical settings. They identified that only in 71-83% of consultations was the nature of the decision or intervention described adequately. Discussion of risk and benefit was less frequently performed (9%) whilst assessment of patient understanding occurred in only 1.5-2% of consultations. There was no evidence provided on the preferred format of evidence that patients liked to receive.

Clearly a lot of these competences require physician skill and awareness but if recommending roles for the patient, such as preferred format of information or decision-making role preferences, then the interaction between physician and patient is equally as important.

## 1.5 The doctor-patient interaction.

The consultation is recognised as a core element of patient interaction and engagement with several attempts to try and analyse and categorise the important features and techniques (54-60). Many of these attempts have been considered to be limited:

"In the past two decades descriptive and experimental research has tried to shed light on the communication process during medical consultations. However, the insight gained from these efforts is limited. This is probably due to the fact that among inter-personal relationships, the doctor-patient relation is one of the most complex ones. It involves interaction between individuals in non-equal positions, is often non-voluntary, concerns issues of vital importance, is therefore emotionally laden, and requires close cooperation" (61)

A doctor's approach to the consultation can influence the discussion and decision making, whilst patient values will alter depending on the age of the patient, the severity of the illness faced, and whether the decision is about investigation or treatment.(62)

A literature review of publications relating to the doctor-patient interaction (63), whilst not specifically relating to shared decision making identifies that :

“Communication can be seen as the main ingredient in medical care”.

The authors explore various communicative behaviours found in the studies reviewed, many of which are important to shared decision making such as “medical vs everyday language vocabularies” and “high vs low controlling behaviour”. They also identified that physician behaviour can affect the outcomes on patient satisfaction, understanding and recall.

More recent work on the consultation model conducted by The Health Foundation (64) drew on experiences in shared decision making and identified two dimensions that make interactions within the consultation more complex. The first was priorities, whereby the doctor and patient may have different priorities for the outcome of their meeting or prioritise outcomes differently. The second is described as “tame” or “wicked” problems: a tame problem is definable and solvable, even if difficult; a wicked problem is one where the definition of the problem may vary, and the solutions are likely to have unknowable or unintended consequences. There were many other factors such as patient and doctor fear that drove consultations and an underlying structure or agenda to a consultation created by the doctor but to which the patient was unaware. The authors argue that not only does the doctor–patient interaction need to be viewed in a more complex way but that a broader picture of interactions within the healthcare system need to be considered to ensure patients get the most out of their consultation.

In terms of promoting SDM the authors argue:

“The consultation therefore needs to expand as a construct to accommodate the complexities we know are involved in delivering healthcare today.”

And to promote patient-centredness:

“...a more sophisticated model of the consultation is more likely to genuinely reflect patient and clinician priorities in different circumstances.”

Having considered the nature of informed consent and shared decision making in terms of doctor-patient interaction it becomes clear that communication is pivotal in allowing patients to engage in sharing decisions and it is the doctor’s role to ensure this happens. The doctor, therefore, not only has to be aware of the issues raised by Chaitchik above but also has to be skilled at creating a good inter-personal relationship to allow sharing of information and, most importantly allowing patients to take some control (and hence responsibility) for the decision that is eventually made.

There has been improvement in the training of young doctors in communication skills over the last 20 years. Anecdotally I never received formal training as a medical student in the 1980s but now teach communication skills to medical students in their third and fourth year of study. However, communication skills are only one part of SDM. The Health Foundation report into the MAGIC project (40) highlights the fact that many doctors think they are engaging in sharing decisions during their consultations when in reality they are not. The Health Foundation argue that retraining of doctors and training of medical students should fundamentally change when considering doctor-patient interactions and consultation skills.

“The new model we suggest would change what is seen as the skills required for being a doctor. They would need expertise in understanding uncertainty and to be organisationally literate. A doctor without relationship skills would simply not be a doctor.” (64)

The Health Foundation report also suggests we need to consider the purpose of a doctor-patient interaction within a complex web of technologies and systems that can lead to appropriate preference-sensitive decisions. These techniques are as important for the surgeon taking informed consent, the physician discussing options for cancer treatment and the GP discussing medical care for conditions such as diabetes or atrial fibrillation.

In order to understand more fully the way patients make decisions and how interactions can influence these outcomes it is important to consider the theory behind SDM.

## 1.6 The Theory behind Shared Decision Making

Aspects of decision making will be reviewed later in relation to IC but this section explores specifically the theoretical underpinnings of SDM.

Arguments have been made (15) that in order to produce effective research into shared decision making it is important to understand the theories behind decision making and doctor-patient interactions. Reyna argues that without this theoretical based research some of our concepts of value such as Quality Adjusted Life Years may be incorrect (65).

There are several theories developed from different themes of research into how patients make healthcare decisions and what can influence them. There have been attempts to draw some of these theories together to create a framework.

The Ottawa Decision Support Framework (ODSF) (66) is an ongoing development by the Ottawa Hospital Research Institute, originally under the guidance of Annette O'Connor, to support patients and clinicians in making health care decisions. The Framework draws on theories of:

“...general psychology, 1981 (67)), social psychology (68), decision analysis (69)), decisional (70)), social support (71); (72)), and economic concepts of expectations and values (73).”

It is clear that concepts of shared decision making draw on many different emotional and transactional theories, making it difficult to develop one single framework that will cover all medical situations where shared decision making is considered important. Reyna (15) reviewed three theories of shared decision making that all had similarities, but also had differences.

Through Reyna's evaluation of the three theories Fishbein (theory of reasoned action); Prochaska (transtheoretical model); and Reyna (fuzzy-trace theory) it can be seen that some of the theoretical concepts will also be relevant to Informed Consent. She discusses the perceived wisdom that presenting more options improves patient experience and patient-centred decision making, whereas satisfaction appears to be greater when choosing from a smaller set of options (74). This is consistent with Ubel's theory (75) of offering too many choices; the patient is more likely to stick with their preconceived original choice. Satisfaction is also greater if people can select from their preferred choices rather than their non-preferred choices.

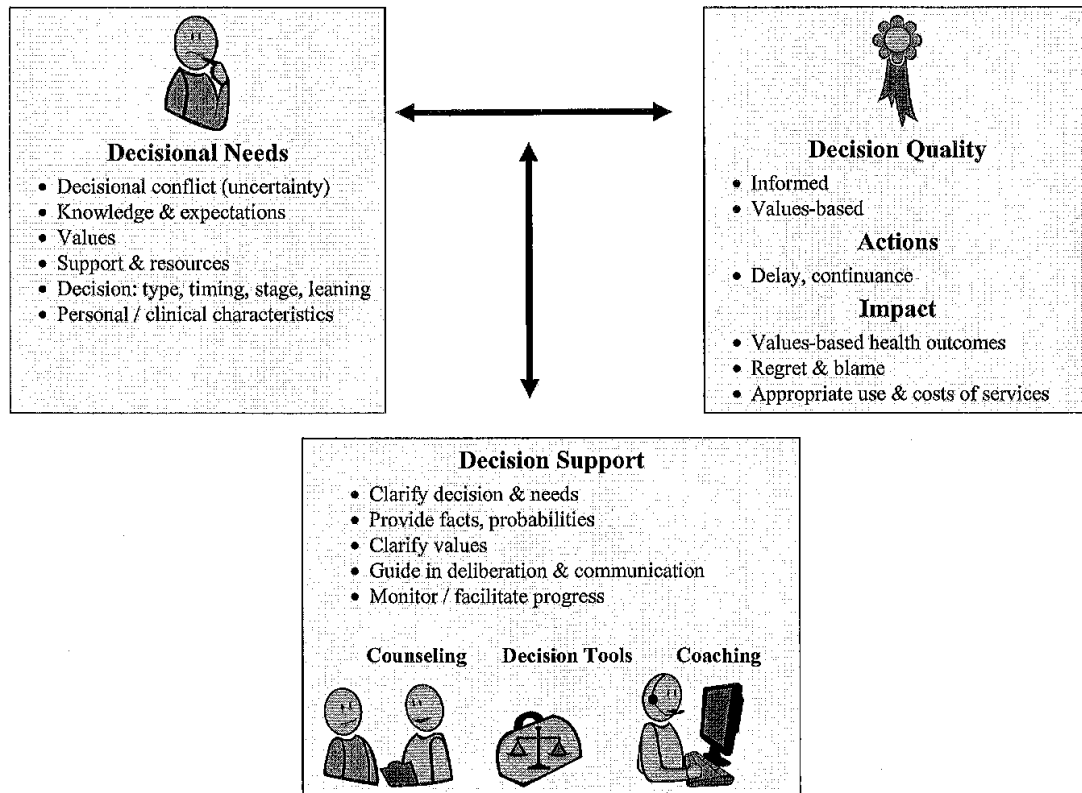
Reyna also highlights the concept of intuition in decision making. Fishbein and Proshka's approaches emphasize reason with a transtheoretical model taking a more sequential view of processes being applied differently at different stages. The fuzzy-trace theory incorporates intuition as a central explanatory idea and also considers emotion and experiences. Again, these are all concepts that are relevant to Informed Consent.

The important concept behind all of these theories is that they apply equally to patients and doctors.

The ODSF takes all of these concepts and theories to create a framework incorporating Decisional needs, Decisional quality and Decisional support.

Figure 1 Ottawa Decision Support Framework

Figure 1. Ottawa Decision Support Framework



Alongside this framework there is a tutorial to help clinicians to consider aspects of patient behaviour or their own behaviour that might be required to support patients in making a decision. Many of these areas are covered in topics above but the “Clarifying Decisional Needs” section raises some further points of interest.

Developing the concept of how patients make healthcare decisions the ODSF considers that patients may be at different stages of how close they are to making a decision and this could influence the support a patient needs to make a decision. Any attempt to use shared decision making is based on making a deliberative type of decision and the ODSF recognises that in the early stages patients may have a more intuitive style and therefore “... decision support may be irritating or unproductive.”

The ODSF does, however, try to clarify potential stages of decision making and support strategies and is consistent with Reyna’s sequential view of processes being applied differently at different stages.



*Table 3 Decision type, timing, stage and leaning (66).*

Patient's stage of Decision Making	Patient's Decisional conflict (uncertainty) is usually:	Appropriate Decision Support Strategy
Not thinking about options	High	Gauge receptiveness to new information (the patient will still be in shock or denial) If the patient is receptive, provide information. If unreceptive, discuss issues that are immediately relevant to the patient.
Actively deliberating	High	Decision support is usually most helpful now.
Close to making a choice	Lower	Gauge receptiveness to discuss what led them to the choice they are close to making
Taking steps already implemented	Low and often will increase with additional decision support	Gauge receptiveness to discussing what led the patient to the steps/choice they have taken. Sometimes, people will start implementing a process even though they are not fully committed to it (e.g. putting a family member's name on a waiting list for a nursing home that specializes in dementia, even though the decision about placement has not been finalized by the family). Others are implementing choices that they tend to reconsider over time (e.g. in cases of menopause, attention deficit disorder).

This table raises the concept of decisional conflict which is frequently used when considering shared decision making and patient decision aids.

The ODSF uses the North American Nursing Diagnosis Association definition of decisional conflict:

“Decisional Conflict is the uncertainty about which course of action to take when choice among competing actions involves risk, loss, regret or challenge to personal life values” (76)

It is usually expressed as verbalised uncertainty but can include:

- Concerns about desired outcome
- Wavering between choices
- Delaying decision
- Questioning personal values
- Being preoccupied with the decision
- Showing signs and symptoms of distress or tension.

O’Connor developed a questionnaire for assessing decisional conflict (77, 78) which is regularly used to assess outcomes when comparing decisional support tools to normal care.

### 1.7 Decision Support Tools

One of the ODSF criteria for supporting shared decision making was decision support which could come in the form of counselling, coaching or decision support tools. Counselling and coaching are often required to support patients making decisions and can come from the clinician themselves or be provided by a third party. Decision support tools are usually problem specific and can be a longer version, a patient decision aid (79), or shorter and cover the most common questions asked by patients contained on one side of paper, an option grid (80).

Patient decision aids are designed to be used prior to a consultation between patient and doctor and often have a high information content whilst option grids are designed to be initiated and used within the consultation. More experience and evidence is available around the use of patient decision aids and standards have been developed to try and ensure the quality of these products.

The International Patient Decision Aids Standards collaboration (IPDAS) is a group of specialists, researchers, patients and interested organisations experienced in shared decision making who have developed criteria essential for good decision aids by an online Delphi Consensus technique (81). The collaborators have subsequently developed an assessment schedule to perform a summative or formative evaluation of a potential decision aid prior to use (82).

Using shared decision making as a benchmark for the development and use of decision aids the original workbook on decision aid development and evaluation was published by O’Connor and Jacobsen in 2003 (8). It highlights the key components of a decision aid which correlate with the stages required in shared decision making, namely:

- Information about clinical condition, options and outcomes: patients need to know about their condition, common manifestations and complications. The options available for management of this condition are then described followed by the outcomes of each option in language and detail that patients will understand.
- Presenting probabilities of outcomes: in order for patients to have realistic expectations of outcomes, probabilities have to be described in a manner patients can understand; quite often this will be “If 100 people like you...” with pictorial options such as Cate’s plots (83)

- Values Clarification Exercise: the description of outcomes may allow patients to judge their value or patients may be explicitly asked to consider the personal importance of each benefit and risk.
- Information about Other's Opinions: some decision aids include examples of how other people have deliberated about the decision to show patients how this process might work.
- Guidance and Coaching in Decision Making and Communication: this has been shown to be helpful in some situations and includes thinking about personal preferences, preferred roles in decision making and indication current position on how close the patient is to making a decision.

The workbook recognises that training of the practitioner is required in preparing them to support patients, which can be done through individual training, guidelines or workshops. There are also many ways that decision aids can be presented e.g. booklets, videos or on-line.

The IPDAS collaboration was established after the Second International Shared Decision Making conference in 2003 following concerns about the quality of evidence and bias presented in some decision aids. It established the most important criteria for development of a decision aid and its content, split into 3 main categories:

- information, probabilities, values clarification, and guidance in deliberation that are context specific
- generic development process
- generic principles to ensure a high quality decision process and choice.

A checklist was designed to assist developers of decision aids to ensure their product met a certain standard (81) as many have been developed (over 500) but few are actually evaluated (115 in the most recent Cochrane review) (30)

The IPDAS collaboration guidance has recently been updated with publication of 12 papers on the development of decision aids (19-23, 25-28, 84-87), including newer developments of internet-based tools and evidence for including patient stories within decision aids, and a further paper reviewing some of the barriers to implementation (18). All these papers suggest that we have many years' experience of developing tools which support patients in making preference-sensitive decisions and it is important that tools developed and used cover all important aspects of patient support. There are concerns that these tools are aimed at more educated patients with recommendations that future research should explore involving patients with poor literacy skills (88). Previous research (89) has identified this as a major concern for information leaflets and consent forms with 40% of patients having a reading age of 13 years old or less.

Moreover, shared decision making and decision support tools are not widely accepted or used in clinical practice and further work needs to be done on how this can be addressed.

## 1.8 Do Decision Aids work?

Based on over 20 years development of shared decision making in medical practice there is evidence from many primary care and secondary care studies of the benefits of this approach for patients. It has to be remembered that the use of shared decision making is for situations where the evidence is equivocal and information is presented with equipoise. As such there is no correct or incorrect decision to evaluate as an outcome; any choice is the correct one if it correlates with the patient's

values. Results from these studies, therefore, tend to be based around patient experience and decisional conflict.

Earlier studies such as that exploring Hormone Replacement Therapy (90) compared the use of standard techniques, such as giving information leaflets, with more complex interactions such as lectures and discussions and the use of a Patient Decision Support tool (patient decision aid). The leaflet only group were less consistent with decision analytic models whilst those using the Patient Decision Support tool were more certain of their choice, with better understanding of likelihood of outcomes.

The original systematic review of patient decision aids (91) identified 17 randomised control trials for analysis and concluded that these tools:

- produced higher knowledge scores
- reduced decisional conflict
- produced greater patient participation in decisions.

There was no alteration in anxiety, satisfaction with decisions or satisfaction with the decision-making process.

Subsequent reviews (30) have now evaluated 115 decision aids, confirming the above findings but also identifying:

- many studies (75.6%) use one or more IPDAS criteria
- more detailed decision aids improved knowledge significantly over simpler aids
- expressed probabilities led to more accurate risk perception in a higher proportion of participants
- the use of explicit values clarification resulted in a higher proportion of patients choosing an option congruent with their values.

In some cases use of the decision aid led to a lower request for intervention such as hormone replacement therapy, prostate specific antigen testing or elective surgery, in other cases there was no difference.

This last point is an important one when considering policy implications to support the implementation of shared decision making and decision aids. Oshima Lee and Emanuel (31) cited the Cochrane Reviews and a report on reduction in hip and knee surgery (92) as reasons to expedite the use of decision aids to reduce health care costs. However, more recent evaluation (32, 93) has questioned whether this will reduce costs in the long term or merely delay decisions on treatment that will be required eventually.

Evidence of the benefits of patient decision aids is growing but there is also growing evidence of the difficulty in implementing their use widely in health care situations. This may partly be due to resistance by practitioners and partly due to lack of policy directives.

### 1.9 Barriers to Implementation of Shared Decision Making.

As mentioned earlier the recent IPDAS review recognises that there are significant barriers to the implementation of shared decision making in routine health care (18). There appears to be no evidence, after controlled clinical trials, of patient decision support intervention evaluation in

routine clinical practice. Previous reviews (94, 95) identify that in the last eight years there has been little progress in adopting shared decision making with the commonest barriers being:

- time constraints ,
- lack of applicability due to patient characteristics ,
- and lack of applicability due to the clinical situation.

The Cochrane review highlighted the paucity of information available on which to make any recommendations about implementation.

More specific reviews relating to the National Health Service (29) recognise the need for:

- information about treatment options to be readily available,
- guidance on how to weigh up the pros and cons of different options
- and a supportive clinical culture that facilitates patient engagement.

There is some concern that the majority of patient decision aids have been developed in North America and not for the UK market, therefore some resistance may exist. The paper also highlights the fact that many practitioners consider that they are already performing shared decision making and cites evidence that this is not the case (96). Indeed, the more recent MAGIC programme funded by The Health Foundation (13) to explore implementation within the NHS found this still to be a barrier.

Time is always considered a barrier to implementation of new methods. Although there is some evidence that using patient decision aids in consultations may only extend consultations by an average of less than three minutes (30) it is still perceived that time constraints within the NHS preclude this extra time required (13). This review of the literature does not include the time taken to train health care staff in techniques of shared decision making or the use of specific decision aids.

The time issue was also highlighted in a King's Fund report which highlighted the NHS focus on outcomes and throughput rather than quality and patient experience:

“To the extent that clinicians in the NHS, particularly those working in hospitals, are under pressure as a result of the incentives hospitals face to increase volume and throughput, there may be a disincentive to spend time with patients on considering alternative options, including no treatment or intervention. Those responsible for clinical pay and rewards and for designing future tariffs and payment systems need to ensure they provide incentives for organisations and clinicians to engage patients in shared decision-making.” (97)

The report also recognises the barriers mentioned above, not just at an individual doctor level but at a level where clinical teams don't know about decision aids, have not been trained in their use and are uncertain where they should sit in the care pathway.

Pay for use of shared decision making or pay for quality outcomes is another difficult area that presents a barrier. A significant proportion of general practitioner income since 2004 has derived from the Quality and Outcomes Framework (98); a pay for performance type scheme covering areas of disease management and organisational practice issues. As the name suggests it is based on outcomes, which can be easily stored in digital databases and retrieved. The measurement of quality in a meaningful and immediate feedback of patient experience is very much more difficult and called “a big prize” in the MAGIC programme.

There have been many tools and theories developed to try and measure shared decision making but no agreement as to the best approach. A review of research evidence, commissioned by the Shared Decision Making Programme, tried to identify qualities and ease of use that would make each measure more acceptable to the NHS (99). The review accessed a wide range of sources although was not systematic in its approach to data collection.

There was a recognition that measurement of decision outcome should be supplemented by measurement of the process and impact on the decision outcome from a clinical perspective should be included.

The review considered three important attributes to assess decision process and quality:

- Whether there is a patient rating scale
- Whether it covers many facets of decision making
- Whether it has been used in the UK.

19 different measurement tools were identified and evaluated and only the Decisional Conflict Scale (78) and the 4 item SURE scale (Sure of myself, Understand the information, Risk-benefit ratio and Encouragement) (100) were considered simple enough to use regularly. They were generic scales that could be used in any condition but did not measure congruence with patient values or disease specific knowledge and understanding.

There is clearly still a difficulty in being able to measure shared decision making and this is exemplified by the fact that despite this review of 19 tools new ones, such as the Decision Process Score are still being developed (101). The development of this score identifies the problem of when to administer the questionnaire. The researchers recognise that the best time to collect knowledge and preference data is immediately after the patient's consultation, although this is not necessarily the end of the decision making process and the Decision Process Score would have to be collected at a separate time.

Costs relating to development of decision aids, keeping them updated and distributing them in various formats for patients and physicians to read at home and in a consultation create considerable problems. These may only be overcome by collaboration between many agencies and would require a significant shift in policy to implement.

### 1.10 Policy Initiatives to support Shared Decision Making

As described above there would need to be policy initiatives to support the implementation of shared decision making in the NHS with multi-agency involvement and timely and appropriate methods of monitoring the process.

Some centres in North America have established their own systems of shared decision making and continue to use these routinely (102) however this is not the norm. In 2007 the US state of Washington took the first steps towards legislating for shared decision making (103). This was enacted to support "the implement a shared decision-making demonstration project" with evaluation of the project in terms of patient and practitioner satisfaction. This has been superseded in the US by a sleeper clause (3506) in the Affordable Care Act (104) which has not yet been implemented but promotes a program to facilitate shared decision making with clear guidance on preference sensitive care and patient decision aids.

As will be discussed in relation to informed consent, the use of legal techniques to promote patient-centred care does not always achieve the appropriate outcomes. Doctors may become more concerned about their obligations under the legal system and, whilst fulfilling these, may ignore the broader context of the paradigm. This, therefore, has the potential to create doctors who are more interested in ensuring they have reached the standards required by law rather than that congruent with patient values.

The Government of the United Kingdom have taken a less pro-active approach to shared decision making and patient decision aids. The Coalition Government published its white paper, *Equity and Excellence: Liberating the NHS* in July 2010 (105) with an entire section devoted to putting patients and the public first. There was a range of measures under the banner “No decision about me, without me” that included collaborative techniques, shared decision making, patients having more information and an expanded use of Patient Reported Outcome Measures (PROMs). There was a clear intention to promote patient involvement in health care decision-making but without legislative authority.

This view has general been supported by guidance for doctors by their regulatory body, The General Medical Council:

“Whatever the context in which medical decisions are made, you must work in partnership with your patients to ensure good care... you must listen to patients and respect their views about their health, discuss with patients what their diagnosis, prognosis, treatment and care involve... respect patients decisions” (106)

The Department of Health have continued in their policy of promotion rather than regulation by initially adapting 3 decision aids produced by The Foundation for Informed Decision Making and subsequently commissioning 38 patient decision aids through Right Care and supported by the Quality, Innovation, Productivity and Prevention programme (107). The NHS funded NHS Choices website (108) is a patient orientated information site on healthcare issues and diseases. Several pages now include treatment option tables designed to facilitate shared decision-making. These cover topics such as glue ear, ulcerative colitis, quitting smoking, prostate enlargement, haemorrhoids, high blood pressure, bunions, acne, varicose veins, rosacea, back pain, angina, erectile dysfunction, carpal tunnel syndrome, vitiligo, urinary incontinence and tennis elbow, and more are being developed.

### 1.10.1 Policy conclusions

The process of implementation has been adopted in different manners by the UK and USA. With no consensus on how to measure effective SDM in a timely manner and no national strategy, either in the form of legislation or financial incentives such as QOF for general practitioners, it is difficult to see how shared decision making can be promoted consistently within the NHS.

There may need to be further research, not only into measuring shared decision making but also considering levers that could be used to promote implementation. Right Care has done a lot of work in developing an Atlas of Variation in Healthcare (109). Not all of these variations can be explained by varying disease prevalence or patient choice. Unwarranted variations in healthcare may be reduced by standardising some healthcare decision processes through the use of shared decision making and patient decision aids. Where this data is readily collectable year on year, an influence on reducing variation in healthcare would provide a major lever to commission implementation of these programmes.

This chapter has already touched upon some of the areas where processes and skills required for SDM are also relevant to IC. The next section will review the development of the legal doctrine of informed consent and how some of the ethical issues surrounding patient autonomy has led to a more patient-centred view of IC which is starting to include some of the implementation strategies of SDM.



## Chapter 2: Informed Consent

It is important to understand that informed consent, in terms of medical transactions, has its basis in legal cases. There is no primary legislation in the UK relating to informed consent and whilst early cases were brought under the criminal charge of battery, which requires evidence to be “beyond reasonable doubt”, cases now are brought under the civil tort of negligence, requiring the evidence of “on the balance of probabilities”. Punishments have also altered with the changes in litigation; criminal cases are punishable by custodial sentences whilst civil cases result in compensation.

It is therefore important to understand the development of the legal doctrine of Informed Consent to appreciate the legal framework it creates today for consideration of obtaining consent before surgical procedures. The legal framework is not the only consideration; ethical developments can impact on discussion about Informed Consent and patient and surgeon factors are also highly important. This section will start by exploring the legal doctrine and move on to consider some of the ethics surrounding patient autonomy in decision making. How patients make healthcare decisions and what can influence these will be explored as well as physician attitudes to the consent process and the role of the consent form.

The section will close with a discussion about a theoretical view of how IC can be improved and a practical application of how this might be achieved.

### 2.1 The history of informed consent

The history of informed consent is covered in excellent detail in Faden and Beauchamps “A History and Theory of Informed Consent” (110), albeit with a North American influence on the topic. This is not altogether unwarranted to consider in a UK setting as the legal doctrine of Informed Consent has developed in countries according to their legal system. The United Kingdom and United States of America share a common law system as opposed to the civil law system of Europe. The common law system is characterised by judges in court developing the law, with a hierarchy of courts where decisions in higher courts are binding on lower courts. From 2009 in the UK the Supreme Court has been the highest court in the land (previously the Appellate Committee of the House of Lords) and its decisions on matters of law can only be superseded by primary legislation.

As the USA, Australia and Canada have a common law system, the case law generated in these countries can influence court decisions and ethical developments in the UK.

Any relationship between the doctor and patient received little attention from the Hippocratic Oath in 4<sup>th</sup> century BC to the 18<sup>th</sup> Century and the Age of Enlightenment (110). The Hippocratic Oath warns about the dangers of patients lying to the physician but little on what the physician should tell the patient other than ‘reveal [...] nothing of the patient's future or present condition.’ (111)

The prevailing consensus until the 18<sup>th</sup> Century was one of paternalism, the doctor assuming that they knew what was best for the patient and instigating treatment. Even during the 18<sup>th</sup> Century there were still strong proponents of this view. John Gregory and Thomas Percival, who were both doctors, wrote extensively on the benefit of maintaining lies with the patient if the deception was considered in the best interests of the patient. This viewpoint was also accepted by the American Medical Association:

'The life of a sick person can be shortened not only by the acts, but also by the words or manner of a physician. It is, therefore, a sacred duty to avoid all things which have a tendency to discourage the patient and to depress his spirits.' (112)

However, writing at the same time was Reverend Thomas Gisborne who had an opposing view that instilling hope should be encouraged, but limited in situations where patients instinctively knew they were seriously ill.

Concerns were raised throughout this period that relatives often knew the prognosis before the patient and could request that this information be withheld from the patient and this was considered appropriate by the medical profession (112). By the 20<sup>th</sup> Century there was greater support for honesty with patients when discussing their health issues (113) although it was still often the case that relatives knew cancer diagnosis and prognosis before the patient (114).

It is only during the 20<sup>th</sup> Century and we start to see courts adopting the concept of patient rights, particularly in relation to surgical procedures, that the doctrine of Informed Consent starts to develop and evolve into the legalistic concepts of the 21<sup>st</sup> Century.

Faden and Beauchamp identify three seminal cases in America in the early 20<sup>th</sup> Century that develop the doctrine of Informed Consent, although they argue that the most often cited, *Schloendorff v Society of New York Hospital* (115) actually progresses the concept of patient autonomy the least.

The plaintiff, Mary Schloendorff was admitted to hospital and consented to examination of a fibroid under anaesthetic. However, she refused to consent to any further intervention. The surgeon identified that the mass was malignant and proceeded to remove the tumour against the patient's expressed wishes. The court found in the plaintiff's favour, Cardozo J. commenting in his famous quote:

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages."

Although the surgeon considered he was acting in the patients best interests it was clearly contrary to her wishes and the courts considered patient autonomy to make decisions more important.

*Mohr v Williams* (116) related to a claim for battery after the patient (Mohr) had agreed to have surgery on their right ear, but under anaesthetic the surgeon found the left ear to be more diseased, so operated on this instead. The procedure resulted in significant hearing loss in the left ear. In *Pratt v Davis* (117) the surgeon performed a hysterectomy without the patients consent. The surgeon's attorney argued:

"...the employment of the physician or surgeon gives him implied license to whatever in the exercise of his judgement may be necessary"

The judgement in *Pratt* limited the concept of "implied" consent to emergency treatment or where the patient knew the consequences of the proposed intervention.

The *Pratt* and *Mohr* judgements are often quoted together and, with the *Schloendorff* case, started to develop the concept of "informed consent" loosely based around the ethical principle of "patient autonomy".

## 2.2 UK legal developments of the doctrine of Informed Consent

For most of the latter half of the 20<sup>th</sup> Century the UK doctrine of Informed Consent was shaped by one case which was concluded in the court of first instance and wasn't even about Informed Consent, but was about the appropriate standard of reasonable care in negligence cases. Academic lawyers would argue, for these reasons, that the case should not create a precedence in common law, especially in consent to surgery issues. However, many UK doctors are aware of the case of Bolam (118) and the "Bolam Test" it created.

Mr Bolam was a voluntary patient at Friern Hospital and agreed to undergo electro-convulsive therapy (ECT). He was unrestrained and did not receive a muscle relaxant. During the procedure he suffered significant injuries including a fractured pelvis. He sued the hospital for negligence in not providing restraints or muscle relaxants and not warning him about the risks involved. The judge of first instance, McNair, noted that it was common medical practice not to use restraints or muscle relaxants and indeed only to discuss risks if asked to do so. Whilst McNair accepted that standards for someone claiming to be a professional should be above those of a reasonable person he still considered:

"...that he is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art."

This led to the Bolam test, part of the criteria to establish negligence in medical cases, whereby if a doctor could prove that he acted in accordance with a responsible body of opinion, even if there were opposing views, they would be found non-negligent.

This case continued to influence the concept of IC in the UK for nearly 50 years, although it was not without modification and challenges.

In the case of Sidaway (119) the claimant suffered from neck and arm pain. The surgeon recommended surgery but failed to mention a 1% chance of developing paraplegia from the operation. This complication did arise and the patient sued for negligence. Eventually this case led to a hearing in the House of Lords which rejected her claim for damages on the grounds that consent did not require an elaborate explanation of remote side effects. However, Lord Scarman, in his dissenting judgment argued for the "prudent patient" test. Rather than considering the Bolam test in relation to what a reasonable doctor would do, he argued that the frame of reference should be what the reasonable patient would expect to be told.

A further challenge came to the Bolam test in the case of Bolitho (3). Patrick Bolitho, a child, had been admitted to hospital with respiratory problems. Dr. Horn was asked to review the patient by the nurses but failed to do so, on a second occasion she was asked to review Patrick and delegated to a junior member of staff who also failed to review the patient. Patrick suffered brain damage from respiratory failure and eventually died. Patrick's father sued for negligence. Again this case reached the House of Lords with Dr. Horn arguing that even if she had attended to Patrick she would not have intubated him and the result would be no different. In her defence she called Dr. Dinwiddie, an expert from Great Ormond Street Hospital who agreed that he would not have intubated the child. The court found Dr. Horn not negligent but said that the courts had to weigh up different medical opinions and ensure that they were reasonable, responsible, and respectable and have a logical basis.

This was a slight departure from the Bolam test but still considered negligence from a doctor's perspective. It was not until 2004 that the deference to medical paternalism was finally challenged in the courts.

Miss Chester (1) suffered from back pain for six years eventually affecting her walking. A Magnetic Resonance Imaging scan (MRI) revealed a disc protrusion and Miss Chester saw Mr. Afshar, a neurosurgeon. He recommended surgery but failed to warn of a 1-2 % risk of cauda equina syndrome. Miss Chester had the surgery, which the court agreed was performed non-negligently, but she subsequently developed cauda equina syndrome and sued for negligence. The House of Lords agreed that the surgery had been performed non-negligently but the consent had been taken negligently. By not informing Miss Chester of the risk the surgeon had deprived her of seeking a second opinion or declining surgery. Lord Bingham and Lord Hoffman dissented on the grounds of causation – the fact that the negligence in taking consent had not led to the mishap sued for, often known as the “but for” test:

“But for the negligence in taking consent would Miss Chester have suffered the mishap?”

In this case it is not clear that the negligence in taking consent caused the injury and there has been much debate in the legal journals as to what precedent this sets(120, 121). However, it is clear that the courts are prepared to take a more patient-centred view in medical negligence cases and Informed Consent.

### 2.3 Other influences on the legal doctrine of Informed Consent

So far we have seen the development of Informed consent in the UK in terms of some of the landmark cases but the legal doctrine is influenced by other factors. In order for a claimant to successfully sue in negligence they have to prove four facts:

1. That the doctor owed the patient a duty of care,
2. That that duty of care was breached,
3. That the breach of duty led to the loss claimed for (causation), and
4. That the consequences claimed for were not too remote from the breach.

We have already seen in Chester that there was concern as to whether the breach in consent had led to the development of cauda equina syndrome. There have also been concerns raised about the issue of discussing risk. Some have taken the paternalistic view that a risk approximating to 1% should be discussed with the patient at consent taking, however, others have argued that a patient-centred perspective should be taken as in the case of *Rogers v Whitaker* (an Australian case) (122).

Miss Whitaker had suffered an injury to her right eye aged nine. She saw Mr. Rogers, an ophthalmic surgeon who recommended surgery to the right eye that might improve eyesight and appearances. He duly conducted the surgery with no improvement in sight of the right eye but Miss Whitaker subsequently developed sympathetic ophthalmia in the left eye rendering her virtually blind. Cambell J. commenting:

“The development of this condition after the operation and the consequent loss of sight in her left eye were particularly devastating for the respondent as she had been almost totally blind in her right eye since a penetrating injury to it at the age of nine.”

The risk of such an event is estimated to be 1 in 14,000. The court held in favour of Miss Whitaker because she had expressed concern at the initial consultation about any effects on her left eye.

Although this case relied heavily on the Bolam test it also drew on cases from America (*Canterbury v Spence* (123)) and Canada (*Reibl v Hughes* (124)) which held that the "duty to warn" arises from the

patient's right to know of material risks, a right which in turn arises from the patient's right to decide for himself or herself whether or not to submit to the medical treatment proposed.

## 2.4 The current status of the Legal Doctrine

Whilst there has been a move away from a doctor-centred approach to information giving in IC towards a more “prudent patient” approach there is still much criticism of the legal approach.

The approach taken towards causation in Chester has not been universally applied (125) meaning that such litigation will still need to be approached on a case by case basis. The other major concern about the legal doctrine is the scope. Courts generally deal with the narrow concept of the discussion of risk, without reviewing broader considerations such as patient involvement in the decision-making process or autonomy (which itself is a contentious issue), both of which shall be reviewed later in the chapter.

## 2.5 The current state of Informed Consent litigation in England

The picture given above is one of a claim of negligence in relation to breaches of duty relating to Informed Consent. These are claims brought in the civil courts requiring evidence based on “the balance of probabilities”. This was not always the situation with cases formerly brought in the criminal courts on the grounds of battery; conviction requiring the higher evidential basis of “beyond reasonable doubt” and resulting in a fine or imprisonment.

The negligence route is now preferred by claimants because of the lower evidential requirement and the prospect of damages being paid. The National Health Service (NHS) established the NHS Litigation Authority in 1995 to “manage negligence and other claims against the NHS in England on behalf of our member organisations.” (126)

They have a specific negligence claim category: “Failure to warn: Informed Consent”

This covers medical negligence claims of which an element is related to dissatisfaction with the consent process. An information request under the Freedom of Information Act (127) reveals the extent of the problem and current trends in pay-outs.

*Table 4 NHSLA claims under “Failure to warn: Informed Consent”*

Year of Settlement	Number of Claims	Closed - Nil Damages	Settled with damages	Sum of Damages Paid	Sum of Total Paid
2007/08	183	61	122	£8,995,091	£14,891,958
2008/09	187	77	110	£8,144,326	£13,541,263
2009/10	250	92	158	£14,853,248	£25,568,823
2010/11	225	76	149	£9,555,861	£17,051,839
2011/12	234	81	153	£14,855,103	£24,097,560
2012/13	292	111	181	£12,272,954	£21,678,979
<b>Total</b>	<b>1371</b>	<b>498</b>	<b>873</b>	<b>£68,676,584</b>	<b>£116,830,422</b>

This shows a gradual increasing trend in damages paid, but also highlights that over 40% of costs are due to legal fees. Overall the NHSLA estimates its current liabilities for all outstanding potential negligence claims as £22.7 billion.

Clearly a focus on improving the consent process has the potential to reduce conflict and resorting to court action. Recourse to litigation is a problem in the UK and especially the USA, with both countries medical professions producing research over many years to try and identify the contentious issues surrounding IC and how to better manage them.

## 2.6 The Ethics of Informed Consent

Ethics is the “moral principles that govern a person’s behaviour or the conducting of an activity” (128) and is a key principle when considering the interactions of doctors and patients, especially in relation to Informed Consent. The morals of an action are considered to be the rights and wrongs of that action in relation to the prevailing views of society. This is clearly a very different concept from the legal doctrine of Informed Consent, although courts may still become involved in some of the deliberations.

Early ethical considerations were taken from the writings during the Age of Enlightenment, but as discussed earlier were written by physicians for physicians (112). Further adaptations to the ethics of practicing medicine had to wait until the 20<sup>th</sup> Century.

When considering the ethics of obtaining consent there are two broad sources to be considered, medical treatment in a therapeutic setting and medical research. Information from therapeutic settings are provided either from court cases, as discussed earlier, or from studies exploring issues surrounding Informed Consent. Although some of the early American cases described by Faden touch on patient self-determination they do little more to advance any values associated with good consent-taking and the phrase “informed consent” was not identified until a 1957 Californian case (129).

Medical research involving patients had somewhat more sinister origins in the 20<sup>th</sup> Century when considering what might be ethically acceptable.

During the Second World War the Nazis, under the supervision of Josef Mengele at their concentration camp at Auschwitz, embarked on a systematic programme of human experiments, without the subject’s consent, that often resulted in death or disfigurement. After the end of the war the majority of Nazi doctors were tried at the Subsequent Nuremburg Trials (1946-7). This led to the development of the Nuremburg Code (130) a set of ten principles that should guide future medical research. These principles can be summarised as:

1. The subject must consent voluntarily.
2. The experiment should yield fruitful results.
3. The experiment should be done on animals first.
4. No physical or mental suffering to be involved.
5. No risk of injury, disablement or death.
6. Degree of risk cannot be greater than the importance of the problem.
7. Preparations will safeguard against injury or death.

8. Conducted by scientifically qualified people.
  9. Subject has the right to stop the experiment.
  10. The people in charge must stop the experiment if they see an untoward effect on the subject.
- (34)

Updates to these principles have occurred periodically in two formats, firstly the World Medical Association Declaration of Geneva (1948) (131), last updated in 2006, which is meant to be an updated Hippocratic Oath incorporating modern ethical values for all practising doctors, and the Declaration of Helsinki (1964) (132), last updated in 2013 which encompasses research on human subjects.

The experimentation in the Nazi camps and the subsequent ethical codes have all highlighted what can happen if patient perspectives are not taken into consideration. They all raise the concept that the physician does not “always know best” and, in fact, it is more important to consider patient perspectives in medical interactions, especially research settings where the outcomes may be uncertain. These led to the on-going ethical debate, when patients are making health decisions, between paternalism and patient autonomy.

### 2.6.1 Paternalism and Patient Autonomy in Informed Consent

Within any medical encounter there is always an imbalance of power in the doctor-patient interaction, and this will alter with the nature of the encounter as well as the individuals involved.

The prevailing concept until the mid-20<sup>th</sup> Century was one of medical paternalism (133) which Wear identifies as doctors who were “committed to the patients best interests” without involving them in the decision-making process. He argues that these were not necessarily “bad” doctors as their aim was to treat or reassure patients to the best of their abilities.

With the new research ethics and court cases described earlier came the concept of patient autonomy or patient self-determination. Patients should be informed about procedures, risks and alternatives and be able to make informed choices as to what is best for them. However, there have been concerns raised about responsibilities of physicians and their duty of care towards patients if patient autonomy becomes a central theme of health care decision making. Meisel and Kuczewski (11) comment on some of the attacks on patient autonomy in informed consent :

“Most of these attacks are based on the idea that there is a fundamental incompatibility between the patient autonomy that informed consent is intended to promote and physician responsibility for a patient's well-being and on the fear that well-being will be severely compromised.”

They argue that some commentators would have patient autonomy likened to a shopping trip whereby the doctor sets out the choices available to the patient and it is up to the patient to select the option most congruent to their values. In this setting there is no interaction between doctor and patient to assess values and the doctor can leave the patient to their choice even if, in the doctor’s opinion, this is a bad choice.

Quill and Brody (134) would argue that a doctor objectively presenting risks and alternatives without expressing some valued judgement is confusing independence with autonomy “and assumes that the physician's exercise of power and influence inevitably diminishes the patient's ability to choose freely”. They argue that doctors must exert their “authority” only insofar as it helps enhance or empower patients to make a decision for themselves. In shared decision-making defended by a

standard Enlightenment approach, power to influence a decision must ultimately and exclusively rest on patient preferences, not on physician expertise or a concept of stewardship.

Natalie Stoljar (42) explores autonomy and informed consent from a philosophical viewpoint, drawing largely on the work of Charles Taylor. She defines autonomy as:

“A person is autonomous when she has the capacity to govern herself, to make choices, and to formulate goals unimpeded by the choices and goals of others”.

She argues that a person’s autonomy is derived from the relational concepts of historical, social, class, race and gender factors. In health care ethics, she argues, the doctrine of informed consent requires the health care provider to make relevant information available then allow the patient to make their choices. Presented in this way she identifies that autonomy requires an “exercising” of self-determination rather than an “opportunity” to do so and a “strong” evaluation of the situation rather than just weighing up what is disclosed to them, the “weak” option.

In the example of whether to take hormone replacement therapy or not Stoljar recognises that consideration is not only based on medical evidence but on personal factors including education, race, class, personal experiences of the menopause, cultural norms such as looking young is attractive and attitudes of family members to the menopause.

Arthur Caplan (135), on the other hand, considers that if you focus entirely on patient autonomy in relation to informed consent in health care settings then the patients situation will not be improved. He notes that the imposition of autonomy in societies that don’t understand it, don’t want it or consider putting personal self above all others as arrogant, can be “grimly isolating or misguided”. He continues that all autonomy will inspire hope and this may trump rational thought and suggests a return to a “bit more medical paternalism”. Too many decisions are presented as options without recommendations and this should be countered by more expert opinion.

Returning to Meisel and Kuczewski (11) they introduce the notion of shared decision-making into informed consent as a process that can accommodate patient autonomy whilst continuing the notion of expert opinion and physician responsibility. They argue, through exploring some of their myths about informed consent, that the use of shared decision-making techniques can balance the competing interests of autonomy and beneficence. They conclude that any discussion should be treated as a timely process that allows the doctor to recognise the patient’s decision-making style and does not press the patient to decide quickly.

“Do not make them think that you do not have time for them. Because if you do, regardless of how much information they are given, they are going to be angry, and another name for an angry patient is plaintiff.”

This section has reviewed the concept of patient autonomy from its 20<sup>th</sup> century origins in biomedical research and court cases. The philosophical concept of autonomy seems difficult to reconcile with the practicalities of health care and, whilst there has been a move away from paternalism, it appears that wholesale patient autonomy is also inappropriate, one commentator noting that, in theory, a patient could request a certain treatment that the doctor would have to acquiesce to, even if they thought it totally inappropriate.

There have been attempts to measure patient autonomy in health care decision-making (62), the Autonomy Preference Index being one such instrument. Ende et al found there was a difference between patients desire to make decisions and to be informed. Patients generally wanted doctors to make the decisions but to be kept informed. The greater the severity of illness and the older the



patient the less likely they were to want to be involved in the decision-making process. Other studies have shown that different diseases lead to different levels of compliance, dependant on whether the patient's own behaviour is regarded as most important to manage the condition (136).

The view, therefore, should be recognition that each party has important influence to bring upon decisions about health care and that these influences will differ depending on the patient, their age and the condition being considered. Progress has to be towards an equalizing of medical facts and risk prediction on one side with patient values and experience on the other, and it may be necessary to consider that a patient will not make decisions in the same way every time. Whilst this has been a key aim of the development of Shared Decision Making as a concept, along with tools to encourage this to happen (such as Patient Decision Aids and Option grids) there has been less development on timescales and process, as suggested by Meisel and Kuczowski, to assist in balancing patient strengths in SDM and applying them to IC.

## 2.7 How patients make healthcare decisions

In order to understand how to enable and empower patients to make health care decisions, based on their individual values and preferences, it is important to understand how they make decisions.

Decision making can be defined as:

“Choosing between alternative courses of action using cognitive processes of memory, thinking and evaluation” (137)

Models of decision theory often split the process into two distinct categories:

1. Rational decision-making where there is an evaluation of information, weighing up the pros and cons of options and working out a sensible, logical option.
2. Intuitive decision-making where there is no reason and logic but “gut feeling”.

This intuitive decision-making is often described as “Non-functional” and can often lead to poor decisions.

Non-functional decision-making includes:

1. Spontaneous decisions with little deliberation
2. Impulsive decisions
3. Procrastinating and putting off decisions
4. Compliance where decision-making is handed over to authority
5. Fatalistic – “whatever will be, will be”.

Trying to involve patients in the decision-making process is based on the assumption that “non-functional” decision-making leads to poor decisions, and that patients want to be involved in the process. The work by Schmitt et al (136) revealed that often patients didn't want to be involved in the decision-making process. Croskerry et al (138) explore this dual process theory that has emerged as the model for understanding the complex processes of human decision-making. They explore the issues in health care systems more from the viewpoint of clinical decision-making by the doctor but the processes are the same. They argue that the rapid “intuitive” mode is often right but is the area where the majority of faults in decision-making lie, however, they can be improved by a more reflective or analytical approach.

Redelmeier et al (139) identified that patient decisions were often made intuitively and appropriately for them but could be influenced by several factors. Framing the information on risk,

for example, in a positive or negative way could influence the decision; safety and danger are often viewed by patients as categorical and they often struggle to understand risk reduction. Vranceanu et al (140) explored the gradual shift away from a disease-focused model of consultation, consistent with medical paternalism, toward a more patient centred approach and how good communication skills could facilitate evidence-based practice. Emotion is also a factor that Redelmeier and others (141) have found to influence the decision making with losses considered more significant than gains.

Presenting too many options can also lead to patients selecting their original (intuitive) pathway. Ubel (75) gives the example of someone on the way to the library, they see a poster advertising an interesting lecture and may be tempted to alter their plan and attend the lecture. In the next scenario the same person sees a poster for the lecture and a poster for an interesting film. Ubel argues that the person is more likely to continue on to the library in the second scenario because they are now presented with too many options.

### 2.7.1 Informed Decision-Making

Having considered how patients make healthcare decisions and what might influence this and before considering what encompasses shared decision-making it is necessary to consider what informed decision-making is and how doctor-patient interactions can influence the process.

Informed decision-making is defined as:

“An informed decision is one where a reasoned choice is made by a reasonable individual using relevant information about the advantages and disadvantages of all the possible courses of action, in accord with the individual’s beliefs.” (142)

This model, whilst congruent with the concept of patient autonomy in decision-making, does not encompass an interaction between patient and health care professional. It discusses “relevant information” without reference to how information can be obtained and how to decide if that information is relevant. We have already seen that patients rarely make decisions this way and not just because doctors don’t provide the information. Ubel described how offering too many options may affect decisions, whilst emotional influences, information framing and even personality traits (143) can influence patient decision-making processes.

Bekker et al (142) argue that too few research studies identify an explicit theory of decision making prior to inception. Of the studies they identified and evaluated they found little evidence to support information and education as facilitators of informed decision making, compared with the context and social influences.

When considering informed decision making in a health care setting there is also the concern over retention of information. Whilst “relevant information” may be provided there is no guarantee that patients will either understand that information or remember it when making their choice. The starting point for exploring information retention by patients may be very low. Byrne et al (144) interviewed patients between two and five days post-operatively and many patients couldn’t name the operation whilst a proportion could not even name the organ operated on.

### 2.7.2 Information provision: methods and retention

Many studies in orthopaedics have shown little benefit with educational intervention although some have shown slight increase in retention of operative risk information 2 weeks after the operation (145). Turner et al (146), however found the opposite. They explored the issue of retention of information in patients undergoing knee and hip arthroplasty and found that giving an information leaflet at the time of consent did not improve recall six weeks later. They argued that:

“...an information booklet may provide nothing more than proof for the surgeon of information provision to the patient.”

Although this may not improve memory retention it may be an important defence argument to support the doctor in court.

Johnson et al (147) explored the issue relating to Informed Consent in knee arthroplasty and randomised patients into three groups:

1. Standardised informed consent with a paper handout detailing risks and benefits
2. Standardised informed consent with a paper handout and video discussing risks and benefits
3. As for group 2 but including formal nurse education.

They used a 15 item questionnaire immediately following the consent process and 6 weeks later. There was no significant difference in satisfaction with the consent process ( $p=0.79$ ) or retention of information ( $p=0.31-0.81$ ) between the three groups. These conclusions have, however, not been universal. Agre et al (148) found that when consenting patients for colonoscopy and upper gastrointestinal endoscopy the use of a videotape and physician explanation was preferred by patients than either alone. The study did not explore retention of information but did identify that video may eliminate the problem of readability of written information, although understanding the video information was not tested. It was also suggested that such a technique would ensure that patients received the same amount of information.

The Internet and websites are another source of information for patients but many sites are unregulated. Studying this effect in relation to orthopaedics Hungerford et al (149) found that information acquired from websites was not helpful for the patient and meant the physician “ then has to spend time disabusing the patients of the misinformation they have accumulated.” They also found there was a lot of promotional information from pharmaceutical companies that the physicians had to explain. Hungerford et al recommended surgeons producing their own information leaflets and either developing their own websites or recommending accredited websites. In the UK, NHS Choices website (150) is one such site run by the National Health Service to inform patients.

Despite a lot of research into risk and information giving, some would argue that reviewing this one aspect of informed consent is too narrow and tends to be promoted because of concerns over litigation.

“Because of the retrospective and adversarial nature of the legal system, the notion of informed consent to treatment has taken on a defensive flavor. This plays out, for example, through heightened attention to disclosure of risks.” (151)

Carmen and Joffe go on to argue that courts have generally not considered failure to understand as invalidating informed consent but relying more on a failure to disclose. They argue, along with others (152) that one of the main barriers to adequate informed consent is time pressures on clinicians in “modern productivity-focused health care systems.”

Despite there being little evidence to support information and education as a means of improving decision making, researchers have continued to explore areas relating to informed consent that may enhance the process for patients. By exploring consent in clinical settings and research trials, researchers have continued to try and identify potential areas for improvement. Nishimura et al (24) recently published a review of biomedical consent taking which included multimedia interventions, enhanced consent forms, extended discussion and test/feedback techniques. All techniques seemed to show some improvement in patient understanding compared to standard methods but were greatest for enhanced consent forms and extended discussion.

## 2.8 The consent form

It is generally accepted that prior to performing an operation it is imperative to get the patient to sign the consent form, agreeing to undergo the procedure. As a medical profession it is not usual to get patients to sign consent forms to have blood taken or to start medication, often defined as simple or implied consent (12). However, for more complex procedures such as surgery patients are required to sign a form. The signing of the consent form falls under one of Meisel and Kuczewski's informed consent myths.

“Perhaps the most fundamental and pervasive myth about informed consent is that informed consent has been obtained when a patient signs a consent form. Nothing could be further from the truth, as many courts have pointed out to physicians who were only too willing to believe this myth. Consent forms are used as a matter of routine in both treatment and research settings because many hospital administrators, physicians, and their attorneys see these forms as providing protection against liability, despite the fact that they actually provide little protection.” (11)

Meisel and others (153) argue that the signed form only indicates that the patient has read what is on the form and does not support any other discussions. However, patients often consider that the consent form is actually a legal document (154) or conveys some medico-legal protection to the surgeon.

Given this, there are concerns that if the form is not filled in correctly it would actually support a patient in a lawsuit. Several audits and research projects relating to consent form signing indicate that completion of consent forms is poor (153, 155, 156), with Callanan finding that descriptions of orthopaedic operations were inaccurate in nearly half of cases. Ahmad et al (157) explored this issue in relation to distal radial fracture treatment. There was a range of complications mentioned on the consent form with variable frequency ranging from infection (95.6% of forms ) to stiffness (42.2% of forms) but more concerning was the fact that 31.1% of forms had abbreviations and when junior doctors took the consent they only performed 6.7% of procedures.

Others (158-160) have argued for more standardisation of consent forms to eliminate some of these problems. Atrey(158) and Barritt (159) promote the concept of pre-printed forms for orthopaedic procedures that have subsequently been adopted by the British Orthopaedic Association. It is argued that these forms are clearer and less open to interpretation whilst avoiding the common pitfalls of abbreviations and poor handwriting. Barritt goes further in his “audit” to show that the new forms enhance patient understanding and information retention. I would argue that this paper was

research rather than audit (161) and that what it actually showed was by revisiting consent at every hospital contact as an entity in itself it enhanced the process for the patient.

Thompson (160) identifies that the problem can often be one of retaining consent forms when the form is signed weeks before the procedure. He recommends an automated informed consent process with a digital library of standardised, procedure specific forms that can be linked to relevant and reproducible educational leaflets. Indeed the prospect of lost consent forms and having to consent patients in the pre-operative holding area has been shown to lead to increased litigation in a review of orthopaedic cases over a 24 year period (162).

Berry (163) explored patients attitudes to timing of information giving and consent taking. Generally patients preferred to receive information about their prospective operation at the initial outpatient appointment and to sign the final consent form on admission to hospital for the procedure. Although this is not totally at odds with Bhattacharyya's findings where consent was taken in the pre-operative holding area it does indicate differences with current practice at the Orthopaedic Department participating in study 2 (see later). Berry also found that hospital staff were more interested in introducing a consent taking clinic sometime before hospital admission.

Problems identified in the past such as junior doctors taking consent (164) when they were ill-informed about risk and procedures have largely been eliminated with the adoption of the General Medical Council guidelines on Informed Consent (5). They recommend that the doctor performing the procedure is the best person to take consent.

Surgeons have expressed pressures, when giving information and taking consent, from external sources such as pharmaceutical companies or press and politicians (165, 166). Jones identified problems with direct marketing to patients by some companies that led to patients demanding unreasonable treatments. He also found that press and politicians tended to deal with the positives of new treatment options only, which made the surgeon's job of explaining risk and uncertainty even more difficult. Suk recognized that, particularly in orthopaedics, surgeons may have responsibilities to product manufacturers as well as employers, but it was the responsibility to patients through obtaining informed consent that was paramount.

There are other factors that can influence patient understanding and retention of information when giving consent for medical procedures. Patient anxiety is a common factor that can lead to an unwillingness to sign consent forms (167, 168) especially in cases of major surgery (169), although some have found that patients did want risks associated with the procedure to be discussed even if it did increase anxiety (170).

## 2.9 Patient perspective on Informed Consent

What has been explored so far has shown the great concern in medical, ethical and legal circles to the concept of risk, information giving and patient retention of information. Many have argued that this approach relies too heavily on the legal doctrine of Informed Consent and much of the literature discusses litigation avoidance. This "negative" view of Informed Consent does not explore patients' understanding of the concept or what they would like from a discussion with the physician.

### 2.9.1 Patient understanding of Consent

In order to explore patient understanding of consent issues Amarasekera et al (171) used questionnaires given to persons over 16 years old attending hospital. The first 1000 completed questionnaires were analysed to explore some of the fundamental concepts of self-autonomy,

confidentiality and battery with only 18%, 13% and 5% respectively of respondents agreeing with each concept. Again the concepts tend to be legalistic with only 21% of respondents thinking a surgeon liable if a rare, unmentioned complication occurred. Overall, though, patient understanding of Informed Consent was poor with the researchers concluding:

“It is time for surgeons, legal experts, and the public to confer and make informed consent a practical, user-friendly tool rather than the legal obstacle that it is today.”

Whilst it is difficult to argue with this sentiment it is important to understand what patients want or expect from the process and how professionals might make progress towards this.

### 2.9.2 Language

In terms of medical “jargon” there is evidence that patients often don’t understand the information presented (172, 173) and terms such as “internal fixation” are rarely comprehended especially when presented in abbreviations such as “ORIF” (open reduction and internal fixation). Kikuchi also recommended the importance of engaging family members in discussions to try and enhance patient understanding. As we have already seen it is debatable whether written information enhances the patient understanding and hence consent process. Studies in research settings (174) and orthopaedic surgical settings (175) suggest that written information given to patients to aid the consent process can often be difficult to understand. Stanley et al (176) explored this issue in relation to vascular surgery and found that enhancing consent with information leaflets did not improve retention of information and in both the standard and enhanced groups understanding of risk was poor.

A systematic review of interventions to improve understanding in research consent (177) found similar results with written information, multimedia and enhanced consent forms; the most effective intervention appeared to be with a neutral educator who could spend one-on-one time with the participant.

It can be seen that just providing the information that doctors consider appropriate or think might enhance the consent process is of little value to the patient and there seem to be two considerations apart from the patient-friendly quality of the information that may play a part. The more obvious one is that the information being provided is what doctors think patients would want to know rather than what patients actually want to discuss but the second one is the patient’s psychological approach to the consent process.

### 2.9.3 Patient Mind-set

McNealy et al (178) interviewed 33 patients recovering from cholecystectomy for chronic conditions and found a spectrum of attitudes towards surgery from “profound mistrust to unquestioning faith”. They identified that increasingly intolerable symptoms was the main reason that patients eventually opted for surgery but often never fully reconciling their concerns. Tan et al (179) interviewed 100 patients prior to cataract surgery, finding that 32 did not wish to know “anything at all” about risks and preferred to leave decision making to their ophthalmologist. Four patients were unaware there were any risks and when informed that there were, declined further discussion.

Both ends of the spectrum, “profound mistrust” and “unquestioning faith”, present their own problems. If there is profound mistrust then it will take time and discussion to gain the confidence of such a patient. Patients with “unquestioning faith” still require discussion of procedures, risks and alternatives, even if only to fulfil legal obligations of informed consent. This presents its own

problems as Tan's four patients would still warrant discussion of risk factors prior to surgery and this may create anxiety or confrontation.

#### 2.9.4 What do patients really want to discuss?

Attempts have been made to try and identify what patients want to know, particularly in relation to surgical procedures, prior to signing the consent form. Berman et al (180) used qualitative interviews with 20 patients who had undergone abdominal aortic aneurysm repair or who had declined to do so, to explore their perspective on consent giving. They found that patients did not appreciate the scope of options available to them and seemed inadequately informed prior to making a decision. Again it was clear that patients required different amounts of information during the process and, like McNealy, trust was an important factor. Courtney et al (181) and El-Wakeel et al (182) used questionnaire surveys with patients to explore what they wanted to know from the informed consent process. Courtney found that when patients were presented with statements about the process they ranked options for treatment highest followed by risks of procedure, then meeting the surgeon, followed by the actual surgical technique. When these patients were then given options they would like more information on, "recovery time" was top of the list, followed by options for treatment, legal rights and then meeting the surgeon.

El-Wakeel et al approached 100 patients who were not awaiting surgery but presented them with the scenario that if they did require surgery or investigation what they would want to know. They developed a 15 question survey to explore how important each topic was to the patient. They asked patients to score this on a visual analogue scale (0-100). A median score of 95% was achieved by "major complications", "not undergoing the procedure", "future management" and "long-term effects on work". Least concerns were raised about "technical details of the procedure and "minor complications"

From these findings there is a sense already that legal obligations on discussing risk and technical details of the procedure are what would concern surgeons whilst patients may be more interested in factors having an impact on their quality of life such as recovery time or effects on work. Newton-Howes et al (183) developed a questionnaire to explore just these issues with 256 patients and 37 doctors at one hospital. What they found was that patients do indeed have different priorities from surgeons, and this is presented in the table below:

*Table 5 Preferred priorities to discuss at consent (Newton-Howes et al)*

Priority Ranking	Patients	Doctors
1	the major risks	the general nature of the procedure
2	quality of life	major risks
3	outcome	consequences of not undergoing the procedure
4	consequences of not undergoing the procedure	alternative options
5	quantity of life.	consequences of the procedure in regard to management

Patients are more interested in factors that impact on their lifestyle whilst doctors are more concerned at discussing management implications for the patient. From these findings it becomes obvious that patients who are initially mistrustful of the surgeon or surgery itself are unlikely to have their fears allayed when surgeons are working to a different agenda.

## 2.10 Informed Decision Making and Informed Consent

Some researchers have started to explore these discrepancies and problems by trying to engage patients in greater understanding of their illness and options. Brenner and Bal (184) used two recent American court cases to highlight doctors duties in educating the patient and telling them about all options available, not just the proposed treatment. In a separate paper (185) they argued that an approach to informed consent should follow an educational model to enhance patient understanding. Verheggen et al (186) explored the decision-making model in relation to clinical trials. They interviewed 198 patients and 32 clinical trial specialists and found that patient's level of trust for the study and integrity of the specialist had implications for patient understanding. They proposed a patient motivation classification and an Informed Decision Making checklist at the outset to direct patient educational needs.

Others (187) found that surgeons rarely discussed patient roles in consent giving or assessing their understanding. They suggested it was better to use patient concerns as a focus of discussion than a list of pros and cons for the procedure. By doing this, important patient-identified issues could be addressed and trust may be improved by addressing patient values.

Kusec et al (188) found that written information for patients concerning cholecystectomy, when written by doctors or specialists, was difficult to understand . However, when these documents were re-written by patients they were better understood. They also suggested certain lay-person profiles that could be used as resources for helping the doctor\_patient communication.

## 2.11 Conclusions on Informed Consent

So far we have explored the legal and ethical doctrines surrounding informed consent. The legal doctrine is very much based on risk disclosure, and as most doctors are concerned about litigation this is often the presiding viewpoint discussed around consent issues. Ethical debate deliberates



more on the unequal balance in a doctor-patient interaction and that in the past paternalism has tended to prevail. However patient autonomy is now much more at the forefront of ethical debate, particularly since the horrors of the Nazi regime's human experimentation. There may not be consensus as to what autonomy is or whether it can be truly exerted in a medical encounter, but it has driven the debate on how we should approach decision-making with patients.

For many years the legal experts have had concerns about doctor's approach to informed consent (4) and the collusion of the courts to a doctor dominated process but cases such as Chester have started to address some of these issues.

Progress is slowly being made towards concepts that will enhance patient engagement in the informed consent process, with greater understanding of risks, options and patient-centred factors such as quality of life issues. However, concerns remain that the process is often driven by hospital throughput agendas and, therefore, doctors revert to covering the legal issues. What is evident from research so far is that concepts of informed decision making are only starting to make in-roads into the Informed Consent arena. The newer paradigm of Shared Decision Making has little influence on the doctrine of IC in the UK and is only beginning to have some influence in America.

## 2.12 Two important papers to progress patient-centred Informed Consent

Concluding this review of IC there has been one particular theoretical paper and one project that, accidentally, has identified where Informed Consent could be improved. As we have seen there are many different approaches to Informed Consent with, often, conflicting evidence as to what does or does not improve the patient understanding and experience. However, a lot of these techniques can be lost due to the hospital management concentrating on targets, which can have disastrous results (189).

Lidz et al (10) recognised that the concept of Informed Consent was controversial and created much disagreement between commentators. Their approach was more to explore the implementation of Informed Consent rather than the doctrine itself; comparing an "Event" model to a "Process" model.

They describe the Event model as "a discrete act that takes place in a circumscribed period of time". Physicians provide information and then allow patients to decide whether to accept their recommendations. Discussion of risks and procedures satisfies the legal requirements without assessing patient values and understanding. The consent form is then viewed as central to this transaction by clearly stating the facts discussed. Lidz et al argue that such a one-off event does not take into account patient or physician's further evaluation of the patient's condition or the fact that situations may change.

On the other hand they argue that a "Process" model can incorporate their identified phases of patient care, namely:

1. Establishing responsibility – this would incorporate Physician responsibility and expertise
2. Defining the problem- In most non-emergency situations this would require asking open questions initially followed by more specific questioning, then exploring patient concerns and quality of life issues.
3. Setting goals for treatment- this would include general risks and benefits as well as more specific patient risks.
4. Selecting an approach to treatment- this would include the legal requirements including alternatives to the specified treatment and what would happen if the case of no treatment.

5. Extended treatment and follow-up- this would require on-going interactions between patient and physician and include discussions on the next stages and recovery.

This model requires recurrent interactions between patient and physician, addressing patient concerns that may alter over time.

They recognise that there are some limitations to this model, particularly in terms of physician time and, in the American system, how this might be reimbursed by insurance companies.

One inadvertent example of how a process model can achieve improved outcomes was seen in Barritt et al (159), an audit to explore whether using pre-populated, procedure specific consent forms (Orthoconsent form) for knee arthroscopy and total knee replacement improved patient understanding compared to standard consent forms. 100 patients undergoing knee arthroscopy and 60 patients undergoing total knee replacement completed questionnaires relating to knowledge of their operation. The process involved 2 cycles of auditing. Whilst we have already seen that the consent form holds little legal or educational value and many forms are incomplete it was surprising to find that using the new forms raised the mean score from the questionnaires from 56.7% to 80.5% ( $p<0.01$ ) in knee arthroscopy patients and 57.6% to 81.6% ( $p<0.01$ ) in total knee replacement. Anything that improves the quality of documentation on a consent form and patient knowledge has to be welcomed, however deeper analysis of the study revealed a possible reason for the results.

First cycle

In the first cycle of the audit 50 patients for knee arthroscopy and 30 patients for total knee replacement were recruited.

- Consent was taken by a senior member of staff (specialist registrar or above)
- Discussion at the out-patient clinic was at the discretion of the surgeon.
- The hand-written consent form was signed at the outpatient appointment.
- Patients were seen for their routine pre-operative assessment and were allowed to ask questions.
- Patients were seen on the morning of surgery and asked to confirm consent to the procedure.

Second Cycle

Again the authors recruited 50 patients for knee arthroscopy and 30 patients for total knee replacement.

- Consent was taken by a senior member of staff (specialist registrar or above)
- Discussion at the out-patient clinic was at the discretion of the surgeon.
- The patient signed the hand-written consent form and were presented with the new Orthoconsent form and instructed to read the documentation thoroughly.
- The patients were again presented with the Orthoconsent form at the pre-operative assessment clinic and instructed to read the documentation thoroughly.
- On the morning of surgery the patients were asked to sign the Orthoconsent form as well as the traditional hand-written form.

It becomes quite clear that patients have been exposed to two different processes with results that cannot be accounted for just by using a different consent form.

The first cycle approaches consent more in accordance with Lidz's "Event" model with consent taken at the first encounter. The second cycle actually approaches consent as a separate entity at each contact with the hospital, so it now becomes an integral part of the consultation, the pre-operative clinic and the admission to hospital. Whilst this project was classified as an audit and there was no validation of the questionnaire used, it provides an interesting insight into how surgical informed consent could be improved by adopting a "Process" model of revisiting the actual consent at each hospital contact that allows patients time to access other resources (e.g. friends, family and the internet) with the knowledge that they will be able to discuss any new issues or concerns as a matter of routine.

### 2.13 Conclusions of the literature review

By exploring the paradigms of Shared Decision Making and Informed Consent separately it is clear that they have developed from different modalities of health care provision and over different timescales. However, it is also apparent that many commentators consider the two paradigms to be concordant in certain situations, such as elective surgery. By exploring the history and issues of each it becomes clear that patient communication and patient engagement are at the centre of both. This can only be achieved by a doctor who is trained in techniques of exploring patient values, allowing patients to understand and reflect on options and providing materials relevant to each patient to support them in their decision making.

The barriers to implementing both paradigms effectively are also similar in terms of time, trained workforce and healthcare policies and protocols based on throughput and outcomes rather than quality and process. It is to this end that Lidz and Applebaum's paper on "Event and Process" gains central significance to this body of work. Although there are certain minimum legal standards in Informed Consent and there is no consensus on patient autonomy, it is the implementation of the paradigms by doctors and nurses that can create much greater patient involvement and satisfaction.

Both paradigms can gain from recognition of the other but for patients to make preference-sensitive complex health care decisions, they should not be approached by medical staff as a "one-off event", but a journey or process that allows patients to explore and understand options and risks over a series of healthcare interactions.

Although Informed Consent has been theoretically described as concordant with Shared Decision Making, no papers have been identified that explore the practicalities and implementation of each, and established whether this is the case. Comparison of the two paradigms in clinical practice can be used to explore this association and establish whether implementation of each paradigm can be improved upon by comparison with the other.

## 2.14 The Research Question

The literature reviewed in the introductory chapters has led to the formulation of the following title and research question:

**Shared Decision Making and Informed Consent in health care: An exploration and comparison of patient and health care professional experiences in primary and secondary care.**

**Can implementation of each paradigm be informed and improved upon with reference to the other?**

In order to explore and answer this research question two studies described in this thesis will be analysed to:

- Explore the relationship between Informed Consent and Shared Decision-making
- Compare the practical implementation of each paradigm to establish whether either can be improved

To achieve these aims the thesis will describe how the following objectives were implemented:

- Interviews with patients and health care professionals who have used a patient decision aid for consideration of insulin therapy in type 2 diabetes mellitus (T2DM)
- Interviews with patients and surgeons when considering informed consent for unilateral hip arthroplasty for osteoarthritis
- What processes influenced patient decision-making in each study
- Compare the findings from each study in terms of “How patients make healthcare decisions”
- Describe how the consideration of findings from each study might be used to inform improvements in implementation of the other paradigm.

## Chapter 3: Methodology

### 3.1 Introduction to the two studies

The Research Question

**Shared Decision Making and Informed Consent in health care: An exploration and comparison of patient and health care professional experiences in primary and secondary care.**

**Can implementation of each paradigm be informed and improved upon with reference to the other?**

In order to answer this research question it was necessary to:

- Explore and describe what factors influence patient and Healthcare professionals' attitudes to consent giving in a shared decision-making environment.
- Explore and describe what factors influence patient and surgeon attitudes to consent giving in elective hip arthroplasty for osteoarthritis.
- Compare these factors and establish whether SDM and IC can be improved upon by reference to findings from the other paradigm.

To achieve these aims it was necessary to explore SDM and IC in separate studies, using the literature review from each paradigm to inform the conduct of each. These separate studies had the common themes of exploring patient and HCP experiences and attitudes to either SDM or IC, particularly in terms of how patients actually make decisions about treatment. Having explored the issues under each paradigm, it was then proposed to compare findings from each study and synthesize a pathway in each setting that might best support a patient in their decision making. These pathways, or exemplars, would draw on current knowledge and new findings from the studies.

The findings of "How patients make healthcare decisions" would be explored under the four main themes identified from the literature review, namely:

1. doctor-patient interactions
2. how the presentation of information can influence decisions
3. external factors that might influence decision making such as family or friendship influence on patients or hospital policy on the doctor
4. the concepts and tools of Shared Decision Making

The individual aims and objectives of each study are set out below.

**Study 1. Evaluation of the implementation of a Patient Decision Aid to improve decision quality and glycaemic control in people with type 2 diabetes making treatment choices in general practice.**

Research Questions

1 "Are shared decision making strategies acceptable to patients and healthcare professionals?"

2 “How does the use of a patient decision aid influence decision processes of patients and healthcare professionals?”

Objectives used to achieve these aims included:

1. Audio-recorded and transcribed individual in-depth interviews with patients who had used the PANDAs Patient Decision Aid to support their treatment decision.
2. Audio-recorded and transcribed individual in-depth interviews with health care professionals who had used the PANDAs Patient Decision Aid with these patients
3. Audio-recorded interviews with patients and health care professionals using the PANDAs Patient Decision Aid
4. Use of the OPTION Instrument (96) to assess patient involvement in the decision making process.

### **Study 2. Informed consent for unilateral hip arthroplasty for osteoarthritis**

Research Questions

1 “How and when do patients about to undergo unilateral hip replacement for osteoarthritis gather and interpret information to make a decision about surgery?”

2 “What factors influence patients when considering consent to the operation?”

3 “What factors influence surgeons when obtaining consent from patients for the operation?”

Objectives used to achieve these aims included:

1. Audio-recorded and transcribed individual in-depth interviews with patients before and 3 months after surgery
2. Audio-recorded and transcribed focus groups with patients approximately 6 months after surgery
3. Audio-recorded and transcribed in-depth interviews with consultant orthopaedic surgeons regularly taking consent for this operation.
4. Collection of Patient Reported Outcome Measure (PROM) data before and after surgery.

Research techniques deployed in both studies:

1. Qualitative individual in-depth interviews
2. Qualitative use of focus groups
3. Use of quantitative scores - to measure patient involvement in shared decision making and in the form of Patient Reported Outcome Measures to assess quality of life changes after surgery
4. Sampling techniques
  - consecutive series
  - purposive sampling
5. Data analysis – Framework analysis

## Results synthesis

Comparison of results from each study will be synthesised to establish a conceptual framework of how decision making process might look when considering current practice and new evidence.

### 3.2 Choice of Research Methodology

Research methods can be divided into different categories depending on the type of research being undertaken. In medical research studies methods are broadly categorised as qualitative or quantitative, whereas if considering types of reasoning they may be classified as inductive or deductive. If considering scientific philosophy they may be considered as naturalistic or positivistic. All have some similarities but are not entirely congruent.

In research terms quantitative work is based on collecting absolute values that can be compared with other absolute values and, through the means of statistical analysis, can compare one outcome or intervention with another. In medical research, quantitative methods are frequently used to compare the outcomes of one intervention to standard or usual care. Statistical analysis is then used to establish if one treatment or intervention is superior to another. These types of studies tend to recruit large numbers of patients whose demographic is close to the normal population for that intervention. Researchers will then try and establish that results from their sample is relevant to the whole population (generalisation). Quantitative work may also use standardised data collection techniques such as questionnaires.

Qualitative research is involved in interpreting things in their natural setting and "... turning the world into a series of representations including field notes, interviews, conversations, photographs, recordings and memos to the self." (190) Qualitative research is, therefore an interpretative approach to interactions within the social world (191). Qualitative research has been described as trying to answer where, what, who and when questions (192, 193), although it can be used alongside quantitative research when this technique does not adequately explain why or how a phenomenon occurs (194). Qualitative studies tend to use techniques such as interviews to explore sociological phenomena such as doctor-patient interactions. Recruitment numbers tend to be small because large quantities of data are collected. The small sample size encountered in this type of research is not intended to be representative of the general population but to ensure a broad spectrum of opinion is sampled (maximum sample variation).

Deductive and inductive reasoning are often used in sociological context but can be extrapolated to broader research fields. Deductive reasoning starts from a broad spectrum of information and is gradually refined into a narrower spectrum where a specific hypothesis is developed and can be tested. The researcher collects specific data to test their hypothesis and leads to conformation or otherwise of the theory. This is similar to quantitative research.

Inductive reasoning starts from specific observations that may detect patterns from which a hypothesis may be postulated. From this approach more generalised conclusions may be drawn. This is more typical of a qualitative approach to research.

Positivism is derived from the philosophy of science and is based on what scientists can observe and measure. Essentially positivists believe there is a truth to be found and by observing phenomena and measuring them it is possible to discover that truth. Again this is similar to the quantitative methodology of research. Karl Popper, a physicist and mathematician, strongly believed that theories were created by scientists and although they couldn't be proved true, if they were not shown to be false they were corroborated. Popper strongly disapproved of treating psychology and

sociology as sciences. Thomas Kuhn, on the other hand was a philosophy lecturer and believed that all science incorporated social phenomena.

Naturalistic observations involves observing individuals in their normal environment. The researcher observes phenomena and draws their own conclusion from these findings. This is more in tune with Kuhn's philosophy but leads to the problem of interpretation of data, "the double hermeneutic" (195). This is where the individual under study interprets their environment and the researcher then interviews or observes the individual and interprets this data, using all the biases they have developed throughout their life. This has qualities similar to qualitative research in medicine and explains why it is important for qualitative researchers to be reflective of their own background and potential biases in data interpretation.

A combination of methodologies can be used within one study; quantitative studies can be combined with interviews to create a greater understanding of the setting of the statistical results. Alternatively qualitative data can be triangulated by quantitative methods, such as questionnaires, to increase confidence in the findings. Such mixed methodological studies can produce richer and more credible results.

Both studies used mainly qualitative techniques with some quantitative data collection to triangulate the interview data. The techniques used in this thesis are described in general terms below before exploring in detail the specifics of each study.

### 3.3 Data Collection Methodology

#### 3.3.1 Qualitative data collection

##### *3.3.1.1 In-Depth Interviews*

In this form of data collection the researcher interviews the patient in an unstructured or semi-structured way. It is recognised as one of the main methods of data collection in qualitative research (196). These interviews often incorporate certain themes that the researcher wishes to explore, but in a structure flexible enough to allow the participant to discuss topics in an order dictated by them. The researcher will often have developed a topic guide from the literature with all the areas they wish to cover, even if the order is participant led. The interviews are often interactive with the researcher encouraging the participant to explore issues more comprehensively whilst also moving on to new topics. The researcher may explore belief systems that underpin some of the participant's comments, an explanation of participant-derived information being as important as the information itself. Participants may also be asked for ideas or suggestions to try and solve some of the issues discussed.

For these reasons in-depth interviews are usually conducted face-to-face with audio-recordings to enable the researcher to review the discussion on its own merits and in light of findings from other interviews. The researcher usually takes contemporaneous field-notes to supplement the findings of audio-recordings as certain nuances may not come across in audio-recordings or to describe the setting of the interview.

Kvale (197) suggests that these types of interviews could be approached either like a miner where there is hidden knowledge waiting to be discovered or like a traveller where the researcher explores and develops new insight with the participant. This second approach views the researcher as very much an integral part of the data development as well as data collection.



The researcher in both studies approached the data collection as a “miner” using the techniques of “content mapping” and “content mining”.

### Content Mapping

In-depth interviews are used to achieve both a wide breadth of coverage for the chosen topic whilst also covering important issues in depth. Content mapping are questions designed to open up the area of interest to broad discussion. They are the first questions to be asked and are usually broadly framed to encourage the participant to discuss their own experiences and choose topics that are most important to them.

The interviewer may want to focus the participant on a particular topic, this may be by highlighting something the participant said and asking them to expand on this, or they may ask the participant to structure responses more e.g. by asking for events in chronological order. Alternatively, the researcher may want to broaden the perspective of the discussion by asking the participant to consider their comments in a wider sphere. This may stimulate the participant to consider influences that may not have occurred to them before. This may also be used to explore positive and negative opinions of experiences.

### Content Mining

These are questions used to probe more deeply into topics that the participant has already raised. They can be divided into 4 main categories:

1. Amplificatory probes. These are questions used to ask the participant for a fuller description of the experience or phenomenon. The participant may be asked several times, with different questions, to elaborate further.
2. Exploratory probes. These are questions used to explore participant’s views or opinions that underpin their actions, behaviour or experiences.
3. Explanatory probes. These are questions often looking for why a participant behaved in a particular way or held a particular opinion. Just asking “Why?” may be too blunt and needs modifying to encourage a participant and not to sound judgemental.
4. Clarificatory probes. These questions may be used if language is uncertain or there may be inconsistency with previous comments. It may just be that the researcher wishes to ascertain the order of events, which may seem obvious to the participant.

### Facilitating the interview

#### Venue

The venue for an interview is often for the participant to decide and should be one that is quiet, private, comfortable and conducive to concentration. In reality most interviews are conducted in the participant’s home, but there may be reasons why another venue is required, sometimes a quiet workplace environment may be easier. For the interviewer it is important if extraneous distractions such as televisions can be switched off, or for professional interviews if telephone lines can be redirected for the duration of the interview.

#### Recording

It is preferable if the researcher can audio-record the interview and take as few notes as possible to avoid distraction and maintain the flow of a conversation-style discussion. As long as this mode of recording is acceptable to the participant it can provide a non-intrusive record of the discussion.

Audio-recording gives an accurate representation of the language and tone of discussion and, in combination with verbatim transcribing, provides data that can be reviewed in an iterative manner. It also permits review of primary data by other researchers to reduce bias in interpretation of the data.

Video-recording, particularly of the consultations, was considered as a data collection technique but concerns had been raised in the literature about creating bias in selection and behaviour of participants (198). The reason for wanting to record the consultation was to explore patient-HCP interactions and to triangulate findings from the in-depth interviews. Assessment of patient engagement and HCP skill at facilitating this could be achieved through analysis of audio-recordings and, given the concerns about the intrusiveness of video-recording, audio-recorded data was the chosen data collection technique for the consultations between patients and health care professionals.

#### Neutrality and self-disclosure

Legard et al (196) recognise the importance and influence that the researcher can have on data collection in qualitative settings. Returning to Kvale's metaphors (197) the "miner" may be considered as a conduit through which the data is collected, analysed and theories developed whereas the "traveller" is an integral part of collaboration with the participant and their influence will generate further themes of discussion.

The researcher can, therefore, become an integral part of data generation and as such can have a considerable influence or bias on the results. This may depend upon the personal viewpoints and opinions of the researcher as well as their professional background. Not only can this overtly influence the interview but perceptions of the researcher by the participant can also influence discussions. In health services research researcher bias and reflection is equally as important when interviewing patients or professionals (199).

Some commentators (200) argue that qualitative interviewers should be empathetic without becoming over-involved, whilst others (201) would argue that in sensitive situations the researcher should express more self-disclosure than appearing to be a remote data extractor. It is clear that the amount of self-disclosure will depend on the topic being explored and the characteristics of the participant and interviewer.

It is important that the interviewer is aware of the influence that self-disclosure can have on the quality of the data and that this is reflected during the analysis process and acknowledged in the strengths and weaknesses of any qualitative study design.

#### *3.3.1.2 Focus Groups*

Group discussions are another form of qualitative data collection technique that can be a useful source of opinions when exploring a research topic. The data collected from focus groups can be very different from individual interviews and may be influenced by group dynamics (202). Their origins relate to social science research before the Second World War but subsequently became a tool for market research (203) in the 1950s. They have been used extensively for political purposes in the late 20th Century but are now used widely in health research to explore patients' experiences of diseases and health service provision (204).

The process of running a focus group and the data collected can be very different from in-depth interviews.

“Group interactions between members of the target population during focus groups may encourage participants to make connections to various concepts through the discussions that may not occur during individual interviews.” (205)

Although focus groups have been described as a quick and cheaper way of elucidating data than the use of individual interviews, they also have some significant advantages. They:

1. do not discriminate against people who cannot read or write
2. can encourage participation from those who are reluctant to be interviewed on their own ( such as those intimidated by the formality and isolation of a one to one interview)
3. can encourage contributions from people who feel they have nothing to say or who are deemed “unresponsive patients” (but engage in the discussion generated by other group members) (202)

However, it must also be recognised that group dynamics can enhance or inhibit the flow of discussion. If one contributor becomes dominant or another contributors views are contrary to the rest of the group, this may inhibit fuller discussion and lead to the assumption that there is consensus when, in reality, there is not (206). Farnsworth and Boon also identify that conflict between participants can divert the discussion away from the desired topic. As with individual interviews the relationship, or any perceived relationship imbalance, between interviewee and the researcher can influence the discussion, particularly if sensitive topics are being explored (207). In certain circumstances it may be important to consider the composition of the focus group before inviting participants. Regardless of this the researcher plays a vital role, not only in steering the group to consider the topic concerned but also to be aware of and manage the group dynamics.

#### Running a Focus Group

Thought should be given to the venue and ambience of the group setting. Kitzinger (202) suggests that the setting should be relaxed, comfortable, with refreshments and sitting round in a circle to create the right atmosphere. She recommends a group of four to eight participants as the appropriate number. Finch and Lewis (208) identify five stages to successful running of a focus group namely:

1. Scene setting and ground rules.  
The researcher should welcome everyone with friendly conversation and thank them for attending. Once everyone is present the researcher should introduce themselves and an outline of the topic, purpose and any funding issues. Confidentiality must be stressed and the researcher should outline expected roles of participants.
2. Individual introductions  
Audio recording starts and the researcher asks each individual to introduce themselves to the group. This allows everyone to start speaking as well as listening to others. It also allows the transcriber to assess who is speaking during the discussion stage.
3. The opening topic  
The researcher introduces the topic and promotes discussion with opening questions. The researcher is quite active in the initial stages to engage all participants and direct the discussion
4. Discussion  
The researcher now needs to balance the discussion, ensuring all participants’ views are considered and there is no dominance by one individual. However, the researcher also needs to become less of a focus of the discussion, allowing the participants to debate topics

amongst themselves. The researcher still has to steer the discussions towards topics of interest and move away from areas that might have entrenched views.

#### 5. Ending the discussion

The researcher has to signal to the participants that the discussion is coming to a close by using phrases such as “the final topic” or “just before we finish”. It is often best to finish on a positive note such as suggestions for how things could be improved. The researcher then has to thank everyone and stress how helpful the session has been. They may have to be prepared to stay longer as participants often carry on discussions once the recorder is switched off.

To get the best data out of convening focus groups the researcher must have good organisational skills as well as being able to make people feel relaxed and getting a balance between allowing the group to interact whilst avoiding dominance, reticence or conflict between individuals.

### 3.3.2 Quantitative data collection

From the research questions raised by this body of work and described at the start of this chapter it is clear that the questions to be answered are “how” and “what” questions suggesting that a qualitative methodology is appropriate. However, this is not the sole strategy in data collection and analysis. The primary care project on T2DM describes, as a research strategy, using the quantitative OPTION Instrument (96) to triangulate qualitative data.

This is a 12 item scale to evaluate patient involvement in decision making (Appendix 1) with audiotaped consultations being analysed by two researchers independently. It was validated in 186 general practitioner consultations and is, therefore, ideal for use in the process evaluation of the PANDAs project. Each of the 12 items are scored from 0 - No attempt to involve the patient in the decision-making process to 4 - The behaviour is observed and executed to a high standard. The audio recordings and transcripts are independently assessed for each domain and an overall score is rated (maximum 48). The researchers then meet to discuss overall scores for each consultation as well as each of the 12 domains. Any discrepancies are reassessed, with review of the data if necessary, until consensus is reached and a final score awarded.

Analysis of the scores on their own can give an insight into how different groups (e.g. practice nurses or general practitioners) manage to involve patients in the decision-making process. Use of such a quantitative instrument can also enlighten findings from qualitative interviews and be used to triangulate information derived from individual interviews with the participants in the consultation.

The secondary care project on IC also used some quantitative data collection to inform interviews and triangulate data from those interviews (209). All patients who undergo hip arthroplasty in England will complete a Patient Reported Outcome Measure (PROM) before surgery and approximately 3 months after surgery. The PROM in question is the Oxford Hip Score (210), a 12 item tool validated against the SF-36 and Arthritis Impact Measurement Scales (211) that is used to evaluate quality of life issues in relation to osteoarthritis of the hip (Appendix 2). The authors of the tool recognise it was originally designed “to be primary measures of outcome in randomised, controlled trials...” but that it was suitable for use in other situations if certain precautions were taken.

“If the treatment of different cohorts of patients is being studied in a non-randomised setting, it is essential that both the pre-operative and post-operative scores are obtained. The change in the score should be analysed in addition to the post-operative score.” (212)

In each of the 12 items on the scale the patient assesses the severity of their symptoms attributed solely to their hip problem and how this is affecting their quality of life in each domain over the previous 4 weeks. The patient has to tick one of five boxes per domain that most closely represents their perceived quality of life. The researcher is then tasked with scoring the questionnaire and there has been some confusion over this. With 5 options per domain the original scoring system was from 1 to 5 giving a total score of 12 to 60 with 12 being the best outcome. This was felt to be counter-intuitive and the scoring system was adapted to 0 to 48 with 0 now being the worst outcome. This scoring system could be achieved by calculating a score from the original system and subtracting the score from 60 or rating the 5 options in each item from 0 (worst outcome) to 4 (best outcome).

Given the proviso above about using the score in non-randomised settings, collection of this data from patients being interviewed before surgery and 3 months afterwards was considered an appropriate quantitative method that could inform discussion at the post-surgery interview and be used to triangulate data from pre- and post-surgery interviews when considering changes in quality of life associated with the operation. It was not considered appropriate to statistically analyse data from the quantitative data due to a small sample size and licensing limitations.

### 3.4 Sampling Techniques

#### 3.4.1 Qualitative Sampling techniques

Sampling in qualitative research serves a different purpose from that in quantitative research. Lincoln and Guba (213) identify that qualitative research seeks to explore phenomena within the studied population and it is not for the researcher to try and extrapolate the findings to a wider population. The sampling is not meant to be statistically representative and certain characteristics may be positively desirable in the participants.

##### *Purposive or theoretical sampling*

Purposive or criterion based sampling (214) is the selection of participants for inclusion, based on particular characteristics that will help to answer the research question. Participants are selected on purpose to explore a certain issue, although there will be diversity in the population chosen based on other characteristics. For example in study 2, exploring informed consent, it is essential that all participants have experienced or are about to experience unilateral hip arthroplasty, however, age, sex and occupation are less important.

Theoretical sampling (215) is a technique more suited to use in grounded theory. A small sample of participants are interviewed and the data analysed, if there are gaps in the data or themes are not adequately covered then further, targeted recruitment occurs to complete the missing data. This is an iterative process that can occur several times until data saturation is achieved.

Opportunistic and convenience sampling are qualitative techniques that can be used based on coming across suitable candidates during the course of fieldwork or sampling based on ease of access.

For the two studies described, the use of opportunistic or convenience sampling was not considered appropriate when exploring health issues related to particular experiences (use of a decision aid in T2DM or informed consent for unilateral hip arthroplasty). When considering data analysis there were some a priori issues to be addressed in each study, precluding the use of grounded theory and, therefore, rendering theoretical sampling inappropriate.

Both studies used a purposive sampling technique for approaching patient recruitment for individual interviews or focus groups derived from each study protocol.

### *Patient Recruitment*

In both studies patients were recruited because they were about to, or had recently experienced a contact with health care professionals (HCPs) requiring an informed choice about treatment options.

Patients for the T2DM study were purposively recruited if their general practice had been randomly allocated to the intervention arm of the main PANDAs trial. Patients from these practices, recruited to the main trial, would then have used the PANDAs Decision Aid and could then express opinions on the utility and implementation of the tool.

In the Informed Consent study, individual interviews with patients were purposively recruited from the list of one orthopaedic surgeon because they were about to experience unilateral hip arthroplasty for osteoarthritis. Recruitment from one surgeon was selected so that patients experienced the same pre- and post-operative care. For the focus groups patients who had had unilateral hip arthroplasty for osteoarthritis within the last 6 months were recruited from the list of several orthopaedic surgeons to ensure diversity of experiences to aid discussion.

### *Health Care Professional Recruitment*

In study 1 (T2DM) health care professional recruitment was based on the purposive sampling criteria of the patient and then asking the corresponding health care professional to participate. This was to ensure diversity of recruitment based on patient characteristics whilst creating patient–health care professional dyads that permitted cross-analysis of interview data with each other and with the consultation data.

In study 2 (Informed Consent) recruitment of orthopaedic surgeons was to some extent a convenience sample. The local secondary care NHS trust was identified as having seven orthopaedic surgeons who regularly performed unilateral hip arthroplasty and took consent for this procedure. It was, therefore, considered appropriate to approach all of them to participate in the study. Consent techniques were considered to appropriately reflect what patients had experienced by interviewing surgeons who took consent at the same NHS hospital that the patients had attended. It was also clear that surgeons had different consent processes for NHS and private work and therefore concentrating on NHS practices was essential as patients were recruited from the NHS sector.

Using qualitative methodology requires rigor in data collection techniques, interpretation and analysis to try and eliminate some of these biases that can develop.

### 3.4.2 Quantitative sampling techniques

Probability sampling or random sampling is commonly used in quantitative research so that the sample in the study closely resembles that of the general population. It may be that some characteristics could be over- or under- represented yet this can be adjusted for statistically in the final analysis. Sample sizes tend to be pre-determined by calculations of power relating to the expected difference to be measured in the separate groups. The concept with quantitative data is that any findings from the study can be extrapolated to the general population; that is they are generalizable or have external validity.

Although quantitative data collection was used within both studies, this was to help triangulate data and inform interviews and data analysis. It was inappropriate to analyse the quantitative data in isolation and create separate outcomes from the qualitative data. As such no probability sampling was used in either study as selection of the participant population was based on the qualitative paradigm with its own inherent sampling techniques.

### 3.5 Rigour in qualitative methodology

Quantitative research uses concepts such as internal validity, external validity, instrument reliability and intra-observer reliability to ensure the “trustworthiness” of findings. Lincoln and Guba (213) use the naturalistic paradigm to suggest four key areas of rigour: Credibility, Transferability, Dependability and Confirmability, which have become the framework for establishing rigour in qualitative research and, to some extent are synonymous with the quantitative concepts of rigour.

#### 1. Credibility

This is a series of processes to make the findings of the research more believable. The authors identify the three main activities that will increase the probability of credible findings as:

- Prolonged engagement
- Persistent observation and
- Triangulation of data.

Other techniques suggested include peer debriefing or peer review of the data and refining the hypothesis as data is collected and analysed.

#### 2. Transferability

This is a major divergence between positivism and naturalistic research paradigms. The positivist will try and create a hypothesis applicable to the general population or a specific subset, whilst the naturalist will describe a hypothesis applicable to the population they have studied. Lincoln and Guba argue that it is for other researchers who wish to generalise a naturalist hypothesis to demonstrate any applicability to the new setting.

#### 3. Dependability

This is the concept that if the study was repeated would the findings be the same. A positivist attitude is that the results of their research would be the same wherever and whenever conducted. However, naturalistic research takes into account individuals beliefs and opinions, which may change over time or in different settings. Results may, therefore be different and the researcher can only suggest why these may change. It may be possible to reduce variability by recruiting as broadly as possible different characteristics from within the chosen setting.

#### 4. Confirmability

This is to be aware that the observer can bias the results. The researcher needs to be aware of their biases and this can be helped by a reflexive journal written during the data collection and analysis process. Also asking colleagues to do data analysis of some results and feed back to the original researcher can “quality assure” the process.

Methodology discussed above and described in detail below pertaining to each individual project addresses the rigour required to generate “trustworthiness” in the research findings. This approach alongside discussion of the reflexivity by the researcher and discussion on strengths and weaknesses represents a systematic approach to qualitative research whilst recognising where bias can influence findings where limitations have been considered and may need to be addressed in future.

### 3.6 Bias

“...a particular tendency or inclination that prevents unprejudiced consideration of a question” (216)

Mays and Pope (217) recognise that:

“All research is selective - there is no way that the researcher can... capture the literal truth of events. All research depends on collecting particular sorts of evidence through the prism of particular methods, each of which has its strengths and weaknesses.”

As described earlier, findings from qualitative research reflect data from a particular time and setting and are not usually transferable or generalizable to other situations, however, this does not mean that accounts of the methods used are irrelevant. It is still vital to describe methods in data collection and analysis in detail so that future researchers could follow the same techniques and reach similar conclusions. If methods are adequately described and consideration of bias discussed, then the reader has a better concept of what could have influenced the study and how these were minimised.

Pannucci and Wilkins (218) identify causes of bias that can occur: pre-trial, during the trial or after the trial and whilst they may be geared more for quantitative research some of the criteria are relevant for qualitative study designs.

#### 3.6.1 Pre-Trial Bias

##### *3.6.1.1 Bias during study design*

When considering bias in qualitative work we do not have to consider instrument validity or reliability, but the research tools, usually interview topic guides and data collection methods, need to be standardized to reduce bias. It may be that several researchers are interviewing patients and, therefore, topic guides are developed to ensure some uniformity of the data collection. It is important to remember that some variability is desirable in qualitative research to encompass a broad spectrum of opinion.

##### *3.6.1.2 Selection bias*

Again quantitative methods can reduce bias by a process of randomisation of participants to different interventions. As discussed above qualitative recruitment is more selective but still needs to be described fully so that critical analysis can identify any bias. Selection techniques may include inviting a series of patients until data saturation is reached; in these cases comparison of patient characteristics with national statistics can identify any bias.

##### *3.6.1.3 Channelling bias*

This is where patients may be selectively offered one treatment over another depending on characteristics such as age. Again by comparing participant statistics with national statistics can identify any discrepancy.



### 3.6.2 Bias during the Trial

#### 3.6.2.1 Interviewer bias

Interviewers may approach the aspects of data collection, recording or interpretation in different ways and this may partly be based on their own experiences or on their understanding of the objectives or outcomes of the research. It is often not possible to “blind” interviewers to the objectives of the research, but consideration of reflexivity by the interviewer in qualitative data analysis can alert readers to the potential influences of the researcher on the outcome.

#### 3.6.2.2 Recall bias

This is a process whereby patient’s outcome from treatment, whether good or bad, may influence their recollection of events prior to the intervention. For example, patients who have had a poor outcome from their hip surgery might recollect events about the consent process differently from those who had a good outcome. This can be reduced by interviewing patients before and after surgery and by using other methods to triangulate outcomes such as the Oxford Hip Score.

#### 3.6.2.3 Performance bias

This is the situation where variations can occur due to clinician experience or based on the site recruited to the trial. It is usually minimised by a cluster randomisation technique – randomisation is based on the site, eg the general practice in the PANDAs study, rather than the individual. This cluster randomisation process was used in assigning practices to control or intervention. If individual patients had been randomised you might get contamination whereby two patients at one site could meet in the waiting room and discuss their involvement in the study, one experiencing the decision aid and one not.

### 3.6.3 Bias after the Trial

#### 3.6.3.1 Citation bias

Positive results are more likely to be submitted for publication than negative results and sponsors may be unwilling to publish unfavourable results. Many trials are now required to be registered in an approved clinical trials registry (219) and campaigns for publication of all trial data have been extensively promoted (220, 221). Despite these interventions it is not possible to eliminate all bias in this category.

#### 3.6.3.2 Confounding bias

Confounding factors are not usually a problem in qualitative research as you are not trying to isolate the effects of one substance over others that might cause the same effect. Also in qualitative work the researcher is exploring phenomena within the study population and not trying to extrapolate that work to a more general population.

(Adapted from Pannucci et al (218))

Another technique to reduce bias or to allow readers to identify bias and influence within qualitative work is to follow an accredited checklist when reporting such work. One such method is the “Consolidated criteria for reporting qualitative research” or COREQ (222) which has been adopted by several journals including BMJ Open and PLoS ONE (223, 224).

The original research was a systematic review of qualitative data reporting that identified major themes important to assessing the quality of the studies. The researchers developed a 32 item checklist grouped into three domains that could be used when submitting work for publication or reviewing published qualitative work. The three main domains covered are:

1. Research team and reflexivity: this covers areas such as occupation, qualifications and gender
2. Study design: this covers the theoretical framework, participant selection, the setting and data collection.
3. Analysis and findings: This covers how the data was analysed and reported.

(For full COREQ criteria see Appendix 3)

The structure of COREQ and the comprehensive coverage of the checklist when considering quality for reporting interviews and focus groups was considered a pragmatic and acceptable format to follow when collecting and reporting data from the two studies. This framework for reporting was adopted, alongside considerations of rigour as proposed by Lincoln and Guba (213) as well as considerations of bias espoused by Pannucci (218).

The significant feature apparent from all of these considerations is the influence of the researcher on the whole process, especially the 3 domains described in COREQ. It is, therefore, vital that throughout this whole project the researcher considers his potential influence and bias on the data and findings. For this reason the researcher outlined his personal history relevant to the project at the beginning.

### 3.7 Background to Reflexivity

A key feature of recruitment, data collection, interpretation and presentation is aiming to be as objective and neutral as possible. Whilst we have discussed that through qualitative research there may not be an “absolute truth” to be found and researchers may approach topics with different preconceptions, their different findings are equally as important as long as the reader is aware of the influences.

Finlay and Gough discuss different types of reflexivity in their book “Reflexivity” (225) which can include introspection, critical realism, postmodern deconstruction and more specific examples of feminism. Many of these examples explore the interaction between researcher and participant but the chapter by Ilja Maso (226) explores reflexivity at every stage of the project.

Maso identifies the research question as having three components:

1. The research question is a search for something and “must be an expression of a real and living doubt.” This may be something that the researcher is passionate about and motivated to explore.
2. The answer to the question is unsettled
3. The “motives, beliefs and conceptual framework open up a range of answers and... the direction in which to look for them.”

It is clear that ideas, prejudices and presumptions of the researcher can influence the question and direction of development of the research project.

Maso also explores the development of a theoretical framework and subsequent analysis based on relevant scientific and non-scientific literature, as well as consulting people with the relevant knowledge and experience. From this information-gathering phase the researchers will make interpretations that influence the first phase of data analysis. Further analysis will depend upon conformation, negation or a change in the initial hypothesis again dependant, to some extent, on researcher influence.

These are influences to be considered separately from the commonly defined influence of roles and perceived roles during the researcher-participant interaction. As discussed earlier there are many

situations where the researcher may not wish to divulge information about themselves in case it influences the participant's response. On the other hand, in sensitive situations, self-divulgence may encourage the participant to reveal more information relevant to the research question.

Reflexivity is being aware of prejudices and influences in all areas of the research project and discussing how they may have influenced some of the findings from the project.

### 3.8 Data Analysis

This is the process of organising the data collected, such as transcribed interviews, into smaller "chunks" that can be related to a main theme of the research. These "chunks" are then grouped together under their appropriate thematic heading and can then be reviewed as a group. Computer software such as NVIVO 8 (227), as used in this project, can assist in organising the data but requires the researcher to do the analysis themselves.

Qualitative data analysis can take several forms, not all of which are relevant to pragmatic Health Services Research. The two main analytical models used in social sciences research are Grounded theory and Framework analysis, although other less frequently employed models can be used such as discourse analysis or narrative analysis.

#### 3.8.1 Grounded theory (215)

This is a process whereby the theory is developed from the data rather than having any a priori concepts to be fulfilled by the data. It is discovered empirically and can be extended indefinitely as there is no framework to restrict the data. Any theory that develops from the data can be revised as more data is collected and analysed. As there are no pre-set categories or direction to the data collection then the number of interviews can become very large with a huge amount of data that will take a long time to evaluate.

#### 3.8.2 Framework analysis (228)

This was a technique developed by Richie and Spence (229) to assist with data analysis in applied policy research. However, it has rapidly become an accepted methodology for many areas of research including health care research (230). Framework analysis is best suited to situations where there is a limited time period for results to be available, or where there are some specific pre-determined topics that need to be addressed by the qualitative analysis.

This technique allows the researcher to establish a preliminary framework developed from the literature review, specialist knowledge and other sources before data analysis commences. These a priori issues should not just be a re-iteration of any topic guide but should reflect initial areas of importance to answer the research question. As data analysis progresses there may be new themes within the framework that develop or sub-themes within themes become apparent.

Using Framework allows the researcher to do some analysis during the data collection process and can be used to refine further the topic guides or result in re-analysis of previous data when new themes emerge; an iterative or constant comparative process. The analysis process is divided into five distinct categories:

1. Familiarization
2. Identifying a thematic framework
3. Indexing
4. Charting
5. Mapping and interpretation (229)

Familiarization is the initial step of the researcher reading and re-reading the transcripts and notes so that they become cognescent of some of the key themes recurring throughout the data. As an initial process there may be a large amount of data to review so sometimes selecting a representative sample of all the data modalities collected will suffice.

The second stage of identifying the thematic framework follows on from familiarization with the data. There may be some a priori issues already established but the researcher needs to explore the data for new themes that are emerging. This stage requires the researcher to make judgements about what is important and relevant to the research question. This is also a stage that may be re-visited several times as new themes develop and transcripts have to be reviewed again, comparing the data with the new framework.

Indexing is the process of identifying sections of the transcripts or notes that correspond to the relevant theme within the framework. These sections of data are then tagged according to the relevant theme or sub-theme. This section again requires researcher judgement and input but can be assisted by computer software programmes which can be used to tag and organise the data.

Charting is the process of extracting the indexed data from their original source and assigning them to a chart of theme headings. The data still remains identifiable as to its origin but is now grouped with data from other sources relevant to that individual theme or sub-theme. The use of computer software has again made this task easier to manage.

Mapping and interpretation is the formal analysis of the data from the themes to answer the research question. This is the section of analysis that requires most reflexivity on the part of the researcher as their pre-conceived ideas can influence the outcome of the results.

### 3.9 Conclusion

Qualitative research has come under much criticism, particularly in health care where a lot of research is dependent on creating quantifiable results that can be generalised from the study setting to the general population. Mays and Pope highlight this:

“The most commonly heard criticisms are, firstly, that qualitative research is merely an assembly of anecdote and personal impressions, strongly subject to researcher bias; secondly, it is argued that qualitative research lacks reproducibility--the research is so personal to the researcher that there is no guarantee that a different researcher would not come to radically different conclusions; and, finally, qualitative research is criticised for lacking generalizability.” (217)

However, it is evident that these criticisms have been reviewed and addressed at every stage of the qualitative research project development, operationalization and analysis. By following the steps highlighted in this section it is possible to produce rigorous and relevant results that will stand up to scrutiny. In terms of generalizability that is for other researchers to argue, qualitative research is relevant to the time and setting of the data collection and patient recruitment should reflect the broad spectrum of opinion rather than try and reflect patterns within the general population.

## Chapter 4: Conducting the research

### 4.1 Overview of the chapter

The thesis draws on two research projects conducted by the author in two different settings, one in primary care exploring Shared Decision Making and one in secondary care exploring Informed Consent.

Study 1 explored the issues of SDM in primary care when implementing a PDA for use by patients with T2DM considering insulin therapy. The current use of patient decision aids is mainly in research settings with no regulation for their implementation and no guidance for their use in routine practice.

The primary care project explores the use of a PDA in patients with type 2 diabetes mellitus (T2DM) considering insulin therapy. Information in this setting is provided in a systematic format which has been derived from the literature (the PDA) with clearly signposted opportunities to review information or reflect on personal values. This study explores patient and HCP opinions of using an SDM approach and PDA to assist in making difficult treatment choices.

Study 2 used the process of IC in relation to unilateral hip replacement for osteoarthritis to explore secondary care issues of SDM. This was set against a background framework established by legal precedents and guidelines issued by regulatory bodies (5). The secondary care project uses hip arthroplasty as a vehicle for exploring the issues of IC from the perspective of patients and orthopaedic surgeons. It explores information acquisition and delivery and whether this occurs in a systematic way that integrates with the obtaining of consent prior to surgery. It explores whether IC is a central theme to the hospital contacts prior to the operation and if the implementation of informed consent is concordant with the theory that informed consent and shared decision making should be synonymous in elective surgery of this type (12).

The regulatory issues and methods used are described individually under each study heading; results will be presented separately and then compared; the discussion will consider this comparison of the findings and implications for potential improvements to the implementation of SDM and IC.

## 4.2 Study 1. Primary Care: The evaluation of the implementation of a Patient Decision Aid (PDA) in a primary care setting.

(For The Patient Decision Aid see Appendix 4)

(For regulatory and associated documents see Appendix 5)

### 4.2.1 Background

The PANDAs study (6) was a cluster randomised control study exploring the effects of a Patient Decision Aid (a complex intervention) on HbA1c levels and decisional quality in patients with type 2 diabetes mellitus (T2DM) considering insulin as the next therapeutic option. The study was conducted across 49 general practices in South Yorkshire with 175 patients randomised, 95 to intervention with the PDA and 80 to the control arm (normal diabetes care). The unit of randomisation was the general practice so that all participants within one practice received either intervention or control.

Part of the MRC guidelines on the development and evaluation of complex interventions (231) is the incorporation of a process evaluation. This is a qualitative study nested within the RCT to evaluate patient and practitioner views on the content and implementation of the PDA. This was the part of the study that the researcher developed, performed the interviews and analysed the data for.

### 4.2.2 Why Type 2 Diabetes Mellitus (T2DM) was considered an appropriate vehicle to explore SDM

#### 4.2.2.1 Type 2 Diabetes Mellitus (T2DM)

T2DM is an increasingly common disease which is mainly managed in primary care. The average UK prevalence of diabetes in England is now 5.8% (232) with three million people having diabetes in the UK; by 2025 it is estimated that this will rise to five million people suffering from diabetes, mainly type 2. Initial treatment may be by diet alone but gradually, as blood sugar control deteriorates, patients often require tablets. These may be used individually or in combinations to improve blood sugar control, however, even tablets may not be enough and eventually some patients will need to consider insulin. This is a difficult decision for patients to make as it requires not only self-injecting but also the risk of more serious side effects such as hypo-glycaemia and more intense primary care monitoring. This has to be balanced against the potential benefits of reducing average blood sugars such as reduced risk of developing renal or cardiovascular disease. Such a decision with several options including that of making no change to the current treatment regime is ideally suited to support with a patient decision aid (8).

#### 4.2.2.2 Developing the research question

The review of the evidence was conducted in three distinct ways:

1. Specialist opinions were sought from people working in the fields of diabetes management, qualitative research and shared decision making
2. A review of journal articles in PubMed and MEDLINE through the National Center for Biotechnology Information (NCBI) at the U.S. National Library of Medicine (NLM). Search terms were: shared decision making; type 2 diabetes mellitus; patient autonomy; insulin therapy.

3. A review of guidelines published by recognised bodies on the management of type 2 diabetes mellitus.
4. References for other articles and books were followed up from the citations quoted in the articles found through the search in 2 and 3.

Through this process it was evident that there was no clear guidance on when patients with T2DM who were on maximally tolerated oral therapy should consider insulin therapy (233). The use of patient decision aids in such a setting of equivocal evidence was considered appropriate and at the time there was little evaluation of process in the reporting of trials of patient decision aids (234).

The PANDAs study (6) had already been approved to explore the effectiveness of a patient decision aid in the management of patients with T2DM. The study had been developed as a cluster randomised control trial in primary care comparing the use of the Decision Aid with routine care.

Patient decision aids are considered to be complex interventions:

“Complex interventions in healthcare, whether therapeutic or preventative comprise a number of separate elements which seem essential to the proper functioning of the intervention although the “active ingredient” of the intervention that is effective is difficult to specify” (235)

Evaluation of the PANDAs PDA followed the Medical Research Council guidance. This guidance was updated from 2000 to 2008 with particular reference to process evaluation to explain how the PDA influenced decisions. As I joined the study team early in 2009 this was an ideal opportunity to use the updated guidance to plan and develop a process evaluation for the PANDAs study.

“Including a process evaluation is a good investment... to understand how context influences outcome and to provide insights to aid implementation” (231)

The process evaluation was, therefore, designed to explore issues important to patients and healthcare professionals in the utility and implementation of the PANDAs PDA, not only in relation to the main study, but also with reference to routine diabetes care without using a patient decision aid.

The main research questions developed from the process evaluation were:

- 1 “Are shared decision making strategies acceptable to patients and healthcare professionals”
- 2 “How does the use of a patient decision aid influence decision processes of patients and healthcare professionals”

These research questions were considered under the broader context of shared decision making in the NHS and particularly in relation to “how patients make healthcare decisions”.

#### 4.2.3 Regulatory issues

##### 4.2.3.1 Ethics approval.

The Cluster RCT part of the PANDAs study had received ethics approval from North Sheffield Local Research Ethics Committee in 2007. The process evaluation part of the study was submitted as a substantial amendment to the original proposal and approved by the same ethics committee in 2009.

##### 4.2.3.2 Governance approval

Research governance approval for the process evaluation was received from Sheffield Health and Social Research Consortium and an honorary contract was issued to AB to interview patients and staff in primary care settings in Sheffield, Doncaster and Rotherham.



#### 4.2.3.3 Funding

The PANDAs study and process evaluation were funded by a National Institute for Health Research grant through its Research for Patient Benefit programme (RfPB), Grant Number PB-PG-0906-11248.

From September 2010 to August 2012 AB was also funded for his research through the NIHR In-practice Fellowship grant IAT I-PF 010 003.

#### 4.2.4 Study Design

##### 4.2.4.1 Qualitative methods

This study is a process evaluation as described by the MRC guidelines. As such it is a qualitative study nested within a quantitative cluster RCT. The aim of a process evaluation is to try and identify how a complex intervention is being implemented in a specified health care setting, and the experiences of users of that intervention in routine practice. In order to answer such questions a qualitative approach is considered appropriate (236). During the main PANDAs study questionnaires were used for data collection but for this part in-depth interviews were considered most appropriate. Both patients and Health Care Professionals (HCPs) who had used the PDA would be interviewed on their experiences. As individual experiences were being sought a focus group design was not thought to be appropriate. It was also considered important for users of the PDA to be interviewed soon after use of the PDA (within 2 weeks) to ensure retention of information and, particularly for HCPs, to ensure their recollections were not influenced by other consultations.

As patients who had used the PDA would be interviewed in isolation from the HCPs they had seen for their consultation it was considered important to also audio-record the consultation itself. This would allow cross-referencing of information provided by the dyad of patient and HCP.

All interviews and consultations were audio-recorded and transcribed verbatim.

##### 4.2.4.2 Quantitative methods

The theory behind the development of PDAs is one of encouraging patients into a more deliberative pattern of decision making with a sharing of health care decisions rather than a paternalistic or beneficence model. It was, therefore considered important to evaluate to what extent the PANDAs PDA and implementation model allowed patients to engage in sharing the decision about whether to start insulin. The audio recordings and transcripts from the consultations were analysed for patient involvement in the decision-making process using the OPTIONS Instrument (96).

For the purposes of this research the independent reviewers of the consultations using the OPTIONS instrument were AB and IB.

#### 4.2.5 Research Tools

##### 4.2.5.1 The PANDAs Decision Aid (Appendix 4)

The Patient ANd Decision Aids (PANDAs) trial is described earlier. The PANDAs Decision Aid is a tool designed to assist patients with T2DM when considering whether to add insulin therapy to better control their blood sugars. It was developed using guidance from the IPDAS collaboration (81) and the Ottawa Decision Support Framework (237) and consists of several sections that may influence patient decisions in different ways. Use and implementation of the Decision Aid will vary from patient to patient and practitioner to practitioner. As such it is a complex intervention to assist SDM and requires qualitative evaluation to understand how it influences decisions as well as patient and health care practitioner (HCP) attitudes to the implementation of such a tool.

#### 4.2.5.2 Interview guides

For the in-depth interviews with the patients and HCPs separate interview guides were developed from the literature review and support from CJN. Further specialist opinion on development and use of the interview guides was provided by MJ. The interview guides were developed to explore the aims of the process evaluation and to ensure the important topics were covered equally from a patient and HCP perspective.

#### 4.2.5.3 OPTIONs Instrument (Appendix 1)

This is an instrument and measurement scale validated in British general practice to assess the skill with which the HCP tried to involve the patient in the decision about a specified health problem. It is designed for two independent reviewers to analyse transcripts of consultations and score each of 12 criteria on a scale of 0 to 4. 0 indicates no attempt by the HCP to involve the patient in discussion about their healthcare whilst 4 indicates a high standard by the clinician in trying to involve the patient. Scores generated range from 0 to 48 with 48 showing a high standard of patient involvement in all areas identified as important for SDM.

Two independent reviewers are required to review audio-recordings and consultation transcripts and score according to the 12 domains. The reviewers then meet to discuss their scores and reach consensus on each domain and allocate an overall score between 0 – 48.

### 4.2.6 Recruitment Methods

#### 4.2.6.1 Purposive sampling

It was essential that participants interviewed for this project had used the PANDAs PDA. A purposive sampling strategy (214) was, therefore, used to recruit patients from the intervention arm of the main PANDAs study.

Initial expressions of interest for the process evaluation were sought from HCPs who dealt with diabetes care in practices that had agreed to participate in the main PANDAs study and been randomly assigned to the intervention arm. The HCPs were identified at the time of practice recruitment and training for the main study in techniques of SDM and particularly the PANDAs PDA.

#### 4.2.6.2 Patients

Patient recruitment was targeted at patients who had agreed to take part in the PANDAs study; their practice had been randomised to the intervention arm and they were attending for their first appointment for the main study. In order to achieve diversity of opinion certain patient characteristics were considered important. These were:

“How close was the patient to making a decision about insulin therapy” and

“Their control preference in relation to healthcare decisions about T2DM”.

It was described earlier that patient’s preference for involvement in decision making may change with age or with the severity of the outcome to be considered. However, when a health care outcome has been identified, such as whether to start insulin or not, then a patient will usually express some opinion as to how they would wish to be involved with that decision. The Control Preferences Scale (238) was derived from grounded theory to establish five main categories that describe how patients would like to make healthcare decisions. “These roles range from the individual making the treatment decisions, through the individual making the decisions jointly with the physician, to the physician making the decisions.”

The patient preferred role for making the decision about starting insulin therapy was included in a questionnaire at the initial contact with patients enrolled in the main study and differences could be purposively selected for in patient recruitment to the qualitative study.

#### *Patient consent*

Once patients had agreed to participate in the main PANDAs study and signed the consent form they were asked if they were prepared to take part in a separate but linked evaluation that would involve an interview and audio recording of their consultation with the HCP. The patients were then taken through the separate qualitative patient information sheet and given a copy to keep. If the patients were willing to proceed they were asked to sign a separate consent form. Interviews were to take place within two weeks of the consultation, the majority (six out of eight) taking place on the same day.

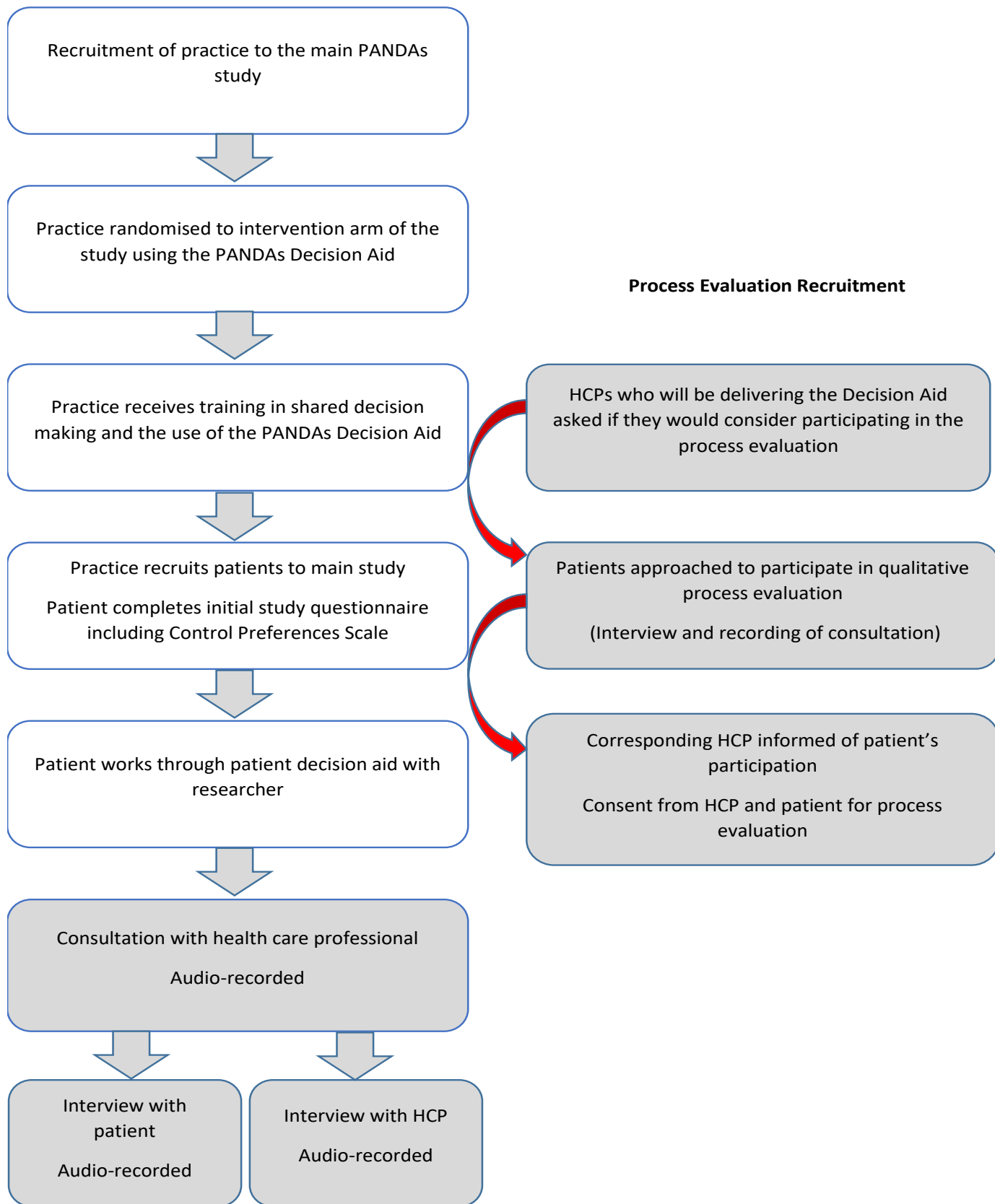
#### *4.2.6.3 Health care professionals*

HCPs had to be recruited from practices that had used the PDA in the main study and were willing to be interviewed and have their consultation with the patient recorded. Recruitment of the HCP was dependant on the patient they were seeing agreeing to participate. In reality the HCP was approached at the time of practice recruitment and training in the use of the Decision Aid; if the HCP did not wish to be interviewed then we could not recruit any patients from that practice for the process evaluation. Diversity in terms of practice nurse or general practitioner was desirable but dependant on patient willingness to participate in the qualitative evaluation.

#### *Health care professional consent*

HCPs had already been approached to take part in the evaluation when the practice was randomised to the intervention arm. Patients were approached in practices where the HCP was willing to be interviewed. Once a patient had consented to the evaluation the HCP was informed and given the HCP information leaflet. They were then asked to sign the consent form. Audio recording equipment was set up in the consultation room whilst the patient was working through the PDA with another researcher.

Figure 2 Shared Decision Making Participant recruitment



#### 4.2.7 Data collection

A total of eight patients and their corresponding health care professionals were recruited. This resulted in sixteen individual semi-structured interviews being conducted. There were also eight consultations audio recorded between the patient-HCP dyads. Interviews lasted approximately 45 minutes and consultation length was variable.

To reduce recall bias it was proposed that the interviews take place within two weeks of the consultation. In reality six of the eight patient interviews occurred immediately after the consultation, the other two occurring within the two week timeframe. All the HCP interviews occurred immediately after the interview by a different researcher from the one who interviewed the corresponding patient. All interviews were audio recorded.

#### 4.2.8 Data analysis

##### 4.2.8.1 Qualitative

Audio recordings were transcribed verbatim and the subsequent data managed with NVIVO 8.

The use of Framework analysis for the interview data permitted some a priori themes to be established and explored within the data. It was important to recognise that these themes were not just re-iterations of elements of the interview guides. Although these guides did cover important themes, each study had its own specific questions as well as the comparison of SDM and IC.

The themes were established through the systematic process of a Framework approach to data analysis, namely familiarisation, identifying a thematic framework, indexing, charting and mapping and interpretation (Section 3.8.2)

Patient and HCP interviews were initially analysed separately and if new themes emerged the previous interviews were re-analysed with reference to these new themes. The corresponding patient-HCP dyadic interviews were compared and also analysed alongside the transcribed consultation.

Once the transcribed data had been charted onto the emergent themes and quotes in the transcription were tagged accordingly. The resultant themes were considered in the broader context of “how patients make health care decisions”.

Quality assurance of the transcription analysis and grouping of themes under the meta-themes was achieved by reviewing two interviews with two separate colleagues in the research department who were experienced in qualitative data analysis.

##### 4.2.8.2 Quantitative

The audio files and transcripts from the eight consultations were reviewed separately by AB and IB using the OPTION Instrument for HCP skill in engaging the patient in the decision making process. Once each had scored the consultation a meeting was convened to compare overall scoring and scores for the 12 separate parameters. If there was non-concordance the transcripts were reviewed together until agreement was reached.

#### 4.2.9 Ethical considerations

The researcher was aware that as both a researcher and general practitioner, his experience and perceived role by participants could influence the results. This would occur both in data collection and data analysis.

HCPs were aware of my role as a general practitioner (GP) in Sheffield and this was important so they could be confident of my understanding of issues around the decision to consider insulin in T2DM. If I was interviewing the HCP I ensured they were aware that this was in my role as a researcher and was not going to comment on care or management of the patient. This was essential to gain trust from practice nurses and GPs in discussing opinions freely.

Patients were informed of my role as a GP but also that I would not discuss management of their condition as it was inappropriate for me in the role of researcher. Patients were advised, if they had medical management concerns to direct these to their HCP and if they had concerns with the conduct of the research to contact NM the Principal Investigator.

It was not anticipated that the research would touch on strong emotional needs of patient or HCP and this was the case.

Confidentiality and anonymity were discussed with participants to ensure openness in their responses. The anonymous publication of any quotations was approved by all participants and included on the consent form.

#### Welfare of the researcher

All interviews and consultations occurred within the settings of primary care premises during busy clinic times with two researchers present, one to deliver the PDA and interview the HCP and one to interview the patient. It was, therefore, not considered a formal necessity to inform anyone else, although other members of the PANDAs team were aware of our whereabouts.

#### Data storage

Data consisted of paper copies of patient and HCP identifiable data such as consent forms and OPTIONS scores, and electronic data such as audio recordings and transcriptions. All paper information was stored in locked cabinets in a locked room on University of Sheffield premises. Only AB had direct access to this data. Anonymised electronic data was stored on password protected University of Sheffield fileservers.

#### Transcriber confidentiality agreements

All transcriptions were done by a third party with a confidentiality agreement between the transcriber and the AUPMC. All anonymised transcriptions were remotely transferred to the University fileserver from a secure website.

#### Payment of participants

HCP participants were not paid for their participation in the study, although practices were reimbursed through the main PANDAs funding for administrative time. Patient participants were paid £15 in the form of vouchers for appreciation of their time in the PANDAs main trial. They were not paid extra for the qualitative study.

#### 4.2.10 Research bias

It is not possible to eliminate all bias from research, but by defining and clarifying the research methods at every stage it is possible to reduce bias through rigour and highlight where potential compromises have occurred.

#### *4.2.10.1 Pre-trial bias*

One area of bias here is the development of the interview guides used for patients and HCPs. These were developed from the literature and to address some themes that were identified before data collection. They were developed collaboratively with AB, CJ and MJ to ensure a broad experience base.

Inclusion and exclusion criteria were set at the practice level and patient level for the main study. These may have excluded patients who were willing or appropriate to interview, but patient recruitment had to take place from patients who had experienced the PDA.

HCPs had to express an agreement to be interviewed prior to approaching the patient. Patients were purposively invited from the intervention arm of the main study. There was, therefore, no control over HCP characteristics as these were entirely dependent on patient participation.

#### *4.2.10.2 Bias during the trial*

Interviews were conducted by AB and BC, ensuring that whoever had delivered the PDA did not conduct the patient interview as this might restrict patient expressions of opinion. Using two researchers to conduct interviews can lead to differences in delivery due to different professional backgrounds, but variability is part of the qualitative paradigm and can result in more informative data. By expressing reflexivity the researcher has tried to illuminate their own background and potential biases, for the reader to draw their own conclusions.

Recall bias was addressed by limiting the interview to a maximum of two weeks post consultation with the PDA. This was to ensure patients could recollect most of their discussion, whilst HCPs would not be influenced by subsequent consultations. In reality all HCP interviews occurred immediately after the consultation; six out of eight patient interviews occurred immediately after the consultation with two occurring within two weeks.

Variability in delivery of the PDA and patient preference as to whether they wished to discuss the PDA during the consultation could lead to bias. However, this process was considered closest to delivery of such a tool in a non-research setting, giving an insight into the use of PDAs in routine NHS care. Again it was considered more appropriate for a qualitative study to explore experiences in a “normal” setting.

#### *4.2.10.3 Bias after the trial*

This form of bias can occur due to selection of citations and analysis of the data. The researcher has tried to reduce this element of bias by discussing citation selection criteria and drawing broadly from medical, sociological and psychological literature. Although data analysis was conducted by AB, a random selection of interviews and consultations were analysed by two colleagues (LW and HT) within the department and the framework for analysis also reviewed. Preliminary results have been reviewed by NM and presented to research audiences to strengthen review and rigour.

## 4.3 Study 2. Secondary Care: Informed consent for unilateral hip arthroplasty for osteoarthritis

(For regulatory and associated documents see Appendix 6.)

### 4.3.1 Background

Study 2 explores the secondary care setting of informed consent in elective unilateral hip arthroplasty. As discussed earlier, IC is an area with formalised guidelines from the GMC (5) and Department of Health (239) as well as a growing body of case law, although not governed by primary legislation in the UK. Discussion in previous chapters identifies that IC in relation to unilateral hip arthroplasty satisfies criteria established by several observers for the concordance of SDM and IC (9, 10, 12).

Guidelines issued are for doctors taking consent to be aware of and to follow; these are often informed by outcomes from court cases specifically exploring issues of informed consent and duty of care. Whilst these guidelines direct doctors they are not totally encompassing of what IC involves. As Alasdair Maclean (240) claims, they may direct a doctor to the outcome of what is discussed, for example risk of complications, but they do not direct the process. This study, therefore, explores patient experiences of the Informed Consent process beyond the legal requirements of IC. It explores these processes in terms of information disclosed as well as on-going opportunities to discuss IC issues prior to surgery and whether these meet patient expectations. Discussion prior to surgery is also influenced by surgeon attitudes to consent taking and hospital processes to facilitate on-going dialogue between patient and health care professionals. For these reasons consultant orthopaedic surgeons regularly taking informed consent for unilateral hip arthroplasty in NHS settings were also interviewed in this study.

### 4.3.2 Why unilateral hip arthroplasty was considered an appropriate vehicle to explore IC

#### 4.3.2.1 *Unilateral Hip Arthroplasty*

The condition of osteoarthritis and particularly the operation of unilateral hip arthroplasty was chosen to explore the issues of IC and SDM for several reasons. The operation is a common procedure, the NHS performed over 70,000 such procedures from April 2010 to April 2011(108) with the Northern General Hospital in Sheffield performing 806 per year (108). It is, therefore, a relatively common operation meaning that recruitment of patients should not be protracted.

The operation is a routine elective procedure, emergency procedures such as for fractured hip were excluded by the protocol, with options of doing nothing, taking more analgesia or surgery, making it an appropriate vehicle to explore the comparison of shared decision making and informed consent (12).



#### 4.3.2.2 *Developing the research question*

The review of the evidence was conducted in three distinct ways:

1. Prominent legal cases pertinent to the development of the legal doctrine of informed consent in the UK were identified from discussion with academic lawyers. Reviews of these cases and their implications were followed up in legal journals using LexisNexis (241).
2. A review of journal articles in PubMed and MEDLINE through the National Center for Biotechnology Information (NCBI) at the U.S. National Library of Medicine (NLM). Search terms were: shared decision making; informed consent; patient autonomy; hip arthroplasty
3. References for other articles and books were followed up from the citations quoted in the articles found through the search in 2.

Through this rigorous process it was established that there was no agreement of what informed consent encompassed in terms of legal, ethical and medical perspective. Some research had been done in various specialities to establish that current practice was not ideally meeting patient expectations, although none had interviewed patients and consultants on the topic of informed consent. Some had used questionnaires but these can be restrictive in not allowing free responses, only responses to fixed questions. A patient decision aid has been developed for patients considering knee replacement surgery (242) and has been considered for hip replacement surgery (14), but as Adam's article points out there has been little published evidence on shared decision making or patient decision aids in orthopaedic surgery.

Apart from some of the theoretical papers exploring the issues of informed consent and shared decision making (10-12) there has been little research comparing the implementation of the two paradigms.

For these reasons the research questions were very much focused on patient experiences as well as surgeon views on informed consent and processes within the hospital pathway that might facilitate or create a barrier to taking informed consent.

The research questions to be considered by this study were:

1 "How and when do patients about to undergo unilateral hip replacement for osteoarthritis gather and interpret information to make a decision about surgery?"

2 "What factors influence patients when considering consent to the operation?"

3 "What factors influence surgeons when obtaining consent from patients for the operation?"

Objectives used to achieve these aims included:

1. Audio-recorded and transcribed individual in-depth interviews with patients before and 3 months after surgery
2. Audio-recorded and transcribed focus groups with patients approximately 6 months after surgery
3. Audio-recorded and transcribed in-depth interviews with consultant orthopaedic surgeons regularly taking consent for this operation.
4. Collection of Patient Reported Outcome Measure (PROM) data before and after surgery.

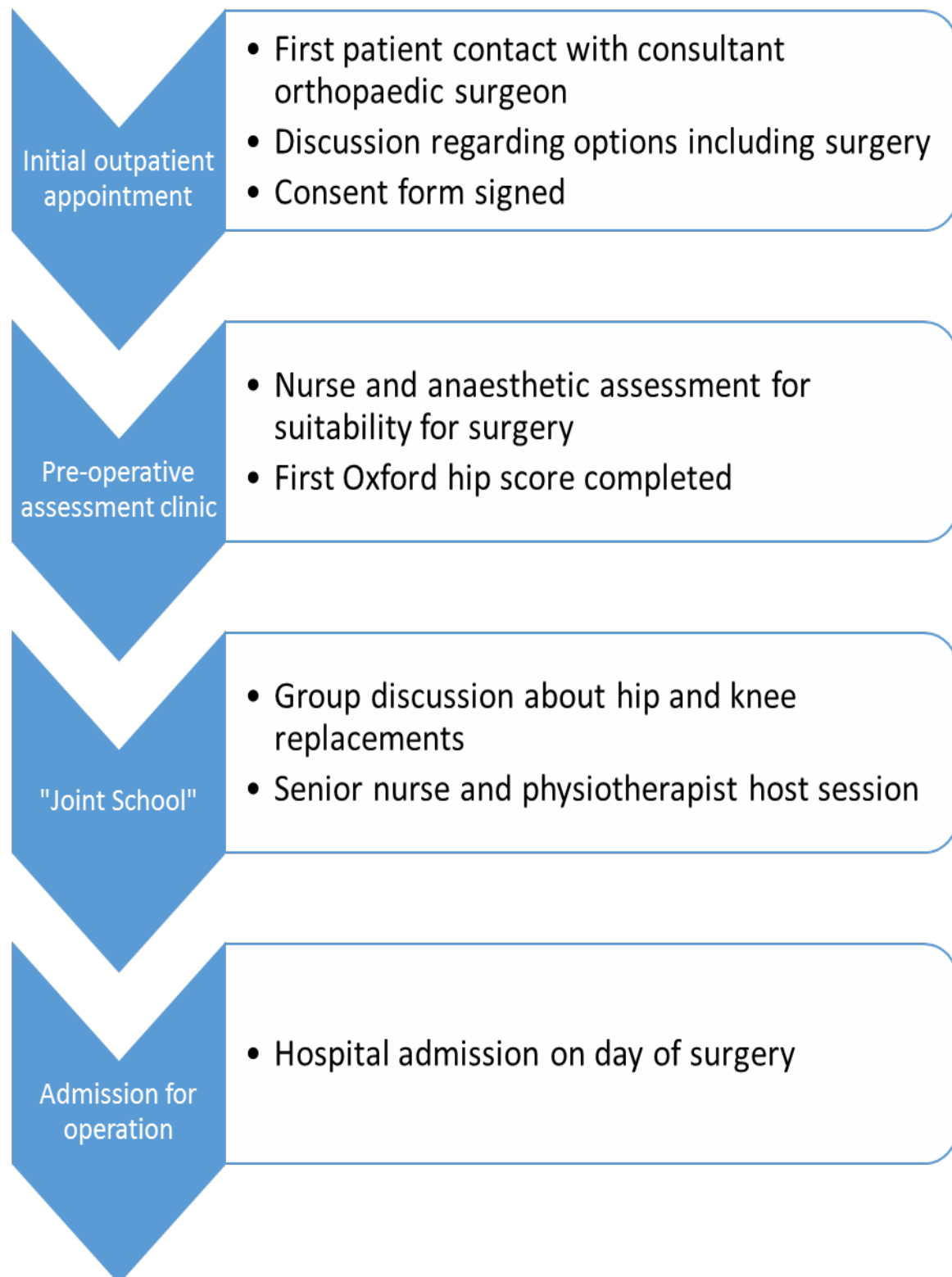
### 4.3.3 The hospital process

In order to better understand the experiences of patients and opinions of surgeons it is important to be aware of the structure of the hospital process. An elective operative procedure has an inherent lag time within the process from first hospital contact to the operating theatre to ensure the patient is fit for surgery; this process allowed time for patient recruitment, interview and collection of hospital PROMs data during the study.

Figure 3 outlines the hospital process for patients undergoing unilateral hip arthroplasty. This process has a number of advantages for this research project, namely:

- There was time to identify potential participants and recruit them before surgery
- There were several patient contacts with hospital services prior to surgery to allow information gathering by the patient
- There was time for patients to seek their own information, if they wanted to, prior to surgery
- Interviews could be planned after all hospital contacts but prior to admission for surgery
- There was time to collect PROMS data from hospital visits to inform interviews
- There was a long recovery time after surgery with multi-agency involvement ( Orthopaedic surgeon, physiotherapist, district nurse, occupational therapist, general practitioner)

Figure 3 Pre-operative hospital pathway



#### 4.3.4 Regulatory issues

##### 4.3.4.1 Ethics Approval

Data collection would involve interviews with NHS patients and staff, therefore, research ethics approval was required before recruitment of participants could commence. This was initially sought for the patient in-depth interviews before and after surgery from South Yorkshire Research Ethics Committee (SYREC). Ethics approval was received on 04/03/2010. Application for the patient focus groups and consultant surgeon interviews was sought as a minor amendment to the protocol to allow me to supervise a BMedSci medical student in research development and data collection. The amendment was approved by SYREC on 09/08/2011.

##### 4.3.4.2 Research Governance

Recruitment of patients and surgeons was going to take place from the Northern General Hospital, Sheffield; part of Sheffield Teaching Hospitals NHS Foundation Trust. Approval was also required from the Research and Development Department of the Trust as well as Governance approval and the granting of a research passport to access data from the trust.

Approval for the original proposal and protocol, as well as the subsequent amendment, was granted from the Research and Development and Governance departments of the trust. I was granted a research passport initially for one year which was subsequently extended for a further year until data collection was complete. My supervised medical student did not require a research passport as they were already based at The Northern General Hospital and as a medical student had implied access to patients and doctors as part of their course.

##### 4.3.4.3 Funding

This study was funded through two sources. The study itself was funded by a research grant from The Royal College of General Practitioners Scientific Foundation Board, Grant Number SFB-2010-05 and AB received a personal grant from The National Institute of Health Research through its In-practice Fellowship scheme for two years to conduct the research and develop further research interests; grant number IAT I-PF 010 003.

##### 4.3.4.4 Oxford Hip score Licence

This study involved the use of the Oxford Hip Score PROM which is validated for monitoring the outcomes of hip surgery on a department wide basis. My use of the PROM was at an individual level which was neither validated nor approved. As this was an unlicensed use of the data collection technique I had to request a licence from the Oxford Hip Score licence holders (Iis Innovation Ltd) for my specific project and to gain approval for my administering the tool prior to the second interview to help inform that interview. The licence was duly granted to The University of Sheffield on 10<sup>th</sup> February 2011 to permit data collection for triangulation purposes (see appendix 2).

#### 4.3.5 Study Design

##### 4.3.5.1 Qualitative Methods

As an exploratory process of patient and surgeon experiences and expectations a qualitative research technique was considered most appropriate. Previous studies had used questionnaires to elicit responses from patients in relation to their experiences of informed consent (182, 243). Other research has explored patient experiences and expectations when compared with what surgeons considered patients needed to know (183) and revealed a significant mismatch. For the aims of this study a quantitative analysis was considered to be too restrictive in allowing patients and surgeons to express opinions.

This study proposed to explore patient expectations and experiences prior to surgery as well as interviewing the same patients after surgery to identify if their needs had been met in relation to informed consent. These patients were selected from the list of one orthopaedic surgeon to ensure they experienced a similar process of informed consent. Further work used focus groups to explore patient experiences of informed consent from different orthopaedic surgeons and interviews with the consultant orthopaedic surgeons themselves to explore factors that might influence the informed consent process. Findings from patient interviews and focus groups would be compared with surgeon opinions and practices in consent-taking and what influences their practice.

#### *Data collection techniques*

##### 1. Patient In-depth interviews

This form of data collection was chosen to explore individual experiences of information gathering and consent giving in a series of patients undergoing unilateral hip replacement. Interviews were conducted just prior to surgery and again three months after the operation. Patients were recruited from the list of a single consultant orthopaedic surgeon to ensure conformity of consenting techniques but different patient values.

##### 2. Patient Focus Groups

This data collection technique was chosen for a group of patients who had had unilateral hip arthroplasty within the previous 6 months by different surgeons. The opportunity to discuss experiences in a group setting has been shown to enhance understanding of situations by exploring different experiences. For this reason patients were recruited from the lists of different consultants as consenting techniques were known to be different.

##### 3. Consultant surgeon In-depth interviews.

This method of qualitative technique was chosen partly through practicality (it was difficult to get surgeons together for focus groups) and partly because individual interviews would allow surgeons to express their own ideas and expectations without any perceived pressure from their peers.

#### *4.3.5.2 Quantitative methods*

The Oxford Hip Score is recognised as a validated tool to use in research settings to assess outcomes at orthopaedic department level. Although it is not validated to assess outcomes at an individual patient level the results can provide information to inform patient discussion and be used to triangulate qualitative data. It was, therefore, proposed to collect individual Oxford Hip Scores from the pre-operative assessment clinic and again at the post-operative patient interview for those patients participating in the in-depth interviews.

#### 4.3.6 Research Tools

##### *4.3.6.1 Interview Guides*

Once data collection by in-depth interviews and focus groups had been decided upon, it was important to ensure that certain significant topics were covered in all contexts. Whilst in-depth interviews do allow researchers to explore many issues and patients to talk freely about their experiences and expectations the literature review helped to identify key topics of importance. These were developed into topic guides to ensure that these key areas were covered in all contacts with patients, and corresponding topics were covered in interviews with the consultant orthopaedic surgeons. Separate topic guides were developed for the pre-and post-operative interviews to reflect the fact that some topics were important to follow up whilst new topic areas became relevant post-operatively. These were developed by AB and NM with reference to the literature whilst the

interview guides for the patient focus groups and consultant surgeons were developed by AB, AW and NM.

#### *4.3.6.2 Patient Reported Outcome Measures*

One of the important aspects of qualitative research is trying to triangulate data, using different sources of information, to confirm information provided at interview. In order to triangulate data on patient quality of life it was proposed that quantitative data from the Patient Reported Outcome Measure (PROM), the Oxford Hip Score (210) could be collected in patients being interviewed before and after their operation. This would provide more data on the patient's opinion of their quality of life before and after the operation, and help to inform discussion at the second interview.

The Oxford Hip Score is a validated 12 question PROM designed to evaluate patient quality of life relating to hip symptoms only. Each question has five responses with an original score ranging from no interference with activities (score 1) to most severe disruption of activities (score 5). Each question gives a score range from 1-5 and an overall score of 12 (no interference with any activities) to 60 (most interference with activities). This scoring system was considered to be counter intuitive(212) so after several suggestions each question is scored 0 (most disabled) to 4 (least disabled). The overall score is now reversed so that a score of 0 is the most disabled whilst a score of 48 is least disabled. The authors make it clear that when using the tool the method of scoring is made obvious. In terms of this study the scoring system was used whereby 0 was the most disabled score and 48 the least disabled.

Oxford Hip Scores are routinely collected pre-operatively by the hospital performing the operation and post-operatively by The Health and Social Care Information Centre (244). Pre-operative data could be collected directly from the hospital as long as the patient consented to this data-sharing. Post-operative data collection was more difficult as timing was important to inform the interview and accessing or retrieving centralised data could prove difficult.

The other concern was using these scores for non-validated purposes. The Oxford Hip Score has been evaluated and validated to compare departmental outcomes from surgical intervention of hip arthroplasty (210). My proposal was to use this data to compare with qualitative data on quality of life in individual patients before and after surgery. I was not going to compare pre- and post-operative values to assess surgical outcome, which is in accordance with the licence granted.

### 4.3.7 Recruitment methods

#### 4.3.7.1 Patients for In-depth interviews

Certain basic criteria were important to include or exclude to ensure maximum diversity of patient opinion whilst maintaining a single standard of hospital experience. These criteria are highlighted in the table below.

Table 6 Patient Inclusion/Exclusion criteria.

Inclusion criteria:	Exclusion criteria:
Osteoarthritis	Inflammatory joint disease
Consideration for unilateral hip replacement by general practitioner.	Consideration for bilateral hip replacement
Allocated to the list of a single consultant orthopaedic surgeon	Trauma related surgery
Age >40	Need for an interpreter
English spoken without need for interpreter	Other chronic debilitating disease

It was proposed that recruitment for this section of the study should be from the waiting list of one orthopaedic surgeon at one NHS hospital site. This method was chosen to ensure that patients experienced uniformity in hospital contact and experience of consenting techniques as practices vary between surgeons and hospitals. Patients were identified by the surgeon's secretary as having been referred for consideration of unilateral hip arthroplasty for osteoarthritis. The patient had seen the consultant orthopaedic surgeon and recommendation to proceed to hip replacement had been documented.

Invitations and patient information leaflets were posted out by the secretary with replies directed to myself. If patients wished to be included in the study a preferred method of contact was requested. Patients were then contacted by me to arrange a first appointment for consent to participate in the study and interview prior to surgery.

Patients identified as willing to participate in the interview process were contacted by their preferred method. In practice this was either by telephone or e-mail. Patients were asked when their initial outpatient appointment had been and when their pre-operative assessment clinic appointment and "Joint School" appointments were. Initial face-to-face contact was arranged for the

time between “Joint School” and the operation as this was when all pre-operative contact with the hospital had been completed.

At the initial interview the patient’s eligibility for inclusion in the trial was confirmed and the patient was again given the patient information leaflet to read and a consent form to view. The main aims of the trial were discussed and patients asked if I could obtain a copy of their first Oxford Hip Score from the hospital. The right to withdraw from the study at any time without affecting their care was emphasised. Contact details, if they had any concerns with the study, were also highlighted. Even if patients did not proceed to surgery it was explained that their views were equally as important. Patients in this group were informed that a post-operative interview would be organised approximately three months after surgery.

The patients were then asked to sign the consent form and the first interview commenced.

Post-operatively patients were contacted approximately two months after surgery to arrange an appointment for the second interview within one month and a patient information leaflet was sent to patients again to remind them of the aims of the study. The second interview was arranged at a convenient site and time for the patient. The information leaflet was again reviewed and if the participants were willing to proceed to interview consent was considered to be covered by the original consent form. The second interview then commenced.

#### *4.3.7.2 Patients for focus groups*

In order to obtain the most information from a focus group, diversity of experience and opinion is important. Therefore, for this element of the project patient recruitment was based on patients having different experiences of the consent process. Patients were recruited from the NHS lists of two orthopaedic surgeons who were known to have differing consent techniques and who had not been included in the interview element of the study. As patients were to discuss their experiences of IC and hospital process it was proposed that patients should have had unilateral hip replacement for osteoarthritis within 6 months prior to being approached. This was considered an appropriate timescale to allow patients to have recovered but retain information about their experiences.

A suitable list of candidates was drawn up from the list of two orthopaedic consultant surgeons at the Northern General Hospital, Sheffield and invitations sent out by their respective secretaries. Replies were returned to AB and AW. If patients wished to be included in the study a preferred method of contact was requested. Patients were then contacted to arrange attendance at one of two focus groups arranged at Samuel Fox House in the grounds of the Northern General Hospital. This was considered an appropriate venue as the site was familiar to all patients but the venue was away from the orthopaedic department to highlight that we were independent from that department.

Patients identified as willing to participate in the interview process were contacted by their preferred method. In practice this was either by telephone or e-mail. Patients were sent an information leaflet about the study explaining the aims of the study and participation in a focus group. Patients were invited to attend one of two focus groups that would be jointly chaired by AB and AW.

When patients attended for the focus group they were again presented with a patient information leaflet to read and a consent form. The opportunity to withdraw consent at any time was highlighted as were the contact details if participants wished to complain. If the patient was willing to take part in the focus group they were asked to sign the consent form.



#### *4.3.7.3 Orthopaedic Surgeons for In-depth interviews*

Orthopaedic surgeons from the Northern General Hospital Orthopaedic Department who regularly take consent and perform hip arthroplasty were approached to take part in individual interviews. Seven surgeons were identified as potential participants in this element of the study. An initial proposition of a single focus group proved unsuccessful due to time constraints on consultant time; therefore an individual interview approach was adopted. Consultant surgeons were approached directly and by invitation through their NHS secretary to participate in the interviews.

The surgeons were initially contacted through their NHS secretaries about the study and a surgeon information sheet was sent to all seven surgeons. The surgeons who were interested in participating were initially contacted to identify a possible time of week for convening a focus group.

Unfortunately, due to surgical commitments no time of week suited all surgeons. It was therefore decided to offer individual in-depth interviews at a time convenient to each surgeon.

Appointments were arranged with each surgeon, an information leaflet was again available for them to read and a consent form presented. If the surgeon was willing to continue with the interview they were asked to sign the consent form before data collection began.

#### 4.3.8 Data collection

Sixteen patients were recruited for the “before and after” surgery interview, resulting in a total of thirty-two interviews. Each interview lasted between 30-45 minutes. Eight patients were recruited to the focus groups, resulting in two focus groups of four patients each being convened. Four consultant orthopaedic surgeons who regularly obtained consent for hip arthroplasty were interviewed.

All individual interviews with the patients and consultants were audio recorded digitally and stored as MP 3 files. Both focus groups were audio recorded digitally and again stored as MP 3 files. All files were stored securely on password-protected University of Sheffield servers.

The pre-operative Oxford Hip Scores for the patients being interviewed were collected from the Northern General pre-operative assessment clinic. Post-operative Hip Scores were collected by AB at the start of the second interview, with data from both helping to inform patient assessed progress following the operation.

#### 4.3.9 Data analysis

##### *4.3.9.1 Qualitative*

Qualitative data collected from three sources; patient before and after surgery interviews, patient focus groups and surgeon interviews, were audio recorded and transcribed verbatim.

As in the T2DM study (section 4.2.8.1) some a priori themes were identified as important to the overall thesis aims and, therefore, Framework analysis was again considered the most appropriate form of data analysis. Once more the analysis followed the same five processes described in section 3.8.2.

The before and after surgery patient interviews were analysed initially considering the aims of the individual study and the overarching theme of “how patients make healthcare decisions”. If new themes emerged from the analysis, previous interviews were re-considered in light of these new findings.

The focus groups were analysed along the themes generated from the individual interviews but, because patients had experienced different consenting processes, data from the focus groups was used to inform the final study themes and thesis meta-themes.

Orthopaedic surgeon interviews had different a priori themes, particularly in relation to consenting techniques and opinions about informed consent. However, it was possible to review comparable themes from patient and surgeon perspectives to generate overall themes for the study and group these under the thesis meta-themes.

Quality assurance of the transcription analysis and grouping of themes under the meta-themes was again achieved by reviewing a patient and surgeon transcription with two separate colleagues (LW and HT) in the research department who were experienced in qualitative data analysis.

#### *4.3.9.2 Quantitative data*

This was collected in the form of Oxford hip scores for patients in the interview group. Pre-operative scores were obtained from the pre-operative clinic prior to the first interview and were used to inform discussion about quality of life prior to surgery.

Post-operative scores were collected by AB at the start of the post-operative interview, three months after surgery. The score was then compared with the individual pre-operative score and used to inform discussion at the second interview. Recovery from surgery and change in quality of life were considered important variables that might influence patient perception of the consent process.

#### 4.3.10 Ethical considerations

Participant perception of the researcher was again considered an important factor. In terms of patient interviews and focus groups it was important that participants were aware of my professional role as a GP, but, although part of the medical profession, I was not linked to the orthopaedic department where they had their surgery. It is important patients have confidence in who is interviewing them but, to ensure they considered they could talk openly, it was essential that they were confident individually identifiable comments would not be fed back to the department.

Orthopaedic consultant interviews created a conflict of interest for the researcher as he knew some of them socially. This conflict was overcome by the interviews being conducted by AW a BMedSci student attached to the project. AB was involved at all stages of development and analysis but did not conduct the interviews.

Confidentiality and anonymity were confirmed prior to signing the consent form.

#### Welfare of the researcher

Patient interviews were conducted in the patient's home apart from one post-operative interview conducted at the patient's place of work. A colleague at the AUPMC was informed of the timing and venue of the interview and the expected time back at the department to ensure any concerns were followed up. The focus groups were based in the AUPMC and surgeon interviews occurred in the orthopaedic department, although AW informed AB of date, time and duration of these interview.

#### Data storage

Data consisted of paper copies of patient and surgeon identifiable data such as consent forms and Oxford hip scores, and electronic data such as audio recordings and transcriptions. All paper information was stored in locked cabinets in a locked room on University of Sheffield premises. Only

AB had direct access to this data. Anonymised electronic data was stored on password protected University of Sheffield fileservers.

#### Transcriber confidentiality agreements

All transcriptions were done by a third party with a confidentiality agreement between the transcriber and the AUPMC. All anonymised transcriptions were remotely transferred to the University fileserver from a secure website.

#### Payment of participants

All patient participants received £15 in gift vouchers for their time. Travel expenses were provided to patients attending the focus groups. Surgeons received no financial incentives to participate.

#### 4.3.11 Research bias

This is discussed to identify areas where bias was assessed and limited, whilst recognising it is not possible to eliminate all elements of influence on the study.

##### *4.3.11.1 Pre-trial bias*

Development of the interview guides were based on the literature review, expert experience and some a priori themes that were relevant to the research question. Although themes were slightly different for patients and surgeons the guides were developed simultaneously to ensure important topics would be covered from both viewpoints.

Patient recruitment for interviews was chosen from one surgeon's list. A continuous series of patients were invited until data analysis showed theme saturation. It was expected that 10-20 patients would be required. In reality sixteen patients were required from a consecutive series of thirty-four patients. Surgeon selection was much more restricted from one site. Seven surgeons were identified as suitable, although only four agreed to participate. Although this is a small sample size the results indicate a broad spectrum of consenting techniques and opinions, fulfilling the diversity of qualitative data collection.

##### *4.3.11.2 Bias during the trial*

Patient interviews were conducted solely by AB. This can have the advantage of uniformity of enquiry and recollection of pre-surgery interviews at the post-operative interviews. However, this can also lead to bias so AB has discussed his background and motivations for conducting the research. AB made clear to all participants his medical background and independence from the orthopaedic department. It was also made clear that information would be anonymised and identifiable data would not be published at any time.

It was noted that patients for the focus-groups were younger than interview participants and it was recognised that this may be due to ability and willingness to travel, which may have limited patient recruitment.

AB knew many of the orthopaedic surgeons socially so it was considered inappropriate for him to interview them. AW, therefore conducted the interviews. AW was a research medical student and this would have created power imbalance in the interviews but this was considered less influential than ABs involvement.

Recall bias for patients was addressed during the interviews and focus groups by different means. At the second interview patients were reminded of our discussion at the first interview and their pre-

operative Oxford Hip scores, before outlining the scope of the second interview. This was to assist recollection of events several months previously. Patients selected for the focus groups were included if they had had surgery within six months. This was to allow time for recovery but still time to recollect events from pre-operative hospital contacts.

#### *4.3.11.3 Bias after the trial*

By discussing methods for reviewing literature and drawing from backgrounds of medicine, law and ethics the researcher has tried to show rigour at all stages of the study. Data analysis was conducted by AB and reviewed by AW. A random selection of interviews and focus group data were also reviewed by two independent researchers in the department and the framework for analysis reviewed. Preliminary data has been reviewed by NM and presented at research conferences for critical feedback.

## 4.4 Summary of Chapter

Two different studies have been discussed here to explore issues around SDM and IC in different settings. It has been identified earlier that consideration of SDM and IC can be concordant in situations of elective surgery. These studies were, therefore, conducted to explore separately the issues of SDM with the use of a patient decision aid and IC in an elective surgical setting. By exploring these two paradigms in relation to “how patients make healthcare decisions” it is apparent from the literature review that it is appropriate to then compare outcomes from both studies.

By analysing the data from both studies under the four meta-themes relating to how patients make healthcare decisions, it is possible to compare results and synthesize a model for how each paradigm may be implemented by reference to the other. The four meta-themes relating to how patients make healthcare decisions are:

1. doctor-patient interactions
2. how the presentation of information can influence decisions
3. external factors that might influence decision making such as family or friendship influence on patients or hospital policy on the doctor
4. the concepts and tools of Shared Decision Making

The results from the two studies will be shown separately in the next section but will then be compared under the meta-themes.

## Chapter 5: Results Section

### 5.1 Overview of this section

The results from each of the studies will be presented separately as participant characteristics and quotes will be relevant to each project and its individual aims and objectives. The themes presented have been developed from the audio-recorded interviews and consultations. Further results from the quantitative tools will be described to illustrate and triangulate the qualitative data analysis. Evidence was also provided from contemporaneous field notes.

Quotations to illustrate points will be pertinent to the individual project but also the comparison of the paradigms of Shared Decision Making and Informed Consent. Themes relevant to each project will be presented separately but will also be shown in the results synthesis with reference to the overarching theme of “How patients make healthcare decisions” and the subsequent meta-themes, namely:

1. doctor-patient interactions
2. how the presentation of information can influence decisions
3. external factors that might influence decision making
4. the concepts and tools of Shared Decision Making

The results for each study are presented in the format of:

Participant characteristics

Quantitative data results

Qualitative data results.

The process of how qualitative and quantitative data informed the analysis and subsequent conceptual framework is discussed in the next chapter.

## 5.2 Study 1. Primary Care: Evaluating the use of a Patient Decision Aid (PDA) in patients with T2DM considering insulin in a primary care setting.

### 5.2.1 Participant Characteristics

This project, embedded within the PANDAs main study, purposively recruited eight patients who had used the PANDAs Decision Aid and their corresponding health care professionals. Eight patients were approached and they all agreed to participate. The patient characteristics are summarised in table 7 and the corresponding HCP characteristics are outlined in table 8.

*Table 7 PANDAs patient participant characteristics*

Patient	Gender	Age (years)	Education (years)	Control preference (Pre-consultation)
A	f	72	11	collaborative
B	f	59	13	collaborative
C	m	81	9	autonomous
D	m	70	28	autonomous
E	m	66	11	passive
F	m	62	16	autonomous
G	m	73	10	passive
H	m	39	17	collaborative

*Table 8 PANDAs HCP participant details*

HCP	Occupation	Sex
1	Practice Nurse	F
2	GP	F
3	Practice Nurse	F
4	Practice Nurse	F
5	GP	F

Table 9 PANDAs Patient–HCP dyads

Patient	HCP
A	PN (HCP 1)
B	GP (HCP 2)
C	GP (HCP 2)
D	PN (HCP 3)
E	PN (HCP 3)
F	PN (HCP 4)
G	PN (HCP 4)
H	GP (HCP 5)

Patient recruitment reflected both male and female participants as well as a broad spectrum in terms of age, years of education and decision-making preference in relation to choices about the management of T2DM. Consultation dyads were a majority of patient-practice nurse encounters with a minority being patient-general practitioner encounters. This broadly reflects the management of chronic diseases in NHS primary care settings at the current time, particularly the management of T2DM.

### 5.2.2 Quantitative data results

The OPTIONs scores presented below indicate the researcher-assessed skill with which the health care professional enabled the patient to become involved in the decision about management of their T2DM. The scores reflect the skill and focus of the HCP in involving the patient in the decision-making process rather than the extent to which the patient became involved in the decision, as this latter aspect more reflects the control preference expressed by the patient. All scores are an overall score and represent the consensus of the two reviewers AB and IB.

Table 10 *OPTIONs scores for consultations*

Patient	Clinician	Consultation length (minutes)	OPTION score (Maximum 48)
A	PN	20	31
B	GP	13	15
C	GP	4	10
D	PN	17	30
E	PN	17	27
F	PN	29	28
G	PN	16	34
H	GP	7	15

**Notes:** PN = Practice Nurse, GP = General Practitioner; OPTION (Observing Patient Involvement) score based on a 12 item measure (see Appendix 1), scores range from 0 to 48, higher scores indicate greater skill at involving patient in decision making.

### 5.2.3 Qualitative results

Qualitative data sources included patient and HCP transcribed interviews, transcriptions of the corresponding consultation and field notes collected by the researcher. Analysis of these data sources revealed several main themes with a number of sub-themes relevant to that main theme.

These main themes and sub-themes for the individual study are presented in the table below.



*Table 11 Themes developed from Individual In-depth interviews with patients and health care professionals from study 1 on T2DM*

Main Theme	Sub-theme
Factors influenced by the Decision Aid	Clarification of treatment choices
	Patient education
	Influence on the decision
Health care professional factors	Time factor
Outcomes	Decisional conflict
	Knowledge
Patient factors	Locus of control
	Pre-conceived ideas
	Pre-expressed decision
	Risk perception

These themes were then considered in relation to “How patients make healthcare decisions” and the four meta-themes identified at the start of this chapter. By analysing the data under these meta-themes it was then possible to compare qualitative results from the two studies. The table below shows how the sub-themes from the T2DM study map onto the overarching theme and meta-themes of the thesis. Some sub-themes are relevant to more than one meta-theme.

Table 12 Mapping of study sub-themes to overarching theme and meta-themes

Overarching theme and meta-themes	Sub-theme from T2DM study
How patients make healthcare decisions	Decisional conflict
	Knowledge
	Locus of control
	Pre-conceived ideas
	Pre-expressed decision
	Risk perception
Doctor-patient interactions	Pre-conceived ideas
	Time factors
How the presentation of information can influence decision making	Clarification of treatment choices
	Patient education
	Influence of the Decision Aid on the decision
External factors that might influence the decision	Influence on the decision
The concepts and tools of Shared Decision Making	Clarification of treatment choices
	Patient education
	Influence of the Decision Aid on the decision

#### 5.2.4 Qualitative results in relation to the meta-themes

The results are considered in relation to “How patients make healthcare decisions” and are then presented in relation to the meta-themes pertaining to this.

##### 5.2.4.1 Overarching theme: How patients make healthcare decisions

Several patient themes were relevant to how patients make healthcare decisions ranging from their knowledge and pre-conceived ideas prior to the consent process, locus of control in terms of how they like to make decisions relating to decisions about insulin therapy and their perception of risk. From table 12 these headings are in order.

## **Study themes:**

### Decisional conflict:

There is a decisional conflict scale (78) that can be calculated from patient responses to pre-defined questions. The scale assesses to what extent a patient feels uncertain about the decision they have made. This information is also expressed by patients as emotional feelings:

HCP

*"At the end of the day the decision is yours."*

Patient

*"I know it is but I don't want to be foolish."*(Patient E consultation)

The conflict may also be characterised by a third party conflict:

*"That's the other drugs I'm on. Dearie me. Erm. I must, should be on insulin. There's a little voice in the back of my head going yeah, so."* (Patient F)

However, the conflict sometimes arises not through the decision itself but through the consequences of trying to implement that decision. Patients seem well aware of their choices and benefits of each but are concerned about implementing them, either through injecting themselves if they choose insulin or having to be more careful with diet and increasing exercise if they choose this option:

HCP

*"...we trying to reduce the risk of other problems happening, because you know, you're more at risk of developing heart problems, eye sight problems, urine problems, feet problems, circulation. So by thinking about having insulin, you would reduce the sugar level."*

Patient

*"Yeah I think best you can do is I'm not keen on insulin idea."* (Patient G consultation)

*"I've got no problems with having to make decisions on my lifestyle. The biggest problem I've got is getting into the habit of doing it! Two different things. Decisions – easy, getting into a habit is harder still, but that's why Nurse C is fetching my wife in to, sort of, change habits. And I've got a friend involved with swimming, who's ten year younger than me, so I've got somebody there who's helping me with that side, I've got support from other people and it does help, you can have your own mindset but it's going from saying 'yes I'll do that', to doing that."* (Patient E)

Patients therefore seem to understand healthcare consequences of their decisions but are concerned about effort and changes they will have to implement to achieve this success.

### Knowledge

Improving knowledge and understanding of the causes of high blood sugar, the complications of T2DM and the implications of treatment was recognised by both patients and HCPs as important factors in how patients make healthcare decisions.

i) The causes of high blood sugar:

*“Yeah, it’s (the PDA) made me understand I’ve got to stick to my diet a little bit better than what I have been doing. Well when it was telling me about my sugar levels going up and up and it’s me that’s inducing it, you know, so if I’ve got to watch my diet, it’s me that’s creating it.”* (Patient E)

ii) The complications of T2DM

*“Yeah, well it has (the PDA), it’s given me lots more information...because you don’t realise that you can have as many complications as that, you know. I know they say that it can affect your sight, you know, and that but I didn’t realise it could affect such a lot of other things. So yeah.”* (Patient A consultation)

iii) The implications of treatment

*“Yeah, I didn’t realise the insulin would only bring it down a certain amount, I thought it’d bring it down a lot. But this is first time I’ve know about it but doctor’s informed me since that I will be taking me metformin as well.”* (Patient A consultation)

The HCPs discussed with the patient, during the consultation, where they felt the patient had benefitted from the knowledge-base provided by the decision aid:

HCP

*“Yeah, I mean I think looking at the booklet with you, you clearly understand particularly about using the decision aid and the decision aid has, I think, made you come to a conclusion with the education of starting insulin.”*

Patient

*“Yeah, well it has, it’s given me lots more information.”*

HCP

*“Do you think it’s increased your knowledge a little bit about diabetes?”*

Patient

*“I think it has, yeah.”*

HCP

*“From the complications side of things?”*

Patient

*“It has, yeah, because you don’t realise that you can have as many complications as that, you know. I know they say that it can affect your sight, you know, and that but I didn’t realise it could affect such a lot of other things. So yeah.”* (Patient A consultation)

The HCP also considered that use of a decision aid and a SDM approach also enabled patients to understand decisions that clinicians made rather than being aware of a decision but not understanding why the decision was made:

*“I have to refer you’ and then it’s like they don’t know why and all they know is that we’re referring you. So I think when you use the decision aid I think they actually have much more understanding of why you’re referring them.”* (HCP 2 (patient B))

### Locus of Control

As described earlier we used the control preference scale to identify how the recruited patients like to make health care decisions, however, it was also noted that preference for these decisions is dependent on the perceived seriousness of the decision. During the consultations and interviews patients expressed how they like to be involved in the decision about whether or not to start insulin for T2DM.

Some patients preferred the HCP to be involved in making the decision:

HCP

*“OK, so we’ve definitely come to a decision that we’re going to go ahead with insulin?”*

Patient

*“Yeah, if you think it’s beneficial for me, I’ll take your advice.”* (Patient A consultation)

HCP

*“Yeah, yeah. So your decision today, then, would be...”*

Patient

*“To take your advice and move forward.”* (Patient E consultation)

Some patients were very clear that the advice of the HCP was paramount in influencing their decision and they would follow any advice totally:

*“As I said to the guy in there, I said look, if C said as of today you are taking insulin, like it or lump it, that’s the deal. And I’d be stabbing my leg tonight. And, err, it’s all this sticking your finger to, to see if your what your what your blood’s like. And I’ve got very sensitive fingers.”*  
(Patient F consultation)

Other patients were clearer that the decision was theirs to make and whilst they could accept advice the final decision was up to them:

*“Well their advice basically is to go onto insulin, but the decision is mine and they make this quite clear. Of course, hm, I can’t stand people who try and control me and it’s not on. I listen to advice and I take advice by nature, yeah. But not dictation, dictatorial, I won’t have that. I’ve got to have some input somewhere, even if it’s just reluctantly to say ‘yeah’.”*  
(Patient D)

There were some differences as to whether collaborative advice could come from a decision aid or whether professional advice was more influential:

*“I can make decisions on my own body, but if I got a professional giving me advice and able to answer questions I need to have answered, then that’s great. So no matter what this book says at the end of the day, professional advice is the thing that you really need.”* (Patient E)

Most patients, however, would prefer to follow the advice of the professional even if they consider that they are satisfied with their current diabetes control:

*“Well what I should have done, as you do really, if C or the doctor said ‘we want you to go on insulin’ then I’d do it but I must say, I’m quite happy the way I am.”* (Patient G)

With some patients there is clearly a conflict between how they feel and following what the HCP advises but they would accept that what the HCP advises is in their best interests. However, these results highlight that HCPs need to be aware that some patients will follow advice almost regardless of what they say. Others will listen but not necessarily follow any advice given or advice provided in written information. HCPs also need to be aware that patient’s opinions and decisions are sometimes influenced by factors outside their control.

One concern raised by a patient that affected his trust in the care he received was the use of evidence-based medicine that resulted in continually shifting targets. This patient felt that just as they were achieving a new target the goalposts moved again:

Patient

*“No, this is the point, and so I have a problem with a lot of these manmade figures... because as soon as I achieve them you lower them.”*

Interviewer

*“Keep moving the goalposts.”*

Patient

*“Yeah, you’ve got down to seven, we’re now going to move it to so and so. And they did this with cholesterol and cholesterol is a big annoyance of mine because one of the nurses here gave me a book on cholesterol, it’s a lovely booklet, explaining it in laymen’s terms and everything. And there’s good cholesterol and there’s bad cholesterol, but all they ever tell you is you’ve got a reading of seven, but they don’t tell you four are good and three are bad, or seven are bad, or seven are good...”* (Patient D)

### Pre-conceived ideas

If patients have pre-conceived ideas about treatment options then this may influence the way they make a decision, particularly if some of those ideas are unfounded. Some of the expressed ideas may also reflect a patient's reluctance to take medication or make a change and they express ideas as barriers as to why they don't want to make a change. If these ideas are entrenched and not addressed during a consultation the patient is likely to continue to believe them and this can create barriers to understanding and making an appropriate decision for them.

Some misconceptions may lead to unrealistic goals which would thwart any attempt to improve management of their condition:

*"I would love actually, to get off all tablets. Insulin, everything." (Patient F consultation)*

Other ideas merely create barriers that have to be identified, discussed and if unfounded then identified as so:

*"One is I think if you see people taking insulin, people automatically register 'oh, they're a druggie', that's a big thing because I do go around quite a bit and I'd hate people to think I was a drug addict. Does that sound a bit pompous?" (Patient D consultation)*

These misconceptions can be quite entrenched and, therefore, will require a significant amount of work to dispel such beliefs as this quote from the same patient indicates:

*"Then travelling to different countries, they view medication different ways, there's many people been locked up in prison for months, quite innocent people for carrying aspirins or co-codamol, things like that, I don't want to be among that lot, 'what's that', 'oh I inject myself with it', 'oh yes?! Come along this way," (Patient D)*

Some of the barriers seem specifically designed to counteract the medical advice on the progression of T2DM and the fact that there is an inexorable progression from diet to tablets to insulin:

*"...and the positive side is you're going to reduce my risk by a few points. Mine's genetic, I'm almost certain, my mother in her latter years, they found she was diabetic" (Patient D)*

Some of the opposition to this progression of treatment is even more detached from the health considerations but again, if not identified and managed appropriately could lead to a breakdown in the patient-HCP relationship:

Patient

*"Or is it people going over the top and making a load of money out of it, commercial side."*

Interviewer

*"I see, with the drugs, the insulin..."*

Patient

*"Well not just drugs, you've got your doctors make quite a lot of money out of it, I mean, it can't be ignored, I mean, I have a blood test every three months, they get paid extra for it, don't they. And I'm not saying that sways or doesn't but you have to think of it all, somebody somewhere is making a fortune out of diabetes, they must be, by the number of people on it..."(Patient D)*

Eliciting patients concerns and pre-conceived ideas is vitally important because, whilst using a PDA may improve knowledge and reduce decisional conflict, if there is still a foundation of mistrust then decisions made will not be totally appropriate for that patient.

#### Pre-expressed decision

Having entered the PANDAs trial, patients would clearly have an idea that they were going to be asked about management of their diabetes and consideration of insulin. However, these patients were already known to the HCPs involved in the study and would have expressed some opinion about such a decision prior to the study. The patients were asked about their decision prior to starting the study and the HCPs were asked if patients had expressed any opinion.

The HCPs expressed some general opinions about patients starting insulin:

*“Most patients shy away from insulin. I don't know whether they're perhaps wary of it, frightened of the implications. They would rather take a tablet than have insulin. W never said anything about insulin other than that he wouldn't want to go on it as most patients say that.”* (HCP 4 (patient G))

Whilst some comments were more specific to individual patient opinions and how they sometimes try to avoid the subject:

*“When P actually attends surgery (laughs) consultations, which can be hit and miss, erm, he's not wanted insulin at all, he's not wanted to go down that route, he's always wanted to, I'll try and look at my diet, I'll look at exercise, I'll try and remember my tablets more frequently, that type of scenario.”* (HCP 4 (patient F))

The HCP consideration that most patients wish to avoid insulin is generally correct:

*“Yeah, a couple of times it's been mentioned to me about going on insulin. And I've always feared it, you know, I've feared it.”* (Patient C consultation)

*“Yeah, I'm anti-insulin for all sorts of reasons.”* (Patient D)

But this is not always the case:

Interviewer

*“On a scale of 1 to 10, if you think about how far along in the decision-making process you were before you set eyes on the decision aid.”*

Patient

*“I suppose, erm, I suppose I was always a 10, because of the way I think about things. Y'know, if I, if you today said just finish now here's your first load of insulin, I'd say alright then.”* (Patient F)

It is, therefore, important to elicit patients' pre-expressed decisions prior to consultations about significant health decisions. This is not to try and by-pass important discussions or elements of SDM in these interactions because even if patients are clear already about their decision use of SDM and a PDA can still be beneficial as expressed by this patient:

*“... with the booklet and what I had in my mind at the time, because I was convinced that that's what was going to happen today and I were convinced I were going to stay away with it, but I decided to go onto insulin.”* (Patient C)



### Risk Perception

The perception of risk and what that means to a patient is important for them to inform their decision. One of the purposes of a decision aid is to enhance patient understanding of risk, consequently leading to a more informed decision that is more aligned with patient values. However, the interviews from this study indicate that patients rarely understand risk, or question the validity of the evidence. HCPs also recognise that patients rarely comprehend risks.

HCP

*“And obviously this has given you something to think about.”*

Patient

*“It doesn’t do a lot for me actually.”*

HCP

*“It doesn’t do a lot for you?”*

Patient

*“No. I mean the difference between 22 and 29”*

HCP

*“But think about – yeah, but if you were one of those three it would be a big difference.”*

Patient

*“Yeah, but one of those three could be run over by a bus. I mean that’s what life’s all about. These are probabilities, you know.” (Patient D consultation)*

HCPs consider, as a professional, they are more aware of what risk means but consider presenting figures to patients may encourage them to focus on the wrong values.

*“I don't think that actually gives them the, doesn't scare them enough I don't mean, I don't particularly want to scare them but if they're HA1C is between 7 and 7.9, 29 people get complications, 71 don't. To the patient that, they will pick up on the 71 don't. Rather than 29 do. Yes it's very difficult to get across to patients what risk is. Whereas if you're professional you look at it and go actually that's quite high.” (HCP 4 (patient G))*

Sometimes patients do require more explanation than is provided in the PDA. This would be provided by discussion with an informed HCP and once that has taken place the patient can better understand the risks.

Patient

*“Well they gave you a percentage of what your blood sugar is. How do they work it out? I mean 17% are going to get complications and 82% don’t get it. How can they say that really?”*

HCP

*“Well the information that’s in the booklet is information that has been put together from lots of other research that has been done. So all of these figures would have been found out*

*from researching people that have got Type 2 diabetes like you have and if you follow these people over a long period of time you can find out what complications they've got or, you know, look at information in hospitals. So that's how they would have got all that information."*

Patient

*"Ah, I'm with you now."* (Patient G consultation)

This last exchange highlights the importance of a complex intervention; the delivery of the PDA and the interaction between patient and professional all combine to create an environment for greater patient involvement in the decision-making process.

#### 5.2.4.2 Meta-theme 1: Doctor-Patient Interactions

##### Time factors

As identified in the previous section the interaction between patient and HCP can be vitally important in aiding the patient understanding of information provided. This relationship has also been shown to have significant impact on some of the decisions patients make; some patients considering they have to follow the advice given, even if they would prefer to make a different choice.

Time constraints are obviously an issue that can impact upon consultation styles and techniques, affecting the interaction between patient and HCP. The HCPs generally felt that consultations with the patient took longer when using a decision aid, but considered this beneficial overall to the interaction. Such longer interactions could reduce consultation frequency if patients were more satisfied with their discussion using a PDA.

*"I think they need to take longer if you're using the decision aid.*

Interviewer

*Right. And is that worth it?*

HCP

*Yes, because I think the education that comes out of the decision aid is better."* (HCP 1 (patient A))

*"Yeah, I mean quite – I think the patients really appreciated the time that was spent with them and I think certainly for the patients I saw, they were really, you know, they found it very interesting..."* (HCP 2 (patient B))

The HCPs considered the use of PDAs in primary care as beneficial to onward care at the hospital and to answer questions at home. One HCP considered the lack of patient engagement if a patient was referred to the hospital and how improved engagement in primary care could negate this:

*"I don't think that's too much time. I think that takes the time it takes because it's such a big decision for people and they may not have that time when they get to the hospital appointments so I think that's where it works very well."* (HCP 2 (patient B))

Another HCP thought that use of a SDM approach and a PDA would result in better educated patients that would require less HCP involvement:

*“Yes, because I think the education that comes out of the decision aid is better. Because I think the patients can then refer to the booklets, maybe ask some of their own questions or refresh their memory, which then probably prevents them from coming to the surgery, taking a 10 minute appointment when they want a quick answer.” (HCP 1 (patient A))*

The overall consensus of HCPs was that extra time with the patient was worthwhile when using a PDA as it enhanced patient understanding through the interaction and this might reduce the need for frequent interactions as patients were more satisfied with their consultation.

#### 5.2.4.3 Meta-theme 2: How the presentation of information can influence decision-making

##### Clarification of treatment choices

Several patients enrolled in the Process Evaluation were known to the HCPs on a regular basis for management of their diabetes and the HCPs in these consultations mentioned that they had discussed with these patients about starting insulin in previous consultations. However, the interviews with patients and HCPs identified that the use of a PDA did help to clarify the treatment options available and that the use of numbers did have some impact with patients.

These two excerpts identify not only that matched patient-HCP dyads recognise the usefulness of presenting risk to clarify options, but also the fact that some patients do find the representation of numbers helpful:

*“But I think they’re really good at showing, you know, if it’s this then this is the number, if it’s this then this is the number. I think that very clearly shows what the benefits are of going on insulin” (HCP 2 (patient B))*

*“And then you read it again, and all of a sudden if you take insulin and you think, God, that’s a big drop, when you read ... 7.6 to 5.6. That would put me at somewhere normal. ... And then your diabetic symptoms will improve and you think, and you look at the figures below and you think, that’s a big drop.” (Patient B)*

Sometimes, by clarifying the options, the use of a PDA empowers the patient to approach the HCP about trying alternative treatments if they consider they have not fully explored all possibilities:

*“Well I did think about asking if there were anything I could do rather than go, you know, straight onto insulin and it does give you your options in here, to like stay as you are or try and see if there was some more treatment that you can have, just something with your diet or, it gives you the options in this booklet, yeah”. (Patient A)*

The other clarification that the use of a PDA can bring is to some of the misconceptions patients have:

Patient

*“You see I didn’t know whether if I went on insulin I’d stop the tablets but I don’t do I?” (Patient A consultation)*

*“I think it clarifies the fact that they take insulin as well as tablets because how many patients walk out of our room, if you’re talking about something different from diabetes that they don’t recognise that it’s as well as and I think the book makes it quite clear.” (HCP 1 (patient A))*

Again, not all of this information may come solely from the PDA and as a complex intervention the discussion with the HCP is equally as important:

*“And I was exploring whether, the possibility of maybe going on insulin while I’m at home and going on pills while I’m on holiday and she didn’t seem to think it was...” (Patient D)*

### Patient Education

The educational element of the PDA was recognised as an important factor by patients and HCPs. One HCP commented on the fact that patients picked up on some of the educational elements even when she had considered she had discussed these several times before. The use of a PDA seemed to help patients understand concepts where direct discussion had failed to do so:

*“I think it’s very good because it educates patients as well and it shows us, probably not what we are telling them but perhaps what patients have not picked up from what we hope that we’re telling them and the people that I see, certainly I know that they’ve been told about the complications but it’s probably way back in their mind and all of a sudden they think ‘oh, I don’t think I knew about that’. So I think from that point of view education wise I think it’s very good” (HCP 1 (patient A))*

Even a patient with an autonomous control preference who had been quite negative about some other aspects of the process noted:

Patient

*“Well no. I’ve learnt quite a bit just sat here. I didn’t realise that you could be on tablets and insulin.” (Patient D consultation)*

The HCPs did consider that the educational value of the PDA with patients on their diabetes and management did lead to a greater understanding of where changes had to be made:

*“Yes because I think it (PDA) showed her the holes in her diet.” (HCP 2 (patient B))*

*“And that it (PDA) also reinforced the complications. So he knew the risks he was taking and whatever. So I think it was very useful from that point of view” (HCP 2 (patient C))*

The PDA not only improved understanding of treatment options it also improved understanding of the symptoms of diabetes:

*“I think it really highlights the problems that they are experiencing is due to their poorly controlled diabetes, whereas previously I think they just would have thought, oh it’s because I’m getting older or this is happening because of whatever.” (HCP 3 (patient E))*

This educational benefit seemed to extend to:

- the complications of diabetes

*“...but I didn’t realise that you could get heart disease through diabetes, you know.”* (Patient A)

- the benefits of insulin,

*“I mean like I say the only thing I didn’t know was how far the insulin would bring it down.”*  
(Patient H)

- the side effects of treatment

*“Well I didn’t know until I read this what the side effects could be...”* (Patient G)

The use of a PDA was considered to have a greater benefit in patient education than just consultation alone and seemed to improve understanding in areas of symptomatology and management of T2DM. By improving understanding patients are more knowledgeable after using a PDA and seem to make decisions with less conflict.

#### *Influence of the Decision Aid on the Decision*

The results from this section have already indicated that the decision aid helped to clarify treatment choices and to help the patient understand more about their condition. The interviews then explored whether patients and HCPs considered that using the PDA actually influenced the decision that the patient made. It was clear in some cases that the PDA did influence the choice that the patient made and this was reflected by patient and HCP:

*“Certainly for this lady I think it helped her make a decision, whilst she did ask me my opinion and I think the majority of patients always ask the health professional what their opinion is. And she’d not had any of this before she read this booklet. So clearly this booklet has given her the indication and helped her make the decision to start insulin.”*  
(HCP 1 (patient A))

Interviewer

*“So have you moved on in terms of making your decision?”*

Patient

*“Yes, yes, I have... now I’ve read this booklet and talked to S, I think I’m more, I know that I need to do it, you know, to bring it down,”* (Patient A)

This may have been to start insulin as in the case above or to improve their exercise and diet as in the patient below:

Interviewer

*“Do you think that (using the PDA) helped him to make a decision?”*

HCP

*“Yes I do. I think it’s made him think more about what he’s actually doing and hopefully he will go away and make some changes.”* (HCP 4 (patient G))

Interviewer

*“And did you think it was useful when it came to making a decision?”*

Patient

*"Well it helped me to make a decision. I've a better chance if I change me diet and that, then I might be better off."* (Patient G)

Even if the PDA didn't directly influence the decision made by the patient it still had an impact on the deliberation before the patient made their choice:

*"I think it makes you think in depth about what you really think about it, and you don't just react, you really think about why you do or you don't want to use insulin."* (Patient B)

However some patients will have made their decision before they attend and nothing can alter that decision:

*"No, nothing's altered, really. I'd more or less made my mind up months and months ago that this was the way I wanted it to go"* (Patient D)

Some patients found that it was the combination of PDA and consultation that influenced the decision although they admitted that having the information presented in the PDA format did help them to understand the information better.

#### 5.2.4.4 Meta-theme 3: External factors that might influence decision making.

##### Influence on the decision

When discussing with patients and HCPs what influences the patient choice on treatment option most recognised that there was a mixture of factors. As discussed above the PDA itself clearly presented information in a way that allowed patients to understand better their condition, options and complication risks, however, professional advice was also valued:

*"I can make decisions on my own body, but if I got a professional giving me advice and able to answer questions I need to have answered, then that's great. So no matter what this book says at the end of the day, professional advice is the thing that you really need."* (Patient E)

Although this patient considered that the professional advice was the most important influence he also mentioned another unexpected external influence on his decision and persevering with that choice:

*"But from leaving here, it's (the PDA) been left on my dining table and my wife, between leaving here and me going back home, has read it and said -it's rather useful. And she made a few comments herself, 'well some of these things you've got to stick to and you're not sticking to'."* (Patient E)

This raises the issue, not only of making a decision but also the support available to the patient to persevere with their chosen option. One patient who was a widower was aware of the actions he needed to take to improve his symptoms and complications but, because he lived alone, had no support or encouragement to persevere with any change:

*"I don't think for him that (his decision) will have been influenced much by this (the PDA) because I think where he is in his life, he's not really bothered."* (HCP 2 (patient C))

#### 5.2.4.5 Meta-theme 4: The concepts and tools of Shared Decision Making

This is covered in the PANDAs analysis under themes on the PDA itself namely:

- clarification of treatment choices
- patient education
- influence on the decision

It is clear from the quotes mentioned above that the majority of patients experienced some benefit from the PDA, whether this was clarifying some of their misconceptions about disease symptoms, educating them about complications or actually influencing the decision itself. Even in some patients who were classified as autonomous in their decision making and had admitted they would not be influenced by the PDA it still provided some educational benefit (Patient D).

One of the main considerations by patients was the fact that, although the PDA was quite easy to understand it was not a tool that could generally be used on its own; the PDA required some explanation to go with it and professional input to discuss the consequences of each choice;

*“Well it’s not a bad way of laying it out, I mean once it’s explained to you, but I mean to pick it up and try to understand it straight away, I mean it needs a little bit of explaining before you...”*(Patient G)

The PDA was not considered too complicated to be only of use with a professional; it was recognised as having benefit with other family members even if they had not been in the consultation:

*“So in some cases it could be useful for the nurse or whoever to go through it with ‘em. But there again, if they do have those problems there is someone at home who can read this information ‘cause it’ll help the family as well as the person because families have to deal with diabetes ‘cause most families have to come to terms with some changes in everybody’s diet, don’t they.”* (Patient B)

The PDA could not cover every eventuality on its own but in conjunction with professional input could progress the discussion further such as on the devices used for injecting insulin:

*“...if I need to use insulin and because you’re automatically given a pen now and the way it’s taken or whether it comes in cartridge and you slot it in that is going to be a lot easier than fiddling, trying to draw a needle.”* (Patient B)

It seems, therefore, that just providing written information on its own may have some benefits but when combined with professional input and in a format available to carers and family it can have a much greater impact.

## 5.3 Study 2. Secondary Care: Informed consent for unilateral hip arthroplasty for osteoarthritis

This study involved the recruitment of patients to two separate qualitative components, namely before and after surgery in-depth interviews of patients from a single consultant's list and focus groups for patients who had undergone surgery with different consultants. There was also a qualitative component of in-depth interviews for surgeons who regularly obtained consent for hip arthroplasty.

### 5.3.1 Participant characteristics

#### 5.3.1.1 *In-depth interviews*

A total of 19 patients agreed to participate in this component of the study from a consecutive series of 34 patients meeting the criteria for entry from the list of one orthopaedic surgeon. Of the 19 who agreed to participate three became ineligible because:

- One patient could not be contacted despite supplying telephone numbers and address.
- One patient had surgery before participating in the pre-operative interview
- One patient had surgery at a different hospital under a different surgeon.

In total 16 patients participated in the interview element of the study and agreed to selected hospital data collection as well as completing both interviews. Demographic details were collected to show the broad spectrum of representation of the participants and to highlight the home circumstances of patients that might have an impact on their recovery such as carers/family who live with the patient.

Comparison with national statistics shows a close correlation, although the sample size is too small to be statistically significant, and qualitative methodology does not necessarily allow comparison with national statistics.



*Table 13 Demographics of patients participating in in-depth interviews*

Patient identifier	Sex	Age	Employment status	Self-declared ethnicity	Number of people at home
1	F	79	Retired	Afro-caribbean	1
2	M	69	Retired/manual	Caucasian	2
3	F	68	Retired	Caucasian	5
4	F	64	Lawyer/employed	Caucasian	2
5	F	84	Retired	Caucasian	1
6	F	82	Retired/clerical	Caucasian	1
7	M	66	Retired/manual	Caucasian	2
8	M	51	Semi-skilled/employed	Caucasian	1
9	F	74	Retired/administrative	Caucasian	1
10	F	80	Retired/sales	Caucasian	1
11	F	78	Retired/clerical	Caucasian	2
12	M	72	Retired/managerial	Caucasian	2
13	M	68	Retired/semi-skilled	Caucasian	3
14	F	74	Retired/manual	Caucasian	2
15	M	81	Retired/managerial	Caucasian	1
16	F	74	Retired/healthcare	Caucasian	1

*Table 14 Comparison of patient characteristics to national registry*

	National statistics(245)	Study statistics
Female: Male ratio	60:40	62.5:37.5
Average female age (years)	69.7	75.7
Average male age (years)	67.2	67.8

The participants in this study closely resemble the national picture with a greater preponderance of female patients; these patients having surgery at an older age.

### 5.3.1.2 Focus Groups

Participants for the focus group component of this study were recruited from the lists of two different consultant orthopaedic surgeons from the in-depth interview component. The patients had undergone unilateral hip arthroplasty approximately 6 months prior to the focus groups.

Eight patients were recruited from which two groups of four patients were convened at Samuel Fox House on the site of The Northern General Hospital, Sheffield. Each focus group was facilitated by AB and AW. The characteristics of participants in each group are outlined below.

*Table 15 Patient demographics from Focus group 1.*

Patient Identifier	Sex	Age	Employment status	Self-declared ethnicity	Number of people at home
FG1	F	56	Clerical/unemployed	Caucasian	2
FG2	M	54	Retired/managerial	Caucasian	1
FG3	M	70	Glass worker	Caucasian	2
FG4	F	74	Retired/teacher	Caucasian	2

*Table 16 Patient demographics for Focus group 2*

Patient Identifier	Sex	Age	Employment status	Self-declared ethnicity	Number of people at home
FG5	F	70	Retired	Caucasian	2
FG6	F	67	Retired/social worker	Caucasian	2
FG7	F	76	Retired/clerical	Caucasian	3
FG8	F	70	Retired/teacher	Caucasian	2

Patients were slightly younger than the interview group, perhaps because patients were expected to travel to the venue of the focus groups, whereas interviews were generally carried out at the patient's home.

### 5.3.1.3 Consultant Orthopaedic Surgeon

Seven surgeons were identified as regularly taking informed consent for hip arthroplasty at the Orthopaedic Department in Sheffield. All surgeons were approached directly and through their NHS secretaries to consider taking part in the interviews. Four surgeons agreed to participate and were interviewed individually by AW.

The demographics of the surgeons interviewed for this study are outlined below.

*Table 17 Demographics of the Consultant Orthopaedic surgeons*

Surgeon Identifier	Sex	Age	Self-declared timing of consent form signing	Years as a consultant	Other roles within Department
Surgeon 1	M	44	Mixture of first consultation and at a second "consent clinic"	9	Governance lead
Surgeon 2	M	49	At a second "consent clinic"	13	Training Programme Director
Surgeon 3	M	55	At a second "consent clinic"	20	Previous Clinical Director Previous Training Programme Director
Surgeon 4	M	48	Usually at first consultation	14	Previous Clinical Director

All the surgeons specialised in hip and knee arthroplasty and represented a broad spread of experience and other clinical roles within one orthopaedic department.

### 5.3.2 Quantitative data results

Hospitals that perform hip arthroplasty are expected to collect anonymised data on patient quality of life scores as measured by the Oxford Hip Score. Hospitals are required to collect this data prior to surgery and approximately three months after surgery. This data is then anonymised and uploaded to a national registry to evaluate performance of the department as a whole. Although the scoring system is not validated for analysis on an individual patient basis it was considered to be useful data to collect to inform the second interview, particularly in terms of patient perceptions of improvement after the surgery.

These scores were collected by the hospital at the pre-operative assessment clinic and the post-operative scores were collected by AB prior to the second interview.

The scores are calculated out of a maximum of 48 (which represents no impact on quality of life i.e. best outcome) and are shown in table 5 below.

*Table 18 Oxford hip scores before and after surgery.*

Patient Identifier	Pre-operative Oxford Hip Score (0-48)	Post-operative Oxford Hip Score (0-48)	Change in Oxford Hip Score
1	8	27	19
2	15	25	10
3	19	31	12
4	14	42	28
5	14	32	18
6	15	33	18
7	22	45	23
8	21	26	3 <sup>a</sup>
9	12	38	26
10	19	41	22
11	17	46	29
12	11	34	23
13	2	20	18
14	15	44	29
15	4	34	30 <sup>b</sup>
16	46	43	-3 <sup>c</sup>

<sup>a</sup> Patient was awaiting further surgery after infection of the prosthesis

<sup>b</sup> Patient had bilateral hip arthroplasty

<sup>c</sup> Patient declined surgery as symptoms improved prior to surgery

### 5.3.3 Qualitative results

Although the qualitative data from this study was collected in three different components, namely patient in-depth interviews before and after surgery, patient focus groups to explore different experiences of consent and surgeon in-depth interviews, the analysis and quotes to illustrate these points were taken as a whole. The research questions, aims and objectives were the same for all components of qualitative data collection and, therefore, results can be analysed together. By analysing the data in this way it was also possible to match patient views on certain aspects of consent and care with those of the surgeons. So, for example, patient views on written information they receive from the hospital can be matched with consultant opinion of these written materials.

The themes and sub-themes for the Informed Consent study alone are shown in the tables below.

*Table 19 Themes developed from focus groups and pre-operative individual In-depth interviews with patients undergoing unilateral hip arthroplasty.*

Main Theme	Sub-theme
Consultation with the consultant surgeon	Patient decision
	Emotional factors
	Signing the consent form
Hospital pathway	Patient opinion of the pathway
Sources of Information	Information passively received
	Information actively sought
Patient opinion	Values attached to information source
	Knowledge of consent
	Views about consent giving

*Table 20 Additional themes developed from the post-operative individual In-depth interviews with patients undergoing unilateral hip arthroplasty.*

Main Theme	Sub-theme
Patient opinion	Post-operative view of consent signing
	Post-operative view of information provision
	How could the consent process be improved?

Some of the themes developed from the consultant interviews have a different perspective on the informed consent process compared with patient opinion.

*Table 21 Themes developed from the individual in-depth interviews with consultant orthopaedic surgeons.*

Main Themes	Sub-themes
Providing information in the consultation	Use of models/x-rays
	Discussion of options
	Checking patient understanding
Opinion on non-surgeon provided information	Information provided by the hospital
	Information accessed by patients
Obtaining consent	The consent form
	Signing the consent form
	Consent as a process
Barriers and motivators to consent	Barriers and motivators
	Improving the process

Although the main themes and sub-themes from the consultant interviews are shown in the table above, the expression of surgeon opinions through quotations, shown later in this section, will be shown under the comparative patient sub-theme heading. This is to facilitate comparison of patient and professional opinion on the various themes.

The themes from the qualitative data have subsequently been transposed onto the framework of meta-themes on how patients make healthcare decisions. Some themes appear more than once as they are relevant to more than one key framework heading.

Table 22 Mapping of patient sub-themes to overarching theme and meta-themes

Overarching theme and meta-themes	Patient Sub-theme from IC study
How patients make healthcare decisions	The patient decision
	Emotional factors
	Values attached to information source
	Knowledge of consent
Doctor-patient interactions	Emotional factors
	Information passively received
	Values attached to the information source
	Views about consent signing
How the presentation of information can influence decision making	Information passively received
	Information actively sought
	Values attached to the information source
External factors that might influence the decision	Patient opinion of the hospital pathway
	Information actively sought
	Values attached to the information sources
The concepts and tools of Shared Decision Making	How could the consent process be improved?

### 5.3.4 Qualitative results in relation to the meta-themes

The results are considered in relation to “How patients make healthcare decisions” and are then presented in relation to the meta-themes pertaining to this.

#### 5.3.4.1 Overarching theme: How patients make healthcare decisions

The decision by the patient whether to give consent to undergo surgery or not is dependent on several factors identified by the project ranging from patient knowledge of consent, values attached to different sources of information and emotional factors. These are presented here in the order they are shown in table 22.

#### **Study Themes**

##### The patient decision

The decision made by the patient was often to have surgery, but this seems to be rarely based on discussion with the surgeon. Several patients commented that it was the pain they were experiencing that made them decide to have the operation:

*“Well he explained everything to me and I said I wanted the operation because if I could get rid of some pain it would be a help to me”* (Patient 6)

*“Well I would say the pain’s made my own mind up,”* (Patient 2)

*“I’m not without pain! Oh yes and of course it’s being immobile and not being able to walk”* (Patient 11)

This was often reflected when asked how the patient felt when they were offered an operation:

*“I can’t get it quick enough because I think it’s gonna make a big difference...”* (Patient 2)

*“I was just so relieved at that time that he’d said yes you can have one that I didn’t really consider it all...I was pleased that I wasn’t given a choice to tell you the truth,”* (Patient 3)

*“I knew I needed a hip replacement so I didn’t really have a decision to make”* (Patient 11)

*“I weren’t really bothered because I know I’ve got to go in and they’ll do what they’ve got to do.”* (Patient 13)

There is a sense from most of the patients that they were expecting to be offered an operation at the consultant consultation and would readily accept this offer because of the pain they were suffering. The patients often experienced relief when offered the operation with little expressed opinion that a discussion about risks would alter their opinion.

There is a perception from the surgeons that this is also the case:

*“...by the time the patients get to us they know that they have been referred because they might benefit from a hip replacement so ... the vast majority of them will already have a degree of expectation about what’s going to happen. So they’re already reasonably well informed and they know that they are going to be offered a hip replacement in most cases.”* (Surgeon 4)



However the statement “So they’re reasonably well informed...” does not reflect the patient view that they would have the operation regardless of how well informed they might be. Indeed the surgeons were at odds over this matter and their statements were often based on assumptions:

*“...patients, they’re usually pretty savvy about what arthritis is. Patients usually know.”*  
(Surgeon 4)

Surgeon 3 and 1 tended to rely on their years of experience to judge whether patients understood or not:

*“...you can often see by their face what is going in or not going in,”* (Surgeon 3).

*“...your experience of many years of taking histories that you can spot the patients who can clearly understand what’s going on and not.”* (Surgeon 1)

These considerations do not take into account other factors that may influence the patient’s ability to make a reasoned decision or even to retain the information provided.

### Emotional factors

Patients often expressed “happiness” that they were being referred by their GP for hip surgery and several expressed “relief” when offered the opportunity of surgery:

Interviewer

*“And when he said yes ok we’ll do the operation how did you feel about that?”*

Respondents:

*“Good”* (Patient 4)

*“Well relived like, know what I mean?”* (Patient 7)

*“Relieved that it was going to be done”* (Patient 9)

*“Alright, I wanted it doing there and then”* (Patient 14)

However one patient highlighted one of the problems that can arise when expectations are (or sometimes are not) realised:

*“Now he chatted to me a lot and I’m sorry that you get, you’re so uptight that you don’t absorb it all. You just get a general idea of things.”* (Patient 12)

These statements show there is a huge expectations of being offered the procedure but once this is achieved the emotions can interfere with retention of information about the discussion before and

after the offer. It is clear from other comments that recollection of discussions and even whether a consent form was signed were very vague:

Interviewer

*“Did he explain if you had an operation what they would do with the operation?”*

Patient

*“I think he did. I’m sure he did. Oh isn’t it awful? That poor man’s gone to all that trouble to explain and it’s gone. I’m sure he did.”* (Patient 12)

Patient

*“I don’t remember much about the operation, about the interview, but I think I was almost asked the question do you want an operation?”*

Interviewer

*“At the time of that consultation at the hospital did they ask you to sign a consent form then for the operation or not?”*

Patient

*“Possibly I’m not quite sure to be honest.”* (Patient 16)

The surgeons often considered that the patient had already made their decision about surgery

*“I think the patient’s usually made the decision when they come.”* (Surgeon 4)

Perhaps because of this the surgeons may feel that their purpose, once an operation is considered is merely to discuss the risks and alternatives without assessing understanding:

*“...what they take in I don’t know”* (Surgeon 3).

*“I don’t go through routinely and say ... ‘can you tell me what I told you?’”* (Surgeon 1)

Surgeon 2 said that he did not routinely check patient understanding for hip arthroplasty but did use “talk back” techniques when dealing with bad news for patients and their family.

Surgeon 3 commented that the onus for understanding the information was not necessarily the sole responsibility of the surgeon:

*“...that the patients take some responsibility and say ‘I don’t understand that’”* (Surgeon 3)

This area of information retention and understanding appears to be a major area of mismatch between patient experiences and surgeon perceived roles.

#### Values attached to information source

The content of information given to patients is important, as is the format; some patients prefer discussion, others find written or electronic information helpful but what is also important is understanding the values patients attach to the various sources of information. Some of these will be provided and sanctioned by the hospital, but other sources may be external to the hospital; it is important to understand how patients value these external sources and whether the surgeons respect these values.

The patients were all very clear that they most valued discussion with another person as the important factor in receiving information. However, they were somewhat divided on who was the best provider of that information and maybe influenced the decision most. Several patients valued the discussion with the surgeon:

*"I think Mr X gave me the confidence, really really when he was talking you felt, when you heard and spoke to him you felt more confident," (Patient 2)*

*"So the valuable information I need and the expert advice from Mr X is erm, do I need an operation?" (Patient16)*

However, other valued sources of information were other people who had had the surgery, The Joint School and even personal experience if they had had surgery on the other hip:

*"The people that have them done I think." (Patient 14)*

*Interviewer*

*"So actually you're past experience is probably the most valuable -*

*Patient*

*That's been most valuable thought that I've had." (Patient 16)*

*"I've got three friends that have recently had hip operations. Very intelligence, sensible friends..., just from their own experience and I've found that very good." (Patient 12)*

*"Yes, and then I felt, more at ease after I'd been to this clinic, this Joint School, I knew what was going on. Maybe something like that, telling you, giving you more information earlier, might have been more useful." (Patient 3)*

There was much less value attached to written information or details on the internet:

*"No, I'm just not bothered about reading anything else because as I say I've got to go and have it done" (Patient 13)*

*Interviewer*

*"Do you think it would be useful to have something written?"*

*Patient*

*No, not really" (Patient 14)*

The surgeons considered that it was important that they give the patient a lot of the information which would then be reinforced by other hospital attendances such as Joint School:

*"I fairly strongly think that the best way to do it is to give the patients they information they need at the time of the first consultation" (Surgeon 2)*

*"I know they come to Joint School and pre-op, so I know they've got a lot of opportunities to get information which reinforces what we've said." (Surgeon 4)*

The surgeons certainly appreciated the importance of information giving at these other hospital appointments but do not necessarily equate them with the consent-obtaining process as the consent form has already been signed with some surgeons before these appointments.

It is, perhaps, just as well patients did not value the written information particularly as there was confusion amongst the surgeons about what written or other advice was provided by the hospital:

*“So you don’t give them a booklet?”*

*“Err we’ve run out. We used to give them a booklet but I think we’ve run out.”* (Surgeon 4)

*“We did make a DVD here, I don’t know whether they actually use it.”* (Surgeon 1)

One of the surgeons did consider that written information did have its place though:

*“I don’t think you’ll get the situation where every patient understands every nuance...however I think that the provision of written material and either a video or work-based material is the way forward.”* (Surgeon 3).

Surgeons were more critical about external information. They were concerned that patients may talk to friends who had a good or bad outcome that would influence their decision when the patients’ risk factors were different. They did, universally, avoid recommending web-based information for several reasons:

*“The internet is completely unregulated. There’s lots of good information, there’s also a lot of bad information”* (Surgeon 4)

*“I don’t use websites”* (Surgeon 3).

*“There are internet resources on the NHS Choices website which is reasonable but it’s a bit difficult for them to search”* (Surgeon 2)

*“If you go on a lot of the sites the first 10 or 15 are sponsored by companies, so they’re wonderfully glossy”* (Surgeon 1)

Although these other resources may be adjunctive to discussion, the real value on both sides appears to be face-to-face discussions over a period of time that can reinforce earlier information.

### Knowledge of consent

It has already been identified from the data that surgeons will sometimes make assumptions relating to patient understanding and knowledge of some of the key facts surrounding hip surgery. This section looks particularly at the concept of “consent” and what it means to patients and surgeons.

In some cases the concept of consent was understood and often related to everyday activities but the notion of “informed consent” was new:

*Interviewer*

*“Have you heard the phrase informed consent?”*

*Patient*

*“No.”* (Patient 3)

When the notion of “informed consent” was presented, the patient’s partner commented:

*“My guess is that that information was presented... but whether there was then time to think about it, before you signed the bit of paper, I think is debatable.”*

Other patients had a clearer concept of “informed consent”, although it was a notion that they were familiar with through their own work:

*“I would say I’d given informed consent, because I know what it’s about, I fully understand what it’s about and I’m agreeable to having the information. And that’s part of my professional training. (Patient 4)*

The purpose of signing the consent form was also viewed as an expectation from the hospital rather than anything of importance to the patient:

*“Well you just sort of give the surgeons permission to do whatever they have to do. I think you have to sign the consent form. (Patient 9)*

*“Well, I suppose it’s just to cover the hospital isn’t it?” (Patient 13)*

The surgeons had all experienced a range of opinion to the consent process. Some patients were unwilling to accept informed discussions:

*“You do get patients who come along and say ‘you do what you think’s best’. I try and turn that round and really try and make them contribute to the decision but sometimes, you know, there’s no shifting them.” (Surgeon 2)*

This view was confirmed by Surgeon 1 who viewed the surgery as “lifestyle choice” and as such it was more important for the patient to make the decision rather than expecting the surgeon to do so:

*“...it’s a lifestyle operation so they have to make the choice and there’s still quite a lot of patients out there who don’t like that.” (Surgeon 1)*

The general consensus of the surgeons seemed to be that it was their duty to explain about the surgery and obtain consent even if the patient was somewhat resistant to this and just wanted to be told when their operation would be:

*“There are some young patients who are quite blasé about (the) consent process...saying just get on with it” (Surgeon 2)*

Which is consistent with some of the patient opinion:

*Interviewer*

*“And how did you feel when he said you know you need the hip doing?”*

*Patient*

*“Alright, I wanted it doing there and then.” (Patient 14)*

*“I think if he’d have said “Stand on your head for a day” I would have done it, you know. I just wanted to get something done.” (Patient 13)*

It is clear the surgeons consider they have this duty to inform, although not necessarily to ensure the patient has understood and even if the patient would rather just move on to the next step they still need to go through the information process.

#### 5.3.4.2 Meta-theme 1: Doctor-patient interactions

There were several sub-themes that matched the theme of doctor-patient relationships from the data analysis. Some of these also match the previous section of how patients make healthcare decisions. The sub-themes that matched this theme were:

- Emotional factors
- Information passively received
- Values attached to the information source, and
- Views about consent signing

The perception of patients about their interaction with the surgeon influenced how patients felt emotionally about their consultation, although no patients expressed the distrust reported by X (ref). The value patients placed on this relationship also influenced patient values on the information they received. The surgeons also described, indirectly, how they often take for granted that patients want the operation and will understand what they are told.

##### Emotional factors

Sometimes the patients were concerned that the surgeon might think that they were somehow exaggerating their symptoms and, therefore, would not be offered surgery:

*Interviewer*

*“So when Mr X said to you yeah we’ll do your hip, how did you feel at that point?”*

*Patient*

*“Well relieved like, know what I mean? That I’m not like I didn’t try to fool anybody”  
(Patient 7)*

There were, however frustrations sometimes expressed with the surgeons, especially if the surgery was delayed to allow the patient to lose weight. Although there was a perception that all the surgeons were equally as good:

*“Mr X did ask me did I just want him or would I be satisfied with one of the other surgeons. I said you’re all as good as each other.” (Patient 9)*

There was sometimes anger expressed that the surgeons could not be more exact as to how long this delay might take:

*“You need it doing really ... I might see you in six months, I might see you in eighteen months” – this was his attitude at the time. So we’ve been back to hospital again and seen this Mr X this time cos I complained about Mr Y didn’t I, eh? Because his attitude were terrible towards me.” (Patient 15)*

Some of the problems raised with consultations may be not only the attitude of the surgeon but also the way they discuss information. One surgeon described quite clearly the risk of being overweight to the researcher but it seems patients sometimes just feel their surgery is being delayed.

*“But once their BMI is over 40 I try to put them off surgery...there’s good medical evidence now that people with a BMI over 35 have a higher risk with surgery in terms of respiratory complications and pressure ulcers.” (Surgeon 2)*

*Information passively received and*

*Values attached to the information source*

The patients did often defer to the surgeon in terms of “knowing what the patient needed”

*Interviewer*

*“So, from the information that you’ve had ... which information do you feel has been the most important for you?”*

*Patient*

*“Mr X, he’ll know.” (Patient 1)*

*“I think Mr X explained better, which naturally you would expect it to be better when you’re talking to a surgeon what does the job.” (Patient 2)*

As described earlier some patients did consider they received more valued information from other sources, although information from the surgeon was always valued to some extent.

From the surgeon perspective the relationship seems to be one of efficiency without necessarily engaging the patient in dialogue or trying to engender trust or understanding. The surgeons did recognise that hip surgery had certain risk factors relevant to all as well as specific risk factors relevant to a few:

*“... effectively you’re weighing up risks and benefits of surgery and there are generic risks that everybody faces and then there are specific patient risks depending on co-morbidities.” (Surgeon 4)*

The surgeons do, therefore look at personalised risk factors but then tend to approach the information giving process with a series of assumptions and time pressures:

*“You often say to them ‘do you know what we’re talking about, do you understand this...? And they say yes or whatever and usually you don’t question it too much” (Surgeon 3).*

*“If they’re interested and if there’s time I will sometimes show them a hip” (Surgeon 4)*

The implication here is that surgeon’s approach the patient interaction as a requirement to inform patients of the procedure and risks and if there is time they may extend some of these processes further but not always and not necessarily dependant on patient need. Checking patient understanding seems to be reduced to a yes/no answer which does not necessarily reflect patient understanding, and if the patient says they do understand it is not assessed.

### Views about consent signing

Although patient and consultant views about signing the consent form do not directly specify doctor-patient interactions, attitudes to this process do indicate general attitudes to the relationship.

Patients often experience conflict in terms of signing the consent form that they don't feel they can ask the surgeon about. As discussed earlier, patients often consider that they need the operation and experience relief when offered the operation. This emotion extends to signing the consent form where patients consider they may delay the operation even if they have not received enough information to satisfy themselves that they are "informed" about the consequences:

*"I think he quickly said what was going to happen but I didn't take it in, I think I... when we went to this clinic, school, what do you call it, Joint School, some of them hadn't signed their consent forms yet, and I thought ooh, I signed mine pretty quickly then. But I think possibly a bit later would've been better, but as I say I didn't want to hold up the procedure."*

(Patient 3)

Some patients did consider that even though they had signed the consent form they felt able, if necessary, to contact the hospital and reconsider the procedure:

*"So yes I signed it there and then. If I'd wanted to think about it I would have said can I think about it and come back and sign it at a later stage."* (Patient 4)

Some patients, however, clearly felt confused by all the information received and were uncertain if they had even signed the consent form for the operation:

*Interviewer*

*"At the time of that consultation at the hospital did they ask you to sign a consent form then for the operation or not?"*

*Patient*

*"Possibly I'm not quite sure to be honest."*

*Interviewer*

*"What's that?"*

*Patient*

*"Yes I signed this thing here (the consent form)."* (Patient 16)



Some of this confusion was created because patients were asked to sign several forms including ones for bone donation and blood transfusion:

*“Not for the actual operation. I’ve signed one for the blood transfusion if it’s necessary – touch wood I’ve never needed. I’ve also signed for one, you know this bone... signed for permission to use the bone if when they’re doing the operation they find that some of it’s useable for somebody else.” (Patient 10)*

Some of the surgeons had a policy of bringing patients back a second time for signing consent forms particularly to answer any questions the patients might have thought about and to reinforce information before signing the consent form:

*“(I) bring them back to consent clinic where they in the meantime could have thought of some questions – I tell people to write any questions down. I think having a second bite of them to tell them complications or what the risks involved are is probably a good thing...it’s a lot to take in on one day” (Surgeon 3).*

This approach was also adopted by another surgeon:

*“...they come back and see me for a consent clinic...they have time to talk to other people, they have time to talk to people in pre-assessment” (Surgeon 2)*

However, Surgeon 1, who often consented patients at the first consultation, considered that the consent signing process had been altered by hospital policy:

*“We used to consent them when they came to the pre-op assessment clinic but (that) process has changed so if I have got time I will consent people on their first clinic visit” (Surgeon 1)*

Again this exemplifies an approach of expediency rather than what is in the patient’s interests and Surgeon 1 also commented on using their own assessment of patient understanding:

*“If I think that we know what the risks are and the patient understands everything...I will take informed consent.” (Surgeon 1)*

Patients, therefore, do sometimes express that they don’t understand fully the implications of surgery at the time of signing the consent form and confusion created by being asked to sign many forms. There is a variety of approaches to engaging patients in the consent process by surgeons some of which seem more patient-centred than others.

#### *5.3.4.3 Meta-theme 2: How the presentation of information can influence decision-making.*

This theme is represented by 3 sub-themes derived from the patient and consultant data, namely:

- *Information passively received*
- *Information actively sought*
- *Values attached to information source.*

These sub-themes also bring in the consideration of timing; when the information was given or sought in relation to giving consent for the operation.

### Information passively received

This was information provided by the hospital at the three main patient contacts; the consultant consultation, the pre-operative assessment clinic and the Joint School. The information seems to have been provided in discussion and written form. None of the patients had seen a DVD that one surgeon suggested was played at the Joint School.

Some patients did not consider they received enough information through discussion with the surgeon and this was partly due to a sensation of time pressure:

*"I just get the idea that some of these consultants are pushed for time and so he did what was necessary and offered it me and said you feel happy about that and I said yes."*

(Patient 3)

*"I've only seen him (the consultant) once. After that it was nurses that I saw."*

*Interviewer*

*"Oh ok and what did he say or explain that time that he saw you?"*

*Respondent*

*"He didn't explain much at all." (Patient 5)*

Although some patients did consider that the information they received was adequate:

*"Well I was quite happy with what they told me. Yes, more than happy. Yes, I think they explained everything at that first visit to the hospital." (Patient 6)*

One of the issues raised by the patients was the attitude and approachability of the surgeon. We have already seen that one patient complained because of the attitude of one surgeon. One patient expressed the notion that having an approachable surgeon meant you didn't feel intimidated and could ask questions if needed:

*Interviewer*

*"Did you get the opportunity to ask him questions?"*

*Patient*

*"Well I felt I could have done. I wasn't intimidated by him. He was a very, he was a very nice person, lovely. And I wasn't intimidated but I don't remember whether I asked him questions. Apart from the fact could I have the same hip as I'd got in the other side? I could be cheeky enough for that." (Patient 9)*

There were mixed views about the use of x-rays to explain arthritis and the operation to the patients. In some cases the use of the x-ray added nothing to the value of the consultation:

*"So obviously showed me x-rays like double Dutch to me, but they know what they're looking at." (Patient 7)*

Whilst with others the use of seeing their x-ray was helpful:

*"And he explained the operation. And he explained that from the x-ray... and he was very pleasant. We had a nice chat." (Patient 9)*

There was a sense, described in Wear (133) that because of the gulf in culture and experience between patient and surgeon that maybe patients didn't need to understand the processes involved and a busy surgeon just needs to get on with their job:

*Interviewer*

*"Did you feel as if you had the opportunity to ask Mr X questions?"*

*Patient*

*"Not really. Not a lot. He were thorough but they're like always in hurry aren't they? They haven't time to listen to you really a lot, you know. They always pass you on. They always say if you've got anything, see a nurse or see some, you know they pass you on because well, we can understand a consultant's life" (Patient 15)*

Written information was another area that caused some confusion with the patients and the surgeons were a little uncertain as to what patients received.

*"He didn't go into a lot of information...and they give you what you've just mentioned, a load of booklets to read and look at." (Patient 15)*

However, patients either didn't read the written information or found so many different leaflets, none of which were actually about the operation but were more about hospital procedures:

*Interviewer*

*"And did the hospital give you any leaflets or booklets or anything to read through?"*

*Patient*

*"Yes, yeah, I got all sorts."*

*Interviewer*

*"Have you read them?"*

*Patient*

*"Not really, no!" (Patient 8)*

*"I had the letter sending me to the er, pre-op clinic and they sent some paper, go back. When I saw Mr X he sent me off then to be weighed and the lass who was doing that gave me some forms to fill in and the occupational therapy point of view i.e. heights of seats and that sort of thing. Erm and I got some more paperwork in a folder then. I then went to the pre-op clinic and they took the bits and pieces and I filled in the questionnaire. Erm, and the nurse there gave me a diary sheet to fill in. And then I went yesterday and they've given me a sort of ward routine, this is what we do, this is when we do it."*

*Interviewer*

*"Right ok. Erm, but I mean regarding the procedure itself rather than obviously that have you been..."*

*Patient*

*"I don't think I've had anything, not that I can think of." (Patient 4)*

Patients who had previously had surgery on the other hip had been given exercise sheets and lists of “Dos and Don’ts” after surgery but did not receive any written advice this time:

*“(Last time) I got a booklet with a lot of don’ts saying don’t do this and don’t do that. What you can’t do for six weeks, what you can’t do for three months and what you can never do again, I remember this booklet. But now that doesn’t, you don’t get any sort of exercise or anything.” (Patient 9)*

So these patients tended to look out there previous written information to help them after surgery this time whereas first-time patients got no written advice about managing at home:

*“...but I should imagine for a new person, for the first timers, yes it could be pretty daunting just not knowing what you can or can’t do.” (Patient 9)*

As discussed earlier the surgeons had little awareness of whether patients received written information about the operation or a DVD at the Joint School. They also mentioned that they thought the department had run out and needed to get some more reprinted.

The pre-operative clinic is set up to assess the general fitness of a patient to undergo anaesthesia and surgery; understandably patients found little value towards consent from this visit but did value the discussion format of the Joint School:

*(when asked about information at the Joint School)*

*“Yes I did. A lot more information than even when I’ve had these done, a lot more information. Like I said they weren’t just a hip, there were some having knees done.”*

*Interviewer*

*“And did you have the opportunity to ask questions?”*

*Patient*

*“Oh yes. They were very good. I think it were very informative really. I thought I got a good idea” (Patient 10)*

*“...it was at the Joint Clinic I got all the information.” (Patient 9)*

However some patients did not like the discussion format and considered they learnt nothing more from that visit:

*“We went to joint clinic – that were really – we thought it were really a waste of time because they didn’t tell us anything that they told us like what they’d do like after the operation and whatnot, but I mean you’re not bothered really.” (Patient 13)*

What is evident from all the data illustrated by these quotes is that people awaiting surgery valued different formats of the hospital information-giving process. Some preferred the one-to-one surgeon consultation, some valued information sheets and particularly missed ones giving advice on post-operative rehabilitation whilst others got most benefit from the discussion format of the Joint School.

As already discussed some surgeons considered the information they provided as the most useful for the patient whilst others allowed patients to experience the other formats and search for information themselves before considering asking the patient to sign the consent form.

Information actively sought

Several patients did not seek any further information themselves, they trusted the surgeon and were merely waiting to be admitted for the surgery:

*Interviewer*

*“Have you tried to get information about hip replacements anywhere else at all?”*

*Patient*

*“No.” (Patient 1)*

*Interviewer*

*“And have you sort of tried to get information from anywhere else?”*

*Patient*

*“No. No.” (Patient 6)*

*“I don’t go on the internet because I don’t want to know.” (Patient 9)*

However most patients had discussed hip replacements with people they knew had undergone the same operation. Many of them valued the discussion element of one-to-one with these acquaintances and were influenced to some extent by what they had to say:

*Interviewer*

*“Have you sort of spoken to anyone sort of who’s had hip replacements?”*

*Patient*

*“Yes I have. I had one yesterday, she said she went on fantastic. And I’ve also spoke to others who’s had hip operations and seemed to get over that quicker than knee operations” (Patient 10)*

*Interviewer*

*“So you’ve not been seeking out other people to find out how their operations have gone on?”*

*Patient*

*“Oh yes, well my friends you see, I mean there’s, golly there’s four of them that have had hip operations... I mean she’s marvellous. She’s eighty five. She had a hip operation. I mean she flew off to Palm Springs last Christmas on her own you know, I mean that’s the sort of success I’m hoping for.” (Patient 12)*

*Interviewer*

*“And with the friends that you know that have had hip replacements, what do you think about how they’ve got on?”*

*Patient*

*“They’ve got on all right.”*

*Interviewer*

*“Is that important for you to know that?”*

*Patient*

*“Yeah. They’ve been all right haven’t they?” (Patient 15)*

Information from other sources was less commonly sought although at the time of interviews there was some concerns about metal on metal hips which had recently been in the news. Some patients did, therefore seek out this specific information, either from the national press or even medical journals and the internet:

*Interviewer*

*“You mentioned as well obviously on the telly yesterday there was the news about the...”*

*Patient*

*“Yes last night I heard I put my ears up when they’re talking about, I mean after this scare about implants they’re now talking about implanted hip joints where there’s metal on metal...”(Patient 16)*

*“...it was in the newspaper I think the same day as I heard it on the radio” (Patient 14)*

*Husband*

*“She’s read the British Medical Journal. Their cover story in...”*

*Patient*

*“...Metal on metal... So I pulled that up on the computer and we knew what the Exeter was but we didn’t know what the Exeter Elite was.” (Patient 3)*

What seems apparent from the patients is that they found value when exploring information about specific concerns, such as the metal on metal hips. However, when using the internet to search for generic information about hip surgery they found this source less useful:

*“I’ve looked on the internet. I can’t say I’ve picked up much from there I must admit” (Patient 4)*

This is maybe partly through lack of information technology skills or being unaware of the information available:

*“Well I have got a what you call a notebook, netbook. I’m not very good at it. So like say I haven’t tried to get in touch with anything like.”*

*Interviewer*

*“So you’ve not come across anything called the NHS Choices web site?”*

*Patient*

*“No” (Patient 7)*

Surgeons certainly view the internet as unregulated which can lead to misinformation, therefore they do not direct patients to websites. Patients seem to be a mixture of some who have no access or interest in the internet or use it regularly but only find benefit when looking for something specific. General information about hip surgery was much more valued from discussions rather than written or digital sources.

#### *Values attached to the information*

This is discussed under the previous two headings on sources of information.

#### *5.3.4.4 Meta-theme 3: External factors that might influence decision making.*

The main sub-themes correlating to this theme from the Informed Consent study were:

- *Patient opinion of the hospital pathway*
- *Information actively sought*
- *Values attached to information sources*

The second and third sub-themes have already been covered in relation to previous themes so this section will concentrate on opinions of the hospital pathway:

#### *Opinion of the hospital pathway*

Although this section deals with processes within the hospital setting, rather than exploring the information provided by the hospital it explores how processes within the hospital pathway affect the decision-making and personal experience. The two factors that seem to have the greatest impact on patient reported experience are:

- The lack of information to the patient to provide clarity on when to expect appointments and what to expect at each visit, and
- Timing of information provided.

Patients seemed to be expecting their operation date to arrive shortly after they had had their consultation and signed the consent form. Patients, therefore seem unaware of future appointments such as pre-operative assessment clinic; seemingly unaware of the necessity of such appointments and subsequently considering that this may just be a delaying tact by the hospital:

*“Because all I’ve been worried about well not worried, bothered, is I kept thinking every week they’d send for me. Oh they sent for me but not for the operation. I think I’ve had every test it’s possible to have except an eye test.” (Patient 5)*

Occasionally this frustration can lead to a request to see the surgeon again but when this is declined by the hospital it creates even further frustration:

*“You see I’ve asked to be transferred to another surgeon because Mr X did ask me did I just want him or would I be satisfied with one of the other surgeons. I said you’re all as good as each other. Anybody will do. But ... the appointments clerk....wouldn’t transfer me. When I spoke to her last week I asked her if I could be transferred. She says no. And the 23<sup>rd</sup> February is only a provisional date so it might not be then. So you know, I would now appreciate to go back and see a surgeon just to find out why they keep bumping me off like this.” (Patient 9)*

This frustration can even start before being seen at hospital. A new system of booking appointments with hospitals was introduced in 2009 called “Choose and Book”. It allowed GP practices or, more commonly, patients themselves to ring a call centre and book an appointment date and time to suit them at a hospital of their choice. However, this process was viewed by one disgruntled patient as a greater workload for them that created uncertainty because paperwork wasn’t completed appropriately at the hospital:

*“I had to make my own appointment to start off with and then I had to ring up because I hadn’t got paperwork to find out that the first one had been put back. I hadn’t got paperwork for the second one, I’ve had to ring up to be told that’s been put back and...actually... it’s only provisional.” (Patient 9)*

One of the surgeons did confirm that some of the policies do not appear totally transparent to the patients because of waiting list initiatives. So even though the patient may be told at the first consultation they are going to have hip surgery they are not yet on the waiting list for their procedure:

*“...the policy now is...they get medically pre-assessed and if they’re deemed fit they can formally go on the waiting list, if they’re not deemed fit they don’t go on the waiting list. So, ideally it keeps the waiting list under control.” (Surgeon 3).*

It has been identified that patients sometimes do feel overwhelmed by the amount of information they receive, not just about the surgery but also the leaflets on hospital policies such as infection control. This can lead to a lack of retention of information with one patient not even sure if they had signed the consent form, until they found it in their pile of papers. The surgeons do realise there can be information overload that can influence the decision making:

*“...but I think there is a danger you can give people too much information.” (Surgeon 1)*

*Interviewer*

*“Before you signed your consent form you’d had enough information and you’ve been able to ask questions?”*

*Patient*

*“Too much.” (Patient 8)*



Unfortunately there was no suggestion of how this might be improved upon.

The timing of information was the other factor that could influence patient decision-making. A number of patients commented that they got all the information they needed prior to surgery, but it was evident that a lot of this information was not derived from the initial consultation when they signed the consent form. As already highlighted, patients were very keen to have the operation to reduce their pain and hence did not want to slow the process down but “consent” had been obtained prior to information that may have influenced the decision:

*Interviewer*

*“At that time when you saw the registrar and then Mr X did they explain what to expect after the operation or was that something that you were told about later on?”*

**Patient**

*“No. That’s something that came later with the nursing staff...when it’s a consultation you only get so much information can’t you? I mean the assessment and this Joint Clinic, that’s the idea for giving you more information isn’t it?” (Patient 10)*

*(Discussing the consultation)*

*“And all he’s put on my medical records it’s unbelievable. He’s just put “Hip” and I need a load of information” (Patient 15)*

The surgeons are aware that the patients do get a lot of information on their journey from consultation to theatre:

*“To a certain extent I rely on the outpatient staff...there’s the pre-assessment clinic where they can ask questions and they can see physios...there’s also now the Joint School where they have a series of talks and you know discuss what’s going to happen to them” (Surgeon 2)*

*“...but I know that they come to Joint School and they’re to come to pre-op assessment clinic so I know they’ve got a lot of opportunities to get information” (Surgeon 4)*

The surgeons, however, differ to some extent on their view as to whether this process of information provision is part of the consent process or not:

*“...a lot of them I consent actually in clinic on the first visit...they’d come back to see other people but they don’t see me. I try to use that (consent clinic) for the ones it’s more likely to be more complicated consent type processes.” (Surgeon 1)*

*Interviewer*

*“So do you see the Joint School and pre-operative assessment clinic as key parts of the consent process?”*

*Surgeon*

*“I do because it’s just more information for the patient and they’ve seen another person again and they’ve had more questions and the more they know upfront the better”*  
(Surgeon 3).

It is clear from this that although the hospital may have processes in place to provide information in different settings and formats for the patients it is still up to the surgeon’s discretion how to implement these in relation to obtaining consent. It cannot be up to the patient to decide how this process is engaged with obtaining consent as they are not kept informed of the process in advance. It is the surgeon who has to integrate these processes rather than implementing information provision in isolation of obtaining consent.

#### *5.3.4.5 Meta-theme 4: The concepts and tools of Shared Decision Making*

The main sub-theme linked with this theme is:

- How could the consent process be improved?

Shared decision-making has well defined concepts and tools such as patient decision aids (PDAs) to assist implementation in medical encounters. Although this Informed Consent project has not specifically looked at PDAs in obtaining consent, patients and surgeons were asked what might improve the process and a number of suggestions included different modes of information provision. This rarely consisted of web-based provision as being of any value from the patient or surgeon perspective.

When patients were asked how the IC process could be improved, if at all, responses started to reveal more of the areas where they thought information was missing and how this could be addressed:

*“...if a nurse or someone had told me a little bit more about it then, it would have put me mind at rest. But I would still think there would be a sheet, your schedule, tell you, you have the operation during the day, four hours later they’re going to get you out the bed, y’know, this sort of thing, by the next day you should be able to walk yourself to the toilet.”*  
(Patient 3)

Patients had complained about how the amount of paperwork they had received could be confusing, yet the patient above did not consider they received the right written information and this was confirmed by another patient:

*“It’s the guide, just a little guide, I mean a little form would have been handy. You can do this, you can’t do that. If you’ve problems with this, you know, that sort of thing.”*  
(Patient 12)

Some of the improvements were in attitude and delivery of the information:

*“Well I think these nurses shouldn’t be so abrupt as what they were. Like talking to you sharply. ‘You’re not ill, we’re not going to look after you’” (Patient 5)*

There were mixed views about seeing the surgeon for a second time before surgery, some thought that this was beneficial:

*Interviewer*

*“So do you feel it was actually helpful to see him at the end?”*

*Patient*

*I think so. I mean he’s the man who’s going to be – so yes, I would say yes, definitely.”*  
(Patient 8)

Whilst others did not, although they maybe did not fully appreciate the reasoning of providing information at different appointments and then checking everything with the surgeon:

*“I did that (consent clinic) with this knee didn’t I? I went back to see Mr Y after all the clinics. Didn’t have a joint clinic then. I don’t think it made any difference apart from the fact I hadn’t signed a consent form. But I don’t think he told me anything that I didn’t actually know.”*  
(Patient 9)

This patient was, however, concerned about the lack of information relating to what to expect and when. They felt that they couldn’t organise holidays because dates kept being moved and there could be no certainty about the date for admission they now had:

*““It’s the uncertainty especially with people that like live on their own and they have to organise things and get things sorted at least. It would be nice for a proper guaranteed date”. (Patient 9)*

This patient also found the pre-operative assessment clinic could have been done better, although their view may be partly accounted for by the fact that they had not been told or understood the purpose of the this clinic, namely to ensure they were fit for surgery:

*“I think the pre-op thing could be done a lot different. You know you go in say at 10 o-clock and you see old Nurse Smith, yeah ‘come this way’ and she does blood pressure, she – I don’t know they do your heart and things like that and you’re not going from that room – that is it – it’s for the nurses’ benefit and not for the patients’ benefit.” (Patient 9)*

Several patients did consider that being able to talk to someone at the hospital who had recently had the operation would be very helpful:

*“I think talking to people who’d had it done would be of more benefit to first timers than all the tea in China. (Patient 4)”*

Most patients either did not have access to the internet or did not use it to search for information about hip surgery. One patient did think that a website at least had the advantage over leaflets in being able to cover large volumes of information without making bulky paperwork:

*“I mean the thing about using the web site rather than written information is that you can search on it and it really doesn’t matter how many questions you put on.” (Patient 3)*

As already discussed the surgeons did not recommend websites because of the unregulated nature of the information or the possibility of manufacturer promotion. However, the surgeons did admit that they had developed a website for their private practice, with information controlled by them, and that if developed solely for their NHS department then they would consider recommending it.

*“I work in the private sector as part of a group and we have a website...that has a lot of very good information on it which is actually in video form. There are internet resources on NHS Choices website which is reasonable...” (Surgeon 2)*

When another surgeon was asked about websites they confirmed that they did not refer patients to websites but:

*“I think it would be nice to have a Trust-based one.” (Surgeon 3).*

Other suggestions, by surgeons, to improve the consent process were based around updating their leaflets and re-making their video which the surgeons thought the patients viewed at Joint Clinic but, in fact, no patients had seen this. One surgeon did comment on a technique that they had used whilst training which they considered may help improve patient understanding:

*“Before I became a consultant I worked in Australia and the practice (had) a video the patients would watch and there were questions at the end they had to answer and if they got them right they got through to the next question and if they got them wrong it took them back to the video...I thought that was quite a good way of doing it.” (Surgeon 2)*

This theme seems to represent some of the issues that are approached through a shared decision-making programme. The information provided to patients in this situation needs to be relevant to Informed Consent and highlighted as such. Patients are presented with a lot of information on hospital processes that can cloud what is required to be understood to give informed consent. Clarity of information is, therefore, vital.

Clarity of process is also an important factor that can lead to frustration and problems in the consent process. It is understandable that appointments have to be postponed sometimes but when patients want and expect their operation as soon as possible it is important they understand when and why other appointments are necessary for the process towards surgery.

The final point from this theme is that there is additional information that can be provided to patients but this needs to be current, evidence-based and relevant. This could be provided in several formats as patients do not overwhelmingly select one method of information provision. The surgeons are aware of techniques to assess patient understanding of information but may feel from the time pressures imposed by the Trust that this is not possible.

### 5.3.5 Results from the patient focus groups

Transcriptions from the focus groups were analysed using the same framework that had been developed from the individual interviews. The debates were lively and focused on the difference in consenting experiences by patients pre-operatively as well as the differences in follow-up experiences.

The patients had been purposively recruited from the lists of two different orthopaedic consultants, one who generally consented patients at the first consultation and one who had a second “consenting clinic”. The themes arising were similar to those covered by the patient and surgeon interviews.

Post-operatively patients had different experiences of equipment provision and follow up from district nurses for wound care. This provided great insight into peoples' expectations pre-and post-operatively.

For purposes of clarity quotes have only been taken from the individual interviews. However, the depth of information provided by the focus groups is reflected in the comparison of results and discussion sections.

## 5.4 Results Comparison

Although both studies were considering separate medical conditions in different settings they both explored patient involvement in treatment decision making during non-emergency healthcare interactions. Consideration of the decision to be made allowed the patient time to consider options and gather information themselves if they wished, prior to any commitment. The studies were framed against different theoretical backgrounds; the informed consent work framed by legal prerogatives, professional guidelines and a process governed by the medical profession whilst the diabetes work was developed specifically to enhance shared decision-making in a long-term condition where evidence was equivocal.

Patient decision making in both studies is characterised by treatment choices where one valid option is to make no change. This is accompanied by understanding the condition, risks associated with each option and the best choice for each patient is that congruent with their own values.

The proposed end result in each situation is to have a patient who, informed about the treatment, risks and alternatives to their satisfaction and having their own personal values taken into account, can then make a choice on which option to take. Differences in the process of achieving this result can improve understanding of each setting by contrasting one with the other. For example when considering informed consent there is a minimum standard to achieve, governed by case law and guidance derived from this, whereas diabetes management in primary care has no legal basis other than the "duty of care" concept.

Whilst these contrasts can improve understanding and will be discussed in the next chapter the two studies also show how there are similar steps in patient information synthesis from initial consideration of the decision to be made and the final execution of that decision.

As has been discussed throughout this thesis there are four meta-themes for consideration in this process, under the overarching issue of "how patients make healthcare decisions", and both studies provide evidence that these are relevant in each situation. Again these meta-themes are:

1. Doctor-patient interactions
2. How the presentation of information can influence decisions
3. External factors that might influence decision making such as family or friendship influence on patients or hospital policy on the doctor
4. The concepts and tools of Shared Decision Making

The themes from each study are synthesised under patient-only factors that influence decision-making followed by each of the four meta-themes, in the tables below and then compared.

Table 23 Patient-only factors that can influence how patients make healthcare decisions

Individual projects	Patient-only factors
PANDAs Process Evaluation	Decisional conflict
	Knowledge
	Locus of control
	Pre-conceived ideas
	Pre-expressed decision
	Risk perception
Patient themes from Informed Consent project	Patient decision
	Emotional factors
	Values attached to information source
	Knowledge of consent
Surgeon themes from Informed Consent project	Signing the consent form
	Barriers and motivators

Table 24 Meta-theme 1. Doctor-patient interactions

	Meta-Theme 1
Individual projects	Doctor-patient interactions
PANDAs Process Evaluation	Time factor – health care professional
Patient themes from Informed Consent project	Emotional factors
	Information passively received
	Values attached to information source
	Views about consent signing
Patient themes from post-operative interviews	Post-operative view of consent signing
Surgeon themes from Informed Consent project	Discussion of options

Table 25 *Meta-theme 2. How the presentation of information can influence decision-making*

	<b>Meta-Theme 2</b>
<b>Individual projects</b>	<b>How the presentation of information can influence decision-making</b>
PANDAs Process Evaluation	Clarification of treatment choices – Decision Aid
	Patient education – Decision Aid
	Influence on the decision – Decision Aid
Patient themes from Informed Consent project	Information passively received
	Information actively sought
	Values attached to information source
Patient themes from post-operative interviews	Post-operative view of information provision
Surgeon themes from Informed Consent project	Use of models and x-rays
	Discussion of options
	Information provided by the hospital
	The consent form
	Improving the process

Table 26 *Meta-theme 3. External factors that might influence decision making*

	<b>Meta-Theme 3</b>
<b>Individual projects</b>	<b>External factors that might influence decision making</b>
PANDAs Process Evaluation	Influence on the decision
Patient themes from Informed Consent project	Patient opinion of the hospital pathway
	Information actively sought
	Values attached to information sources
Surgeon themes from Informed Consent project	Information accessed by the patient
	Consent as a process

Table 27 Meta-theme 4. The concepts and tools of Shared Decision Making

	Meta-Theme 4
Individual projects	<b>The concepts and tools of Shared Decision Making</b>
PANDAs Process Evaluation	Clarification of treatment choices
	Patient education
	Influence on the decision
Patient themes from post-operative interviews	How could the consent process be improved
Surgeon themes from Informed Consent project	Use of models and x-rays

These themes cover the decision-making process from a patient perspective ranging from patient-only factors to interactions that might influence the process and finally some active management techniques that might have a positive effect to assist patients in their deliberations.

The previous chapters highlight how these themes are relevant to the individual studies and each of these areas is reviewed below to show how the two studies reflect similarities in patient decision making and where differences occur.

#### 5.4.1 Patient-only factors that can influence how patients make healthcare decisions.

##### *Study 1. Shared Decision-making in T2DM*

The agenda for decision-making in this study was often set by the healthcare professional (HCP) in terms of organising blood tests and reviewing patients, with a view to discussing alterations to treatment if considered necessary. This compares with the IC study, where patients were often keen to seek further treatment because of disabling symptoms.

However, there were still emotional elements when patients were presented with options such as not wanting to seem “foolish”.

There were a range of factors that patients considered most influential in their decision-making, some being written information and some being the discussion with a professional. What was more evident was that information provision in the form of the PDA and improving knowledge and understanding was more important to patient deliberation, when treatment changes were proposed by the medical fraternity rather than sought by the patient.

What was also evident in this study was the importance of patient expressed control preference when presented with decision options. Patients in this setting often had some symptoms but they were not debilitating and therefore patients were more likely to use their own control preferences for making decisions.

##### *Study 2. Informed consent.*

The results from this study reveal that there is often a trigger factor for patients seeking or being referred to the orthopaedic surgeon; the main triggers being pain and reduced mobility. This is



generally followed by an expectation from patients that an operation will be offered and this will improve their quality of life. The surgeons often suppose that the patient has a reasonable level of understanding and, therefore, a lot of explanation is not always provided.

There is evidence that emotional factors were an important influence; in this setting expectations of being offered surgery were high and so relief was a factor for many patients when told they could have the operation. This sensation of relief, however, did limit further discussion and understanding of the concepts by the patient.

Patient values attached to information and sources was variable, but again did influence patients in their deliberation. Surgeons generally considered that the information they gave was the most important but this was often dissociated from the notion of informing the patient to take better consent. Patients rarely understood the concept of “informed consent” and the legal framework was not something they considered when deliberating on their options.

The main difference between the two studies was who initiated the consultation process. In the T2DM studies the process was driven by the HCPs with part of the discussion to encourage patients to consider the best option for them. In the IC study patients initiated the process, were keen to progress to surgery and emotions of relief or disappointment were far more prominent.

#### 5.4.2 Doctor-patient interactions

##### *Study 1. Shared Decision-making in T2DM*

As mentioned earlier, initiation of the process to engage patients in this decision came from the HCP. By the time of the study most patients had an on-going relationship with the HCP in terms of chronic disease management. Most patients, therefore already had established trust in the HCP and valued their opinions on these matters. The use of the PDA was seen by both parties as an adjunct to that relationship, often reinforcing and reiterating important messages. One patient’s mistrust was placed more on the medical profession generally with “goalposts” forever being moved. This patient felt that, just as you were achieving a target, the profession changed the guidelines and made attainment more difficult. This echoes some of the sentiments of patients in the informed consent study when trying to achieve weight reduction before surgery. It appears that in both situations guidelines are altered or imposed without satisfactory explanation to the patients and this can be detrimental to the relationship.

##### *Study 2. Informed consent.*

Patients generally valued their discussion with the surgeon and valued the information they received during that consultation. There was no expressed impression that one surgeon might be better than another. However, when patient expectation of surgery did not meet with surgeon approval, such as in the case of delaying surgery to achieve weight loss, there was more dissatisfaction. Once there was this sense of dissatisfaction patients started to be more critical of surgeon attitudes as well, although there was never any expressed mistrust of the surgeon.

Surgeons tended to approach the relationship with several assumptions of patient knowledge-base that were then never fully explored. Surgeons concentrated on their legal duty to inform, particularly about risk, whilst patients, through a mixture of willingness to have the procedure and relief when offered, were prepared to acquiesce to this for fear of delaying surgery.

Patients sometimes were confused about information or what documents they had signed as they received so much information in one go, with information on the operation mixed up with forms on bone sample retention and hospital policy.

The agenda for the consultation was obviously driven by the medical profession with little aberration to include patient directed initiatives.

In the T2DM study the HCPs were more engaged in encouraging patients into making a decision rather than the IC study where the decision to have surgery was almost assumed and therefore the relationship was more perfunctory to ensure legal compliance and fulfil hospital agendas.

#### 5.4.3 How the presentation of information can influence decisions

##### *Study 1. Shared Decision-making in T2DM*

This study was evaluating specific information given in a specific manner, namely the PANDAs PDA which engaged the patient in completing the booklet with a researcher. This process already addresses some of the issues raised in the IC study of information provision in written form without any professional engagement. By providing information in a PDA the patient was given a fixed amount of information, with the opportunity to ask the researcher (or later the HCP) if they were uncertain about something. The PDA was also specifically designed to require patients to consider their own values in relation to this information.

This process was well received by the HCPs who valued the information provision in the PDA and the opportunity to review that information systematically at each consultation with the patient.

The patients particularly valued the improvement in their understanding of the disease symptoms and complications provided by the PDA, but still greatly appreciated the consultation and relationship with the HCP.

##### *Study 2. Informed consent.*

Information provision was recognised to be passively received by the patients from the hospital or actively sought by them. From the hospital provided information there appeared to be two particular barriers to the information being valued by the patient. First, the volume of information on many different facets of their journey towards surgery often confused the patient. Secondly, the provision of written information without explanation was also not well received. Patients rarely read information leaflets they were given and were sometimes unaware of what they had signed. Although not universal, the patients more generally valued opportunities to discuss concerns such as at the Joint School.

Patients rarely sought information generally on hip replacements other than through casual discussion with friends and acquaintances, however, if there was a specific question such as metal-on-metal hips patients were more likely to seek further information. The internet was rarely used by patients and not recommended by surgeons.

Sources of external information were sometimes valued by surgeons but their main perspective was that they, the surgeon, provided most of the information and the other hospital contacts reinforced that information.

What seems to be lacking in IC study and present in the T2DM is the focused provision of information on the decision to be made with the elicitation of patient values and the opportunity to discuss any concerns in a one-to-one setting.

#### 5.4.4 External factors that might influence decision making

##### *Study 1. Shared Decision-making in T2DM*

Shared decision-making focuses on a single decision to be made and what knowledge the patient may need to make that decision, in accordance with their own values specific to them. Information provision, therefore, tends to centre on the one decision; whether to start insulin or not in this case. Factors external to the patient HCP dyad that influenced the decision making process included patients' encounters with others who had used insulin. A number raised concerns, and often misconceptions, such as insulin making you go blind, when actually it is the condition that does so. It was, therefore, very important to elucidate these pre-conceived ideas in order to tailor the education component of the PDA towards individual requirements.

As T2DM is a chronic long-term condition there was never perceived to be a deadline to make a decision, the HCPs were aware that patient education could lead to a better decision for that patient. Other external factors became evident such as the patient's carer/family becoming involved in the decision making and ultimately implementation of any decision that was made.

##### *Study 2. Informed consent.*

As has already been discussed, patients in this study were expecting to be offered a treatment to improve their symptoms (pain and poor mobility), but the study was looking at the influences on giving "informed consent". The obtaining of consent is the domain of the surgeon and the giving of that consent is for the patient to execute. There were factors external to this dyad that influenced the obtaining/giving of informed consent which fell into two main categories:

- Information on the procedure from sources other than the surgeon, and timing of that information
- Hospital procedures and pathways that affected the process.

Information was clearly given by the hospital, in relation to the proposed surgery, from sources other than the surgeon and after the initial consultation. Patients also, to a greater or lesser extent, sought information about hip surgery prior to the day of surgery. Patients valued these sources to a different extent but many sources, other than the surgeon, were appreciated. The surgeons were aware that information provision relating to the surgery was not just from them. As hospital policy and the pathway to surgery dictated when other appointments occurred, these sessions were often attended after signing the consent form.

The hospital procedures, therefore influenced what was incorporated into the Informed Consent process. Surgeon perception of what was important for the patient to know prior to signing the consent form also influenced the process. The hospital had instigated a lot of information provision either peripheral to the informed consent process, such as hospital infection policy leaflets, or unrelated to the primary surgery, such as signing consent forms for bone retention. This lack of clarity between information directly necessary for the provision of informed consent and peripheral information caused some confusion with a number of patients.

External factors obviously made a difference to decision making in both studies, however, the IC study appears to have a more rigid, less flexible approach to information provision and valuing external sources whilst the T2DM study adopts a much more focused provision of information. The T2DM study has a more flexible approach to external sources and when the decision should be made; namely when the patient is ready.

#### 5.4.5 The concepts and tools of Shared Decision Making

##### *Study 1. Shared Decision-making in T2DM*

This study was clearly developed with SDM in mind and the use of a PDA, one of the tools to assist patients in their decisions. What was again evident from the results of this study was the use of written information on its own was considered less useful than use of the PDA in conjunction with discussion with a professional. A number of patients valued the discussion element more than the PDA itself but recognised the improved knowledge and understanding they had about the decision to be made. Even patients with a strong autonomous control preference still experienced benefit from the PDA. The HCPs appreciated the breadth of information coverage of the PDA and the structure this could bring to a series of consultations to ensure all necessary information was covered on each occasion until the patient had reached a decision.

Although the use of the PDA did not use a specific talk back technique it did incorporate a small quiz to ensure patients understood the options and it asked patients to consider whether they needed more information before making a decision.

##### *Study 2. Informed consent.*

The main concepts of SDM as described by Charles et al (38) are relevant to the process of decision making in the IC study. Combined with the concept of preference-sensitive decisions where one option is “to do nothing” then hip arthroplasty is concordant with these themes. One surgeon described it as “lifestyle surgery” meaning that it was not emergency surgery important for the survival of the patient, but to relieve symptoms. As such there is no guidance as to who must or must not have surgery, it is up to the patient and surgeon to discuss procedures, risks and alternatives in accordance with patient values and work towards a decision. The legal framework makes it essential for the surgeon to work with the patient to ensure that any consent given is based on an understanding of disclosure and risk. The legal framework, therefore, only provides a minimum standard to be achieved.

There were several suggestions from the patients that centred on improved communications either in terms of talking to people who had recently had surgery, improved attitude by staff and provision of discussion with written information. There was no suggestion from patients or surgeons about internet provision.

One surgeon also suggested a technique they had used in Australia to assess patient understanding before the patient could move on to the next stage.

All of these suggestions are concordant with the concepts of SDM, which does not always need specific tools to implement the process.

Participants in both studies clearly appreciated written information but not in isolation; discussion of the written information was considered important. Techniques for assessing patient understanding were not used in the IC study although one surgeon commented on a technique they had seen in Australia. Review of patient understanding was an element of the PDA in the T2DM study. Overall the importance of patient and specialist collaborating to reach a valued decision for each patient was considered important.

## Chapter 6: Discussion

In this chapter the findings of the two studies are reported in relation to the original aims and objectives of the thesis, as well as referencing this work to previous literature about what is already known on the topics of Shared Decision-making (SDM) and Informed Consent (IC). The key findings from the research will be discussed in relation to the title:

**Shared Decision Making and Informed Consent in health care: An exploration and comparison of patient and health care professional experiences in primary and secondary care.**

**Can implementation of each paradigm be informed and improved upon with reference to the other?**

A conceptual model of the decision-making processes identified from these studies is presented and comparison made between implementation in a Shared Decision Making setting and that made in an Informed Consent setting.

An exemplar of a patient journey through each decision-making process will be used to indicate where perceived deficiencies in each process occur and how they could be improved upon by considering skills and processes identified in the other study.

The findings from this thesis will then be considered with reference to national policies and initiatives on improving patient participation in health care decisions. Consideration will also be given to implications of potential legislative interventions.

The implications of results from this thesis will consider how they might influence Shared Decision Making and Informed Consent at individual and policy levels. The strengths and limitations of the methodological approaches will be explored to highlight the rigour of the research processes underpinning the findings.

Consideration of future research on this topic will also be suggested.

### 6.1 Background to the Discussion

Evidence for the discussion of SDM and IC in this thesis is based on research from peer-reviewed journals and guidance published by various authorities (5, 105, 106, 246). Consideration has to be given also to legislative documentation and the common law, breaches of which can lead to negligence claims or criminal charges.

SDM has come under legislative scrutiny, particularly in the USA with state legislation (103) preceding S3506 of the Affordable Care Act (104) to enshrine SDM approaches to health care decisions nationally. The UK government supported the involvement of patients in decisions about their health (105) with promotion of SDM techniques without legislative authority. The implementation of SDM is supported through initiatives by NHS England to commission services incorporating these techniques (247). More recently the Government has issued an NHS Mandate for 2014-2015 (248) with annual updates. These Mandates are legally binding on the NHS Commissioning Board, pursuant to The Health and Social Care Act 2012 (249) and The National Health Service Act 2006 (250). Several sections of The NHS Mandate are relevant to this thesis:

Section 2 encourages patients to "... manage and make decisions about their own care and treatment."

Section 3.1.i is specifically about improving outcomes from planned treatments including hip surgery and talks about working in partnership with patients.

Section 4 Talks about improving patients' experiences of outpatient clinics and primary care services.

These are clear moves towards incorporating patient values into health care decisions.

IC has a more defined basis in common law, from the early 20<sup>th</sup> century American cases such as *Schloendorff* (115), through the UK cases of *Bolam* (118) and *Sidaway* (119) to the ruling in *Chester v Afshar* (1) raising the possibility of consent taking as being done negligently. Criticism of these cases is based on their concentration on disclosure of risk with no consideration of assessing patient understanding. There is potential, therefore, for surgeons to focus on legal requirements, which are backed by GMC guidance (5), rather than on patient involvement in the decision-making process. It will be considered later whether the NHS Mandate promoting the consideration of patient values is relevant to IC.

The discussion will start by considering whether it is appropriate to compare the paradigms of Shared Decision-making and Informed Consent generally, and more specifically in the case of comparing therapy decisions in T2DM with those faced by patients considering unilateral hip arthroplasty for osteoarthritis. Once this is established, it is appropriate then to consider how elements of each paradigm might be used when considering the other paradigm in a clinical setting. Any improvements by using such techniques would be evaluated by assessing patient experiences of the new models.

## 6.2 Is Shared Decision Making concordant with Informed Consent?

In order to establish whether it is appropriate to compare patient decisions with a PDA with those in an elective surgical setting, it is necessary briefly to revisit the literature on this subject and compare this with findings from this research. If this is established as an appropriate comparison then processes from either modality may be considered for use to promote patient decisions in the other.

The paradigms of SDM and IC have been compared in the literature by words such as congruent (corresponding in character), synonymous (equivalent in meaning) or concordant (consistent with). However, these comparisons have been at different levels. King and Moulton (9) discuss IC in broad terms of medical decisions about investigations and treatments; Meisel and Kuczewski (11) consider the effect on patient autonomy and physician responsibility if IC was "conceived as a process of SDM" whilst Whitney et al (12) explored SDM and IC in different clinical settings. Their conclusion was that SDM and IC overlap and are applicable for decisions that are high risk and have more than one choice, for example elective surgery. Whitney uses the term concordant which is the term used in this thesis. The theory tells us that in certain situations both paradigms are appropriate but it does not explore how processes and outcomes might differ by combining them.

When considering informed consent in relation to unilateral hip arthroplasty for osteoarthritis it does fulfil the criteria established by Whitney et al (12) for elective surgical procedures being concordant with SDM. This is, however, only one consideration of the topic, albeit an important one. It is also necessary, for the purpose of this thesis, to consider informed consent in the context of the defining criteria for SDM. It has been suggested (17) that there is not one definition of SDM, nor an agreed set of criteria that could be used to define the paradigm. However, the elements proposed by Charles et al (38) are the most commonly cited and this is the definition used in this thesis. Many of the myriad themes identified by Makoul (17) that are said to be incorporated into SDM (Table 1) are covered by the practical definition given by Charles.

It is necessary to review Charles' (38) four basic tenets in defining SDM and consider whether these are appropriate to informed consent in unilateral hip arthroplasty.

The four criteria are:

- (1) That at least two participants--physician and patient be involved;
- (2) That both parties share information;
- (3) That both parties take steps to build a consensus about the preferred treatment; and
- (4) That an agreement is reached on the treatment to implement

The surgeon and patient are both involved in considering the options and treatment implications; when obtaining consent the surgeon needs to disclose information on procedures, risks and alternatives whilst the patient needs to share their concerns and values to reach an informed choice. It is considered best practice (5) for the surgeon performing the operation to obtain consent, but there are more people involved in the consent process than just patient and surgeon. The IC study identifies information provision orally at the initial consultation, the pre-operative assessment clinic and the Joint School. Written information is provided for the patient, and consideration must be given to patient values on external information sources.

More than two people are involved in this decision-making process but it is incumbent on the surgeon to elicit patient preferences and "build a consensus about the preferred treatment". An informed choice can only be achieved once the patient is informed of all alternatives risks and procedures relevant to them, and evidence from this thesis is that this occurs over several contacts with the hospital.

Agreement on which treatment alternative to implement for osteoarthritis of the hip can only be considered in an SDM capacity once patients have received all information from the hospital and had their values-based questions answered. It is evident that these criteria have not been fulfilled at the initial consultation but occur over a period of time.

It is a sensible rider to Charles' criteria that health care decisions using SDM techniques are likely to be best made over a series of consultations and that IC for hip arthroplasty does satisfy these criteria, but only when obtaining consent at the end of the process.

### 6.2.1 Comparing decisions in T2DM and unilateral hip arthroplasty

SDM is not just about who is involved in the decision-making process and that the patient and HCP should be equally involved in the steps towards making an informed choice. It is also about the type of decision to be made. It has been suggested (8) that the techniques of SDM are not appropriate when there are clear standards of care that a clinician must adhere to, or guidelines to direct the clinician. Decisions appropriate for SDM are, therefore, where there are choices between two or more options with no clear evidence that one choice is superior to another. These types of decision are described as preference-sensitive as clinically there is no recommendation of one choice over another, the decision resting on patient preference which is ultimately based on patient values. In these scenarios, options presented to the patient should be done so with equipoise (49) with clinicians balancing the expression of the benefits and risks of each choice.

The decision on whether to start insulin for T2DM, and when, is one such decision where the evidence is equivocal. There are no clear standards of care or guidelines on when to consider insulin for T2DM, although advice is given by charities such as Diabetes UK (251) and The National Institute for Health and Care Excellence (NICE) (233).



NICE have issued some advice on the topic of insulin treatment for T2DM subsequent to the completion of the PANDAs study:

“Insulin treatment may be started in a person with type 2 diabetes when blood glucose levels are inadequately controlled despite:

- Dual therapy with metformin and a sulfonylurea if the person is markedly hyperglycaemic and prefers to start insulin rather than adding another drug.
- Triple therapy with oral glucose-lowering drugs” (233)

This still does not amount to a guideline as it describes patient preferences and “glucose levels inadequately controlled” which is open to significant interpretation. The development of the PANDAs PDA is, therefore, still relevant today and based on preference-sensitive decision-making and presenting information with equipoise. A summary of treatment options presented to patients in the PANDAs study are shown below:

1. Carry on with their daily routine and your blood sugars (HbA1c) and risk of complications will remain the same
2. Take greater care of dietary and exercise factors and your HbA1c will improve a little with a subsequent reduction in your risk of complications. However, this will be offset by changing your daily routine.
3. Start insulin therapy and there will be a greater improvement in your HbA1c with a greater reduction in your risk of complications. However this may be offset by weight gain and risk of hypoglycaemic events.

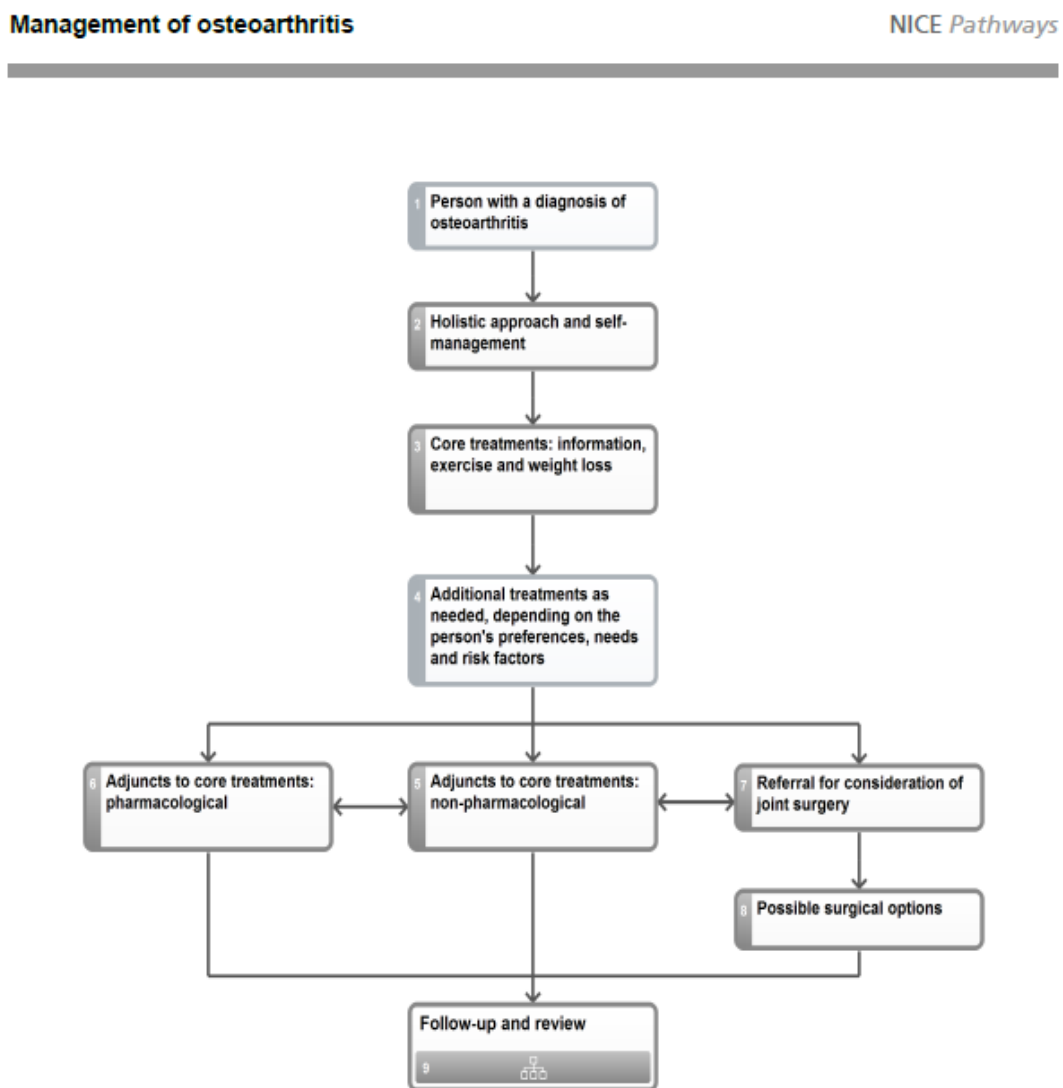
There is no clear evidence that one choice is more appropriate for a patient than another and patients will have to consider the benefits and sacrifices of each option. This is clear evidence of preference-sensitive decision making.

In terms of considering hip surgery for osteoarthritis patients are also presented with a choice of:

1. Carrying on with their daily routine. They will continue to require analgesia and their mobility will be reduced; or
2. Undergoing unilateral hip arthroplasty. They are likely to have less pain and greater mobility but this is offset by risks of surgery, anaesthetic and recovery times.

This is in line with current NICE guidance on arthroplasty for osteoarthritis highlighted in their flow diagram of the “Management of Osteoarthritis” (252).

Figure 4 The management of osteoarthritis



This clearly states that treatments such as surgery are one of the options to be considered, based on the person’s preferences, and again there is no guideline to suggest that this course of action should be taken.

This opinion was also expressed by one of the surgeons in the study, stating that consideration of hip arthroplasty was a “lifestyle choice”. The implication is that this is not a decision about a life or death intervention but making a choice based on balancing the benefits and risks of surgery. The surgeons also expressed the opinion that patient engagement in the decision was important even if this was sometimes assumed by the surgeon, or the patient expressed that there was not enough time for such deliberations.

When using the definition of SDM provided by Charles there is strong evidence from practice and NICE evaluation that the deliberations facing patients relating to informed consent in unilateral hip

arthroplasty fit with this model. Surgeon opinion also supports the concept that decisions about hip arthroplasty are consistent with a model of patient choice and preference.

### 6.2.2 Comparing an SDM Framework with IC

Another consideration is whether IC in relation to hip arthroplasty fulfils the Ottawa Decision Support Framework (ODSF(66)) triumvirate of Decisional Needs; Decision Quality and Decision Support (Figure 1).

The ODSF uses a three-step process to:

- assess client and practitioner determinants of decisions to identify decision support needs;
- provide decision support tailored to client needs; and
- evaluate the decision making process and outcomes.

Through this process it is possible to assess decisional needs in terms of factors such as knowledge, uncertainty and personal characteristics; as well as supplying decisional support in terms of clarification, values assessment and facilitation of the process. The results comparison and synthesis of the two studies, discussed later, identify that these are characteristics and requirements of both studies, defining that SDM techniques are applicable to the Informed Consent scenario of unilateral hip arthroplasty.

The PANDAs Decision Aid was designed specifically to support and address issues raised through the ODSF in relation to decisions about insulin therapy in T2DM. The development of the PANDAs PDA and implementation in the main study was strongly influenced by the theories underpinning the ODSF. Informed consent for unilateral hip arthroplasty is influenced by several factors such as legal doctrine, ethical debate and hospital policies. Many of the influences on IC relate to liability of the surgeon or his/her employer as much as considering patient decisional needs and support. The latter are generated through ethical debates around patient autonomy and are the elements aligned with the ODSF work. Whilst legal cases tend to focus on disclosure of risk, much of the research and commentary on IC focuses on the three steps described in the ODSF. The research study on IC explores the elements of decision support needs and information provision in preparation for surgery.

In the IC study there is also the added factor of the consent form whose objective is viewed differently by patients, HCPs and lawyers. Signing the consent form may be viewed as a culmination of the decision-making process when dealing with surgical consent as the patient would appear to have agreed to the operation. Patients in this study certainly viewed signing the form as a necessity to allow the surgeon to proceed with the operation, whilst surgeons viewed the form as documenting the discussion about risks that had taken place. Meisel (11) identified the misconception that a signed consent form provides protection against liability in negligence cases. Others (153, 155, 156) have noted the poor quality of completion of these forms, potentially putting the surgeon at greater risk of being found negligent if sued.

In terms of considering the ODSF framework it is described as a process that requires assessment of decisional needs, support to fulfil those needs and evaluation to ensure the process has been satisfactory. Lidz (10) also describes a one-off event model of IC, and a process model that they consider is more appropriate.

This thesis identifies that decisions made with a decision aid support this process model, with information and patient decisional needs assessed on each visit with the HCP. The IC model

evaluated here consists of a mixture of one-off “events” and a more prolonged process. The consent form was often signed at the initial consultation and not revisited thereafter (an event model) whilst patients continued to receive further information about their operation at subsequent appointments with the hospital.

The final element of the ODSF framework is evaluation of the decision-making process. Whilst this, in part, may encompass the provision of opportunities for patients to have their concerns addressed it must also include assessment of patient understanding of the information and decision. This is achieved, using decision aids, by a section giving patients opportunities to check their understanding of the main points and to reflect on whether they need further guidance. Several studies (144-147) have identified poor understanding by patients of operative techniques and recollection of complications. This study also suggests that surgeons tend to rely on their own assessment of whether they think a patient understands the implications of their decision. One surgeon did comment that when he had worked in Australia, patients were given a knowledge test before they could proceed to the next stage of an information DVD. None of the surgeons had used such techniques in this country.

The theory surrounding IC is concordant with the ODSF framework of SDM but the current implementation of the consent process studied does not fulfil all stages of that framework.

Having reviewed the evidence and established that IC is concordant with SDM in the study settings presented it is important to consider how the current knowledge and study findings advance our understanding. By comparing current knowledge with new findings it is possible to generate a conceptual framework that incorporates “How patients make healthcare decisions” into a patient-centred model for preference sensitive decisions.

### 6.3 Developing the Conceptual Framework

What has been established so far from this body of work is that, although SDM and IC have different origins relating to health care provision, they can overlap in certain medical settings such as elective surgery. One of the core premises behind the development of SDM is that when patients are engaged in discussions about health care decisions, they are more knowledgeable and more likely to make decisions consistent with their own values. This is borne out consistently by Cochrane reviews on SDM and patient decision aids (30, 91, 234, 253).

IC has been driven more by case law judgements, which often reflect changing social norms, from the “prudent doctor” view seen in Bolam (118) to the “prudent patient” view proposed by Lord Scarman in Sidaway (119) and finally the patient-centred view in Chester (1). Subsequent guidelines, such as those from the GMC (5), have drawn on this legislation and promoted this patient-centred approach to IC.

It is evident that there are situations when treatment may be lifesaving and delay could jeopardise patient survival, such as the gunshot wound example given by Whitney (12). In these cases expediency often “trumps” patient involvement in decision making, and rightly so. However, in situations where there is a choice of options, one of which is to do nothing, and these choices may vary depending on patient values, then IC becomes concordant with SDM. The theories and processes promoted by SDM become relevant for IC and, through comparison of the two paradigms, a new conceptual framework can be drawn.

This conceptual framework draws upon what is already known about the paradigms of SDM and IC whilst encompassing the new evidence presented here. The output for this conceptual framework is:

“Incorporating patient-centredness in health care decisions that should be preference-sensitive”

This is a core concept of SDM and an aspiration of models of health care promoted in the NHS over the last few years (105, 248).

In order to maintain this statement as a core principle of NHS health care provision it is important to understand how patients make healthcare decisions about treatments and investigations. The theory talks about rational decision-making with evaluation of information and choosing a logical option, or intuitive decision-making that can lead to poor decisions. Current evidence in medical decision-making suggests this is over-simplistic with factors such as framing of information (139) and the number of options presented (75) influencing decisions.

This new conceptual framework proposes that there are several patient-specific factors that determine how a patient will make their health care related decision and these are influenced by many factors from initiation of the decision pathway to the final decision.

### 6.3.1 How patients make healthcare decisions – patient-specific factors

#### 1. Who initiates the process?

The first factor which originates from new findings in this thesis is who actually initiates the decision pathway. In the T2DM study it is evident that patients have a long-term relationship with their HCP and discussions may already have been had about insulin. Initiation of this discussion is driven by the HCP with guidelines on when patients with T2DM should have blood monitoring and when to consider escalating treatment. The agenda is driven by the medical profession.

In the hip arthroplasty study patients will often have seen their GP several times with pain and poor mobility, an X-ray will have been taken showing osteoarthritic disease and a discussion about surgery will have taken place. Although this may seem a medically driven process it is clear from patient quotations presented in this thesis that patients expect surgery and can't get it done soon enough. They perceive that the operation will always be beneficial and often draw on others' experiences of benefits in pain and mobility. Both of these processes can lead to patient misconceptions.

#### 2. Patient misconceptions

Patient interviews in the T2DM study revealed that patients had concerns about insulin causing blindness rather than diabetes mellitus and one patient expressed their concern at being considered a “junkie” if seen injecting themselves with insulin. The patients in the hip arthroplasty study were all convinced that surgery would be beneficial, and in a setting pressurised by throughput targets it could be easy to confuse this with knowledge and understanding of risk.

In both these settings, engaging the patient in dialogue is important to identify misconceptions that may affect patient judgement and result in decisions not congruent with their own values on risk, complications or side effects.

### 3. Role of emotions

This was identified as another significant factor that could affect decision-making. In the T2DM study the patient who thought insulin made you go blind had seen his mother deteriorate and become dependent on others when she became blind. Several patients in the hip arthroplasty study commented on the relief they felt when they were offered surgery, often to the extent that they failed to retain any further information from the consultation and at least one patient failing to realise they had even signed a consent form.

### 4. Control preferences

This is a factor identified as being important from the literature review (238) but expressed by Patient D in the T2DM study who was clear that the decision was his to be made and was sceptical about drug company involvement and financial incentives to practices. Whilst discussion about options with patients like this may have little impact on the final decision it is still an important opportunity to ensure that their perceptions are not misguided. Even this patient did admit they got some information from the PDA.

#### 6.3.2 Meta-Themes

The influences on “How patients make healthcare decisions” have been described throughout this thesis as the meta-themes from the data analysis. There are four meta-themes described and they all influence the way patients make decisions to varying degrees.

##### *6.3.2.1 Meta-theme 1 Doctor (or HCP)-patient interactions*

This was a core theme identified from the literature review with communication being seen as the main ingredient (63) but difficult to define (61). This thesis explores some of the issues within this interaction that can affect the communication process.

#### 1. Who initiates the process?

Although this was an important independent factor directly influencing how patients make healthcare decisions it also influences communications within the consultation. In the T2DM study, with HCPs initiating the decision-making process it is incumbent upon them to take the patient on an intellectual journey through disease knowledge and complications, treatment options and consequences and exploring values and misconceptions. The HCPs task is not to “convince” the patient into one decision or another but to ensure the decision is based on as wide a discussion as possible.

In the hip arthroplasty study, patients are almost expectant of surgery and find any barriers, such as further outpatient appointments, frustrating. There is a pressure from patients to get to surgery quickly. The surgeon’s task is, therefore, more difficult as they have to initiate discussions and processes that can frustrate patients but are essential to creating an informed consent. This can sometimes lead to assumptions being made.

#### 2. Assumptions in the consultation that remain unexpressed

Assumptions can sometimes be made that patients considerations are based on factual knowledge. If these are not challenged then misconceptions might not be identified, such as insulin and blindness. However, what is evident more from the hip arthroplasty study is the assumptions surgeon’s make about patient understanding. More than one surgeon expressed the idea that they

could tell, due to their experience, whether a patient understood the information. There was often little or no attempt to check patient understanding of the concepts being discussed.

Misjudged assumptions without assessment can clearly influence the decision a patient may make.

### 3. Competing agendas

It was evident from previous studies (182, 183) that there is often a mismatch in what patients want to learn about their surgery and what surgeons consider important. Patients are much more focused on hospital stay and recovery, whilst surgeons are more interested in talking about surgical techniques and risk. Understandably the surgeon is guided by a legal framework that puts risk discussion at the forefront. However, it is important to recognise that this is only one part of a discussion around patient-centredness and other issues also need exploring.

#### *6.3.2.2 Meta-theme 2 How the presentation of information can influence decision-making*

It has already been suggested that the way information is framed (139) can influence patient decision making. The T2DM study also considered whether the decision to be made was highlighted.

##### 1. Identifying the decision to be made.

Although it might seem clear what decision is to be made this is not always apparent. In the T2DM study it would be assumed that the decision is whether to start insulin or not. However, the PDA provides 3 options; continue as currently and make no change, follow the dietary and exercise advice more carefully or start insulin. The hip arthroplasty study may also seem a choice between surgery or no surgery but the NICE evidence suggests a third option of increasing or optimising analgesia. Analysis of consultations using the OPTIONS instrument in study 1 revealed that the nature of the decision to be made was not always identified clearly by the HCP.

##### 2. Written information provided with oral discussion

This was a key area in the literature review where evidence was inconclusive as to the best method of information delivery to improve retention. Discussion on its own was valued by patients in both studies, although patients in the hip arthroplasty study experienced differing benefits from discussion with different professionals. What was particularly evident from this study, though, was the amount of written information provided to patients without discussion. These included leaflets on blood transfusion, bone retention and hospital infection policy. Patients rarely read these and one even forgot they had signed the consent form because of all the paperwork. These studies support the work that suggests the provision of written information is important but only when combined with discussion.

##### 3. Isolating and signposting discussion about the decision

The last scenario also highlights the importance of ensuring discussion and information about the decision to be made is isolated from other information provision. The use of a PDA in the T2DM study was designed to perform this function, however, without such a tool in the hip arthroplasty study, written information provision became overwhelming and was not isolated from other considerations. This had the effect of either confusing patients or leaving information unread because important information was not separated from general information.

### *6.3.2.3 Meta-theme 3 External factors that might influence decision making.*

External factors were considered to be those outside the direct HCP-patient interaction or hospital led process of information provision. These may range from the role of family and carers to the influence of cultural norms and health care policy.

#### 1. Sources of information other than the HCP or hospital

This is a topic that has had little coverage in the literature, but as a practicing GP is seen every day, when a patient wishes to discuss something they have heard on the radio, read in the Daily Mirror or seen on the internet. Both studies identified that patients can be influenced by information from other sources. This may be family experiences of T2DM therapies or a friend who has done well from hip surgery. They are important sources of information to the patient so should be evaluated as such by the HCP, whilst reflecting current medical practice and individual circumstances.

#### 2. Role of the family and carers

This was considered a separate topic from 1 above because of an unexpected finding in the T2DM study. This was the use, at home, of the PDA by family members to support and encourage the patient to make lifestyle changes. This extends the role of information provision before a decision to one that can support change management as well, as long as it is written in an easily understandable format.

#### 3. Social and cultural norms.

Munro et al (254) discussed how social norms around the acceptability of Caesarean section can influence the rates of normal delivery compared to surgically assisted delivery. Concerns about carrying needles and injecting oneself can create a concern about being viewed as a drug abuser, especially at airport security checks. Many people (70,000 a year (108)) are having hip surgery, often quite elderly and having good results with reduced pain and improved mobility. Patients often view these positive outcomes of a friend's surgery without considering the risks.

#### 4. Policy and wider influences on HCP decision making

This was considered an important influencing factor and was highlighted by the Health Foundation review of the consultation (64) that suggested these interactions be viewed within a wider NHS context. In the T2DM study one patient raised concerns about the influence of drug companies on treatment choices as well as the payment scheme for GPs through the QOF scheme. The surgeons in the hip arthroplasty study admitted that a patient was not actually considered suitable for surgery and listed until after the pre-operative assessment, even though the consent form may have been signed. Hidden agendas can be strong influencing factors on patient decision making, especially, as the name suggests, when they are unaware of them.

### *6.3.2.4 Meta-theme 4. The concepts and tools of Shared Decision Making*

Many of these themes have been identified above but are important to consider in relation to the paradigm of SDM. In particular, it is the experiences within the consultation that can have important impacts on patient decision-making. It is important to recognise that these considerations should be relevant to IC only if it is considered concordant with SDM in the settings studied.

#### 1. Informed consent can be concordant with SDM.

As discussed previously, in the settings explored, using the practical definition of Charles et al (38), it is appropriate to consider the two paradigms as concordant. It follows, therefore, that the



techniques recommended for SDM are appropriate to consider in an elective surgical setting. It also becomes apparent that some of the concepts of SDM that are poorly implemented under that paradigm, such as discussion with multiple HCPs engaged in the patient's care (30), are actually much better established under IC.

## 2. Focusing on patient values to identify misconceptions

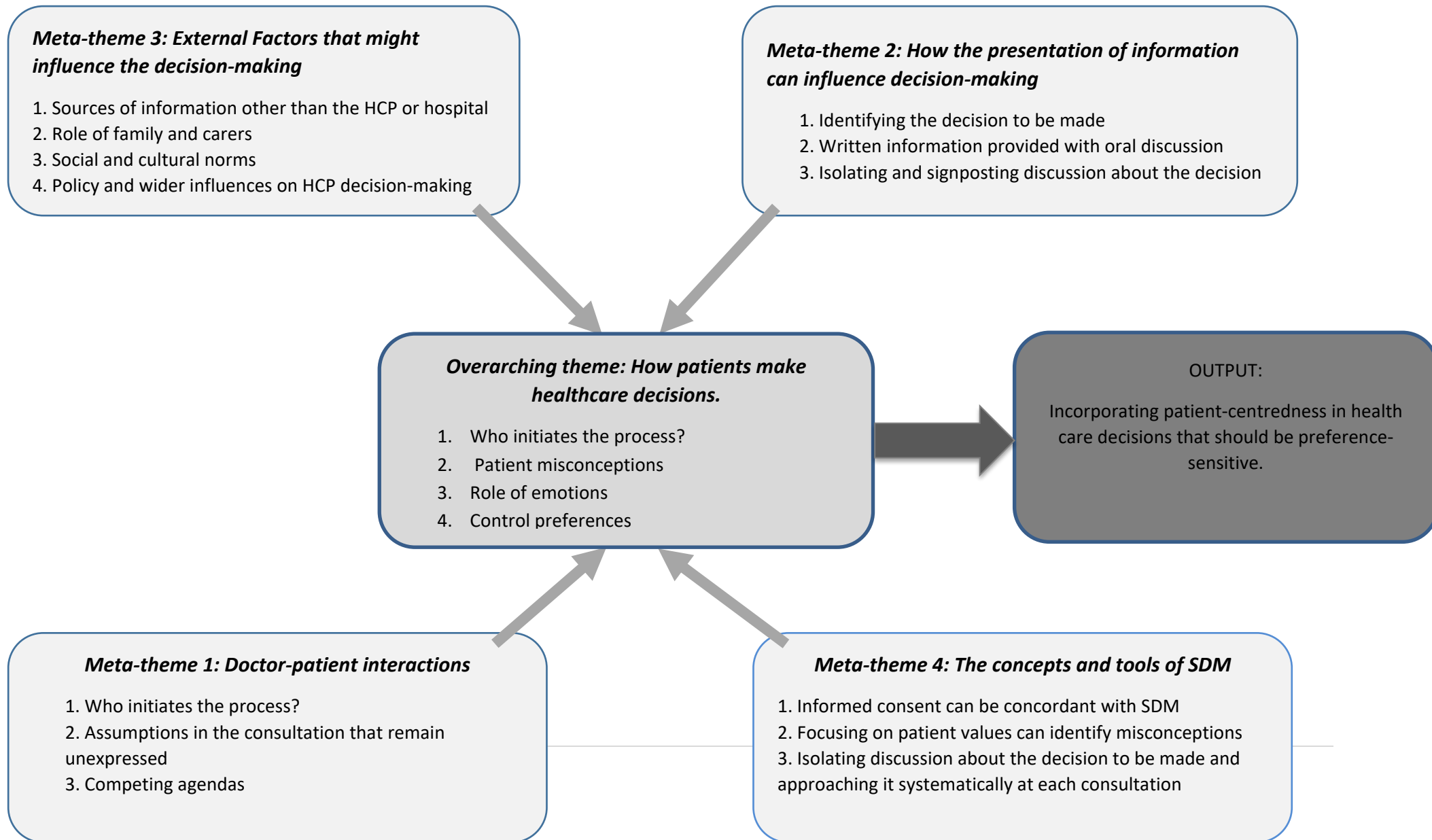
Although the topic of discussing misconceptions is raised earlier it is essential to recognise the mechanism for eliciting these. Although they may arise in general discussion, it is evident from the T2DM study that by exploring patient values systematically in relation to the decision to be made misconceptions can be identified, which can only be addressed once recognised. Exploring patient values does not just try to correlate the patient decision with their values but can also generate a deeper understanding of the condition by addressing misconceptions.

## 3. Isolating the discussion about the decision to be made and approaching it systematically at each consultation.

The literature review identifies that there is often a mismatch about the content of information provision required by patients and surgeons, whilst the current studies highlight the need to isolate and signpost information relevant to the decision. In the T2DM study there was a clear decision to be considered and this was encompassed by the PDA, although OPTIONS score analysis revealed this was not always approached adequately in the consultation. In the hip arthroplasty study the written information provision was often with no discussion and related to factors other than the main decision. There was no SDM protocol or tool to direct discussion at each stage toward the decision to be made. Appointments such as the pre-operative clinic are essential to identify and minimise surgical and anaesthetic risks, but were not identified as such, so patients either did not value them or considered them a delaying tactic by the hospital.

The conceptual framework encompassing this discussion is set out below.

Figure 5 Conceptual Framework: Outline of meta-themes that impact on how patients make healthcare decisions.



Having considered how the comparison of results from the two studies relate to the literature to create a conceptual framework of “How patients make healthcare decisions” with the output of patient-centredness, it is necessary to consider these findings in relation to the original research question.

#### 6.4 Shared Decision Making and Informed Consent in health care: An exploration and comparison of patient and health care professional experiences in primary and secondary care.

Can implementation of each paradigm be informed and improved upon with reference to the other?

##### 6.4.1 Key Findings

The research question is answered in the following pages with reference to the key findings from this research, specifically comparing the experiences of patients and HCPs of Shared Decision Making to the experiences of patients and surgeons when considering consent issues surrounding unilateral hip arthroplasty for osteoarthritis. Informed consent does have the added rigidity of a legal doctrine and legal precedent of case law, but this should be considered as a minimum standard of care, not an expected or ethically appropriate standard. If a surgeon falls below this standard, they will risk being sued in the courts for negligence. There is, however, no express incentive for a surgeon to raise standards above this level, although there may be ethical imperatives.

The two studies explored the experiences of patients and healthcare professionals when considering one medical decision that included the option of doing nothing. The comparison of the two studies’ findings at the conclusion of the results section identify key similarities and differences. Both studies identify topics relevant to the overarching theme of “How patients make healthcare decisions” and the four key meta-themes which are represented to different emphasis in each. There are also major differences between the two studies, such as “who initiates the decision that has to be made?” and how different aspects are either addressed or assumed. The key findings below indicate how evidence differed in the two studies and how, with reference to the literature, outcomes from each can be used to enhance the other.

##### *6.4.1.1 How patients make healthcare decisions*

The main theme of this thesis is exploring how patients make healthcare decisions in two different clinical scenarios, what factors might influence the decision-making process and how experiences from one paradigm might be used to influence or improve the other.

Influences on the decision-making process can be described as internal or personal factors and traits or external factors. The personal factors may be affected by the external factors required to make a decision about healthcare. These external factors are discussed under the four meta-themes of:

- Doctor-patient interactions
- How the presentation of information can influence decision-making
- External factors that might influence decision-making
- The concepts and tools of Shared Decision Making.

This section reviews what is already known about personal factors that can influence decisions and what this study adds to our knowledge. The personal factors are divided into preferences for autonomy, personality traits and emotional factors.

Patients will rely on their own preference for making decisions either autonomously, in collaboration with others or by relying on others judgement. Ende et al described the autonomy preference index (62) to represent this function and found that there was variation between people, but also variations dependant on the decision to be made. Decisions by older patients or about more serious illnesses tended to be less autonomous, whilst there was also a difference in preference between being informed and making a decision. Evidence from the T2DM study indicates that a patient's preference for autonomy in decision-making does affect the subsequent discussion and ultimate decision. Decisions made during the IC process appear much less rooted in this preference. This is maybe because any decision was made prior to seeing the consultant, or that patients had unrealistic expectations of success; all patients expressed that an operation was going to improve their quality of life and the sooner it occurred the better. However, even after several hospital appointments which would include discussion on risks and alternatives, patients were still impatient to have surgery. It appears that the decision to commit to surgery in the IC scenario is initiated by the patient, whereas the decision to consider insulin in T2DM is initiated by the HCP.

The work by Croskerry and Schmitt (136, 138) suggest that sometimes patients do not want to be involved in decision-making or often make intuitive decisions that can sometimes be right but can be improved upon by deliberation. SDM techniques try to move patients from the non-functional intuitive process to the more rational deliberative model. This seems to work in the consideration of insulin therapy for T2DM but in relation to IC the patients expressed a desire for more time to consider options but ultimately agreed to surgery, as they have initiated the process and were certain it would improve their quality of life.

Redelmeier (139) considers the emotional aspects of decision-making more in terms of patient ability to balance losses and gains, with patients overemphasising the loss aspect and having distorted memories of past experiences. This can be seen in the T2DM study with patients more concerned about being labelled "a junkie" at airport customs, or recollections that it was insulin that made their mother go blind when it was more likely to be the diabetes. These are very strong factors that patients considered in rejecting insulin. Antrobus (167) discussed how anxiety could influence a decision whether or not to consent to a premedication study, but the findings of the IC study identify a more fundamental problem with emotion. Expectations were high at being offered surgery and when this was actually realised the patients expressed such relief that they failed to recollect anything subsequently discussed at the consultation. This has major implications in terms of patient engagement and understanding of the procedure and ultimately how "informed" the consent will be.

The ODSF also distinguishes the stage of decision-making that a patient may be at that can influence the outcome of any discussion on healthcare. Again there was evidence from the T2DM study that some patients were closer to a decision than others, but in the IC study all patients had decided upon surgery, making the task harder for the surgeon to consider risks and alternatives. This can lead to the "minimum" option of discussing risk in terms of legal requirement and not considering patient preferences or understanding of any discussion.

Patient comprehension of the term “Informed Consent” is poor (171) and yet vital to patient engagement in pre-operative discussions. Patients need to be made aware of the implications of informed consent and that signing a consent form is not just to protect the surgeon or hospital.

#### *6.4.1.2 Doctor-Patient Interactions*

The interaction between doctor and patient is recognised as vital to the decision-making process and is one of the central extraneous factors that influence how patients make healthcare decisions. It is not just the overt relationship that can influence the decision, there may be hidden or competing agendas that shape the discussion. One view of the competing agendas is in terms of paternalism or autonomy which Wear discusses extensively in his book (133), and though there has been a move away from the paternalistic approach to medicine some have argued that a certain amount of directed beneficence is still required (135). Meisel (11) describes autonomy as a “shopping trip” where options are laid out for the patient to choose from, without any direction, and clinicians can leave the patient to decide, even if they think it is a bad choice. Quill (134) and Caplan (135) suggest doctors need to exert more expert opinion to direct patients or use their “authority” to empower patients to make a choice.

The interaction between patient and HCP was very different in both studies; the T2DM study involved ongoing dialogue over regular intervals with an HCP that the patient had met before, whilst the IC study involved a shorter term arrangement with a surgeon who was generally only seen once prior to surgery, other HCPs often only being seen once as well. It is possible to gain a greater understanding of patients’ attitudes to healthcare issues over repeated visits, as well as patients gaining greater confidence in HCP skills. Verheggen (186) described how patient trust in a doctor can lead to a better understanding of decision-making and lead to an agenda more driven by patient concerns. With a single contact between surgeon and patient there was little opportunity to develop this relationship and arrive at an agenda driven by patient concerns. Again, the feeling of time pressures by patients also influenced this interaction.

The development of good communication skills in IC (140) or adopting the core competences required by physicians for SDM (49) might mitigate against some of these short-comings in the doctor-patient interaction of surgical consent. Patients in the T2DM study certainly appreciated the time to discuss their potential decision when directed with a decision aid and there was an insignificant time difference between consultations with or without the aid (6).

Surgeons taking consent admitted that they often made assumptions about patient wishes and understanding, thereby limiting a patient-driven agenda by failing to explore patients concerns or even misconceptions that the patient may have about treatment risks or options.

The competing agendas in any consultation are far more extensive than a balance between patient autonomy and clinician beneficence. There may be personal competing agendas in relation to IC such as the mismatch in information requirement and provision described by El Wakeel and Newton–Howes (182, 183), or in this thesis which identifies the assumptions made that can limit a surgeon’s ability to address patient expectations because they have not been explored. Wear (133) also describes patients and doctors as “moral strangers” where they are unlikely to share the same values and beliefs or even understand each other’s moral views. Wear argues that this dissociation is aggravated in hospitals where residents (junior doctors) have little time or incentive to engage with

patients. This may also be influenced by cultural norms (42); the patients in the T2DM study expressing concerns about the public opinion if they were seen injecting themselves, or in the IC study the perceived norm that surgery is the best option for treatment of osteoarthritis.

Competing agendas may be at a more intellectual or academic level, both studies identify the issues of medical paternalism against patient autonomy, which is tackled specifically by an SDM approach; the perceived wisdom being that options are weighted equally and so patient engagement is encouraged. In terms of IC there are the agendas of legal issues compared to ethical debate; the legal issues taking priority as surgeons are aware that failing these standards could result in litigation. Ethical issues of patient engagement, autonomy and understanding are addressed in practical terms but having subsequent hospital appointments, including an open discussion at Joint School, but this is dissociated from the consenting procedure.

A further level of conflict within the doctor-patient interaction may arise from local or national policy initiatives. The management of T2DM in primary care is funded through the Quality Outcome Framework (QOF) (98), with GPs being paid for monitoring HbA1c levels (amongst other things) and getting a certain proportion of patients on their diabetes register below target. There is, therefore, financial pressure on practices to reduce patient HbA1c scores which has to be balanced with patient choice. In terms of the T2DM study, patients were more commonly seen by the practice nurse who is not directly affected by the practice achieving QOF targets. The study focused on a small number of patients considering one treatment decision so finance did not seem to influence the discussion.

The other conflict is in terms of time availability. In the T2DM study HCPs did consider that consultations took slightly longer with a decision aid but considered the extra time investment was worthwhile. In the IC study patients did express a concern that there was not enough time to evaluate the information provided and this echoes the King's fund concerns about hospital priorities (97) in terms of case throughput and volume.

The evidence from these studies indicate that the use of SDM techniques does address many of the barriers that can occur within the doctor-patient interaction, encouraging discussion and exploration of any misconceptions or perceived norms. However, the use of SDM techniques still does not address the cultural differences between patients and professionals. Although time and financial pressures seemed to have little effect in this small study, this may be different in routine practice.

In terms of IC the current study suggests that external pressures on the clinician have more influence on discussions than patient-centred concerns. There is evidence that surgeons concentrate on the legal requirements of IC and do not progress to assessing patient understanding or other ethical considerations. There appears to be significant time pressures that do not permit patient-valued discussion. The mismatch in information provision continues, resulting in Lidz "Event" model of IC rather than a "Process" model (10).

#### *6.4.1.3 How the presentation of information can influence decision-making*

The presentation of information was identified as another significant factor that could influence the way patients make decisions. This was not just the format of the information e.g. oral or written, but many other factors such as framing of the information, because patients often view risks as categorical rather than a range.

In terms of SDM the framing of information is directly addressed through Elwyn's (49) suggestion of equipoise; as there are no clear advantages of one choice over another then all choices should be represented equally, with balance given to discussion about risks and benefits of each option. The development of the PANDAs PDA ensured that evidence presented was balanced in this way. In relation to the IC study, it was not clear that information was presented in this way. The consultations were not recorded so it is impossible to comment on the oral provision of information, however, leaflets given to the patient to read were not discussed or explained but provided for the patient to read if they wished.

The provision of written information has raised concern in many papers; Turner (146) identified that providing information booklets without discussion did not improve information retention but may be used as an important defence in court. Written information on orthopaedic procedures was often poorly understood by patients (175) although this may be improved by getting patients to re-write the leaflets for other patients.

The development and implementation of a decision aid is designed specifically to tackle the issues of information provision. The PANDAs PDA is designed to be used with the HCP rather than on its own, with the HCP answering questions raised by the patient. Some patients did suggest it was simple enough to use on its own, but delivery of the tool with the HCP allows pre-conceived ideas and misconceptions to be identified and addressed.

The pre-operative pathway in hip arthroplasty includes provision of information in a number of different ways; one-to-one discussion at the consultation, written leaflets at the consultation and pre-operative clinic and group discussion at the Joint School. While it is seen as important to provide information in different formats this can only be useful if performed in a coherent manner. Patients did often find consultation with the surgeon or group discussion at Joint School very useful, but most did not read the leaflets provided. This may partly be due to the lack of discussion about the information contained within the leaflets but was mostly about the volume and diversity of leaflets. The volume of paperwork given to the patients meant some did not even realise they had signed a consent form or been given a copy to keep. Patients also complained about the complexity; some leaflets were about bone retention for research purposes, some were about blood transfusions, some were about hospital policy on infection control and very few were on the operation itself.

Patients had also expressed a lack of information on recovery after surgery (181) and this was confirmed by the IC study. Patients considered they received little information on what activities they could start and when after surgery, with no information on discharge other than the district nurse would visit them to take their stitches out. Patients who had previously had a hip arthroplasty had been given exercise sheets and often retrieved them to work through again. Although this highlights a change in discharge and recovery practices from hip arthroplasty over recent years, with a move to earlier discharge and a policy of doing what your hip surgery will allow you, this change in policy has not been passed on to patients. By not exploring patient expectations of care after surgery this created a feeling of abandonment by patients. Rather than patients thinking this was a more modern and effective policy they felt that the hospital had performed the surgery and were not concerned about their recovery.

Other sources of information that were considered was the use of videos (148) and the internet (149). The use of a PDA in the PANDAs study did not consider the use of video material although Agre had suggested that the use of video material may eliminate concerns about reading ability.

The PDA was assessed for reading age before being implemented to try and ensure it could be used by most patients.

One of the surgeons in the IC study discussed the use of videos in Australia and they are routinely used in some centres in America (255) where they are posted out to patients to view at home. Videos had obviously been used at the Joint School previously, but there was some confusion amongst surgeons as to whether these would be re-made or not.

What was more evident was the lack of confidence in recommending websites to patients; many were thought to reflect poor recommendations or could be sponsored by drug companies. Even NHS websites such as NHS Choices were not recommended because they were considered “too clunky”. Patients did not express any desire to research hip surgery generally on the internet, although some did look up specific information about metal-on-metal hips when concerns were raised in newspapers and on television.

The age profile of patients considering insulin for T2DM and hip arthroplasty are similar and generally more elderly, a population that is less computer literate. However, more computer literate patients will start to require these interventions and consideration should be given to easily accessible, quality information on-line. One surgeon commented that they had developed a very good website for their private patients and should consider developing the hospital website similarly, so that information was provided and endorsed by the surgeons themselves.

Evidence from this thesis supports findings from previous studies on how presentation of information can influence decision-making but highlights other problems that should also be addressed to improve patient engagement in the process.

1. Information provision can incorporate written material but the contents of such material should also be discussed, otherwise patients are unlikely to read or understand even the best written leaflets.
2. Information relating to IC should be provided in isolation from other information and decision-making considerations. Whilst it is important that patients are aware of hospital infection policies or bone retention schemes, these are separate from surgical consent issues. By mixing this information together patients get confused and are less likely to retain information. Signposting information at each hospital contact that is relevant to consent issues will help patients to focus and Barritt (159) suggested that introducing consent issues specifically at each visit can improve patient understanding. Considerations using the PANDAs PDA were used to concentrate on one decision only.
3. Patients were concerned about recovery and on-going care and if they have unrealistic expectations they are likely to feel “abandoned” by the hospital. Whilst after care may have changed and new practices are routine to hospital staff, this is not necessarily the case with patients.
4. HCPs appreciated the use of a PDA as it covered all important discussion points, created structure to each consultation and ensured that, by working through it on each occasion no topics were missed. This would be important in creating focus in a surgical consent setting.

#### *6.4.1.4 External Factors that might influence patient decision-making*

External factors, in terms of patients considering health care choices, are defined here as processes or interventions not directly linked to the patient-HCP interaction or patient interaction with the



healthcare provider (GP surgery or hospital). These external factors may influence the patient directly or may influence the way health care is provided.

The main external factor that influences patient decision-making directly is the value patients attach to source of information other than from the GP surgery or hospital. Patients can be influenced by experiences of other people and base their decision on this rather than their own values. Examples in the management of T2DM are the patient who refused insulin because his mother had gone blind “because of the insulin”, not because of the diabetes. This deeply ingrained misconception made it very difficult for the HCP to get the patient to even consider insulin. Another example was the patient who was so concerned about being stopped at customs if he had needles and syringes in his bag. Obstacles that could be overcome by a covering letter from the GP had created more challenging decision-making through patient misconception.

Most patients considering hip arthroplasty had either sought out the opinion of others who had had surgery or had chanced upon people who had had hip arthroplasty. Some patients even valued this information above some of that provided by the hospital. As mentioned in the last section, patients occasionally sought information from the internet or even medical journals, but this was often in response to specific concerns. There was little evidence for patients using the internet when considering insulin therapy for T2DM.

What significantly affects the decision-making is the HCP elucidating this information from patients and then addressing the issues concerned. Some may be valid concerns but some may be deeply entrenched misconceptions that the patient attaches significant value to. Some of the misconceptions may be due to changes in policy such as early discharge after hip arthroplasty that patients construe as worsening care rather than clinically proven progress. Again such mismatch between expectations and reality can create conflict and, unless elicited during the consultation process, cannot be addressed.

The use of SDM techniques and core competencies of the HCP (49) are designed to elicit patient concerns and values so that they can be addressed. Surgeons were aware that patients did seek information from elsewhere but did not incorporate this into their consenting discussion. It can even be argued that the surgeons did not incorporate much of the hospital provided information into their consenting techniques, frequently getting the consent form signed at their one and only pre-operative contact with the patient.

It is, therefore, vital to elucidate patients’ sources of information, values attached to that information and reasoning behind those values to empower a patient to make a judgement based on appropriate knowledge and values.

A further factor identified from the T2DM study was the involvement of family and carers in the decision and implementation thereof. Patients were often seen on their own during the consultation with the PDA but were able to take the booklet home. Two patients explained that their partners had found the PDA “lying around” and had read through it. Both commented that their partners considered they were not doing enough with their exercise and diet to manage their diabetes, and that this had encouraged their partners into altering their habits. A tool that is succinct and directed towards the one decision, used with an HCP but readable on its own by patients and carers and available to take home has a clear advantage of engagement of home members involved in patient care. This information also identifies that family members or carers can influence the

decision-making process and should be considered in any decision requiring the balancing of risks and options.

Other external factors that might influence HCP approaches to decision-making include the payment-by-performance scheme of QOF, rewarding GPs financially for achieving reduction in HbA1c in a proportion of their patients with diabetes. Significant influences on surgeons include legal requirements when obtaining consent and hospital policies to manage the necessity for patients to be seen within 18 weeks. (256)

Social and cultural norms can also create significant demand for procedures that are not always clinically necessary. One study (254) identified the social norms associated with lower segment caesarean section child birth compared to vaginal delivery in certain populations, resulting in increased demand for the procedure despite clinical evidence that it is overused already.

The complex web of interplaying factors that influence patient decision-making and HCP empowerment of patients may require re-assessment of the role of the consultation, as suggested by The Healthcare Foundation (64). What is clear from this thesis is that eliciting patient views and values attached to all sources of information is vital to ensure that any misconceptions are addressed and patient decisions are based on sound medical and values-based knowledge.

#### *6.4.1.5 The concepts and tools of Shared Decision Making*

PDA's can be used to concentrate on one decision only which can be useful by excluding extraneous information, but it is clear that when considering surgical consent there are many other important topics to cover, such as infection control. These are not necessarily directly linked to obtaining consent, but incorporate important procedures for the patient to be aware of and may have an impact on post-operative morbidity.

PDA's are only one tool used to promote SDM and can be useful in concentrating on one decision, but it is some of the implementation techniques of SDM that may prove more useful in an IC setting. A review by Ong (63) revealed that physician behaviour can influence patient decision-making and if patients are to make appropriate healthcare decisions for themselves, then physicians need to allow that to happen. Vranceanu (140) recognised the importance of communication skills and Elwyn identified the core competencies required of clinicians to promote SDM (49). These two studies confirm the need for good consultation skills to explore issues important to each patient, promoting patient engagement and incorporation of their values into the decision-making process. It is, therefore, important to utilise discussion with SDM tools.

PDA's were appreciated by HCPs for bringing structure to consultations and may be useful for exploring routine topics. However, patients do have different risk factors that cannot be covered in one booklet and require specific discussion with the HCP. This is equally true for assessing patient values, which can vary significantly. In terms of surgical consent surgeons would always assess physical factors to discuss individual risks as well as the routine discussions, but do not seem as concerned about assessing patient values or understanding. This appears to be a practice driven by legal requirements. Concentrating on guidelines rather than considering what could be done to support a patient to make an appropriate decision can ignore information that is seen as unimportant to the physician but of great importance to the patient.

We know that use of PDAs can improve patient knowledge with reduced decisional conflict and greater participation in discussions (30) but it is also important to give structure to the process leading to the decision. In the T2DM study the decision-making process incorporated enough time for the patient and HCP to discuss information relating to the decision, with an opportunity for patients to make an appointment to return to discuss issues further, until they were satisfied with their decision. The IC process was controlled wholly by the hospital with appointment dates set by them and the intervention date also defined by them. Patients, therefore had to make decisions in set timescales and any postponement put the patient to the back of the waiting list. Hospitals do have imposed timescales to achieve in terms of referral-to-treatment targets (256) and their rigid process appears aligned to this rather than patient preparedness for surgery.

There are, therefore, restrictions to flexibility within a hospital pathway compared to the primary care process. These restrictions do not prevent more patient-centred care, they mean that patient-hospital contacts need to be evaluated from patient and hospital needs. Despite these restrictions, Barritt (159) showed that simple changes could be incorporated into the IC pathway that were more patient centred.

When considering incorporation of SDM techniques this will require three main considerations:

- Incorporation of SDM tools such as PDAs or optiongrids (80)
- Training of staff in core competences and SDM techniques
- Adapting the pathway to allow greater consideration of patient preferences

There are, however, barriers to implementing any of these changes. SDM tools take a significant amount of time and money to develop properly (257), with many originating from North America and, therefore, not necessarily relevant in the NHS (97). The MAGIC programme (13) found that many physicians thought they were already using SDM techniques when in fact they were not. Staff resistance to training and the time involved are already recognised as significant barriers. Implementing a change to practices within hospital pathways may also be met with resistance, not only because of redesigning pathways but also the focus on outcomes and throughput rather than on process and patient experience.

Even by implementing simple changes in the IC process such as signposting information relevant to obtaining consent at each hospital contact would produce significant improvement to patient experiences. Having a consent clinic at the end of the process would acknowledge information provision and gathering as an integral part of the consenting process.

## 6.5 How do the themes relate to the patient journey?

When evaluating “Decision-making in two different clinical settings: A comparison of patient and health care professional experiences of Shared Decision Making and Informed Consent” it is important to consider what each process looks like now and how it may be adapted, with reference to current knowledge and the findings above, to improve patient involvement in healthcare decision-making.

Using current knowledge from the literature review and patient pathways alongside new evidence from this thesis it is possible to consider enhanced pathways for each decision that can promote

patient engagement, result in better-informed decisions and potentially, in the case of IC a more robust process that leads to less litigation.

### 6.5.1 Exemplar of the patient journey

Evidence presented in this thesis confirms that IC in relation to unilateral hip arthroplasty is concordant with SDM (12) and that by comparing the implementation of both paradigms it is possible to identify factors that influence the patient decision-making process in each.

By utilising the learning points from each separate study and applying them to the decision-making processes of the other study it is possible to create an exemplar, or model process that, if followed, would improve patient engagement. With greater patient engagement in the decision-making process, patient satisfaction, their knowledge of the disease and treatment options would improve with potentially less litigation, particularly in terms of IC. This section brings together the learning points from comparison of these two studies to create separate exemplar pathways for consideration of insulin therapy for T2DM and IC in relation to unilateral hip arthroplasty.

Each pathway uses a timeline from initial consideration of the decision to be made until the decision is actually actioned. Each step will consider the new information raised in this thesis and which of the influential themes on patient decision-making has influenced this new pathway. Table 28 reveals the current pathways to enable comparison with the new timelines.

Table 28 Patient journey from initiation of process to instigating treatment option

Stage of patient journey	Patient with osteoarthritis (IC)	Patient experiences	Control of the appointment agenda	Patient with T2DM using a PDA	Patient experiences	Control of the appointment agenda
<b>Initiation of patient journey</b>	Patient request usually after prolonged symptoms	Patient: Expectations Misconceptions		HCP request usually after prolonged follow up	Patient: Fears Misconceptions Resistance	
<b>First contact with HCP</b>	Secondary care	Often valued Sometimes too brief Sometimes confusion Often relief Decision often requested	Structure dictated by the hospital	Primary care	Discussion Exploration of pre-conceived ideas Exploration of values Structure of consultation with PDA	Structure flexible and agreed between patient and HCP until decision reached
<b>Second contact with services</b>	Secondary care Pre-operative assessment clinic	Viewed as a necessity Little additional information Not the most valuable contact Consent not discussed		Primary Care	If required structure created by PDA Ensures decision discussed systematically	
<b>Third contact with services</b>	Secondary care Joint School	Discussion often valued More information on recovery		Primary care	If required structure created by PDA Ensures decision discussed systematically	
<b>Treatment instigation</b>	Operation date set in advance	Often can't wait to get operation done		Patient can make a decision at any time	Uncertainty and decisional conflict reduced by using a PDA	

### 6.5.2 Consideration of insulin therapy for T2DM

For the purpose of this thesis the definition of SDM used is that proposed by Charles et al (38), which encompasses a practical and pragmatic implementation. The decision is what options can the patient consider when they are on maximum tolerated oral therapy but their diabetes is still poorly controlled, as measured by the HbA1c blood test. One of the options to consider in this scenario is the initiation of insulin. The T2DM study within this thesis has identified that consideration of this decision is initiated by the HCP, usually following prolonged intermittent follow up of diabetes management over several years.

There is no clear evidence of the benefit of any of the options over each other:

- Make no change
- Follow the diabetes advice more regularly
- Add insulin

SDM techniques are, therefore appropriate to use and any consultation should consider the core competences proposed by Elwyn (49):

1. Implicit or explicit involvement of patients in decision-making process.
2. Explore ideas fears and expectations of the problem and possible treatments.
3. Portrayal of equipoise and options.
4. Identify preferred format and provide tailor-made information.
5. Checking process: understanding of information and reactions.
6. Checking process: acceptance of process and decision-making role preferences.
7. Make, discuss or defer decisions involving patients to the extent they desire to be involved.

Elwyn et al subsequently developed a tool, The OPTION scale (96), to enable observers to analyse consultations between patients and HCPs in relation to these core skills.

The use of PDAs developed along appropriate guidelines (81) has been shown to increase patient knowledge and understanding, whilst reducing decisional conflict (30). The PANDAs PDA conformed to these criteria (257). By using these techniques and evaluations, alongside comparison with experiences in IC for hip arthroplasty it is possible to establish current best practice.

### 6.5.3 Proposed Exemplar of patient journey for consideration of insulin in T2DM

#### **Initial consultation.**

Discussion on considering options for further treatment of T2DM is initiated by the HCP, usually after prolonged follow up for diabetes management. Patients are often unaware that many of their symptoms relate to poor glycaemic control and often consider them as part of their general health (258). The discussion to consider options therefore requires a patient education element, as patients may be more willing to consider changes if they are aware of the potential benefits in symptoms or risks of complications.

The discussion does require HCP direction to empower the patient (134, 135) rather than just to offer a series of options for the patient to choose from (11). Direction is required to explore possible misconceptions about treatment and educate the patient as to current evidence-based knowledge. However, it is also important for patients to be made aware that their involvement in the process is important and they should be encouraged to express their preferred decision-making option as well as their own values on information provision.

The stage at which a patient is in their decision-making on this one healthcare problem also needs to be assessed (8) so that the HCP (and patient) are aware of how long the process might take to reach a decision.

The use of a PDA addresses some of these areas but clearly requires HCP skill in eliciting some of the more difficult concepts of patient misconceptions or values. To be achieved well this demands good communication skills and knowledge of SDM goals, but also requires confidence by the patient in the HCP to overcome some of their ingrained misconceptions. This, arguably, cannot be achieved by telephone support from an unknown “health adviser” as proposed by the Right Care scheme (99), but by a long-term relationship between patient and HCP.

Analysis of interviews using the OPTION Instrument in relation to patient involvement in the decision-making process identifies a distinct dichotomy between GPs and Practice nurses (PN). The practice nurses had longer consultations and higher OPTIONs scores. This reflects several factors in terms of disease management in primary care. Since the 2004 contract changes chronic disease management is provided more by practice nurses, patients having greater contact with the PN than GP. Due to the nature of preventative disease management rather than illness management for which patients see their GP, consultation length with the PN has been tailored accordingly.

Evidence from this study indicates that PNs are better placed to provide SDM consultations and deliver PDAs than GPs, and PDAs are more appropriate for chronic disease management.

The role of the PDA and SDM does not end with the conclusion of the initial consultation.

#### **Time between initial consultation and next review**

This is a period where patients might wish to gather more information about their condition or options for treatment. There is little evidence that patients use the internet to gather information, although HCPs do suggest patients try websites such as Diabetes UK (251). The study did, however identify an advantage of the PDA over normal care; when left lying about in the house, partners of the patient read the tool and became involved in discussion about the decision to be made as well as implementing changes to lifestyle to improve outcomes. It is not clear whether this was based on risk stratification within the tool or just the fact that the PDA was written in a way that people could understand without HCP support.

Turner (146) identified that providing written information without discussion does not improve retention of information. Discussion with the HCP has already been identified as important in engaging the patient in discussions, but there are benefits in creating a tool that can be re-read on its own. A PDA that allows patients and carers to revisit it at any time without HCP support has added advantages in disease management.

#### **Subsequent Consultations**

The PDA can be used at every subsequent consultation, at the discretion of the patient. HCPs in this study, however, expressed their desire to use the PDA again to create structure to subsequent discussions and ensure no knowledge topics or expression of patient values were missed. By using this structured approach it would be possible to revisit patient concerns or misconceptions.

Use of the PDA subsequently may elicit carer involvement in the decision-making process and lead to discussion about how the implementation of any decision might be better achieved. Patients are

supported in making a decision when they feel prepared and this is evaluated each time with the PDA.

HCPs considered that initial consultations might take slightly longer with the PDA, although this was shown to be not statistically significant (6). It was considered that this extra time would probably lead to better decisions and fewer appointments in future as decisions would be based on patient values.

#### **Added value by considering the IC study results**

One feature that was evident from the IC study was the fact that patients were not unanimous in their preference for methods of information delivery. Some preferred one-to-one discussions whilst others preferred the group format of Joint School. It is possible that delivery of the PDA with one HCP may not be every patient's preferred mode of delivery of information. Patient preference for mode of information delivery was the one area in the OPTIONS score that consistently scored poorly. It is possible that discussion with different HCPs or in group settings may be beneficial in engaging more patients in health care decision-making.

Comparisons with the patient journey for IC in hip arthroplasty overall are favourable. The IC process creates a rigid framework and timescale within which patients have to make their decision, partly driven by nationally imposed waiting times and partly by hospital policy. Patients in the IC scenario often felt there was not enough time for discussion and were confused by the amount of paperwork provided without explanation. The opportunity for patients to take readable information home to discuss with relatives and carers and then have that considered in subsequent consultations is beneficial to both patients and HCPs.

#### **6.5.4 Informed consent for unilateral hip arthroplasty**

In this scenario patients had been referred by their GP for consideration of unilateral hip arthroplasty for osteoarthritis. It is apparent that patients considered this as a referral for definite treatment rather than a consideration of surgery as one option. Theoretical options include the three options proposed by NICE (252):

- Adjuncts to core treatment: pharmacological
- Adjuncts to core treatments: non-pharmacological
- Consideration of joint surgery

It is beyond the scope of this thesis but it is evident that GPs should be making patients aware that referral to an orthopaedic surgeon is to consider the options, including surgery, rather than a referral for surgery.

This thesis provides a new insight into patient perceptions of their referral for surgery, which is not evident from previous research. Patient expectation is that they will have an operation and that operation will be successful. As discussed above in relation to SDM techniques in T2DM, HCPs need consultation skills to identify misconceptions and address them appropriately, possibly at each hospital contact.

Hospitals will have other agendas during the patient journey, particularly to make sure patients are fit for any proposed surgery. It is important to recognise such distractions from the IC process are necessary but should not interfere with discussions about consent.



Apart from the concerns about patient expectations of the process, issues were also identified from the IC study relating to patient experiences. Issues raised included a lack of time to discuss concerns, surgeon assumptions about patient understanding and signing the consent form at the first appointment. Patients felt a necessity to comply in case anything delayed their surgery, and as such were less engaged in any decision-making. Engaging patients in health care decisions leads to greater satisfaction and potentially less litigation. It is, therefore, important to review the IC process in terms of techniques that promote patient engagement in these decision-making processes.

#### 6.5.5 Proposed Exemplar of patient journey for giving IC for unilateral hip arthroplasty.

##### **Referral by GP**

Ideally any prior discussion with the GP should include the fact that referral is for consideration of further options including surgery, not just for surgery itself.

##### **Initial Consultation**

As already happens this should be with the surgeon who is going to perform the surgery, but should be about consideration of options including risks of each option presented with equipoise. Surgery should not be the only option discussed and, whilst legal requirements of risk presentation must be included, should also explore patient ideas, concerns and expectations. It is important to identify patient misconceptions that might affect their understanding of the surgery or risks. Patient values should be elicited in relation to sources of information so that these can be incorporated in future discussions.

Any form of consent should not be sought at this stage as patients' emotions may interfere with their recollections and further information will be provided and sought. It would seem sensible from this body of work to explain to the patient whether the patient is going to proceed on the pathway to surgery and to highlight what further appointments on the pathway the patient can expect, and approximately when they might occur.

The suggestion therefore, would be to develop a tool that could be used as a PDA to cover the areas required for an SDM approach to obtaining consent, but could also be used as the consent form itself. Such a tool can be used to engage patients in the decision-making process, identify misconceptions that can be addressed, create structure to each contact with the hospital and cover topics relevant to consent on each occasion. Patients would develop familiarity with the contents of the tool by taking a copy home and discussing it with carers, relatives or friends. This would require surgeon training in SDM core competences and use of decision aids.

The tool could be used as a consent form if it is discussed and signed at each visit to hospital, with a completed form of signatures on two or three occasions an indication of a "process" of consent rather than an "event" (10). Separate consent forms would not then be required. A copy of the tool could be given to patients with the signed master copy retained in the patient notes as consent forms currently are.

##### **Time between initial consultation and pre-operative assessment clinic**

This is a period where patients sometimes have questions raised by the initial consultation or may seek information from people who have already had the surgery. Evidence from the T2DM study also suggests that a PDA may engage family and carers in discussion about the surgery.

##### **Pre-operative assessment clinic**

The main purpose of this clinic is to ensure the patient is fit for surgery and to discuss any questions the patient has. This is usually carried out by one of the experienced nurses in clinic. This clinic should function in a similar way with preparation for surgery including information leaflets and discussion about fitness for surgery and hospital policy. The discussion about any questions raised by the patient could be addressed by resorting to the PDA to ensure structure and thoroughness of the discussion. The T2DM study indicates that use of PDAs does not need to be restricted to doctors and, in fact, nurses may be better placed to use such a tool. The master copy could be signed again to indicate this discussion.

### **Joint School**

Patients appreciated the discussion nature of this session, with opportunities to ask questions. This session focused on aftercare as well as surgical details and hospital procedures. Structure brought by a PDA would be too strict, particularly as the session involved patients undergoing knee surgery as well. It would also be inappropriate to consider signing individual PDAs as the strength of this session lies in its group discussion nature. The Joint School should continue unaltered but vital information discussed in this session should be considered as part of the consent process.

### **Second consultation with the surgeon (Consent clinic)**

This is a clinic that some surgeons already use in unilateral hip arthroplasty but is not universal. It is the responsibility of the surgeon performing the operation to ensure that patient consent has been obtained (5). When considering consent as a process it is essential, therefore, that it is the surgeon who sees the patient on the final hospital visit before surgery. The PDA can be used again to create a structured discussion of issues relevant to consent taking and it can then be signed again to confirm further discussion and patient agreement to proceed to surgery.

A “process” approach such as this will encourage patients and clinicians to consider more than just the legal requirements. Patient engagement at different appointments is more likely to identify patient misconceptions and address patient concerns. Use of such a tool will signpost discussion about consent issues and separate them from other necessary discussions. The signed PDA is a more robust documentation of discussion over a period of time than a consent form; more likely to fulfil surgeon desires for documentation that would protect them in court (11, 153). Printed documentation would negate the illegibility or poor completion of some consent forms (155-157) and progress the work done by Barritt on pre-populated forms (159).

A master copy kept electronically on a hospital database as suggested by Thompson (160) would allow access to the PDA at different clinics and, hopefully, avoid the prospect of having to consent patients in the pre-operative holding area (162).

These exemplars of a patient’s journey and experiences are derived from the research data of this thesis which is based on literature review, researcher experience and talking to experts in the field.

## 6.6 Considerations of paternalism and patient autonomy

The research into patient experiences in providing consent for hip arthroplasty highlights an overall satisfaction with the outcomes of reduced pain and increased mobility from the surgery, but little understanding of the implications of the process leading up to surgery. Patients expressed a general desire to proceed to surgery as quickly as possible, and were subsequently more interested in the recovery process afterwards, whereas surgeons were driven, to some extent, by a need to cover legally driven agendas. It may prove difficult to introduce further valuable discussion when patients have signed a consent form and wish to proceed to surgery as soon as possible.

There may be an element of sub-conscious collusion in that patients wish to proceed rapidly to surgery whilst surgeons experience time pressures and need to discuss legal minimum standards. This can lead to a tendency towards paternalism in that once the surgeon has decided the patient is suitable for surgery there are time constraints to conclude the consultation. This limits the patient's ability to express any further autonomous decision-making in the initial consultation.

There has been considerable debate about paternalism and patient autonomy, with some (134, 135) arguing that medical paternalism should not be ignored completely but redirected towards empowering patients in their decision-making. This still requires acknowledgement of patient autonomy in decision-making. Cheng (259) argues that in order for patients to express autonomy in decision-making they must consider information rationally. He argues that there are three threats to patient's ability to make rational health decisions:

- Insufficient information
- Irrational beliefs/desires and
- Influence of different framing effects.

Themes identified from these studies concur with Cheng's view of threats to patients making autonomous health care decisions, but diverge from his solutions. He argues that:

“To overcome these problems...it only requires the disclosing of thorough medical information, the provision of good arguments and the presentation of the same information in different perspectives.” (259)

Whilst these conclusions are valid it does not address all the issues identified here. No-one could argue with the provision of “thorough medical information”, an element of any well-prepared decision aid, and the IC study identifies the value of presenting information from different perspectives. Patients valued one-to-one consultations and group discussions with different HCPs. What is not covered by Cheng's argument is eliciting beliefs and desires.

The IC study shows that, when patients initiate the decision-making process, there is often a mismatch between patient and surgeon agendas; patients want to get their surgery as soon as possible and surgeons have to fulfil their legal obligations. In this scenario patient beliefs may never be identified and, therefore, never addressed. The T2DM study revealed that by exploring issues through SDM techniques it was possible to identify misconceptions and try to address them.

This thesis recognises that it is only possible to identify irrational beliefs and desires by exploring patient values, an integral element of SDM, and this is not achieved just through “the provision of good arguments”.

Challenges to decision-making are different in making choices about insulin for T2DM and hip arthroplasty for osteoarthritis. These range from who initiates the process, timescales for making decisions and legal and ethical influences. However, it is evident in both situations that provision of information, exploring patient values and expressing information from different perspectives creates the greatest opportunity for patient engagement. It is beyond the scope of this thesis to explore what patient autonomy actually is, and whether it is achievable, yet this body of work identifies practical steps, through the use of SDM techniques, that can move health care decision-making away from paternalism towards patient-centredness.

Improving complex patient decision-making in health care settings does require consideration beyond the single encounter of patient and HCP. This may include several encounters with different HCPs providing information in different formats. Such processes of decision-making require greater understanding of the wider concepts of the healthcare system as described in The Health Foundation updated model of the consultation (64).

It is necessary, therefore, to view some of the wider policy frameworks in relation to decision making and how the findings from these studies relate to these.

## 6.7 National policies on patient involvement in healthcare decision-making

Policies and directives come from many sources within the NHS such as The Department of Health and affiliated bodies such as NICE, and from bodies promoting patient-centred co-ordinated care such as “The Coalition for Collaborative Care” (260)). Drivers for change have include the Coalition Governments white paper on the NHS (105), re-iterating the phrase “No decision about me, without me” and this has been preceded by regulatory body guidelines on patient involvement and informed consent (5).

NICE Guidelines have a section on Patient-centred care (246) derived from patients’ rights and responsibilities set out in the NHS Constitution for England (256). The NICE guidance states:

“Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals.”

### 6.7.1 Policy Framework

The NHS Institute for Innovation and Improvement have published an essential guide to “Transforming Patient Experience”, quoting 8 criteria from the NHS National Quality Board Patient Experience Framework, which has been adapted from The Picker Institute Framework (261).

1. Respect of patient-centred values, preferences, and expressed needs, including: cultural issues; the dignity, privacy and independence of patients and service users; an awareness of quality-of-life issues; and shared decision making;
2. Coordination and integration of care across health and social care system;
3. Information, communication, and education on clinical status, progress, prognosis, and processes of care in order to facilitate autonomy, self-care and health promotion;
4. Physical comfort including pain management, help with activities of daily living, and clean and comfortable surroundings;

5. Emotional support and alleviation of fear and anxiety about such issues as clinical status, prognosis, and the impact of illness on patients, their families and their finances;
6. Welcoming the involvement of family and friends, on whom patients and service users rely, in decision-making and demonstrating awareness and accommodation of their needs as care-givers;
7. Transition and continuity as regards information that will help patients care for themselves away from a clinical setting, and coordination, planning, and support to ease transitions;
8. Access to care with attention for example, to time spent waiting for admission or time between admission and placement in a room in an in-patient setting, and waiting time for an appointment or visit in the out-patient, primary care or social care setting.

Whilst all of these criteria are not necessarily relevant to every health care decision, the theoretical implications and practical implementation of SDM address a number of issues in this framework.

Although Informed Consent to surgical procedures has a specific set of criteria for information provision established through common law, this is a very narrow focus as described previously and should not exclude the broader principles outlined above. As such the comparison between the practical implementation of SDM and IC for hip arthroplasty highlights areas where the IC process can be developed to fulfil more broadly the relevant parts of the Patient Experience Framework.

#### 6.7.2 Developing SDM and IC to fulfil the relevant criteria of the Patient Experience Framework.

Before considering the relevant individual criteria of the Patient Experience Framework it is important to consider the broad underlying concept, which is one of patient and healthcare professional working in partnership for the best process and outcome for that individual patient. Perhaps the reason this has not been a partnership before is the focus on outcome, the knowledge of which is held mainly by the HCP. This focus and imbalance leads to a disproportionate influence on the decision by the HCP. By creating an equal weighting to factors such as patient values, preferences and needs the influence on the decision can be rebalanced, resulting in a partnership synonymous with Charles' criteria for SDM.

“1. Respect of patient-centred values, preferences, and expressed needs, including: cultural issues; the dignity, privacy and independence of patients and service users; an awareness of quality-of-life issues; and shared decision making”

Although shared decision making is referenced specifically, it is the other factors mentioned that permit the use of Shared Decision-Making as a framework. The T2DM study was developed to incorporate these issues and identified that they are broadly achieved through the appropriate use of a patient decision aid. When compared with the IC study, there is evidence of significant assumptions being made by the HCP (surgeon) rather than patient expressions of values, preferences or needs. This is partly due to the study evidence that patients are keen to proceed to surgery as quickly as possible and, therefore, tend to focus more on the post-operative recovery period, whilst common law dictates that surgeons focus particularly on the disclosure of risk.

Patient request for treatment, as is the case in hip arthroplasty, renders this criterion much more difficult to achieve. It is much simpler for the surgeon to discharge his legal duties and proceed without reference to any of the requirements of this statement, than the HCP discussing the benefits or otherwise of insulin therapy. If this stage is not addressed then HCPs may not be made aware of individual patient misconceptions about treatment or pre-conceived ideas. If these are not addressed then patients may proceed to a decision based on false values, potentially leading to worse outcomes.

“3. Information, communication, and education on clinical status, progress, prognosis, and processes of care in order to facilitate autonomy, self-care and health promotion;”

This statement not only includes the correct information provision but also includes communication of that information in an appropriate manner to assist patient education. This thesis highlights the fact that information can be provided, but not necessarily in a manner that the patient values, or it can be provided with a lot of other information that masks the information relevant to the decision to be made. Thus in both studies patients valued the provision of written information with discussion, rather than written information on its own.

There was evidence from the T2DM study that patient preference for mode of receiving information was rarely assessed but provided through the one-to-one consultation model. The IC process used different models such as discussion groups at the Joint School, although these were provided uniformly rather than through patient preference.

Written information was provided in both studies but to varying degrees. Patients in the IC study discussed their confusion at written information provided by the hospital that was not relevant to their surgery or the IC process. Written information without discussion was often ignored and the sheer volume of information sometimes resulted in patients being unaware that they had even signed a consent form.

This statement also ties in with statement 8, particularly with reference to informing the patient about process.

“Access to care with attention for example, to time spent waiting for admission or time between admission and placement in a room in an in-patient setting, and waiting time for an appointment or visit in the out-patient, primary care or social care setting.”

Patients in the T2DM study were informed of when their appointments were, when their next appointment was due and how to contact the services should they wish to be seen sooner. In the IC study patients often complained of uncertainty as to when their next appointment was and what exactly it would be. These patients are much keener to have intervention than the T2DM patients and, therefore, any delay or uncertainty as to process creates anxiety and ultimately an unhappy patient. Patients were very frustrated if their surgery was delayed for weight reduction, occasionally requesting to see a different surgeon. Whilst in this scenario it may not be possible to give exact dates, patients should be informed of future appointments, who they will be with and their purpose, as well as an expected date for surgery.

Informing patients about the process is likely to create less anxiety, but should also be used to signpost the decision to be made. In terms of the T2DM study the discussion about considering insulin therapy could be addressed at each consultation and structured with the PDA. With the IC study each hospital contact had different remits, not all of which were relevant to the patient

decision to give informed consent. Indeed given the fact that the patient had signed the consent form at the first consultation, the rest of the hospital contacts may have seemed irrelevant to the patient, who was keen to have surgery and signed a form to agree to the procedure. The SDM approach isolates the decision to be made at each contact and ensures this is discussed with reference to patient values. Barritt et al (159), inadvertently took one step towards this process by approaching the consent issue at each hospital contact before surgery and ensuring forms were signed, again if necessary, just prior to surgery.

“5. Emotional support and alleviation of fear and anxiety about such issues as clinical status, prognosis, and the impact of illness on patients, their families and their finances;”

The T2DM study identifies family support as an important factor in helping patients with their decision and supporting them in achieving goals set out by their decision. The Informed consent study identifies a slightly different problem relating to emotional support that arises out of the initiation of the decision-making process. As already discussed it is the patient who initiates the process towards considering surgery and this creates its own emotional problems, mainly around expectations and whether they are fulfilled. This can result in significant relief which, in turn, causes failure to recollect information. This can ultimately have an impact on the informed consent process with patient’s failure to retain important information about their procedure.

“6. Welcoming the involvement of family and friends, on whom patients and service users rely, in decision-making and demonstrating awareness and accommodation of their needs as care-givers”

From the T2DM study there was evidence that patients would go away and discuss their illness and treatment options with family and carers, with decisions not being made immediately but deferred until a patient was ready to make that decision. Time frames in hospital are more strictly governed, with NHS England setting target times from referral by the GP to being seen, and target times to treatment (256). There is, therefore, less of a policy to permit patients as much time as they need to make their decision, resulting in more time pressures and less time to encourage and evaluate family and friends influence. This does not mean to say that hospitals should ignore this issue and, by adopting a policy of highlighting to the patient when outpatient appointments will be and what to expect, this issue can be targeted. By signposting and considering Informed Consent issues at each hospital appointment it is possible to address the family and friends influence within the current framework of appointments.

## 6.8 Strengths and Limitations of my research.

Research, particularly qualitative work, can never be conducted in “ideal” situations as this type of study explores peoples’ opinions, experiences and interactions with their environment. Whilst it is possible to explore these factors in similar settings, they can never be the same and this is part of the qualitative paradigm. It is exploring everyday events through different experiences that informs the research and creates a broad picture of the topic in “natural” surroundings.

Research is often designed to answer a specific research question, but can create more questions. A project that creates more questions is not a limitation but an indication of where greater

understanding of a topic is needed. This next section explores the strength of this research before moving on to the limitations.

## 6.8.1 Strengths

### 6.8.1.1 Qualitative

The strength of any work relies on framing the research question and then using the appropriate methodology to answer that question. This project relied on an extensive literature review of the topic from a medical, legal, ethical and patient-centred perspective. By exploring a topic from different angles it is possible to get a broader perspective. It was, therefore, important to draw on personal experiences (medical and legal) as well as consulting supervisors, patients and experts in the field.

By using qualitative methodology and a combination of in-depth interviews and focus groups it was possible to develop a greater understanding of decision-making issues in two health settings from both sides of the consultation. By interviewing patients and HCPs it was possible to identify some of the issues described in the literature relating to the mis-match between patient and HCP expectations. Exploring these issues further with reference to a theoretical framework gave a rich insight into how patients make healthcare decisions in different settings.

Rather than comparing similar types of decision-making such as one elective surgical intervention with another, the author chose to compare different scenarios and settings where patient knowledge and understanding are highlighted in the literature as vital to effective decision-making. Each topic has its own framework; the elective structure of SDM and the imposed structure of legal doctrine on IC but with other competing ethical interests. This comparison of the two techniques exposes benefits and potential limitations of each approach, allowing practical recommendations to improve the patient experience.

Rigour in qualitative research is important to engender credibility in the results as well as to show that research done in the “real world” outside the strict confines of clinical randomised controlled trials can still be trusted. Using the divisions described by Lincoln and Guba (213) it is possible to show how each study fulfilled the criteria for rigour.

### *Credibility*

In qualitative research this is the accuracy of description of the parameters of the study. Presentation of both studies includes detailed descriptions of how and where recruitment took place, the physical setting of the interview and the environment being explored, as well as demographics of patients and HCPs relevant to the aims of the study. Descriptions, therefore, extend beyond simple age/sex profiles to include relevant factors such as consenting techniques of the surgeons or control preferences of the patients in the T2DM study. Personal experiences of helping patients make health-care decisions and obtaining consent from patients also influenced the research. Triangulation was achieved through the use of quantitative tools such as the Oxford Hip Score and OPTIONs score to compare patient declared experiences in the interviews with more objective or structured techniques. Meticulous detailing of interviews with verbatim transcripts analysed whilst listening to the recordings and cross-referencing to contemporaneous field notes ensured rigour in the analysis stage, as well as using a validated form of analysis, namely Framework analysis. Discussion with colleagues in the Academic Department, PhD supervisors and through student supervision provided feedback on the direction of the research.



### *Transferability*

This is the applicability of the research findings to other settings and is generally considered not appropriate for the results of qualitative research. This concept of generalizability is more applicable to positivist approaches to research where sampling is meant to be representative of the population as a whole or sub-set thereof. Qualitative techniques apply maximum sampling variation to ensure that the data is enriched by experiences from all sections of the population examined, but is not necessarily representative of that population as a whole. This research encompasses very specific decision-making in terms of insulin therapy in T2DM and surgical intervention in hip osteoarthritis. It is possible that some of these findings are relevant to similar scenarios or where decision-making is instigated by the patient or HCP. However, it is for others to make these connections, explored through subsequent research.

By describing settings and patient demographics it is possible to show the variation in sampling across each study.

### *Dependability*

In positivist terms this is the reliability of a study and is based on the assumption of an unchanging world. Qualitative work is based on the influences of changing environment on results, therefore, even observation by the researcher or the introduction of a topic to the discussion can change the results. Change is inevitable when conducting health services research, some of this may be policy driven with the moratorium on orthopaedic referrals between December 2011 and March 2012 affecting some patients in the IC study, but not all. Some changes may be in terms of clinical advances in treatment, for example during the T2DM study guidance was brought out on new injectable treatments for the condition that were not insulin. Decision-making may then be influenced either by the route of treatment (injection vs oral) or the type of treatment (insulin vs newer injectables) Although these changes can render some findings obsolete, if they are underpinned by an accepted theoretical framework such as SDM then conclusions can still be valid.

### *Confirmability*

In all qualitative research there will be researcher bias in collection and analysis of the data. It is important to take steps to reduce this bias, although it is not possible to eliminate it completely.

The author has discussed openly their own experiences and motivation to perform the research as well as being self-conscious during the analysis. Some of the research tools (OPTIONS score) required more than one researcher to analyse and debate the results whilst interviews were reviewed with two other researchers in the Department to check data handling techniques and structure of the analysis framework.

Results from the two studies have been fed back to the recruiting institutions, namely Department of Orthopaedics at The Northern General Hospital and participating practices in the PANDAs trial across South Yorkshire.

#### *6.8.1.2 Quantitative*

The use of quantitative data in both these studies was not to specifically answer the research question but to triangulate data from the qualitative work.

The quantitative data (OPTIONS score) from the T2DM study gives an insight into how different health professionals support SDM in their consultations for chronic disease management. This data

also reveals which areas, considered important in SDM, are least well elicited during the consultation. The dataset was too small to give meaningful statistical results and was not considered for analysis in this way. However, it does provide insight into the differences between practice nurse and GP consultations in chronic disease management and the scores can be cross referenced with patient and HCP interviews to support their opinions.

A recent paper that identified no statistically significant improvement in patient empowerment for setting and achieving goals with a PDA (262), and corresponding editorial (263), recognise the importance of "...illuminat(ing) the black box of clinical encounters". Analysis with the OPTION Instrument does this to some extent, although it does not explore the language of these encounters. Systematically analysing the consultation for the HCPs skill at involving the patient in the decision-making process was cross-referenced with interviews with the two participants. Reviewing these dyadic interviews together revealed close correlation of patient and HCP opinions and reflected the consultation data well. The use of the OPTIONs instrument permitted triangulation of the qualitative data whilst also generating important themes on the concept of "How patients make healthcare decisions". The OPTIONs data informed the development of meta-theme 2 "How the presentation of information can influence decision-making" and the concept of isolating discussions around the decision to be made.

Quantitative data in the IC study was collected in the form of pre- and post-operative Oxford Hip Scores. These scores are validated for analysis in large numbers of patients and not at an individual patient level. The licence obtained for this research (Appendix 2) restricts the use of the scores so as not to permit analysis of the tool at an individual patient level. Again with small numbers of patients statistical analysis would be meaningless. Trends within the scores show an improvement for all patients before and after surgery, the largest gain was for the patient who had bilateral hip arthroplasty and no gain was seen in the patient who declined surgery.

The post-operative scores were collected at the start of the second interview and were compared with results from the pre-operative scores. This gave an impression of changes in quality of life that patients had experienced in relation to their hip surgery. By doing this before the second interview had commenced allowed these quantitative results to be explored further in the subsequent interview and confirm that changes in quality of life were related to hip symptoms and not other causes.

The data from the Oxford Hip Scores therefore had dual functionality: to inform discussion in the second interview and to triangulate data from both interviews on patient expectations of recovery with a Patient Reported Outcome score.

Quantitative data was helpful in triangulating data from the qualitative work, thereby improving credibility whilst also contributing significantly to some of the meta-themes generated from the synthesis of the results.

### 6.8.2 Limitations

Despite attention to detail and rigour in conducting and analysing the research there always remains challenges and limitations to any body of work. Issues raised by conducting the research and preparing the thesis were identified and discussed with research colleagues, specialists in the field

and PhD supervisors. Information from the studies were discussed at advisory group meetings which included patient representatives.

#### Topic

The topic has been limited to informed consent for surgical procedures, which are different from IC in research settings, the main area from which the ethics of patient autonomy is derived. Routine care has predictable interventions with known risks and predictable outcomes. Research settings tend to have predictable interventions but often unknown outcomes or unknown benefits, if any, to the patient. The issue of using patient autonomy as a valid marker for IC scenarios is, therefore, debatable. This is regardless of the fact that there is no consensus of what patient autonomy is in the healthcare setting, and whether it is attainable or desirable.

The concepts of SDM have arisen out of concerns for lack of patient involvement in research setting decision-making and have been adapted to the healthcare arena. Whilst the concept of involving patients in healthcare decision-making is laudable, there is likely to be continued imbalance within the consultation as the professional will have knowledge of procedures, risks and alternatives as well as introducing bias in recommendations. As Meisel noted (11) it could theoretically be possible to present this information and then allow the patient to choose, even if the professional considered this a bad choice.

The research has considered the concordance of IC and SDM to make these comparisons and developed practical considerations that should improve patient experience of both chronic disease management and the Informed Consent process. However, it has been beyond the scope of this work to explore the finer nuances that distinguish decision-making in different settings. One obvious example of this is the difference between patient initiated healthcare decision-making and professional initiated processes. This was touched upon in Tan's paper on cataract surgery (179) where some patients refused to discuss risks and complications further.

#### *Single researcher*

Much of the funding and progress towards a higher degree required the majority of the work to be completed by a single researcher. Whilst this allowed the work to be focused it also meant that some of the findings could be considered biased. Forms of bias were discussed earlier (3.6) and steps taken to minimise these. Certain situations demanded that other researchers became involved such as analysis of consultations with the OPTION Instrument, or where one researcher had delivered the PDA to the patient it was considered inappropriate for them to then interview the patient on delivery of the same. AB also supervised AW, a BMedSci student working on Informed Consent, and it was considered appropriate for AW to conduct the surgeon interviews rather than AB. At other times interview analysis techniques and framework development were reviewed with other researchers to reduce the bias brought by the author alone, however, it was not possible for all interviews to be assessed in this way.

#### *Potential biases from methodology*

The methodology of both projects had the potential to create bias and limit the generalizability of the work.

Selection criteria were developed for both studies to ensure that the aims of the study could be achieved by the patient sample. However, this has the potential of excluding patients or groups of patients from taking part. Some criteria, such as "English spoken" were established for the ease of

developing the paperwork and conducting the research, rather than to specifically exclude a group of patients, although the author is aware that this would be the effect.

Sampling techniques were factors alongside exclusion criteria that could bias findings from the studies. Sampling techniques in qualitative studies are often based on maximum variation sampling, a purposive technique for ensuring diversity of participants (264). The aim is to achieve maximum diversity of certain characteristics in the participants to be studied. This may introduce some selection bias and reduce conformity of the sample population.

Sampling for the T2DM study were from practices who had agreed to participate in the larger cluster RCT, patients from practices that had not agreed to take part were excluded. Diversity of scores in the preference index and how close patients were to making a decision were important factors, but could only be assessed after inclusion in the study rather than used as a screening tool for purposive selection. HCPs were approached during the main PANDAs study to see if they were prepared to take part in the qualitative interviews. HCPs had to be enrolled as part of the patient-HCP dyad and although there was some diversity of roles this was fortuitous rather than purposive.

In the IC study the individual patient interviews were selected from the list of one orthopaedic surgeon. This has the advantage of exploring issues with patients who had all received the same consent process, however, the author is aware that different surgeons have different consenting techniques. It was considered prudent to hold focus groups with a different set of patients who had experienced alternative consent processes and could explore these issues through open discussion rather than individual interviews. The sampling of surgeons was restricted to one department in one hospital, a small pool to sample from in the first place. Diversity of experiences was limited but still identified surgeons with different consenting techniques.

The author chose to use semi-structured interviews and Framework analysis as research techniques for data management. This methodology created some a priori themes developed from the literature review which were considered important to address. Open-ended interviews may have produced different results, allowing patients and HCPs to discuss what was most important to them. The use of a Grounded theory approach (215) is considered more appropriate for the analysis of behavioural research whilst Framework analysis is considered more suitable for evaluation of health care provision.

Observation of study subjects is known to influence behaviour and distort the results, the Hawthorne effect (265) and although the author is aware of this, it is difficult to eliminate completely. It may be mitigated to some extent by ensuring interviewees are aware of anonymity in reporting results and by seeing the participants more than once, if appropriate.

Recall bias can be a further limitation of any qualitative research study. Many of the participants in both studies were in their 70's and 80's, consequently remembering information can be more difficult. In the T2DM study a time limit of two weeks from consultation to interview was imposed to limit the recall bias. In reality most patients and HCPs were interviewed on the same day as the interview. Two patients were interviewed later but still within the two week period, this introduced the findings of family involvement in the healthcare decision and implementation thereof. In the IC study patients were interviewed on two separate occasions, before and after surgery. An original suggestion had been to interview patients twice before surgery and once afterwards. This would have had the added benefit of discussing patient perceptions of events more contemporaneously, but this had to be balanced with the potential of influencing patients' perceptions of the pre-

operative pathway by highlighting topics through questioning that they may have been unaware of. Eventually it was decided that the risk of introducing bias through questioning outweighed the benefit of more contemporaneous recall and only one pre-operative interview was approved.

Gender of the participant was not considered to be an important contributing factor to patient or clinician decision-making. Recruitment of patients was generally aligned to national figures, although there was a female propensity in one of the IC focus groups. HCP recruitment was far more unbalanced, but again reflected national trends; all practice nurses were female and all orthopaedic surgeons were male.

The power balance within the research interviews can be an important factor influencing the results of the data. In all interviews it was made clear that the researcher was working independently of the treating clinicians and that no patient identifiable data would be fed back to them. It was considered important to be as open as possible with patients in revealing my background so they could be honest with me, although there has been debate about whether this is the best approach (200, 201). This was to allow patients to speak freely and openly on the subject. This was particularly important for the author who, as a medical doctor, might be perceived to be biased towards the medical perspectives. This also created the problem that patients might ask my opinion on aspects of their care or illness, so it was agreed that I would not comment during the interviews and only discuss general concepts after the interview rather than specific concerns.

AW had the experience of interviewing consultant orthopaedic surgeons whom she had studied under as a medical student. This created a slightly different power imbalance but was considered more appropriate than AB interviewing because of friendships outside medicine.

Ideally, audio-recording of the consultation between patient and surgeon in the IC study would have allowed further analysis of the doctor-patient interaction and cross-referencing with interview data. This was not possible within the confines of the ethics approval, and to evaluate fully may also have required audio recordings of the pre-operative consent clinic and Joint School. It is also not clear that analysis of surgical consent consultations using the OPTION Instrument is valid.

Finally the clinical setting for orthopaedic surgery is not uniform across the country, or even within the one orthopaedic department studied. The specific department had developed its own pathway to address some of the perceived needs of patients and to ensure patients are fit for surgery. However, as the focus group discussions and surgeon interviews indicate, the surgeons have their own preferred options for obtaining consent. By convening focus groups with patients who had experienced different consent pathways a greater understanding of patient concerns could be obtained. It does mean that making broad recommendations to be considered by other departments might be less meaningful if their pathways differ from those discussed in this thesis. It has been important to identify all the steps in the IC process so that others can identify similarities and differences with their own pathways.

### *Funding*

Funding may be considered a limitation of any research if it creates a conflict of interest. The description of funding is provided here for completeness rather than for any conflict of interest reason.

Both projects received funding from external sources to manage them and permit their completion. The T2DM study was part of a larger project for the development and clinical evaluation of a PDA for

patients with T2DM considering insulin therapy. This was funded through a National Institute for Health Research, Research for Patient Benefit grant (No. NIHR-RfPB PB-PG-0906-1). The NIHR RfPB grants are “to generate high quality research for the benefit of users of the NHS in England.” (266). Part of the remit is, therefore, to show that there is benefit for the end user within the NHS. This qualitative part of the study had to be evaluated alongside the PDA, with some of the analysis directed towards the benefits of PDAs to patient decision making as well as used as a comparator to other SDM models.

The IC study was funded by a research grant from the Royal College of General Practitioners Scientific Foundation Board (Grant No. SFB-2010-05) whilst AB’s research salary was funded by an NIHR In-practice fellowship (Grant No. IAT I-PF 010 003). The NIHR fellowship is to encourage General Medical and Dental Practitioners to develop a research project within the NHS and apply for a higher degree, whilst the RCGP award is to fund an early researcher to establish and complete a study within 18 months. Consequently there were some time constraints on the IC project which were compounded by the moratorium on orthopaedic referrals. This resulted in an extension being granted to the RCGP funding to complete the study. This pressure was not considered to have affected the research as recruitment was ended when preliminary data analysis revealed theme saturation.

## 6.9 Reflexivity

### 6.9.1 Personal

As described earlier my first real exposure to the concept of IC and obtaining consent from patients was as a Junior House Officer in a large teaching hospital. My first post was in General Surgery, followed by Ear, Nose and Throat Surgery. One of my duties was to ensure patients were prepared for theatre after admission to hospital and to “obtain” consent. Reflection on my consenting techniques made me realise that I was not performing the surgery and sometimes had no real idea of what the surgery entailed. Other than discussion in very vague terms of risks of death or serious complications, the process focussed on the incision site and size, what would be done during the operation and roughly how long they would be in hospital. The patient was considered “prepared for surgery” as long as a signed consent form accompanied them to theatre.

At the time I considered I had maybe “cheated” the patients a little but as that was my first 6 months as a junior doctor and I had no intention of pursuing a surgical career it was a thought rapidly eliminated by the survival required for 120 hour working weeks.

It was only much later, when undertaking a law degree that I realised my disquiet was held by others, particularly non-medics. The academic lawyers were disturbed by some of the consent case law over the years and the fact that doctors could rely on the opinion of their own peers to shape the law, rather than the judges and courts imposing their values. We were encouraged to read and re-read “Informed Consent and other Fairy Stories” by Michael Jones(4). The title itself is self-explanatory but it had some very important messages that inspired my research:

- “Existing case law gives a guide to what is considered minimum requirements of good practice in seeking informed consent from patients.”
- “(Lawyers) consider that the failure to tell the truth is so prejudicial as to undermine the very foundations of the legal process. The failure to tell the truth in the context of doctor-patient relationship...is often presented as an essential part of therapy.”
- “Much of the debate about “informed” consent...concentrates on the appropriate standard of disclosure”

In relation to IC the other case that was often discussed was that of Bolitho(3) and the deference of the judge to medical expert witnesses. Although the judge declared that medical opinion should be open to logical analysis and be both reasonable and responsible, there was still concern amongst academic lawyers that the standard of care was being set by medical experts rather than judges.

Jones did touch on some of the aspects of SDM in terms of assessing patient understanding and creating a trusting relationship between doctor and patient, rather than just providing information.

One of my motivations for the research was to consider whether the medical profession could improve the consent-obtaining process rather than relying on lawyers and case law to set the agenda.

### 6.9.2 Functional

As a general practitioner who has been a principal for nearly 20 years and qualified for 24 years, I considered that I had a lot of medical experience to bring to my research, but also a lot of prejudices.

I was used to the rapid decision-making of 10 minute appointments (five when I started as a principal) and differentiating serious illness from the more mundane. This method of working provides little time for reflection unless this is induced by an unexpected, or missed, diagnosis.

The skills that are required as a GP are those of communication and being aware of visual clues; when to remain quiet and let a patient talk to get the most out of their story and when to intervene, either to direct a discussion to one's own agenda or to help a patient out of a difficult topic. When a surgeon sees a patient for obtaining consent for surgery they are focused to some extent on explaining the legal requirements and obtaining a signature, whilst my focus was much more exploratory. There are different skills in completing a consultation in 10 minutes and exploring issues over a 45 minute interview. In order to enhance this transition I attended a course at the NatCen for Social Research in London in 2010 on qualitative research skills and conducting in-depth interviews.

### 6.9.3 Disciplinary

Professional allegiances can influence data collection and analysis. It was important that patients were aware that I was medically qualified, but equally important that they were aware I had no affiliation to their treating physicians, that any criticisms would be for the researcher only and participation would in no way prejudice their on-going care. It was also important that treating physicians were aware that I was not going to interfere, recommend or comment on any of their clinical judgements.

As a GP myself it was important that I dealt with the HCPs in the T2DM study with equal respect. I employ practice nurses in my own practice and respect their knowledge of chronic disease management. It was important that, when dealing with practice nurses from other practices, I approached them with the same level of respect and dealt with them as equals so they felt comfortable during interviews.

In terms of IC there are clear conflicts between running efficient systems to ensure patients are treated in reasonable timeframes and allowing enough time to address patient concerns and obtain better patient consent. There are clear conflicts between legal guidance on IC which should really be viewed as an absolute minimum, the ethical view of the "autonomous" patient and the implementation of medical practice.

It is important to recognise the limitations imposed by considering these interconnecting elements, whilst also using them to create a better process more congruent with patient values.

## 6.10 Implications of findings for Policy and Practice.

### 6.10.1 Implications of key findings for policy

Although there have been tacit moves nationally towards the promotion of SDM (248) and frameworks have been developed from case law for minimum standards for disclosure in IC, there is no primary legislation enshrining either. The implementation of SDM has been alluded to in a number of documents since the Coalition Government took office but has never been addressed head-on (247, 248, 256, 261). This lack of coherent national policy means that implementation can be flexible to meet local needs but also reflects the patchy implementation of practices, particularly SDM. Discussion within this thesis suggests there is little to recommend the US route of legislating for SDM, but with its clear advantages of patient activation and empowerment it should be valued



and nurtured within the NHS. This would, however, require time for training staff in SDM techniques and increased time with patients to ensure their values are elicited and incorporated into decisions.

This pattern is possible as the IC process reveals; clinics can be developed and adapted to target specific areas of the decision-making process for patients and HCPs. What must not happen is that such processes pay “lip-service” to patient engagement; in terms of the IC study patients are often signing a consent form before other appointments to improve their knowledge and understanding. Such process also denies the patient opportunities to discuss information they have found out themselves with the surgeon who is going to perform their operation. The IC process also raises the concern about implementing legal standards; discussions are often focused on one aspect such as risk disclosure rather than the process itself and they can create a minimum standard that is rarely exceeded.

Results from this thesis show the importance of family involvement in decision-making and implementing that decision, the emotions that can affect a patient’s retention of information, especially when expectation is patient driven and that discussions at each contact need to be concerned with the one decision identified.

The author recognises that consent in research settings tends to be pro-active and recently attended a debate on adapting this for situations where there is little or no extra risk to the patient. Consent in surgical settings tends to be reactive to case law and suggests the process can be improved pro-actively by considering SDM techniques. Further, the author is aware that NICE are considering establishing a group to advise it on promoting SDM techniques within their guidelines (Personal communication May 2014).

#### 6.10.2 Implications of the key findings for practice.

In making any recommendations for practice it is important to be aware of the competing interests of time, finance, and patient and HCP variability in decision-making. By ignoring the latter, one ignores the whole concept of SDM and, therefore, misses the potential patient satisfaction that this can bring. These suggestions are based on the findings from this thesis that patients may not have adequate opportunities to express their own values and have them considered, and HCPs may not allow them the time to do so.

Patients may wish to consider the following:

- Seeking sources of information other than that provided by the HCP or hospital is sensible to allow you to identify any concerns you may have.
- Discussing your concerns, however trivial they may seem, at every opportunity with the primary or secondary care provider can be reassuring and reduce anxiety.
- Discussing recovery and quality of life issues is as important as discussing treatment procedures and risks.
- Be aware that you may feel anxiety which can affect your recollection of information and if you consider you have missed information then ask.
- It is not unreasonable to ask friends or family members to attend with you and support you with your decision

Primary care staff may wish to consider:

- Patients may have misconceptions about treatment that need to be addressed before valued discussion about treatment options can proceed.
- HCP initiated decision-making will require patient engagement, possibly on several occasions before a patient-valued decision can be made.
- Focusing on one decision, particularly if a difficult decision for the patient can be helpful
- Creating structure and approaching decisions in a structured approach, such as with a decision aid can ensure all aspects of the decision are considered each time.
- Patients may benefit from discussions with more than one type of HCP or in different settings (one-to-one, group discussions)

Surgeons may wish to consider the following:

- Be aware that patients may have certain expectations of treatment that are potentially unrealistic and need to be addressed
- If patients are expecting to be offered treatment this can create anxiety and once offered treatment they may not recollect information provided immediately afterwards.
- Patient agendas on information provision may differ from surgeon expectations and need to be elicited and acted upon.
- Be aware that patient retention of information and satisfaction may be improved by signposting and addressing the issue of consent at each hospital visit.
- The provision of large amounts of written information without explanation may be detrimental to patient understanding.
- Provide clear information on timescales and appointments so that patients are aware of the process and not left wondering what might happen next.
- Patient values or information requirements might change between initial contact and surgery and should be elicited at each appointment.
- External sources of information may be highly valued by patients, equally they may create unrealistic misconceptions that can only be addressed if elicited.

Managers and Commissioners may wish to consider the following:

- Healthcare decisions eliciting and responding to patient values may take more time but are appreciated by patients and HCPs alike. Commissioning services should consider the quality of the decision-making, not just the quantity of decisions made.
- Creating processes to enhance patient engagement, such as the Joint School, need to focus on the decision being considered and signposted as such.
- Staff need training in the concepts and skills of eliciting patient values and preferences through SDM
- Informed Consent litigation is not an insignificant burden on the NHS and minor adaptations to the current process could improve patient experience and potentially reduce litigation.

### 6.11 Avenues for future research

This comparative study of SDM and IC gives comprehensive accounts of how the two paradigms are, and can be implemented in routine practice. Comparison between the two paradigms reveals more about each than in-depth evaluation of one on its own. The comparison also reveals areas of deficiency in our practice and knowledge. The T2DM study reveals the importance of support in decision-making and implementation of that decision, although it was not long enough to establish whether patients persisted with their original decision. It also revealed the complexity of literature and practice that needs to be incorporated into a PDA to ensure knowledge and patient values are adequately covered. There are many areas of medical decisions where the evidence is equivocal and PDAs and techniques of SDM are appropriate.

One area of consideration in SDM highlighted by the comparison with IC is the involvement of different HCPs and settings to enhance patient understanding. The IC process used doctors, nurses, physiotherapists and occupational therapists to provide information and this was done in one-to-one and group settings. There was no consensus amongst patients as to which was the best delivery of information but they agreed that all had some part to play. Consideration of SDM over a series of meetings with different HCPs in different settings may improve patient engagement.

The author would argue that SDM techniques are appropriate for a much wider range of healthcare decisions. Accordingly he has developed a PDA to deal with decisions around anticoagulation for stroke risk reduction in atrial fibrillation, where there is guidance for some patients and equivocal evidence for others (46), but this is compounded by bleeding risks (267). In some patients where the initial treatment recommendation seems to be directed by relevant guidelines it then becomes equivocal and based on patient preference because of other factors.

Much of the research on IC has been based around the mismatch in information between patient expectation and surgeon provision as well as focusing on retention of information. This work explores the implementation of the IC paradigm in relation to hip surgery and finds that provision of services might be good, but are not focused on the decision to be made and obtaining good (if not informed) consent. Information provision is often clouded by other considerations which negatively affect patient comprehension. There is much work to be done in considering how to adapt the process to focus on the IC issue and work to be done in other surgical specialities to explore consent in other settings.

Attempts have been made to incorporate PDAs into IC decisions (102). Many, such as Ben Moulton et al (268) and Daniel Sokol (269) argue that the “consenting process” needs to change but without providing practical guidance. In-depth exploration and comparison within this thesis suggests PDAs for consenting could be useful to create structure, isolate discussions about consent issues and act as evidence of a consent process if signed at various hospital contacts. The author proposes the development of such decision aids with studies to explore their acceptability as a “consenting tool”, as well as exploring their impact on information retention.

## 6.12 Conclusion

The use of patient and HCP interviews and focus groups in a qualitative and comparative way highlight advantages of SDM techniques and how short-comings in relation to IC could be improved by adopting some of these techniques. It also identifies the how multi-faceted information provision in IC could be used to advantage in enhancing SDM techniques in chronic disease management.

Patients make health care decisions based on many interacting factors. Some of these may be based on the severity of the condition and decision to be made, some on patient pre-conceived ideas that may or may not be correct and some on the provision of information. From a health care professional perspective these decisions are impacted by considerations of legal duties, ethical imperatives and employer pressures.

Becoming too focused on the legal aspects can lead to minimal standards that do little to improve patient engagement in decision-making. Concentrating on the ethical issues of patient autonomy, whilst morally acceptable, does not address the fact that some patients would still defer to the professional's judgement. Whilst having to work within time constraints and performance management of any employing authority it is important to identify where information provision could be improved without impacting significantly on time management.

This thesis has explored practical issues of improving patient engagement in health care decisions and found that even in areas designed to promote patient engagement (SDM) the techniques could be improved further by considering implementation of processes from IC. In terms of IC it is possible to consider implementing some SDM techniques to improve patient engagement and understanding of the processes and decisions to be made.

### *Shared Decision-making*

SDM techniques are acceptable to patients and HCPs and feasible to implement, particularly in a primary care setting of chronic disease management. However, one of the limitations in this area was the poor assessment by all HCPs of patients preferred option for the provision of information. Patients in the IC study did not identify one clear source as their most valued, but appreciated different formats of information provided by different people. By adopting this technique in SDM it will be possible to provide information in a format valued by most patients.

Structure and uniformity brought by the use of PDAs was particularly appreciated by HCPs, ensuring that all important topics were covered at each consultation.

### *Informed Consent*

The agenda for IC is often driven by pressures on hospitals to measure waiting times, throughput and outcomes rather than quality of care. The legal framework creates a minimum standard of risk disclosure in relation to IC but, due to outcomes focused agendas, care rarely has the opportunity to rise above this. Whilst processes such as Joint School have been put in place to address some of the information issues they are dissociated from the patient concept of giving consent, the consent form.

Whilst preparing patients for surgery involves more than obtaining consent it is important to recognise the issues raised within this thesis that can interfere with the consent process.

It is beyond the scope of this thesis to recommend how information relevant to consent can be highlighted. However, the results suggest that using a formally developed PDA to signpost discussion relevant to consent, structure that discussion to ensure all topics are covered at each visit and to act as a signed documentation of a process of consent might be an appropriate development.

Explaining to patients early in the decision-making process what appointments to expect and the function of each contact can help to alleviate the uncertainty associated with patient's expectation of surgery and "the sooner the better".

#### *Implementation of changes*

This would require thorough development of the relevant PDAs using a structured approach such as that proposed by the MRC framework on developing and evaluating complex interventions (7). It would also require significant training of staff in the use of PDAs, the implementation of SDM techniques in most healthcare settings and recognising where the PDAs sit in the care pathway.

## References

1. Chester V Afshar UKHL 41 2004.
2. The Free Dictionary. Bolam test 2014 [20/10/2014]. Available from: <http://medical-dictionary.thefreedictionary.com/Bolam+Test>.
3. Bolitho v. City and Hackney Health Authority 4 All ER 7711997.
4. Jones M.A. Informed Consent and other Fairy Stories. *Medical Law Review*. 1999;7:103-34.
5. General Medical Council. Consent: patients and doctors making decisions together 2008 [cited 2009 04/02]. Available from: [http://www.gmc-uk.org/guidance/ethical\\_guidance/consent\\_guidance\\_index.asp](http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp)
6. Mathers N, Ng CJ, Campbell MJ, Colwell B, Brown I, Bradley A. Clinical effectiveness of a patient decision aid to improve decision quality and glycaemic control in people with diabetes making treatment choices: a cluster randomised controlled trial (PANDAs) in general practice. *BMJ Open*. 2012 January 1, 2012;2(6). PubMed PMID: 23129571. Pubmed Central PMCID: 3532975.
7. 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. PubMed PMID: 18824488. Pubmed Central PMCID: 2769032. Epub 2008/10/01. eng.
8. O'Connor AM, Jacobsen MJ. Workbook on Developing and Evaluating Patient Decision Aids 2003 [06/02/2014]. Available from: [https://decisionaid.ohri.ca/docs/develop/Develop\\_DA.pdf](https://decisionaid.ohri.ca/docs/develop/Develop_DA.pdf).
9. King JS, Moulton B. Rethinking Informed Consent: The Case for Shared Medical Decision Making. *American Journal of Law and Medicine*. 2006;32(4):429-501.
10. Lidz CW, Appelbaum PS, Meisel A. Two models of implementing informed consent. *Archives of Internal Medicine*. 1988;148(6):1385-9.
11. Meisel A, Kuczewski M. Legal and ethical myths about informed consent. *Archives of Internal Medicine*. 1996;156(22):2521-6.
12. Whitney SN, McGuire AL, McCullough LB. A Typology of Shared Decision Making, Informed Consent, and Simple Consent. *Annals of Internal Medicine*. 2004;140(1):54-9.
13. The Health Foundation. The MAGIC programme evaluation 2013 [30/01/2014]. Available from: <http://www.health.org.uk/public/cms/75/76/313/4173/MAGIC%20evaluation.pdf?realName=hrsgE6.pdf>.
14. Adam JA, Khaw FM, Thomson RG, Gregg PJ, Llewellyn-Thomas HA. Patient decision aids in joint replacement surgery: a literature review and an opinion survey of consultant orthopaedic surgeons. *Annals of The Royal College of Surgeons of England*. 2008 //;90(3):198-207.
15. Reyna VF. Theories of Medical Decision Making and Health: An Evidence-Based Approach. *Medical Decision Making*. 2008 November 1, 2008;28(6):829-33.
16. Abram MB. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. Washington. U.S.,: 1982.
17. Makoul G, Clayman ML. An integrative model of shared decision making in medical encounters. *Patient education and counseling*. 2006;60(3):301-12.
18. Elwyn G, Scholl I, Tietbohl C, Mann M, Edwards A, Clay C, et al. "Many miles to go ...": a systematic review of the implementation of patient decision support interventions into routine clinical practice. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S14. PubMed PMID: doi:10.1186/1472-6947-13-S2-S14.

19. Fagerlin A, Pignone M, Abhyankar P, Col N, Feldman-Stewart D, Gavaruzzi T, et al. Clarifying values: an updated review. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S8. PubMed PMID: doi:10.1186/1472-6947-13-S2-S8.
20. Feldman-Stewart D, O'Brien MA, Clayman M, Davison B, Jimbo M, Labrecque M, et al. Providing information about options in patient decision aids. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S4. PubMed PMID: doi:10.1186/1472-6947-13-S2-S4.
21. Hoffman A, Volk R, Saarimaki A, Stirling C, Li L, Harter M, et al. Delivering patient decision aids on the Internet: definitions, theories, current evidence, and emerging research areas. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S13. PubMed PMID: doi:10.1186/1472-6947-13-S2-S13.
22. McCaffery K, Holmes-Rovner M, Smith S, Rovner D, Nutbeam D, Clayman M, et al. Addressing health literacy in patient decision aids. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S10. PubMed PMID: doi:10.1186/1472-6947-13-S2-S10.
23. Montori V, LeBlanc A, Buchholz A, Stilwell D, Tsapas A. Basing information on comprehensive, critically appraised, and up-to-date syntheses of the scientific evidence: a quality dimension of the International Patient Decision Aid Standards. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S5. PubMed PMID: doi:10.1186/1472-6947-13-S2-S5.
24. Nishimura A, Carey J, Erwin P, Tilburt J, Murad M, McCormick J. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. *BMC Medical Ethics*. 2013;14(1):28. PubMed PMID: doi:10.1186/1472-6939-14-28.
25. Sepucha K, Borkhoff C, Lally J, Levin C, Matlock D, Ng C, et al. Establishing the effectiveness of patient decision aids: key constructs and measurement instruments. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S12. PubMed PMID: doi:10.1186/1472-6947-13-S2-S12.
26. Stacey D, Kryworuchko J, Belkora J, Davison B, Durand M-A, Eden K, et al. Coaching and guidance with patient decision aids: A review of theoretical and empirical evidence. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S11. PubMed PMID: doi:10.1186/1472-6947-13-S2-S11.
27. Trevena L, Zikmund-Fisher B, Edwards A, Gaissmaier W, Galesic M, Han P, et al. Presenting quantitative information about decision outcomes: a risk communication primer for patient decision aid developers. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S7. PubMed PMID: doi:10.1186/1472-6947-13-S2-S7.
28. Volk R, Llewellyn-Thomas H, Stacey D, Elwyn G. Ten years of the International Patient Decision Aid Standards Collaboration: evolution of the core dimensions for assessing the quality of patient decision aids. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S1. PubMed PMID: doi:10.1186/1472-6947-13-S2-S1.
29. Elwyn G, Laitner S, Coulter A, Walker E, Watson P, Thomson R. Implementing shared decision making in the NHS. *BMJ*. 2010 2010-10-15 00:09:55;341.
30. Stacey D, Legare F, Col NF, Bennett CL, Barry MJ, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. *The Cochrane database of systematic reviews*. 2014;1:CD001431. PubMed PMID: 24470076.
31. Oshima Lee E, Emanuel EJ. Shared Decision Making to Improve Care and Reduce Costs. *New England Journal of Medicine*. 2013;368(1):6-8. PubMed PMID: 23281971.
32. Katz SJ. Treatment decision aids are unlikely to cut healthcare costs. *BMJ*. 2014 2014-02-05 16:08:38;348.
33. M.Lanning. Section 3. Informed Consent 2003 [26/10/14]. Available from: [http://www.oregon.gov/obce/publications/emebc\\_section\\_3.pdf](http://www.oregon.gov/obce/publications/emebc_section_3.pdf).
34. The Law Dictionary. The Nuremberg Code 2014 [12/01/2014]. Available from: <http://thelawdictionary.org/nuremberg-code-of-ethics/#ixzz2qI0Y0e35>.



35. Levenstein JH. The patient-centred general practice consultation. *South African Family Practice*. 1984;5:276-82.
36. Shared decision-making in health care: Achieving evidence-based patient choice. Oxford: Oxford University Press; 2009. 432 p.
37. PubMed. PubReMiner. Analysis of PubMed Search results [10/03/2013]. Available from: <http://hgserver2.amc.nl/cgi-bin/miner/miner2.cgi>.
38. 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). *Social Science & Medicine*. 1997;44(5):681-92.
39. Murray E, Charles C, Gafni A. Shared decision-making in primary care: Tailoring the Charles et al. model to fit the context of general practice. *Patient education and counseling*. 2006;62(2):205-11.
40. The Health Foundation. Inspiring Improvement: Our history and how we are funded 2014 [30/01/2014]. Available from: <http://www.health.org.uk/about-us/our-history/>.
41. The Health Foundation. Person-centred care resource centre: Shared Decision Making 2013 [20/01/2014]. Available from: <http://shareddecisionmaking.health.org.uk/basics-of-shared-decision-making/> The Health Foundation.
42. Stoljar N. Informed Consent and Relational Conceptions of Autonomy. *Journal of Medicine and Philosophy*. 2011 August 1, 2011;36(4):375-84.
43. Llewellyn-Thomas HA, Crump RT. Decision Support for Patients: Values Clarification and Preference Elicitation. *Medical Care Research and Review*. 2013 February 1, 2013;70(1 suppl):50S-79S.
44. Wennberg JE, Mulley AG, Jr, Hanley D, et al. An assessment of prostatectomy for benign urinary tract obstruction: Geographic variations and the evaluation of medical care outcomes. *JAMA*. 1988;259(20):3027-30.
45. Wirrmann E, Askham H. Implementing patient decision aids in urology. Picker Institute Europe, 2006.
46. Lip GYH, Halperin JL. Improving Stroke Risk Stratification in Atrial Fibrillation. *The American Journal of Medicine*. 2010;123(6):484-8.
47. Olesen JB, Lip GYH, Hansen ML, Hansen PR, Tolstrup JS, Lindhardsen J, et al. Validation of risk stratification schemes for predicting stroke and thromboembolism in patients with atrial fibrillation: nationwide cohort study. *BMJ*. 2011 January 1, 2011;342.
48. Camm AJ LG, De Caterina R, Savelieva I, Atar D, Hohnloser SH, et al.,. 2012 focused update of the ESC Guidelines for the management of atrial fibrillation. *European Heart Journal*. 2012;33:2719-47.
49. Elwyn G, Edwards A, Kinnersley P, Grol R. Shared decision making and the concept of equipoise: the competences of involving patients in healthcare choices. *British Journal of General Practice*. 2000 November 1, 2000;50(460):892-9.
50. Elwyn G, Frosch D, Rollnick S. Dual equipoise shared decision making: definitions for decision and behaviour support interventions. *Implementation Science*. 2009;4.
51. Towle A, Greenhalgh T, Gambrill J, Godolphin W. Framework for teaching and learning informed shared decision making Commentary: Competencies for informed shared decision making Commentary: Proposals based on too many assumptions. *BMJ*. 1999 1999-09-18 08:00:00;319(7212):766-71.
52. Braddock CH 3rd EK, Hasenberg NM, Laidley TL, Levinson W. Informed decision making in outpatient practice: time to get back to basics. *JAMA* ;. 1999 Dec 22-29;282((24)):2313-20.
53. Braddock CH 3rd FS, Levinson W, Jonsen AR, Pearlman RA. How doctors and patients discuss routine clinical decisions. *Informed decision making in the outpatient setting*. *J Gen Intern Med*. 1997 Jun;; ;12((6)):339-45

54. Balint M. *The Doctor his Patient and The Illness.*: Churchill Livingstone; Millennium reprint of second edition 2000.
55. Berne E. *Games People Play*: Penguin; 1964.
56. Byrne PS. *Doctors talking to patients*. London: RCGP; 1976.
57. Kurtz SM, Silverman JD, Draper J. *Skills for Communicating with Patients*1996.
58. Neighbour R. *The Inner Consultation*. Oxford: Radcliffe Publishing; 2004 2nd Edition.; 1987.
59. Pendleton D. et al. *The Consultation: an Approach to Learning and Teaching*. Oxford: Oxford University Press; 1984.
60. Tate P. *The Doctors Communication Handbook*1994.
61. Chaitchik S KS, Shaked S, Schwartz I, Rosin R.,. Doctor-patient communication in a cancer ward. *J Cancer Educ*. 1992;7(1):41-54.
62. Ende J. Kazis L. Ash A. Moskowitz MA. Measuring patients' desire for autonomy: decision making and information-seeking preferences among medical patients. *J Gen Intern Med* 1989;4(1):23-30.
63. Ong LML, de Haes JCJM, Hoos AM, Lammes FB. Doctor-patient communication: A review of the literature. *Social Science & Medicine*. 1995 4//;40(7):903-18.
64. Fischer M. Ereat G. *When doctors and patients talk: making sense of the consultation*. London: The Health Foundation, 2012.
65. Bleichrodt H, Johannesson M. The Validity of QALYs: An Experimental Test of Constant Proportional Tradeoff and Utility Independence. *Medical Decision Making*. 1997 February 1, 1997;17(1):21-32.
66. Ottawa Hospital Research Institute. *Ottawa Decision Support Framework 2013* [04/02/2014]. Available from: <http://decisionaid.ohri.ca/odsf.html>.
67. Tversky A, Kahneman D. The framing of decisions and the psychology of choice. *Science*. 1981 January 30, 1981;211(4481):453-8.
68. Ajzen I. Fishbein M. *Understanding attitudes and predicting social behavior*. New Jersey: Prentice Hall; 1980.
69. Keeney RL. Raiffa H. *Decision Analysis with Multiple Objectives*. New York: John Wiley and Sons, Inc.; 1976.
70. Janis IL. Mann L. *Decision making: a psychological analysis of conflict, choice, and commitment*. New York: The Free Press. A division of Macmillan Inc.; 1977.
71. Norbeck JS, Tilden VP. International nursing research in social support: theoretical and methodological issues. *Journal of Advanced Nursing*. 1988;13(2):173-8.
72. Orem D. *Nursing: Concepts of practice*. 5th ed. St. Louis, MO: C.V.Mosby; 1995.
73. Feather NT. The Study of Values. *Journal of Asian-Pacific and World Perspectives*. 1980;3:3-13.
74. Botti S, Iyengar SS. The Psychological Pleasure and Pain of Choosing: When People Prefer Choosing at the Cost of Subsequent Outcome Satisfaction. *Journal of Personality and Social Psychology*. 2004;87(3):312-26.
75. Ubel PA. Is information always a good thing? Helping patients make "good" decisions. *Med Care*. 2002;40:V-39 - V-40. PubMed PMID: doi:10.1097/00005650-200209001-00006.
76. North American Nursing Diagnosis Association. *Nursing diagnoses: definitions and classifications 2005-6*. Philadelphia: North American Nursing Diagnosis Association, 2005.
77. O'Connor A. Decisional Conflict. *Nursing Diagnosis and Intervention: Planning for Patient Care*. 1997:486 - 96.
78. O'Connor AM. Validation of a decisional conflict scale. *Medical decision making : an international journal of the Society for Medical Decision Making*. 1995 Jan-Mar;15(1):25-30. PubMed PMID: 7898294.
79. *Drug and Therapeutics Bulletin*. An introduction to patient decision aids. *BMJ*. 2013 2013-07-23 11:28:08;347.

80. Elwyn G, Lloyd A, Joseph-Williams N, Cording E, Thomson R, Durand M-A, et al. Option Grids: Shared decision making made easier. *Patient Education and Counseling*. 2013 2//;90(2):207-12.
81. Elwyn G, O'Connor A, Stacey D, Volk R, Edwards A, Coulter A, et al. Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *BMJ*. 2006 Aug 26;333(7565):417. PubMed PMID: 16908462. Pubmed Central PMCID: 1553508.
82. Elwyn G, O'Connor AM, Bennett C, Newcombe RG, Politi M, Durand MA, et al. Assessing the quality of decision support technologies using the International Patient Decision Aid Standards instrument (IPDASI). *PloS one*. 2009;4(3):e4705. PubMed PMID: 19259269. Pubmed Central PMCID: 2649534.
83. Cates C. Cates' Plot 2014 [06/02/2014]. Available from: [http://www.nntonline.net/visualrx/cates\\_plot/](http://www.nntonline.net/visualrx/cates_plot/).
84. Abhyankar P, Volk R, Blumenthal-Barby J, Bravo P, Buchholz A, Ozanne E, et al. Balancing the presentation of information and options in patient decision aids: an updated review. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S6. PubMed PMID: doi:10.1186/1472-6947-13-S2-S6.
85. Barry M, Chan E, Moulton B, Sah S, Simmons M, Braddock C. Disclosing conflicts of interest in patient decision aids. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S3. PubMed PMID: doi:10.1186/1472-6947-13-S2-S3.
86. Bekker H, Winterbottom A, Butow P, Dillard A, Feldman-Stewart D, Fowler F, et al. Do personal stories make patient decision aids more effective? A critical review of theory and evidence. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S9. PubMed PMID: doi:10.1186/1472-6947-13-S2-S9.
87. Coulter A, Stilwell D, Kryworuchko J, Mullen P, Ng C, van der Weijden T. A systematic development process for patient decision aids. *BMC Medical Informatics and Decision Making*. 2013;13(Suppl 2):S2. PubMed PMID: doi:10.1186/1472-6947-13-S2-S2.
88. 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. *The Cochrane database of systematic reviews*. 2011 (10):CD001431. PubMed PMID: 21975733.
89. Powers RD. Emergency department patient literacy and the readability of patient-directed materials. *Annals of Emergency Medicine*. 1988;17(2):124-6.
90. Holmes-Rovner M, Kroll J, Schmitt N, Rothert M, Padonu G, Talarczyk G. Patient decision support intervention: increased consistency with decision analytic models. *Med Care*. 1999;37:270 - 84. PubMed PMID: doi:10.1097/00005650-199903000-00007.
91. O'Connor AM, Rostom A, Fiset V, Tetroe J, Entwistle V, Llewellyn-Thomas H, et al. Decision aids for patients facing health treatment or screening decisions: systematic review. *BMJ*. 1999 Sep 18;319(7212):731-4. PubMed PMID: 10487995. Pubmed Central PMCID: 28223.
92. Arterburn D, Wellman R, Westbrook E, Rutter C, Ross T, McCulloch D, et al. Introducing Decision Aids At Group Health Was Linked To Sharply Lower Hip And Knee Surgery Rates And Costs. *Health Affairs*. 2012 September 1, 2012;31(9):2094-104.
93. 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 2014-01-23 10:32:21;348.
94. Gravel K, Legare F, Graham I. Barriers and facilitators to implementing shared decision-making in clinical practice: a systematic review of health professionals' perceptions. *Implementation Science*. 2006;1(1):16. PubMed PMID: doi:10.1186/1748-5908-1-16.
95. Legare F, Ratte S, Stacey D, Kryworuchko J, Gravel K, Graham ID, et al. Interventions for improving the adoption of shared decision making by healthcare professionals. *The Cochrane database of systematic reviews*. 2010;CD006732(5):CD006732. PubMed PMID: 20464744.

96. Elwyn G, Hutchings H, Edwards A, Rapport F, Wensing M, Cheung W-Y, et al. The OPTION scale: measuring the extent that clinicians involve patients in decision-making tasks. *Health Expectations*. 2005;8(1):34-42.
97. Coulter A. Collins A. MAKING SHARED DECISION-MAKING A REALITY No decision about me, without me. London: The King's Fund, 2011.
98. Health and Social Care Information Centre. Quality and Outcomes Framework: GP practice results 2014 [26/10/2014]. Available from: <http://www.qof.hscic.gov.uk/>.
99. Right Care Shared Decision Making programme. Measuring Shared Decision Making: A review of the research evidence. London: National Health Service, 2012.
100. Légaré F, Kearing S, Clay K, Gagnon S, D'Amours D, Rousseau M, et al. Are you SURE?: Assessing patient decisional conflict with a 4-item screening test. *Canadian Family Physician*. 2010 August 1, 2010;56(8):e308-e14.
101. Sepucha K, Belkora J, Chang Y, Cosenza C, Levin C, Moy B, et al. Measuring decision quality: psychometric evaluation of a new instrument for breast cancer surgery. *BMC Medical Informatics and Decision Making*. 2012;12(1):51. PubMed PMID: doi:10.1186/1472-6947-12-51.
102. The Dartmouth Institute for Health Policy & Clinical Practice. The Centre for Informed Choice 2014. Available from: <http://www.dartmouth.edu/~cecs/cic/index.html>.
103. Washington State Legislature. Shared decision-making demonstration project — Preference-sensitive care. RCW 41050332007.
104. Patient Protection and Affordable Care Act,, Senate and House of Representatives(2010).
105. Department of Health. Equity and Excellence: Liberating the NHS. In: Health Do, editor. London: Crown; 12 July 2010
106. General Medical Council. Good Medical Practice Manchester2013 [09/02/2014]. Available from: [http://www.gmc-uk.org/static/documents/content/GMP\\_2013.pdf\\_51447599.pdf](http://www.gmc-uk.org/static/documents/content/GMP_2013.pdf_51447599.pdf).
107. Sarah Smith. QIPP Programme (Quality Improvement Productivity and Prevention) 2012 [26/10/2014]. Available from: <http://ukpolicymatters.thelancet.com/qipp-programme-quality-innovation-productivity-and-prevention/>.
108. The National Health Service. NHS Choices 2013 [10/03/2014]. Available from: <http://www.nhs.uk/conditions/Hip-replacement/Pages/Introduction.aspx>.
109. Right Care. Atlas of Variation 2.0 2011 [09/02/2014]. Available from: <http://www.rightcare.nhs.uk/index.php/atlas/atlas-of-variation-2011/>.
110. Faden R. Beauchamp T. A History and Theory of Informed Consent. New York: Oxford University Press; 1986.
111. Sokol DK. How the doctor's nose has shortened over time; a historical overview of the truth-telling debate in the doctor-patient relationship. *Journal of the Royal Society of Medicine*. 2006;99(12):632-6.
112. American Medical Association. Code of ethics of the American Medical Association 1847 [11/01/2014]. Available from: <http://www.ama-assn.org/ama/upload/mm/369/1847code.pdf>.
113. Osler W. The treatment of Disease. *Canada Lancet*. 1909;42:899-912.
114. Fitts W. Ravdin I. What Philadelphia physicians tell patients with cancer. *JAMA*. 1953;153:901-14.
115. Schloendorff v. Society of New York Hospital, . 211 NY 125, 105 NE 92 1914.
116. Mohr v Williams. 104 NW 12: Supreme Court of Minnesota; 1905.
117. Pratt v Davis. 79 NE 5621906.
118. Bolam v Friern Hospital Management Committee. 1 WLR 5831957.
119. Sidaway v. Bethlem Royal Hospital Governors AC 8711985.
120. MacLeod E. Has Chester v Afshar Wholly Redefined the Law on Informed Consent to Medical Treatment, or Does the Doctor Still Know Best? : The Student Journal of Law; 2013 [13/01/2014]. 5:[Available from: <http://www.sjol.co.uk/issue-5/has-chester-v-afshar-wholly-redefined-the-law-on-informed-consent-to-medical-treatment-or-does-the-doctor-still-know-best>.

121. Hogg M. 'Duties of Care, Causation, and the Implications of Chester v Afshar' Edin LR2005. p. 156,8.
122. Rogers v Whitaker 175 CLR 4791992.
123. Canterbury v Spence. 464 F2d 772 1972.
124. Reibl v Hughes. 114 DLR (3d) 11980.
125. Gregg v Scott. 2 AC 176: UKHL 2; 2005.
126. National Health Service. National Health Service Litigation Authority 2014 [12/01/2014]. Available from: <http://www.nhsla.com/Pages/Home.aspx>.
127. Freedom of Information Act 2000, (2000).
128. Oxford English Dictionary. England: Oxford University Press; 2013.
129. Katz J. Judges, physicians and patients. The Silent world of Physician and Patient. New York: The Free Press; 1984.
130. Mitterscherlich A. Mielke F. The Nuremburg Code (1947) In:Doctors of Infamy: the story of the Nazi medical crimes. New York: Schuman; 1949.
131. World Medical Association. The Declaration of Geneva 2006 [13/01/2014]. Available from: <http://www.wma.net/en/30publications/10policies/g1/>.
132. World Medical Association. The Declaration of Helsinki 2013 [13/01/2014]. Available from: <http://www.wma.net/en/30publications/10policies/b3/>.
133. Wear S. Informed Consent: Patient Autonomy and Clinician Beneficence Within Health Care. 2nd ed. Engelhardt HT Jnr. Wildes KW, editor. USA: Georgetown University Press; 1998.
134. Quill TE, Brody H. Physician Recommendations and Patient Autonomy: Finding a Balance between Physician Power and Patient Choice. Annals of Internal Medicine. 1996;125(9):763-9.
135. Caplan AL. Why autonomy needs help. Journal of Medical Ethics. 2012 February 15, 2012.
136. Schmitt GM. Lohaus A. Salewski C. Control beliefs and patient compliance: an empirical study exemplified by adolescents with diabetes mellitus, bronchial asthma and alopecia areata. Psychother Psychosom Med Psychol. 1989;39(1):33-40.
137. Decision Making Confidence. Decision Making definition 2013 [26/10/2014]. Available from: <http://www.decision-making-confidence.com/definition-of-decision-making.html>.
138. Croskerry P. Petrie DA. Reilly JB Tait G. Deciding About Fast and Slow Decisions. Academic Medicine. 2014;89(2).
139. Redelmeier DA, Rozin P, Kahneman D. Understanding patients' decisions. Cognitive and emotional perspectives. JAMA. 1993;270:72 - 6. PubMed PMID: doi:10.1001/jama.270.1.72.
140. Vranceanu A-M, Cooper C, Ring D. Integrating Patient Values into Evidence-Based Practice: Effective Communication for Shared Decision-Making. Hand Clinics. 2009;25(1):83-96.
141. Anderson CJ. The psychology of doing nothing: Forms of decision avoidance result from reason and emotion. Psychol Bull. 2003;129:139 - 67. PubMed PMID: doi:10.1037/0033-2909.129.1.139.
142. Bekker H, Thornton J, Airey C, Connelly J, Hewison J. Informed decision making: an annotated bibliography and systematic review. Health Technology Assessment. 1999 1999/03/03;3(1):156.
143. Briggs Myers I. Myers P. Gifts Differing: Understanding Personality Type. California: Davies-Black; 1995.
144. Byrne DJ, Napier A, Cuschieri A. How informed is signed consent? British Medical Journal Clinical Research Ed. 1988;. 296(6625):839-40. PubMed PMID: 51.
145. Mauffrey C. Prempeh EM. John J. Vasario G. The influence of written information during the consenting process on patients' recall of operative risks. A prospective randomised study. Int Orthop. 2008;32(4):425-9.
146. Turner P, Williams C. Informed consent: patients listen and read, but what information do they retain? New Zealand Medical Journal. 2002;115(1164):U218. PubMed PMID: 3.



147. Johnson MR, Singh JA, Stewart T, Gioe TJ. Patient understanding and satisfaction in informed consent for total knee arthroplasty: A randomized study. *Arthritis Care & Research*. 2011;63(7):1048-54.
148. Agre P, McKee K, Gargon N, Kurtz RC. Patient satisfaction with the informed consent process. *Cancer Pract*. 1997;5(3):162-7.
149. Hungerford DS. Internet access produces misinformed patients: managing the confusion. [Review] [3 refs]. *Orthopedics*. 2009;32(9). PubMed PMID: 17.
150. National Health Service. NHS Choices: Your health, your choices 2014 [21/01/2014]. Available from: <http://www.nhs.uk/Pages/HomePage.aspx>.
151. del Carmen MG, Joffe S. Informed Consent for Medical Treatment and Research: A Review. *The Oncologist*. 2005 September 1, 2005;10(8):636-41.
152. Mulsow JJW, Feeley TM, Tierney S. Beyond consent—improving understanding in surgical patients. *The American Journal of Surgery*. 2012 1//;203(1):112-20.
153. Jeyaseelan L, Ward J, Papanna M, Sundararajan S. Quality of consent form completion in orthopaedics: are we just going through the motions? *Journal of Medical Ethics*. 2010 July 1, 2010;36(7):407-8.
154. Dawes PJ, Davison P. Informed consent: what do patients want to know? *Journal of the Royal Society of Medicine*. 1994;87(3):149-52. PubMed PMID: 44.
155. Callanan I, Pegum JM. Gaining patients' consent. Description of orthopaedic operations is inaccurate in half of consent forms. *BMJ*. 1996;313(7053):362. PubMed PMID: 32.
156. Webster PJ, Graham S. Completion of consent forms in colorectal surgery: are we getting it right? *Journal of Medical Ethics*. 2012 September 1, 2012;38(9):574.
157. Ahmad R, Shobaki S, Etezadi V, Raju S, Case R, Ahmad R, et al. Adequacy of consent in patients with distal radius fractures. *International Orthopaedics*. 2009;33(5):1311-3. PubMed PMID: 16.
158. Atrey A LI, Carvell J, et al. Standardised consent forms on the website of the British Orthopaedic Association. *The Bone and Joint Journal*. 2008;90-B(4):422-3.
159. Barritt AW, Clark L, Teoh V, Cohen AM, Gibb PA. Assessing the adequacy of procedure-specific consent forms in orthopaedic surgery against current methods of operative consent. *Ann R Coll Surg Engl*. 2010 Apr;92(3):246-9; quiz 2p following 9. PubMed PMID: 20412675. Pubmed Central PMCID: 3080073.
160. Thompson LN, Banaglorioso T, Putch G. Automated informed consent. *Health Management Technology*. 2008;29(8):12. PubMed PMID: 56.
161. National Research Ethics Service. Differentiating audit, service evaluation and research 2007 [20/01/2014]. Available from: <http://www.nres.nhs.uk/applications/guidance/research-guidance/?entryid62=66988>.
162. Bhattacharyya T, Yeon H, Harris MB. The medical-legal aspects of informed consent in orthopaedic surgery. *Journal of Bone & Joint Surgery - American Volume*. 2005;87(11):2395-400. PubMed PMID: 23.
163. Berry MG, Unwin J, Ross GL, Peacock E, Juma A. A comparison of the views of patients and medical staff in relation to the process of informed consent. *Annals of the Royal College of Surgeons of England*. 2007;89(4):368-73. PubMed PMID: 1.
164. Mulcahy D, Cunningham K, McCormack D, Cassidy N, Walsh M. Informed consent from whom? *Journal of the Royal College of Surgeons of Edinburgh*. 1997;42(3):161-4. PubMed PMID: 30.
165. Jones K. B. Surgeons' silence: a history of informed consent in orthopaedics. *Iowa Orthopaedic Journal*. 2007;27:115-20. PubMed PMID: 21.
166. Suk M, Udale AM, Helfet DL. Orthopaedics and the law. [Review] [42 refs]. *Journal of the American Academy of Orthopaedic Surgeons*. 2005;13(6):397-406. PubMed PMID: 24.
167. Antrobus JH. Anxiety and informed consent. Does anxiety influence consent for inclusion in a study of anxiolytic premedication? *Anaesthesia*. 1988;43(4):267-9. PubMed PMID: 50.

168. Baczkowski AJ. Anxiety and informed consent. *Anaesthesia*. 1989;44(5):446. PubMed PMID: 46.
169. Jelacic M, Bonke B, van Strik R. Anxiety and informed consent. *Anaesthesia*. 1989;44(3):259-60. PubMed PMID: 47.
170. Bowden MT, Church CA, Chiu AG, Vaughan WC. Informed consent in functional endoscopic sinus surgery: the patient's perspective. *Otolaryngology - Head & Neck Surgery*. 2004;131(1):126-32. PubMed PMID: 10.
171. Amarasekera SS, Lander RO. Understanding of informed consent and surgeon liability by the public and patients. *Journal of Orthopaedic Surgery*. 2008;16(2):141-5. PubMed PMID: 19.
172. Kikuchi K, Hara T. Patients' understanding of the informed consent for cataract surgery. *Journal of Ophthalmic Nursing & Technology*. 1996;15(5):216-9. PubMed PMID: 80.
173. McCormack D, Evoy D, Mulcahy D, Walsh M. An evaluation of patients comprehension of orthopaedic terminology: implications for informed consent. *Journal of the Royal College of Surgeons of Edinburgh*. 1997;42(1):33-5. PubMed PMID: 31.
174. Cox K. Informed consent and decision-making: patients' experiences of the process of recruitment to phases I and II anti-cancer drug trials. *Patient Education & Counseling*. 2002;46(1):31-8. PubMed PMID: 14.
175. Sharma P, Arya A, Singh S. Informed consent for orthopaedic surgery: a prospective audit. *Clinical Governance: An International Journal*. 2003;8(3):236-41. PubMed PMID: 66.
176. Stanley BM, Walters DJ, Maddern GJ. Informed consent: how much information is enough? *Australian & New Zealand Journal of Surgery*. 1998;68(11):788-91. PubMed PMID: 41.
177. Flory J, Emanuel E. Interventions to improve research participant's understanding in informed consent for research: a systematic review. *JAMA*. 2004;292(6):1593-601.
178. McKneally MF, Ignagni E, Martin DK, D'Cruz J. The leap to trust: perspective of cholecystectomy patients on informed decision making and consent. *Journal of the American College of Surgeons*. 2004;199(1):51-7. PubMed PMID: 11.
179. Tan LT, Jenkins H, Roberts-Harry J, Austin M. Should patients set the agenda for informed consent? A prospective survey of desire for information and discussion prior to routine cataract surgery. *Therapeutics & Clinical Risk Management*. 2008;4(5):1119-25. PubMed PMID: 36.
180. Berman L, Curry L, Gusberg R, Dardik A, Fraenkel L. Informed consent for abdominal aortic aneurysm repair: The patient's perspective. *Journal of Vascular Surgery*. 2008;48(2):296-302. PubMed PMID: 7.
181. Courtney MJ. Information about surgery: what does the public want to know? *ANZ Journal of Surgery*. 2001;71(1):24-6. PubMed PMID: 40.
182. El-Wakeel H, Taylor GJ, Tate JJT. What do patients really want to know in an informed consent procedure? A questionnaire-based survey of patients in the Bath area, UK. *Journal of Medical Ethics*. 2006;32(10):612-6.
183. Newton-Howes PA, Bedford ND, Dobbs BR, Frizelle FA. Informed consent: what do patients want to know? *New Zealand Medical Journal*. 1998;111(1073):340-2. PubMed PMID: 42.
184. Brenner LH, Bal BS. Rethinking informed consent: tell your patients of all the treatment choices available to them. *Orthopedics Today*. 2009;29(12):24. PubMed PMID: 83.
185. Brenner LH, Brenner AT, Horowitz D. Beyond informed consent: educating the patient. *Clinical Orthopaedics & Related Research*. 2009;467(2):348-51. PubMed PMID: 58.
186. Verheggen FWS, Jonkers R, Kok G. Patients' perceptions on informed consent and the quality of information disclosure in clinical trials. *Patient Education & Counseling*. 1996;29(2):137-53. PubMed PMID: 79.
187. Braddock C, III, Hudak PL, Feldman JJ, Bereksnyi S, Frankel RM, Levinson W, et al. "Surgery is certainly one good option": quality and time-efficiency of informed decision-making in surgery. *Journal of Bone & Joint Surgery - American Volume*. 2008;90(9):1830-8. PubMed PMID: 18.

188. Kusec S, Oreskovic S, Skegro M, Korolija D, Basic Z, Horzic M. Improving comprehension of informed consent. *Patient Education & Counseling*. 2006;60(3):294-300. PubMed PMID: 63.
189. Robert Francis QC. Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry. London: The House of Commons, 2013.
190. Handbook of Qualitative Research. 2nd ed. Denzin NK, Lincoln YS., editor. California: Thousand Oaks, Sage; 2000.
191. Kuper A, Reeves S, Levinson W. An introduction to reading and appraising qualitative research. *BMJ*. 2008 2008-08-07 00:00:00;337.
192. Crabtree B.F. Miller W.L. Doing qualitative research. 2nd ed. Thousand Oaks, California: Sage Publications; 1999.
193. Silverman D. Doing qualitative research: A practical guide. Thousand Oaks, California: Sage Publications; 2000.
194. Denzin N.K. Lincoln Y.S. Handbook of qualitative research. 2nd ed. Thousand Oaks, California: Sage Publications; 2000.
195. Giddens A. The Constitution of Society. Berkeley: University of California Press; 1984.
196. Legard R, Keegan J, Ward K. In-depth Interviews. In: Ritchie J, Lewis J., editor. *Qualitative Research Practice*. London: SAGE Publications Ltd.; 2003.
197. Kvale S. *InterViews: An introduction to qualitative research interviewing*. Thousand Oaks, California: SAGE publications Inc.; 1996.
198. Coleman T. Using video-recorded consultations for research in primary care: advantages and limitations. *Family Practice*. 2000 October 1, 2000;17(5):422-7.
199. Chew-Graham CA, May CR, Perry MS. Qualitative research and the problem of judgement: lessons from interviewing fellow professionals. *Family Practice*. 2002 June 1, 2002;19(3):285-9.
200. Rubin H.J. Rubin I.S. *Qualitative Interviewing: The Art of Hearing data*. Thousand Oaks, California: SAGE Inc.; 1995.
201. Oakley A. Interviewing women- a contradiction in terms. In: Roberts H., editor. *Doing Feminist Research*. London: Routledge & Kegan Paul; 1981.
202. Kitzinger J. Qualitative Research: Introducing focus groups. *BMJ*. 1995 1995-07-29 00:00:00;311(7000):299-302.
203. Merton R.K. *The Focused Interview*. New York: The Free Press; 1956.
204. Murray SA, Tapson J, Turnbull L, McCallum J, Little A. Listening to local voices: adapting rapid appraisal to assess health and social needs in general practice. *BMJ*. 1994 1994-03-12 08:00:00;308(6930):698-700.
205. Center for Assessment Planning and Accountability: Nagle B, Williams N. *Methodology Brief: Introduction to Focus Groups 2008* [24/02/2014]. Available from: <http://www.uncfsp.org/projects/userfiles/File/FocusGroupBrief.pdf>.
206. Farnsworth J, Boon B. Analysing group dynamics within the focus group. *Qualitative Research*. 2010 October 1, 2010;10(5):605-24.
207. Allen L. Managing masculinity: young men's identity work in focus groups. *Qualitative Research*. 2005 February 1, 2005;5(1):35-57.
208. Finch H, Lewis J. Focus Groups. In: Ritchie J, Lewis J., editor. *Qualitative Research Practice*. London: SAGE Publications Ltd.; 2003.
209. Pope C, Mays N. Qualitative Research: Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. *BMJ*. 1995 1995-07-01 00:00:00;311(6996):42-5.
210. Dawson J, Fitzpatrick R, Carr A, Murray D. Questionnaire on the perceptions of patients about total hip replacements. *Journal of Bone & Joint Surgery, British Volume*. 1996 March 1, 1996;78-B(2):185-90.
211. Meenan RF, Gertman PM, Mason JH, Dunaif R. The arthritis impact measurement scales. further investigations of a health status measure. *Arthritis & Rheumatism*. 1982;25(9):1048-53.



212. Murray DW, Fitzpatrick R, Rogers K, Pandit H, Beard DJ, Carr AJ, et al. The use of the Oxford hip and knee scores. *Journal of Bone & Joint Surgery, British Volume*. 2007 August 1, 2007;89-B(8):1010-4.
213. Lincoln YS. Guba EG. *Naturalistic Inquiry*. California: SAGE Publications, Inc; 1985.
214. Patton M.Q. *Qualitative Research and Evaluation Methods*. 3rd ed. Thousand Oaks, California: SAGE publications Inc.; 2002.
215. Glaser BG. Strauss AL. *The discovery of grounded theory*. Chicago: Aldine; 1967.
216. Dictionary.com. 2014 [27/02/2014]. Available from: <http://dictionary.reference.com/browse/bias>.
217. Mays N, Pope C. Qualitative Research: Rigour and qualitative research. *BMJ*. 1995 1995-07-08 08:00:00;311(6997):109-12.
218. Pannucci CJ, Wilkins EG. Identifying and avoiding bias in research. *Plastic and reconstructive surgery*. 2010 Aug;126(2):619-25. PubMed PMID: 20679844. Pubmed Central PMCID: 2917255.
219. DeAngelis CD, Drazen JM, Frizelle FA, et al. Clinical trial registration: A statement from the international committee of medical journal editors. *JAMA*. 2004;292(11):1363-4.
220. AllTrials. 2014 [04/03/2014]. Available from: <http://www.alltrials.net/>.
221. British Medical Journal. Open data 2014 [04/03/2014]. Available from: <http://www.bmj.com/open-data>.
222. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007 December 1, 2007;19(6):349-57.
223. British Medical Journal. Research Checklist 2014 [06/03/2014]. Available from: [http://bmjopen.bmj.com/content/suppl/2011/02/21/bmjopen-2010-000017.DC1/bmjopen\\_research\\_checklist\\_000017.pdf](http://bmjopen.bmj.com/content/suppl/2011/02/21/bmjopen-2010-000017.DC1/bmjopen_research_checklist_000017.pdf).
224. PLoS ONE. Manuscript guidelines 2014 [06/03/2014]. Available from: <http://www.plosone.org/static/guidelines.action>.
225. Reflexivity: A Practical Guide for Researchers in Health and Social Sciences. B. FLG, editor. Oxford: Blackwell Publishing; 2003.
226. Maso I. Necessary subjectivity: exploiting researchers motives, passions and prejudices in pursuit of answering "true" questions. In: Finlay L. Gough B., editor. *Reflexivity: A Practical Guide for Researchers in Health and Social Sciences*. Oxford: Blackwell Publishing; 2003.
227. Bazeley P. Jackson K. *Qualitative Data Analysis with NVIVO*. Second ed. Thousand Oaks, California: SAGE Publications Inc; 2013.
228. Srivastava A. Thomson S.B. Framework Analysis: A Qualitative Methodology for Applied Policy Research. *Journal of Administration and Governance*. 2009;4(2).
229. Ritchie J. and Spencer L. *Qualitative data analysis for applied policy research*. A. Bryman and R.G.Burgess, editor. London: Routledge; 1994.
230. Gale N, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Medical Research Methodology*. 2013;13(1):117. PubMed PMID: doi:10.1186/1471-2288-13-117.
231. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ*. 2008 January 1, 2008;337:a1655. PubMed PMID: 18824488. Pubmed Central PMCID: 2769032.
232. Diabetes UK. Statistics: Diabetes prevalence 2012 (March 2013) 2013 [11/03/2014]. Available from: <http://www.diabetes.org.uk/prevalence-2012>.
233. National Institute for Health and Care Excellence. Insulin therapy for type 2 diabetes 2010 [17/06/2014]. Available from: <http://cks.nice.org.uk/insulin-therapy-in-type-2-diabetes#!evidence>.
234. O'Connor AM, Bennett CL, Stacey D, Barry M, Col NF, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. *The Cochrane database of systematic reviews*. 2009 (3):CD001431. PubMed PMID: 19588325.

235. Medical Research Council. A Framework for development and evaluation of RCTs for Complex Interventions to Improve Health 2000 [13/03/2014]. Available from: <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC003372>.
236. Ritchie J, Lewis J. Qualitative Research Practice. 1st ed. London: SAGE Publications Ltd.; 2008.
237. Ottawa Hospital Research Institute. Ottawa Decision Support Tutorial 2013 [04/02/2014]. Available from: <https://decisionaid.ohri.ca/ODST/pdfs/ODST.pdf>.
238. Degner LF, Sloan JA, Venkatesh P. The Control Preferences Scale. The Canadian journal of nursing research = Revue canadienne de recherche en sciences infirmieres. 1997 Fall;29(3):21-43. PubMed PMID: 9505581.
239. Department of Health. Reference guide to consent for examination or treatment. In: Department of Health, editor. Second ed. London: Crown copyright; 2009.
240. Maclean A. Autonomy, Informed Consent and Medical Law: A Relational Challenge. Cambridge, UK: Cambridge University Press; 2009.
241. Butterworth and Tolley. LexisNexis 2014 [10/03/2014]. Available from: <https://www.lexisnexis.co.uk/en-uk/products/lexis-library.page>.
242. Jayadev C, Khan T, Coulter A, Beard DJ, Price AJ. Patient decision aids in knee replacement surgery. The Knee. 2012;19(6):746-50.
243. Macario A, Schilling P, Rubio R, Bhalla A, Goodman S. What questions do patients undergoing lower extremity joint replacement surgery have? BMC Health Services Research. 2003;3(1):11. PubMed PMID: doi:10.1186/1472-6963-3-11.
244. Health and Social Care Information Centre. Provisional Monthly Patient Reported Outcome Measures (PROMs) in England - April 2012 to March 2013, February 2014 release 2014 [10/03/2014]. Available from: <http://www.hscic.gov.uk/searchcatalogue?productid=14062&q=title%3a%22Provisional+Monthly+Patient%22&sort=Relevance&size=10&page=1#top>.
245. National Joint Registry. Executive summary: Public and Patient Guide to The NRJ's 10th Annual Report 2013 2013 [15/03/2014]. Available from: [http://www.njrcentre.org.uk/njrcentre/Portals/0/Documents/England/Reports/10th\\_annual\\_report/NJR%20Public%20Patient%20Guide%20Executive%20Summary%202013.pdf](http://www.njrcentre.org.uk/njrcentre/Portals/0/Documents/England/Reports/10th_annual_report/NJR%20Public%20Patient%20Guide%20Executive%20Summary%202013.pdf).
246. National Institute of Health and Care Excellence. Patient-centred care 2011 [13/06/2014]. Available from: <http://www.nice.org.uk/guidance/cg123/chapter/patient-centred-care>.
247. NHS England. Shared Decision Making 2014 [04/08/2014]. Available from: <http://www.england.nhs.uk/ourwork/pe/sdm/>.
248. The Department of Health. The Mandate: A mandate from the Government to NHS England April 2014- March 2015: Crown copyright; 2013. Available from: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/256406/Mandate\\_14\\_15.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/256406/Mandate_14_15.pdf).
249. The Health and Social Care Act,, UK Parliament(2012).
250. National Health service Act,, UK Parliament(2006).
251. Diabetes UK. Diabetes UK 2014 [01/08/2014]. Available from: [www.diabetes.org.uk](http://www.diabetes.org.uk).
252. National Institute for Health and Care Excellence. Management of Osteoarthritis 2014 [13/07/2014]. Available from: <http://pathways.nice.org.uk/pathways/osteoarthritis#path=view%3A/pathways/osteoarthritis/management-of-osteoarthritis.xml&content=view-index>.
253. O'Connor AM, Stacey D, Entwistle V, Llewellyn-Thomas H, Royner D, Holmes-Rovner M, et al. Decision aids for people facing health treatment or screening decisions. The Cochrane Library. 2003;1.

254. Munro S, Kornelsen J, Hutton E. Decision Making in Patient-Initiated Elective Cesarean Delivery: The Influence of Birth Stories. *Journal of Midwifery & Women's Health*. 2009 9//;54(5):373-9.
255. The Dartmouth-Hitchcock Medical Center. Hip Replacement Quality Report 2014 [01/09/2014]. Available from: [http://med.dartmouth-hitchcock.org/quality/quality\\_report/HR](http://med.dartmouth-hitchcock.org/quality/quality_report/HR).
256. The Department of Health. The NHS Constitution London2013 [04/08/2014]. Available from: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/170656/NHS\\_Constitution.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170656/NHS_Constitution.pdf).
257. Ng ChirkJenn; Mathers Nigel; Bradley Alastair; Colwell Brigitte. A 'combined framework' approach to developing a patient decision aid: the PANDAs model. *BMC Health Services Research*. 2014 2014/10/24;14(1):1-12. English.
258. Gonder-Frederick L, Cox D. Symptom Perception, Symptom Beliefs, and Blood Glucose Discrimination in the Self-Treatment of Insulin-Dependent Diabetes. In: Skelton JA, Croyle R, editors. *Mental Representation in Health and Illness. Contributions to Psychology and Medicine*: Springer US; 1991. p. 220-46.
259. Cheng K-Y. What does respect for the patient's autonomy require? *Bioethics*. 2013;27(9):493-9.
260. The Coalition for Collaborative Care. Action for longterm conditions 2014 [01/11/2014]. Available from: <http://coalitionforcollaborativecare.org.uk/>.
261. NHS Institute for Innovation and Improvement. Transforming Patient Experience: the essential guide 2013 [05/08/2014]. Available from: [http://www.institute.nhs.uk/patient\\_experience/guide/the\\_policy\\_framework.html](http://www.institute.nhs.uk/patient_experience/guide/the_policy_framework.html).
262. Denig P, Schuling J, Haaijer-Ruskamp F, Voorham J. Effects of a patient oriented decision aid for prioritising treatment goals in diabetes: pragmatic randomised controlled trial2014 2014-09-25 14:23:51.
263. Hargraves I, Montori VM. Decision aids, empowerment, and shared decision making2014 2014-09-25 14:23:51.
264. Maximum Variation Sampling. *The SAGE Encyclopedia of Qualitative Research Methods*. SAGE Publications, Inc. Given LM, editor. Thousand Oaks, CA: SAGE Publications, Inc. 500 p.
265. Roethlisberger F.J. & Dickson WJ. *Management and the worker: an account of a research program conducted by the Western electric company, Hawthorne works, Chicago*. Cambridge MA: Harvard University Press; 1939.
266. National Institute for Health Research. Research for Patient Benefit 2014 [01/11/2014]. Available from: <http://www.nihr.ac.uk/funding/research-for-patient-benefit.htm>.
267. Pisters R, Lane DA, Nieuwlaat R, de Vos CB, Crijns HJGM, Lip GYH. A novel user-friendly score (has-bled) to assess 1-year risk of major bleeding in patients with atrial fibrillation: The euro heart survey. *Chest*. 2010;138(5):1093-100.
268. Moulton B, Collins PA, Burns-Cox N, Coulter A. From informed consent to informed request: do we need a new gold standard? *Journal of the Royal Society of Medicine*. 2013 October 1, 2013;106(10):391-4.
269. Sokol DK. Let's stop consenting patients2014 2014-03-19 11:33:52.

## Appendices

### Appendix 1: The OPTION Instrument

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## OPTION Observing patient involvement © March 2009

Date of Rating: ..... DD ..... MM ..... YY .....      Practitioner: ..... Age ..... Sex .....

Rater Name: .....      Patient: ..... Age ..... Sex .....

Clinician Code: .....      Consultation Type:  New  
 Review  
 Composite

Consultation Number: .....

Consultation Duration: ..... (minutes: seconds) .....      Another Person In The Room?  Yes  No  
Who? .....

Description of Index Problem:



- 1. The clinician draws attention to an identified problem as one that requires a decision making process.**  
0 = No attempt to draw attention to a need for a decision making process (*there is no clarity about problems, or at least no clarity about the decisions to be taken about the problem or problems identified*).  
1 = Very brief or perfunctory attempts to draw attention to the need to embark on a decision making process.  
2 = Baseline skill level: Clinician draws attention to a problem that requires a decision making process.  
3 = Clinician puts emphasis on the decision making process required.  
4 = The skill is exhibited to a high standard (*e.g. supplementary explanations and evidence of patient recognizing the need to engage in the process of decision making*).
- 2. The clinician states that there is more than one way to deal with the identified problem ('*equipoise*').**  
0 = The clinician does not state that there is more than one way of managing problems.  
1 = Perfunctory attempt to convey the existence of more than one option.  
2 = Baseline skill level: Clinician conveys the sense that the options are valid and need to be considered in more depth.  
3 = Explains 'equipoise' in more detail and that options have pros and cons that need to be considered.  
4 = The clinician also explains 'why' choices are available (*e.g. there is genuine professional uncertainty as to the 'best' way of managing the problem – clinical equipoise*); the skill is exhibited to a high standard.
- 3. The clinician assesses patient's preferred approach to receiving information to assist decision making (*e.g. discussion in consultations, read printed material, assess graphical data, use videotapes or other media*).**  
0 = The behaviour is not observed.  
1 = A minimal attempt is made to exhibit the behaviour.  
2 = Baseline skill level: Clinician asks for patient's preferred method of receiving information.  
3 = Doing this behaviour well (*e.g. states that there are many ways in which information can be conveyed; provides reading for outside of consultation*).  
4 = Gives many examples of the types of information formats and media available for the patient, and then provides an opportunity for the patient to select their preferred method or methods.
- 4. The clinician lists 'options', which can include the choice of 'no action'.**  
0 = The behaviour is not observed (*listing options is different from providing details about each option*).  
1 = Minimal or perfunctory attempt is made to list options.  
2 = Baseline skill level: Clinician lists options as distinct possibilities that are available (*e.g. using 'either / or' phrasing to describe the existence of options*).  
3 = Careful listing of all possible options, including the choice of taking no action, or deferring the decision.  
4 = Clinician exhibited this behaviour to a high standard.
- 5. The clinician explains the pros and cons of options to the patient (*taking 'no action' is an option*).**  
0 = No explanation.  
1 = The clinician fails to provide information about more than one option (*according to the extent that each option is described*).  
2 = Baseline skill level: The clinician provides details about the pros and cons of the options.  
3 = The behaviour is exhibited to a good standard.  
4 = The skill is exhibited to a high standard (*e.g. by description of options followed with discussion*).
- 6. The clinician explores the patient's expectations (or ideas) about how the problem(s) are to be managed.**  
0 = No attempt to ascertain patient's views about their expectations.  
1 = Unskilled or perfunctory attempts to uncover patient's ideas or expectations about management.  
2 = Baseline skill level: The clinician explicitly asks the patient what they expected (*thought*) about the actions required to manage the problem(s). Skilled clinicians are able to explore these expectations and ideas (*using open ended questions, suggesting a range of common expectations, using pauses, being alert to verbal and physical cues and so on*).  
3 = This behaviour is exhibited and leads to supplementary questions to clarify expectations or ideas (*e.g. exploration of expectations takes place*). The behaviour is performed to a good standard.  
4 = The behaviour is achieved to high standards and patient's views are discussed and addressed.



<p><b>7. The clinician explores the patient's <u>concerns (fears)</u> about how problem(s) are to be managed.</b>  0 = No attempt to ascertain patient's views about their fears or concerns.  1 = Unskilled or perfunctory attempts to uncover patient's fears or concerns about management.  2 = Baseline skill level: Clinician explicitly asks the patient to voice their fears or concerns about the possible actions required to manage the problem(s). Skilled clinicians are able to explore these fears and ideas (<i>using open ended questions, suggesting a range of common fears, using pauses, being alert to verbal and physical cues and so on</i>).  3 = Exhibits behaviour and leads to supplementary questions to clarify concerns.  4 = Achieved to high standards where patient's fears/concerns discussed and addressed.</p>
<p><b>8. The clinician checks that the patient has <u>understood</u> the information.</b>  0 = No attempt to ascertain patient has understood the information.  1 = Perfunctory attempt to check patient has understood relevant information.  2 = Baseline skill level: Explicit question posed to the patient asking whether they had understood the information provided or obtained from other sources.  3 = The clinician explores nature of the patients understanding by using statements like: "I'd like to check that you have understood the information about the possible options. Would you like to let me know what you now understand about this issue?"  4 = The behaviour is observed and executed to a high standard.</p>
<p><b>9. The clinician offers the patient explicit <u>opportunities</u> to ask questions during decision making process.</b>  0 = No attempt to offer opportunities to ask questions.  1 = Clinician provides pauses, or other opportunities for queries to be raised (<i>e.g. appropriate pace within the discourse</i>).  2 = Baseline skill level: Clinician explicitly asks patient to voice a question (<i>e.g. "Do you have any questions?"</i>).  3 = The clinician is more specific and asks the patient whether they have questions about the options and the management of the identified problem(s).  4 = The behaviour is observed and executed to a high standard. The clinician will allow time for the patient to respond and will check if there are any other or supplementary questions.</p>
<p><b>10. The clinician elicits the patient's <u>preferred level of involvement</u> in decision making.</b>  0 = No attempt made to clarify.  1 = Perfunctory or rushed attempt to elicit the patient's preferred role (active or passive) in decision making.  2 = Baseline skill level: Clinician explicitly asks patient about their preferred role.  3 = Clinician provides further explanation and continues to assess patients role preference.  4 = Clinician asks this question in a way that is easy for patient to understand and which signals that the clinician is sensitive to the decisional responsibility that is being expected of the patient.</p>
<p><b>11. The clinician indicates the need for a <u>decision making (or deferring)</u> stage (<i>how the decision is made is not evaluated – could be paternalistic. How the decision is made between the participants and who takes 'control' is not evaluated</i>).</b>  0 = The clinician does not clearly indicate that a time has come where a decision (<i>or deferment</i>) is required.  1 = Perfunctory or unclear attempt to indicate need for a decision making state.  2 = Baseline skill level: Clear statement such as, "Perhaps it's time now to make a decision about what should be done."  3 = Exhibiting this behavior to a good standard.  4 = Clinician that achieves this task to a high standard and will have signaled the transition from consideration of information and views to one of deliberation and closure.</p>
<p><b>12. The clinician indicates the need to <u>review</u> the decision (<i>or deferment</i>).</b>  0 = No attempt to indicate a need to review or defer.  1 = Perfunctory (<i>e.g. that the patient should be seen again</i>) or rushed attempt.  2 = Baseline skill level: Clinician indicates that the patient should be seen again to re-consider the decision.  3 = The behaviour is performed to a good standard.  4 = The behaviour is observed and executed to a high standard (<i>e.g. makes it very explicit and encourages this approach</i>).</p>

**For psychometric data see:** Elwyn G, Hutchings H, Edwards A, Rapport F, Wensing M, Cheung WY, Grol R. The OPTION scale: measuring the extent that clinicians involve patients in decision-making tasks. *Health Expectations*, 8: 34-42, 2005.

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 <p>decision laboratory</p>	<p><b>For further information:</b>  Decision Laboratory  www.DecisionLaboratory.com  www.OptionInstrument.com  Cardiff University  Email: ElwynG@cardiff.ac.uk</p>	 <p>CARDIFF UNIVERSITY PRIFYSGOL CAERDYDD</p>
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Appendix 2: The Oxford Hip Score Available from:

[http://www.orthopaedicscore.com/scorepages/oxford\\_hip\\_score.html](http://www.orthopaedicscore.com/scorepages/oxford_hip_score.html)

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Appendix 3: Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

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No	Item	Guide questions/description
<b>Domain 1: Research team and reflexivity</b>		
Personal Characteristics		
1.	Interviewer/facilitator	Which author/s conducted the interview or focus group?
2.	Credentials	What were the researcher's credentials? <i>E.g. PhD, MD</i>
3.	Occupation	What was their occupation at the time of the study?
4.	Gender	Was the researcher male or female?
5.	Experience and training	What experience or training did the researcher have?
Relationship with participants		
6.	Relationship established	Was a relationship established prior to study commencement?
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? <i>e.g. personal goals, reasons for doing the research</i>
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? <i>e.g. Bias, assumptions, reasons and interests in the research topic</i>
<b>Domain 2: study design</b>		
Theoretical framework		
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? <i>e.g. grounded theory, discourse</i>

No	Item	Guide questions/description
		<i>analysis, ethnography, phenomenology, content analysis</i>
Participant selection		
10.	Sampling	How were participants selected? <i>e.g. purposive, convenience, consecutive, snowball</i>
11.	Method of approach	How were participants approached? <i>e.g. face-to-face, telephone, mail, email</i>
12.	Sample size	How many participants were in the study?
13.	Non-participation	How many people refused to participate or dropped out? Reasons?
Setting		
14.	Setting of data collection	Where was the data collected? <i>e.g. home, clinic, workplace</i>
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?
16.	Description of sample	What are the important characteristics of the sample? <i>e.g. demographic data, date</i>
Data collection		
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?
20.	Field notes	Were field notes made during and/or after the interview or focus group?
21.	Duration	What was the duration of the interviews or focus group?

No	Item	Guide questions/description
22.	Data saturation	Was data saturation discussed?
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?
<b>Domain 3: analysis and findingsz</b>		
Data analysis		
24.	Number of data coders	How many data coders coded the data?
25.	Description of the coding tree	Did authors provide a description of the coding tree?
26.	Derivation of themes	Were themes identified in advance or derived from the data?
27.	Software	What software, if applicable, was used to manage the data?
28.	Participant checking	Did participants provide feedback on the findings?
Reporting		
29.	Quotations presented	Were participant quotations presented to illustrate the themes / findings? Was each quotation identified? e.g. <i>participant number</i>
30.	Data and findings consistent	Was there consistency between the data presented and the findings?
31.	Clarity of major themes	Were major themes clearly presented in the findings?
32.	Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?



## Appendix 4: The PANDAs Patient Decision Aid

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CONFIDENTIAL

# Starting Insulin Your Choice

When your diabetes tablets are not controlling your blood sugar ...

## Do you need to add insulin?

**This decision aid is for you if:**

- You have type 2 diabetes
- Your blood sugar is not well controlled with your diabetes tablets
- Your doctor or nurse has advised you to add insulin



**This decision aid will guide you through the decision whether or not to start insulin. It will:**

- Give you information about the treatment choices you have when your blood sugar is not well controlled
- Give you information about the advantages and disadvantages of starting insulin
- Help you to think about what is important to you when making the decision
- Help you find out what support you will need when making the decision
- Help you to decide which treatment choice you prefer

**Your doctor or nurse will discuss with you about your decision after you have completed this decision aid.**

### **1. Is there a need to start insulin?**

- People with type 2 diabetes usually need insulin when their blood sugar is high despite taking tablets and having a healthy lifestyle.
- This usually happens 5 to 10 years after the diagnosis when the body no longer produces enough insulin. The only way to have enough insulin in the body is to take insulin injections.
- There are reasons why the blood sugar should be kept under control:
  - High blood sugar can damage your eyes, heart, kidneys, nerves and blood vessels. Damage can lead to blindness, heart attacks, kidney failure, leg amputations and strokes.
  - High blood sugar may make you feel thirsty, tired, pass urine more often, lose weight, have blurry vision, or have skin and urine infections.
- Insulin can improve the blood sugar level and prevent the complications or stop them from getting worse. It also helps to reduce the symptoms of diabetes.

## 2. What happens when people take insulin?

- Insulin is added to your diabetes treatment while you continue with your tablets, diet and exercise. For most people, only one insulin injection at night is required.
- Insulin is given using an injection 'pen'. You can set the dose and press the pen to deliver the insulin through the needle into the skin of your abdomen or the outer part of your thigh.
- Every morning, you check your blood sugar with a meter.
- Your doctor or nurse will explain to you how and when to use the insulin pen and check your blood sugar. You will be followed up regularly by the doctor or nurse until you are confident in using the insulin. You can contact the nurse during working hours if you have any queries about the insulin injections.

## 3. What are people concerned about when they start insulin?

When people start insulin, they often worry about:

- making changes to their daily life
- the needles, the injections and the pain caused by the injections
- putting on weight
- "hypos" – hypos happens when the blood sugar is too low after taking insulin. It makes you feel dizzy, cold and sweaty. Hypos are treated with sugary drinks and food.

**Your doctor or nurse will help to address your concerns.**

#### 4. How is diabetes affecting you?

Diabetes can affect people in many ways. Below are some common problems which people with type 2 diabetes may face.

Tick  any that apply to you.

##### Have you had any of these symptoms OVER THE PAST WEEK?

- |   |  |  |
|---|--|--|
| <input type="checkbox"/> Thirsty                  | <input type="checkbox"/> Tired         | <input type="checkbox"/> Infections                  |
| <input type="checkbox"/> Passing urine more often | <input type="checkbox"/> Blurry vision | <input type="checkbox"/> Weight changes (past month) |

##### How would you feel if the symptoms you have now stay the same for the rest of your life?

- Delighted
- Pleased
- Mostly satisfied
- Mixed (neither satisfied nor dissatisfied)
- Mostly dissatisfied
- Unhappy
- Terrible

##### Which complications has your doctor or nurse diagnosed?

- |  |   |   |
|--|---|---|
| <input type="checkbox"/> Eye disease   | <input type="checkbox"/> Stroke         | <input type="checkbox"/> Numbness hands/feet  |
| <input type="checkbox"/> Heart disease | <input type="checkbox"/> Kidney disease | <input type="checkbox"/> Poor leg circulation |

##### Which of the following apply to you?

- |  |   |                                  |
|--|---|----------------------------------|
| <input type="checkbox"/> High blood pressure | <input type="checkbox"/> High cholesterol | <input type="checkbox"/> Smoking |
|--|---|----------------------------------|

**5. Do you find it difficult to follow the diabetes advice?****Many people with type 2 diabetes find it difficult to follow the medical advice.**How often have you been following the diabetes advice during the **PAST WEEK**?How often did you control your **diet**? Not at all       1-2 days       3-4 days       5-6 days       DailyHow often did you take your **diabetes tablets**? Not at all       1-2 days       3-4 days       5-6 days       DailyHow often did you **exercise** (e.g. walking, cycling)? Not at all       1-2 days       3-4 days       5-6 days       Daily

## 6. What are your choices?

When people with type 2 diabetes have high blood sugar despite taking tablets, they have the following choices:

- **Make no change** and continue with your tablets and present lifestyle. You will return for a review in 3 to 6 months' time.
- **Follow the diabetes advice more regularly (diet, exercise, taking tablets)**, and wait 4 to 6 months to see if your blood sugar drops.  
(Your blood sugar is unlikely to improve if you are already careful with your tablets, diet and exercise)
- **Add insulin** and continue with your tablets.

Working through the next 4 steps of this decision aid helps you decide which option to choose.

**Step 1: Learn about the choices.....**

To make a decision, it is important to know the advantages and disadvantages of each choice.

**Choice 1: Make no change**

If you make no change, your average blood sugar (HbA1c) will remain at .....% or higher. This is higher than the normal level of 7.4%.

If you decide to make no change to your treatment,

**The advantages are:**

- You keep to your daily routine
- No insulin injections
- No side effects of insulin

**The disadvantages are:**

- Continue to have diabetic symptoms (feeling thirsty, tired, pass urine more often, blurry vision, infections and weight changes)

**Your chance of getting complications in 5 years is:**

(heart disease, stroke, kidney disease, eye disease, numbness, poor circulation)



symbols mean stronger study results.



or



symbols mean weaker study results.



**Choice 2: Follow the diabetes advice more regularly (diet, exercise, taking tablets)**


**This choice is not useful to you if:**

- you are already following the diabetes advice carefully
- you are unlikely to follow the diabetes advice more regularly

**If you follow the diabetes advice more regularly, your average blood sugar (HbA1c) will be .....%.**  
This is the same as your best average blood sugar level (HbA1c) in the past one year.

**If you decide to follow the diabetes advice more regularly,**


**The advantages are:**

- No insulin injections
- No side effects of insulin
- Your diabetic symptoms may improve 

**The disadvantages are:**

- have to make changes to your daily routine (diet, exercise, taking tablets)

**Your chance of getting complications in 5 years is:**

(heart disease, stroke, kidney disease, eye disease, numbness, poor circulation) 



 symbols mean stronger study results.  or  symbols mean weaker study results.

**Choice 3: Add insulin**



If you take insulin, your average blood sugar (HbA1c) will drop from .....% to .....%


If you decide to take insulin,

**The advantages are:**

- Your diabetic symptoms will improve 

**The disadvantages are:**

- Have to make changes to your daily routine
- May feel slight discomfort with the insulin injection
- Have to check your blood sugar regularly
- May put on 6 to 8 pounds in the first year 
- May have 'hypos' 3 to 5 times a year 

**Your chance of getting complications in 5 years is:**  
(heart disease, stroke, kidney disease,  
eye disease, numbness, poor circulation) 

Sticker to  
go here

 symbols mean stronger study results.  or  symbols mean weaker study results.

### Summary of the 3 choices

**Choice 1:**  
**Make no change**

**Average blood sugar (HbA1c) is .....%.**

**Advantages:**

- Keep to your daily routine
- No insulin injections
- No side effects of insulin

**Disadvantages:**

- Continue to have diabetic symptoms

**Your chance of getting complications in 5 years is:**

Sticker to go here

**Choice 2:**  
**Follow the diabetes advice more regularly**

**Average blood sugar (HbA1c) is .....%.**

**Advantages:**

- No insulin injections
- No side effects of insulin
- Your diabetic symptoms may improve

**Disadvantages:**

- Have to make changes to your daily routine and follow the diabetic advice more regularly

**Your chance of getting complications in 5 years is:**

Sticker to go here

**Choice 3:**  
**Add insulin**

**Average blood sugar (HbA1c) is .....%.**

**Advantages:**

- Your diabetic symptoms will improve

**Disadvantages:**

- Have to make changes to your daily routine
- Slight discomfort with the insulin injection
- Have to check your blood sugar regularly
- May put on 6 to 8 pounds in the first year
- May have 'hypos' 3 to 5 times a year

**Your chance of getting complications in 5 years is:**

Sticker to go here

**Step 2. Thinking about what is important to you .....**

Now you have to consider whether the advantages and disadvantages of these choices are **IMPORTANT TO YOU**.

Tick  whether each statement is important to you.

Reasons for choosing insulin:	Yes	No
Is it important to you to reduce your blood sugar?	<input type="checkbox"/>	<input type="checkbox"/>
Is it important to you to reduce your chance of getting complications?	<input type="checkbox"/>	<input type="checkbox"/>
Is it important to you to reduce your diabetic symptoms?	<input type="checkbox"/>	<input type="checkbox"/>
Reasons for not choosing insulin:	Yes	No
Is it important to you not to have injections?	<input type="checkbox"/>	<input type="checkbox"/>
Is it important to you not to have to check your blood sugar everyday?	<input type="checkbox"/>	<input type="checkbox"/>
Is it important to you not to put on weight?	<input type="checkbox"/>	<input type="checkbox"/>
Is it important to you not to have "hypos" (low blood sugar)?	<input type="checkbox"/>	<input type="checkbox"/>
Is it important to you to keep to your daily routine?	<input type="checkbox"/>	<input type="checkbox"/>
Other reason that is important to you?	Yes	No
_____	<input type="checkbox"/>	<input type="checkbox"/>

Now, think about which choice has the advantages and disadvantages that are important to you.

Which choice do you prefer? Tick  one

- Make no change
- Follow the diabetes advice more regularly
- Add insulin
- Unsure

**Step 3: What else do you need to help you make a decision?**

**Knowledge**

Find out how this decision aid has helped you learn the key facts.

Tick  the best answer.

	Make no change	Follow the diabetes advice more regularly	Add insulin
a) Which choice has the greatest chance of lowering your blood sugar?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Which choice has the greatest chance of lowering your complications?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If you are unsure about the answer, you can go back to the summary at page 10.

c) If you take insulin, about how many times might you experience 'hypos' in a year?	<input type="checkbox"/> 3 to 5	<input type="checkbox"/> 6 to 8	<input type="checkbox"/> 9 to 11
d) If you take insulin, about how much more weight might you gain in a year?	<input type="checkbox"/> 3 to 5 pounds	<input type="checkbox"/> 6 to 8 pounds	<input type="checkbox"/> 9 to 11 pounds

Check your answers at the bottom of page 14.

**Facts**

Do you know enough about the **advantages** and **disadvantages** of each choice?

Yes  No

**Values**

Are you clear about which advantages and disadvantages **matter most** to you?

Yes  No

**Support**

Have you had enough **support and advice from others** to make a choice?

Yes  No

**Uncertainty**

Do you feel sure about the **best choice for you**?

Yes  No

**Please discuss with your doctor or nurse, if you are still unsure about the decision.**

**Step 4: What are the next steps?**

**Are you ready to make a decision?** Tick  one.

- No, I am not ready       Yes, I am ready

**If you are ready to make a decision, which choice do you prefer?** Tick  one.

- Make no change  
 Follow the diabetes advice more regularly  
 Add insulin

**If you decide to add insulin,**

How motivated are you to do this?      Not Motivated    ①   ②   ③   ④   ⑤    Very Motivated

How confident are you that you can do this?    Not Confident    ①   ②   ③   ④   ⑤    Very Confident

List the things that might get in the way of doing this:

---

---

List the things that will help you to do this:

---

---

**Answers for the key facts:** a. insulin   b. insulin   c. 3 to 5 times   d. 6 to 8 pounds





This booklet belongs to:

**Contact Details:**

Academic Unit of Primary Medical Care  
University of Sheffield  
Samuel Fox House  
Northern General Hospital  
Herries Road  
Sheffield  
S5 7AU  
United Kingdom

Tel: +44 (0)114 271 5922  
Fax: +44 (0)114 271 5915  
Email: [C.Ng@sheffield.ac.uk](mailto:C.Ng@sheffield.ac.uk)

Appendix 5: Type 2 Diabetes study (study 1) Ethics approval and associated documents



# National Patient Safety Agency

## National Research Ethics Service

### NOTICE OF SUBSTANTIAL AMENDMENT

*For use in the case of all research other than clinical trials of investigational medicinal products (CTIMPs). For substantial amendments to CTIMPs, please use the EU-approved notice of amendment form (Annex 2 to ENTR/CT1) at <http://eudract.emea.eu.int/document.html#guidance>.*

*To be completed in typescript by the Chief Investigator in language comprehensible to a lay person and submitted to the Research Ethics Committee that gave a favourable opinion of the research ("the main REC"). In the case of multi-site studies, there is no need to send copies to other RECs unless specifically required by the main REC.*

*Further guidance is available at <http://www.nres.npsa.nhs.uk/applicants/review/after/amendments.htm>.*

#### Details of Chief Investigator:

<i>Name:</i>	Nigel Mathers
<i>Address:</i>	Academic Unit of Primary Medical Care, University of Sheffield, Community Sciences Centre, Northern General Hospital, Herries Road, Sheffield S5 7AU
<i>Telephone:</i>	0114 271 5922
<i>Email:</i>	<a href="mailto:n.mathers@sheffield.ac.uk">n.mathers@sheffield.ac.uk</a>
<i>Fax:</i>	0114 272 2136

<b>Full title of study:</b>	The development and evaluation of the effectiveness of a patient decision aid to improve decision quality and health outcome in type 2 diabetic patients making treatment choices
<b>Name of main REC:</b>	North Sheffield Local Research Ethics Committee
<b>REC reference number:</b>	07/Q2308/53
<b>Date study commenced:</b>	1 August 2007
<b>Protocol reference:</b>	PANDAs Protocol/ Version 4/ 090309
<b>Amendment number and date:</b>	Amendment 3 and 09 March 2009

**Type of amendment (indicate all that apply in bold)**

*(a) Amendment to information previously given on the NRES Application Form*

Yes      **No**

*If yes, please refer to relevant sections of the REC application in the "summary of changes" below.*

*(b) Amendment to the protocol*

**Yes**      **No**

*If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.*

*(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study*

**Yes**      **No**

*If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.*

**Is this a modified version of an amendment previously notified to the REC and given an unfavourable opinion?**

**Yes**      **No**

## Summary of changes

*Briefly summarise the main changes proposed in this amendment using language comprehensible to a lay person. Explain the purpose of the changes and their significance for the study. In the case of a modified amendment, highlight the modifications that have been made.*

*If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.*

PANDAs is designed to evaluate the effectiveness of a patient decision aid in improving decision quality (uncertainties in making decisions, what is important to patients and the decision they make, satisfaction with and regret of the decision) and health outcomes (blood sugar control) in people with type 2 diabetes mellitus considering insulin therapy. We would like to amend the study protocol to include an evaluation of the process of implementing this cluster randomised controlled trial.

The PANDAs study is a complex intervention<sup>1</sup>. It involves patients and clinicians discussing a difficult decision whether or not to start insulin therapy. A patient decision aid is used by both parties to facilitate the decision making process in this study. There are many components which may act independently or interact with each other to influence the study outcomes (decision quality and health outcomes). There are three main components in this intervention: (a) the patient using the decision aid, (b) training of the healthcare professionals and (c) the discussion between the patient and the healthcare professional within a consultation. Each component, on its own, has an impact on how patient makes decisions; together, these components interact with one another to influence the final outcome.

It is, therefore, important not only to look at the outcomes of the intervention, but also the process of the intervention which will help us to understand how the patient decision aid is being used by both parties and how this could potentially affect the patient's decision.

This amendment involves adding a process evaluation component to the protocol. We will conduct and audio-record individual interviews with 10 patients as well as 10 clinicians after they have used the patient decision aid. We will also audio-record the consultations to explore the interactions between patients and clinicians when discussing the decision whether or not to start insulin. We will recruit participants from the existing cluster randomised controlled trial.

---

<sup>1</sup> Craig P., Dieppe P., Macintyre C. et al Developing and evaluating complex interventions: a new Medical Research Council guidance BMJ 2008; 337: 979-83

We will use a qualitative methodology to analyse and interpret the data. The main outcomes of the process evaluation are:

1. the views and experience of patients and clinicians in using a patient decision aid to facilitate decision making
2. the mechanism of how a patient decision aid is being used in a consultation
3. the identification of strengths and weaknesses of the patient decision, and its delivery

To implement the above changes, we will need to use patient and healthcare professional versions of information sheets, consent forms and interview guides appropriate to this phase of the study, six new documents in all. With the revised protocol, we are therefore attaching seven documents for ethics review.

**Any other relevant information**

*Applicants may indicate any specific ethical issues relating to the amendment, on which the opinion of the REC is sought.*

**List of enclosed documents**

<i>Document</i>	<i>Version</i>	<i>Date</i>
Study Protocol	4	09/03/2009
Process Evaluation Interview Guide – Patient	1	09/03/2009
Process Evaluation Interview Guide – Healthcare professionals	1	09/03/2009
Process Evaluation Information Sheet - Patient	1	09/03/2009
Process Evaluation Information Sheet – Healthcare Professional	1	09/03/2009
Process Evaluation Consent Form - Patient	1	09/03/2009
Process Evaluation Consent Form – Healthcare Professional	1	09/03/2009

**Declaration**

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment to be implemented.

*Signature of Chief Investigator:* .....

*Print name:* .....

*Date of submission:* .....



## Participants Information Sheet

**Study Title:** Patient Decision Aid for Type 2 Diabetes  
**Protocol Ref:** ZH25  
Version: V1-090309

**Part 1** tells you the purpose of this study and what will happen to you if you take part.

**Part 2** gives you more detailed information about the conduct of the

### Part 1

We would like to invite you to take part in an evaluation of the Patient Decision Aid for Type 2 Diabetes (PANDAs) study. The evaluation process involves audiotaping your consultation with the Health Care Professional. It will also include a 30 minute (approximately) audiotaped interview with a researcher within two weeks of the initial consultation to find out about your experience in using the Patient Decision Aid.

Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

---

### 1. What is the purpose of the study?

This evaluation is part of the Patient Decision Aid for Type 2 Diabetes (PANDAs) study. The purpose of this evaluation is to find out your experience discussing your diabetes with the Health Care Professional, your experience of using the Patient Decision Aid, and to assess how different factors may influence the patient/Health Care Professional experience.

### 2. Why have I been invited?

You will already have been approached to take part in the Patient Decision Aid for Type 2 Diabetes study as your GP/Practice Nurse has identified that your diabetes might be controlled better. We are also trying to assess patient's experience of using the decision aid.

A total of approximately 10 people with type 2 diabetes who have agreed to take part in the Patient Decision Aid for Type 2 Diabetes study will be invited to participate in the evaluation process of the study.

### **3. Do I have to take part?**

Your participation is entirely voluntary and it is up to you to decide whether or not to take part. We will describe what we are aiming to find out in this study and go through this information sheet with you when you attend the surgery. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This will not affect your treatment or the standard of care that you receive.

### **4. What type of study is this?**

This is known as a qualitative study that uses the method of face-to-face interviews. Sometimes, we don't know what the problems faced by people attending the clinic are, for example, the problems encountered by people with type 2 diabetes when making decisions about their treatment. To find out, we need to interview people with type 2 diabetes who have made treatment decisions before. By recording and analysing their conversations, we are able to obtain useful information from them and find out the problems they have experienced when making decisions about their treatment.

### **5. What will happen to me if I take part?**

If you agree to participate, the researcher will ask you to sign a consent form. The researcher will arrange for your consultation in the PANDAs study, with the Doctor or nurse, to be audio-taped. A follow-up interview will be conducted either immediately after your consultation with the doctor/nurse or at your home within two weeks.

During the follow-up interview the researcher will ask questions related to your experience with the doctor/nurse and using the decision aid. He/she will record the conversation using an audio tape recorder. The purpose of the recording is to allow the researcher to capture all the information discussed during the interview, which is important for them to analyse later. The interview will take about 30 minutes.

### **6. What will I have to do?**

You are required to answer the questions based on your personal experience during the interview. However, you can refuse to answer any questions which you feel uncomfortable and you can stop the interview at any time.

### **7. What are the possible disadvantages and risks of taking part?**

During the interview, sometimes, you might be asked questions about certain topics which are sensitive or may upset you. You can refuse to answer any questions which you feel uncomfortable with, or you can stop the interview anytime.

**8. What happens when the research study stops?**

Your GP/ Nurse will continue to provide medical care for you.

**9. What if there is a problem?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be looked into. The detailed information on this is given in Part 2.

**10. Will my taking part in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

**11. Is the purpose of this study educational?**

Yes. Part of the data from this research will be used for a PhD study.

***This completes Part 1.  
If the information in Part 1 has interested you and you  
are considering participation, please read the additional  
information in Part 2 before making any decision.***

## **Part 2**

### **12. What will happen if I don't want to carry on with the study?**

You can withdraw from the study without giving a reason and without affecting your care.

### **13. What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (Contact Dr CJ Ng at: 2715923 or 07809616941 or Professor Nigel Mathers at: 2715922). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the GP or the local Primary Care Trust.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the NHS but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

### **14. Will my taking part in this study be kept confidential?**

The recorded conversation will be transcribed by a designated secretary. Only the interviewer and the secretary will have access to the audiotape. All information will be coded and anonymised. Once the transcript has been completed and checked by the interviewer for accuracy, the audiotape will be erased by the secretary in the presence of the interviewer.

The information we have collected as paper copies will be stored under lock and key, while the electronic data can only be accessed with a secure password. Only the researchers, sponsors, regulatory authorities and Research & Development auditors will have access to the data.

The data we collect will be used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought. The transcripts will be kept for five years according to the Medical Research Council guidelines.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the surgery will have your name, telephone and address removed so that you cannot be recognised.

### **15. Involvement of the General Practitioner/Family doctor (GP)**

Your GP will be informed about your participation in this study.

### **16. What will happen to the results of the research study?**

The results of this study will be published in medical journals. A summary of the results will be sent to you by post and you will be invited to attend a public seminar.

You will not be identified in any report, publications or presentation without seeking your full consent. Direct quotes from the interviews may be used in reports and publications; however, the quotes will be anonymised to ensure that you cannot be identified.

### **17. Who is organising and funding the research?**

The Sheffield Health and Social Research Consortium is the sponsor of this study and the Department of Health will be funding the research.

### **18. Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and given favourable opinion by North Sheffield Local Research Ethics Committee.

### **19. Further information and contact details.**

General Information about research

You can visit the following web site to obtain more general information about research:

INVOLVE – Promotes public involvement in the NHS: <http://www.invo.org.uk>

Specific information about this research project

Dr Alastair Bradley  
Academic Unit of Primary Medical Care  
University of Sheffield  
Community Sciences Centre  
Northern General Hospital  
Herries Road  
S5 7AU  
Sheffield

Tel: 0114 2269785  
Fax: 0114 2422136  
Email: [A.Bradley@sheffield.ac.uk](mailto:A.Bradley@sheffield.ac.uk)

Advice as to whether you should participate

Dr Alastair Bradley  
Academic Unit of Primary Medical Care  
University of Sheffield  
Community Sciences Centre  
Northern General Hospital  
Herries Road  
S5 7AU  
Sheffield

Tel: 0114 2269785  
Fax: 0114 2422136  
Email: [A.Bradley@sheffield.cac.uk](mailto:A.Bradley@sheffield.cac.uk)

Who you should approach if unhappy with the study

Professor Nigel Mathers  
Academic Unit of Primary Medical Care  
University of Sheffield  
Community Sciences Centre  
Northern General Hospital  
Herries Road  
S5 7AU  
Sheffield

Tel: 0114 2715922  
Fax: 0114 2422136  
Email: [n.mathers@sheffield.ac.uk](mailto:n.mathers@sheffield.ac.uk)

OR

Using the NHS Complaint Procedures, which you can obtain from the surgery or your local NHS Primary Care Trust. You can visit the following web site for more details:  
<http://www.nhs.uk/England/AboutTheNhs/ComplainCompliment.cmsx>

## **Health Care Professional Participants Information Sheet**

**Study Title:** Patient Decision Aid for Type 2 Diabetes  
**Protocol Ref:** ZH25  
Version: V1-09/03/09

**Part 1** tells you the purpose of this study and what will happen to you if you take part.

**Part 2** gives you more detailed information about the conduct of the

### Part 1

We would like to invite you to take part in an evaluation of the Patient Decision Aid for Type 2 Diabetes (PANDAs) research study. This evaluation will find out the Health Care Professional's experiences of being trained and in using and delivering the Patient Decision Aid.

Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

---

### **1. What is the purpose of the study?**

This evaluation is part of the Patient Decision Aid for Type 2 Diabetes (PANDAs) study. The purpose of this evaluation is to find out the experiences of Health Care Professionals in using the Patient Decision Aids and to assess how different factors may influence the patient/Health Care Professional experience.

### **2. Why have I been invited?**

You have been invited because of your experience in using the Patient Decision Aid during the study. Your views and opinions will help us to understand the how patients make decisions about their treatment. You can also provide information on the facilitators of, and barriers to, decision-making in general practice.

A total of 10healthcare providers will be invited to participate in the study. We will also be interviewing 10patients with type 2 diabetes who have used the Decision Aid.

### **3. Do I have to take part?**

Your participation is entirely voluntary and it is up to you to decide. We will describe the study and go through this information sheet with you when you come for the interview. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason.

#### **4. What type of study is this?**

This is a qualitative study using the method of in-depth face-to-face interviews. Sometimes interventions can work separately or by a combination of factors; the aim of the evaluation is to assess how different factors may influence the patient/Health Care Professional experience. By recording and analysing the consultations and interviews we will be able to find out the Health Care Professional's experiences in using the Decision Aid in a consultation.

#### **What will happen to me if I take part?**

If you agree to take part in this part of the study your consultation with a patient who will be using the Patient Decision Aid will be audio-taped. After the consultation, within 2 weeks, you will participate in a one-to-one interview which will be conducted by the researcher. Before the consultation and interview, the researcher will go through the Participant Information Sheet with you. If you agree to participate, the researcher will ask you to sign a consent form.

The researcher will ask questions related to your experience in helping patients to make decisions about their diabetic treatment by using the Patient Decision Aid. The researcher will record the consultation and interview using an audio tape recorder. The purpose of the recording is to allow the researcher to capture all the information discussed during the consultation and interview, which is important for them to analyse later. The interview will take about 30 minutes.

#### **5. What will I have to do?**

During the interview you will be required to answer questions based on your personal experience. However, you can refuse to answer any questions which you feel are uncomfortable and you can stop the interview at any time.

#### **6. What if there is a problem?**

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be looked into. The detailed information on this is given in Part 2.

#### **7. Will my taking part in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.



8. Is the purpose of this study educational?

Yes. Part of the data from this research will be used for a PhD study.

***This completes Part 1.  
If the information in Part 1 has interested you and you  
are considering participation, please read the additional  
information in Part 2 before making any decision.***

## Part 2

### 9. What will happen if I don't want to carry on with the study?

You can withdraw from the study without giving a reason.

### 10. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (Contact Dr CJ Ng at: 2715923 or 07809616941 or Professor Nigel Mathers at: 2715922). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the local Primary Care Trust.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the NHS but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

### 11. Will my taking part in this study be kept confidential?

The recorded conversation will be transcribed by a designated secretary. Only the interviewer and the secretary will have access to the audiotape. All information will be coded and anonymised. Once the transcript has been completed and checked by the interviewer for accuracy, the audiotape will be erased by the secretary in the presence of the interviewer.

The information we have collected as paper copies will be stored under lock and key, while the electronic data can only be accessed with a secure password. Only the researchers, sponsors, regulatory authorities and Research & Development auditors will have access to the data.

The data we collect will be used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought. The transcripts will be kept for five years according to the Medical Research Council guidelines.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the surgery will have your name, telephone and address removed so that you cannot be recognised.

## **12. What will happen to the results of the research study?**

The results of this study will be published in medical journals. A summary of the results will be sent to you by post and you will be invited to attend a public seminar.

You will not be identified in any report, publications or presentation without seeking your full consent. Direct quotes from the interviews may be used in reports and publications; however, the quotes will be anonymised to ensure that you cannot be identified.

## **13. Who is organising and funding the research?**

The Sheffield Health and Social Research Consortium is the sponsor of this study and the Department of Health will be funding the research.

## **14. Who has reviewed the study?**

This study has been reviewed and given favourable opinion by North Sheffield Local Research Ethics Committee.

## **15. Further information and contact details.**

General Information about research

You can visit the following web site to obtain more general information about research:

INVOLVE – Promotes public involvement in the NHS: <http://www.invo.org.uk>

Specific information about this research project

Dr Alastair Bradley  
Academic Unit of Primary Medical Care  
University of Sheffield  
Community Sciences Centre  
Northern General Hospital  
Herries Road  
S5 7AU  
Sheffield

Tel: 0114 2269785  
Fax: 0114 2422136  
Email: [A.Bradley@sheffield.ac.uk](mailto:A.Bradley@sheffield.ac.uk)

Advice as to whether you should participate

Dr Alastair Bradley  
Academic Unit of Primary Medical Care  
University of Sheffield  
Community Sciences Centre  
Northern General Hospital  
Herries Road  
S5 7AU  
Sheffield

Tel: 0114 2269785 or  
Fax: 0114 2422136  
Email: [A.Bradley@sheffield.ac.uk](mailto:A.Bradley@sheffield.ac.uk)

Who you should approach if unhappy with the study

Professor Nigel Mathers  
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Herries Road  
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Tel: 0114 2715922  
Fax: 0114 2422136  
Email: [n.mathers@sheffield.ac.uk](mailto:n.mathers@sheffield.ac.uk)

OR

Using the NHS Complaint Procedures, which you can obtain from the surgery or your local NHS Primary Care Trust. You can visit the following web site for more details:  
<http://www.nhs.uk/England/AboutTheNhs/ComplainCompliment.cmsx>

## **PANDAs Process Evaluation**

### **Patient Interview Guide**

#### Patient Topic Guide

Patients will be purposively selected from practices randomised to the intervention arm of the main cluster randomised controlled trial (RCT).

Patient selection will aim to provide participants at different stages of their decision-making process and who have opted for different treatment preferences. ( insulin vs follow advice more carefully vs make no change)

#### Aims and Objectives

The aim of this element of the study is to explore patients' attitudes to and understanding of the Patient Decision Aid and their experience in using it with the health care professional in the consultation.

This will involve exploring the patients':

- views of the content, format and delivery of the Patient Decision Aid
- views on the consultation with the health care professional
- motivators and barriers to the use of the Patient Decision Aid
- views on the future use/development of the Patient Decision Aid

#### Introduction

- Introduce self and PANDAs project
- Introduce this part of the study
- Talk through
  - Purpose of the interview
  - Length of interview

- Voluntary nature
- Reasons for recording
- Confidentiality
- Any questions

### **Background information**

- Age
- Length of time with diagnosis of DM
- Family members / friends with same diagnosis (? Insulin users)
- How important is DM to patient  
( NB these are factors that may influence decision-making)

#### **1. Patient views on Content and Format of the Patient Decision Aid**

Aim

- To see if language and format of Patient Decision Aid are appropriate.
- To evaluate the guidance in decision-making and value clarification provided by the Patient Decision Aid

“How did you find completing the Patient Decision Aid?”

- 
- Which sections were most useful to you?
- Which sections were least useful to you?

How did you find the language and format of the Patient Decision Aid?

-

- Has it improved your understanding of Diabetes Mellitus? If yes, how?
- Was the Patient Decision Aid useful in helping you to make a decision about your treatment?  
How did you make your decision?
- 
- 

## 2. **Patients' experience of and views on the consultation**

“How did your consultation with the nurse/doctor go?”

(Let patient describe freely what happened during the consultation)

- Content of the consultation
  - Did you and your GP/Nurse use patient decision aid during the consultation?
  - Did the Decision Aid help your discussion with the GP/nurse about your diabetes?
  - Did discussion help your understanding of Diabetes Mellitus?
  - Did discussion help you make a decision? If yes, how? If not, why not?
- Which was most useful in helping you with your decision and why?
  - Patient Decision Aid
  - Consultation with your GP/Nurse
  - Both
  - Any other factors
- Did you find your nurse/GP helpful in supporting you to make a decision?
  - Friendly
  - Informative
  - Receptive
  - Attentive
  - Answered questions

## 3. **Motivators and Barriers to Decision Making**

- Is there anything else that may have helped your decision?
- Is there anything else that may have hindered with your decision?

-

**Implementation of Patient Decision Aid**

Do you have any suggestions how we can improve the Patient Decision Aid in the future?

Do you have any suggestions how else we can help you to make a better decision?



## **PANDAs Process Evaluation**

### **Health Care Professional Interview Guide**

#### HCP Topic Guide

Health care Professionals (HCP) will be purposively selected from practices randomised to the intervention arm of the main cluster randomised controlled trial (RCT).

The HCP will have had a consultation with a paired patient (a patient who has agreed to be interviewed for the process evaluation)

#### Aims and Objectives

The aim of this element of the study is to explore HCP attitudes to and understanding of the Patient Decision Aid and their experience in using the Patient Decision Aid with the patients in the consultation.

This will involve exploring the HCPs':

- views of the content, format and delivery of the Patient Decision Aid
- experience in using the Patient Decision Aid with the patient in the consultation
- motivators and barriers to the use of the Patient Decision Aid
- views on the future use/development of the Patient Decision Aid

#### **Introduction**

- Introduce self and PANDAs project
- Introduce this part of the study
- Talk through
  - Purpose of the interview
  - Length of interview (approx. 30-40 mins)

- Voluntary nature
- Reasons for recording
- Consent to record interview
- Consent to anonymised quotes being used in publications
- Confidentiality
- Any questions

### **Background information**

Role within the practice

- Length of time in practice
- Specialisation in DM? If so for how long?
- How long have you known the patient?
- Are you aware of the patient expressing a decision prior to the study ?
- ( eg. If HGV driver, pressure from family members)

#### **1. HCP views on Patient Decision Aid**

Aim

To find out the HCPs' views on the content, format and delivery of the patient decision aid

“Could you describe your thoughts regarding the Patient Decision Aid?”

- Which sections were most useful?
- Which sections were least useful?
  
- Was the Decision Aid easy or difficult to understand?
- Was the Decision Aid easy or difficult to work through with the patient?
- If difficult, in what way?
  
- Which sections did you spend most time on and why?
- Was any of the information new to you?

- Did it stimulate any further reading on the subject?
- Was using the Decision Aid helpful in assisting the patient to make a decision?
- How do you think the patient came to make their decision?

What did you think about your training in use of the Decision Aid?

- Length of time
- Amount of information

## **2. HCP experience of and views on using the Patient Decision Aid in the consultation**

“Could you describe how the consultation went with the patient?”

(Let the HCP describe freely what happened during the consultation)

- Content of the consultation
  - Did you use the Patient Decision Aid with the patient?
  - Did the Decision Aid help you to discuss their diabetes management?
  - Do you think the discussion helped the patients understanding of Diabetes Mellitus?
  - Did the consultation help you and patient to discuss their decision? In what ways?
  - Did the patient express any views on the Decision Aid during the consultation?
  
- Which was most useful and why
  - DA
  - Consultation
  - Both
  - Other factors

### 3. Motivators and Barriers to Decision Making

- "I would like to compare the consultation using the Decision Aid with a similar consultation without the Decision Aid
  - Was it easier or more difficult to discuss topics?
  - Were there any time issues?
  - If extra time required was is it worth it?
  
- Is there anything else that may have helped you to help your patient to make a better decision?
- Is there anything that may have hindered you to help your patient to make a better decision?
- Do you have any suggestions how we can improve the Patient Decision Aid in the future?
- Do you have any suggestions how we can implement the Patient Decision Aid in your routine practice?
- Any thoughts about the training/ researcher involvement?



School  
Of  
Medicine

Centre Number:

Study Number: ZH25

Patient Identification Number for this trial:

## Patient CONSENT FORM

**Title of Project: Patient Decision Aid for Type 2 Diabetes**

**Name of Researcher: Dr. Alastair Bradley/Maxine Johnson/Professor Nigel Mathers**

**Please initial box**

1. I confirm that I have read and understand the information sheet dated .....  
(version .....) for the above study. I have had the opportunity to consider the  
information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time,  
without giving any reason and without my legal rights being affected.
3. I understand that the data collected during the study may be made available to responsible  
individuals from the NHS , the University of Sheffield, regulatory authorities or the NHS Trust,  
where it is relevant to my taking part in the research.
4. I agree to have my consultation and interview recorded and the recording transcribed  
by the project secretaries.
5. I understand that the information from this study may be published in research journals  
and anonymous quotes may be used
6. I agree to take part in the above study.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person taking consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

When completed, 1 copy for patient; 1 copy for researcher site file; 1 (original) to be kept in medical notes



School  
Of  
Medicine

Centre Number:

Study Number: ZH25

Patient Identification Number for this trial:

## Health Care Professional CONSENT FORM

**Title of Project: Patient Decision Aid for Type 2 Diabetes**

**Name of Researcher: Dr. Alastair Bradley/Maxine Johnson/Professor Nigel Mathers**

**Please initial box**

1. I confirm that I have read and understand the information sheet dated .....  
(version .....) for the above study. I have had the opportunity to consider the  
information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time,  
without giving any reason and without my legal rights being affected.
3. I understand that the data collected during the study may be made available to responsible  
individuals from the NHS , the University of Sheffield, regulatory authorities or the NHS Trust,  
where it is relevant to my taking part in the research.
4. I agree to have my consultation and interview recorded and the recording transcribed  
by the project secretaries.
5. I understand that the information from this study may be published in research journals  
and anonymous quotes may be used
6. I agree to take part in the above study.

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person taking consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

When completed, 1 copy for patient; 1 copy for researcher site file; 1 (original) to be kept in medical notes

Appendix 6: Informed Consent study (study 2) Ethics approval and associated documents



## National Research Ethics Service

### South Yorkshire Research Ethics Committee

1st Floor Vickers Corridor  
Northern General Hospital  
Herries Road  
Sheffield  
S5 7AU

Telephone: 0114 226 9153  
Facsimile: 0114 256 2469  
Email: joan.brown@sth.nhs.uk

04 March 2010

Dr Alastair Bradley  
AUPMC, Sam Fox House  
Northern General Hospital  
Herries Road  
Sheffield  
S5 7AU

Dear Dr Bradley

**Study Title:** Patient Informed Consent Trial<sup>1</sup>"How and when do patients about to undergo unilateral hip replacement for osteoarthritis gather and interpret information to make a decision about surgery."<sup>2</sup>"To what extent is such a decision based on informed consent"

**REC reference number:** 10/H1310/10  
**Protocol number:** 3

The Research Ethics Committee reviewed the above application at the meeting held on the 25 February 2010. Thank you for attending to discuss the study.

#### Discussion

It was observed this was an interesting and well structured study.

You were asked to clarify the interview process and explained the proposal was to hold three interviews. The first would take place in the outpatient department immediately after the patient had seen the orthopaedic surgeon to discuss the operation; the second interview would take place in the pre-op assessment clinic and the third interview would take place approximately three months after the procedure had been carried out when participants would be contacted to arrange a convenient time and place. The third visit could take place in the participants' homes but the first two would take place within the hospital. Recruitment would be arranged through the outpatient clinic. Invitations would be sent out via the orthopaedic department and the reply slips would be directed to you and you would then contact the patients directly. The committee accepted this clarification.

It was queried why participants who chose not to have an operation were being included in the second and third interviews. You explained that consent is largely viewed as briefly seeing the surgeon, having the risk explained and signing the consent form but you felt it was much more of a process from start to finish and it was all to do with the information patients received in order to get a balanced view. Some patients would say they did not want to have surgery, or to have surgery at that point in time, but obviously there were

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The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England



reasons behind their decisions and you thought it was still important to get the views of those participants who decided not to have surgery as well as those who did. Their decision was different but their views of the process would be the same. The committee accepted this clarification.

It was queried whether it was your intention at the meeting to get approval to carry out a pilot study on two or three participants first in order to fine tune the procedure and then carry on with the main study. You agreed it was your intention to refine the topic guide and you also proposed to get some patient feedback as well as reviewing it with the research department and the orthopaedic surgeons before embarking on the main study. The committee accepted this explanation.

It was queried whether you had deliberately limited the study to hip replacement for osteoarthritis and you agreed that you had because you felt the decision making process for conditions other than osteoarthritis would probably be very different. Also, there could be complications from surgery and other problems that might complicate the procedure itself. The committee accepted this clarification.

It was queried whether you felt that ten participants would be sufficient and you explained that that would only become evident during analysis of the data and it was agreed that if necessary up to twenty participants could be recruited.

#### **Ethical opinion**

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

#### **Ethical review of research sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

#### **Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

**Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.**

*For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>. Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.*

*Sponsors are not required to notify the Committee of approvals from host organisations.*

#### **Other conditions specified by the REC**

- 1. Submit revised topic guides produced after the pilot study has been carried out (Version 3 with new dates)**

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2. Submit amended Participant Information Sheet for Patients (Version 3 with a new date as follows:
  - Under the heading "Who has reviewed this study" amend the name of the ethics committee to South Yorkshire
  - After the heading "Who has reviewed this study?" include an additional heading i.e. "Further information/independent advice" under this heading include contact details for the Patients Advisory Liaison Service (PALS)
3. Submit amended Participant Information for the Orthopaedic Department (Version 3 with a new date) as follows:
  - Under the heading "Who has reviewed this study?" amend the name of the ethics committee to South Yorkshire
4. Submit amended consent form (Version 3 with a new date) as follows:
  - In point 3 after "..... taking part in the research." add the following sentence: "I give permission for these individuals to have access to my records."
  - Add an additional point/tick box No.7 as follows: "I agree to my GP being informed of my participating in the study."
  - Add an additional point/tick box No.8 as follows: "I agree to take part in the above study"
5. Question A43 states that you intend to store the research data for three months after the study has been completed and the committee advise that you might wish to store it for longer e.g. for up to a year

The REC nominated the Co-ordinator, Mrs Joan Brown to be the point of contact should further clarification be sought by the applicant upon receipt of the decision letter.

It is responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

#### Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering Letter		11 January 2010
REC application		01 February 2010
Protocol	3	01 December 2009
Investigator CV		01 December 2009
Participant Information Sheet: Patients	2	09 November 2009
Participant Information Sheet: Orthopaedic Department	2	09 November 2009
Participant Consent Form	2	09 November 2009
Supervisor's CV - Prof Nigel Mathers		01 May 2009
Participant Invitation Letter + Reply Slip	2	03 January 2010
Confirmation of Scientific Review		22 December 2009
Flowchart	1	11 January 2010
1st Patient Interview Topic Guide	2	07 January 2010
2nd Patient Interview Topic Guide	2	07 January 2010
3rd Patient Interview Topic Guide	2	07 January 2010

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### Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

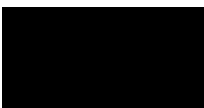
The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email [referencegroup@nres.npsa.nhs.uk](mailto:referencegroup@nres.npsa.nhs.uk).

**10/H1310/10** Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely



pp Miss Jo Abbott  
Chair

Enclosures:

List of names and professions of members who were present at the meeting and those who submitted written comments

"After ethical review – guidance for researchers" SL-AR2

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Copy to:

Mrs Anna Leesley, STH R&D Department

Research Governance Administrator, Sheffield Health & Social Care  
Research Consortium, Research Office, Fulwood House, Old Fulwood  
Road, Sheffield, S10 3TH

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**South Yorkshire Research Ethics Committee**

**Attendance at Committee meeting on 25 February 2010**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Miss Jo Abbott	Consultant in Public Health	Yes	
Dr A H Abdelhafiz	Consultant Physician, Elderly Medicine	Yes	
Miss Stephanie Andrews	Drug & Alcohol Action Team Information Manager	Yes	
Reverend Joan Ashton	Co-ordinator of Chaplaincy Services	No	
Miss Helen Barlow	Knowledge Service Manager	No	
Professor Nigel Beall	Consultant Clinical Psychologist & Professor of Psychology	Yes	
Mr Ian Cawthorne	Chief Pharmacist	Yes	
Ms Susan Hampshaw	New Deal for Communities Evaluation Unit Manager	Yes	
Mr Neil Marsden	Police Staff	No	
Dr Anton Mayer	Consultant in Paediatric Intensive Care	No	
Mrs Andrea Pomitt	District Nurse/Practice Educator	No	
Dr Ganesh Rao	Consultant Clinical Neurophysiologist	No	
Mr Jaydip Ray	Consultant ENT Surgeon	No	
Ms Stephanie Rhodes	Neonatal Sister	Yes	
Dr Saif R Sen	General Practitioner	Yes	
Dr Paul Spencer	Consultant Radiologist	Yes	
Dr Jonathan Train	Consultant Anaesthetist	Yes	
Mrs Kathryn Wall	CHIP Research Nurse	Yes	

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Joan Brown	REC Co-ordinator
Ms Beccy Lewis-Culling	MSc Clinical Research Student - Observer

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## Orthopaedic Department Information Sheet

**Study Title:** PICT; Patient Informed Consent Trial

**Version:** V2 09/11/2009

We would like to invite the patients and staff of The Orthopaedic Department to assist us in a research study. This study will find out how and when patients, who have been recommended to undergo unilateral hip replacement for osteoarthritis by their GP, gather information to make an informed decision whether to proceed to surgery or not.

### **What is the purpose of the study?**

Patients have to make decisions all the time about medical and surgical treatment, and it is clear from studies that patients who make informed decisions have better outcomes from treatment than those whose decision is not informed

There has been recent guidance from the Department of Health and General Medical Council regarding informed consent, and case law such as Chester v Afshar [2004] UKHL 41 has altered the focus of informed consent towards a patient-centred model.

So, the purpose of the study is to find out what sources of information patients use when considering giving or declining consent to undergo unilateral hip replacement. Some of this information may come from the department itself, in terms of discussion with the surgeon, information leaflets or educational videos and decision-aids; some of the information may be accessed from outside the department, for example from GPs, family or friends who have undergone the same procedure.

The study is also trying to determine what values patients attach to the different sources of information to help us to create a patient-centred framework for informed consent.

### **What type of study is this?**

This is a qualitative study exploring patients' experiences, opinions and values. The study involves audio taping interviews with the patient on 2 separate occasions and analysing the data using Thematic Framework Analysis.

### **What involvement is requested of the Orthopaedic Department?**

We are aiming to recruit 2-3 patients into a pilot study to assess the feasibility of the interview process and refine our interview guides. We would then be looking to recruit 10 or more patients into the main study. These patients would have been referred to the Orthopaedic Department by their GPs for consideration of unilateral hip replacement for osteoarthritis. We wish to consider patients who have been referred by Dear Doctor letters or Choose and Book who are then randomly allocated to the list of Mr R. Kerry. The Department's help is requested to identify these patients and invite them to participate in the study. Patients who agree to be part of the study will be contacted to arrange the first interview **within two weeks after their outpatient appointment with the surgeon.**

**A second** interview is arranged at the patient's home approximately 3 months after their surgery. Patients who decline surgery will be invited to attend second interviews at corresponding intervals.

Patients will be asked if the researcher can access their hospital records solely to review pre-operative Patient Reported Outcomes Measures (PROMs) data that has been collected.

Activity in the orthopaedic outpatients and wards will continue as normal and researchers will not be involved in altering or monitoring any clinical activity.

***Inclusion criteria:***

Osteoarthritis

Consideration for unilateral hip replacement by general practitioner.

Age >40

English spoken without need for interpreter

Randomly allocated to the outpatient list of Mr. R. Kerry

***Exclusion criteria:***

Inflammatory joint disease

Consideration for bilateral hip replacement

Trauma related surgery

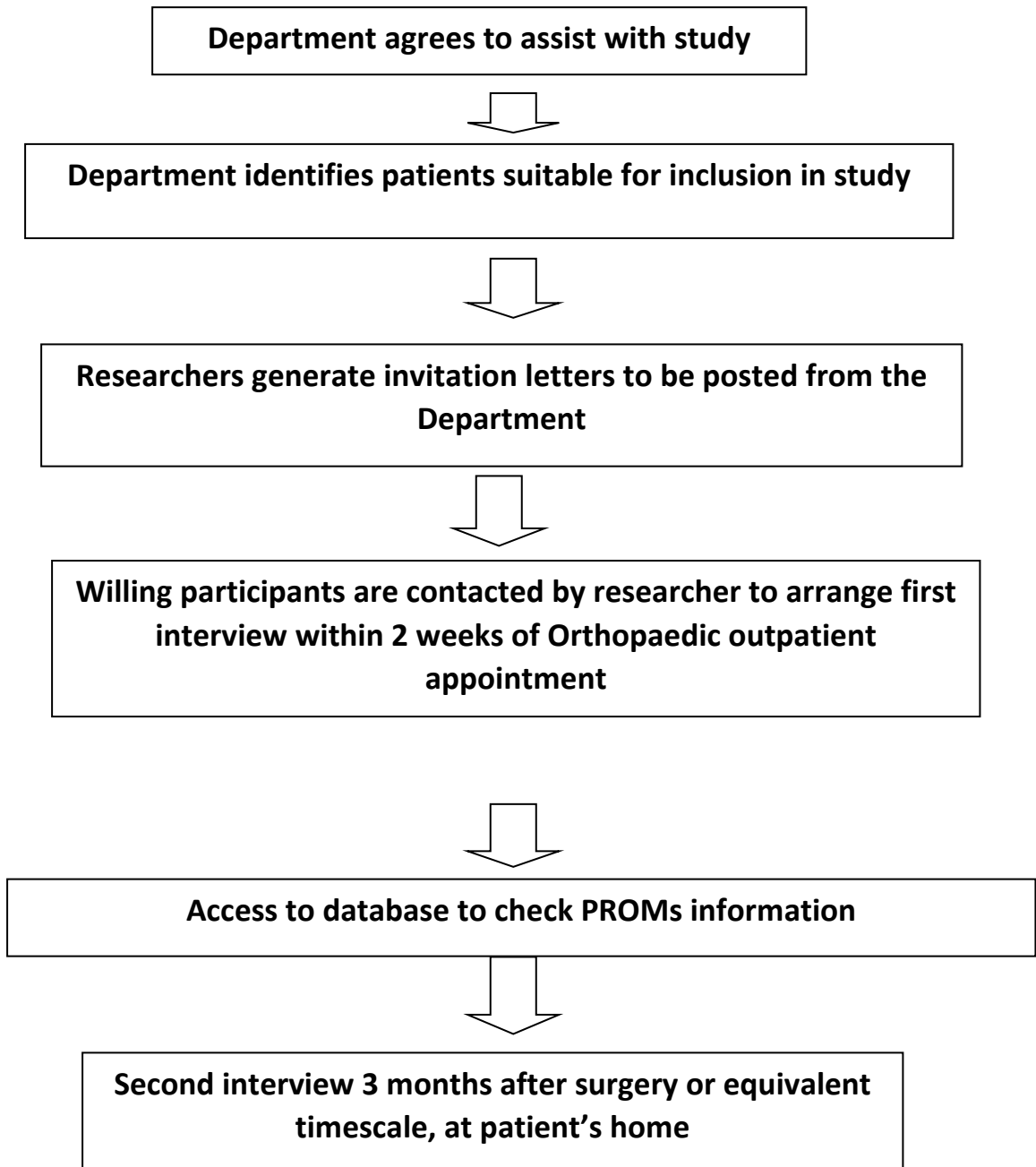
Need for an interpreter

Other chronic debilitating disease

**Feedback to the Department.**

The researchers will keep the Orthopaedic Department informed of the status of patients entered into the research project. The researchers will also arrange a mutually convenient time to inform the Department of the results of the research.

### **Orthopaedic Department Involvement overview.**





**What happens when the research study stops?**

The Department will continue to provide usual orthopaedic care.

**Is the purpose of the study educational?**

Yes. Part of the data from this research will be used for an MD.

**What if there is a problem?**

If you have a concern about any aspect of the study, you should ask to speak to the researchers who will do their best to answer your questions. Contact Dr. Alastair Bradley on 0114 2269786 OR Professor Nigel Mathers on 0114 2715922. If you remain unhappy and wish to make a formal complaint, you can do this through the University of Sheffield's Registrar and Secretary.

**Will patient's participation in the study remain confidential?**

Yes. We will follow ethical and legal practice and all information about patients will be handled in confidence.

Patients' medical records will remain with the Department of Orthopaedics. All information from patient interviews and PROMs questionnaires will be coded and anonymised. Information collected on paper will be kept under lock and key whilst electronic data will be stored on a password protected University computer. Only the researchers, sponsors, regulatory authorities and Research and Development auditors will have access to identifiable data.

The data collected will be used solely for the purpose of this research.

**What will happen to the results of the research project?**

The researchers will write reports on the project and its findings. The results will be presented at meetings and published in medical journals. Any data used will be anonymised so you will not be identified at any time. Any quotations used will also be anonymous. If you wish we will send you a copy of the final report once the project has been completed.

**Who is organising and funding the research?**

The University of Sheffield is the sponsor of the project and the Royal College of General Practitioners will be funding the research.

**Who has reviewed the study?**

The study has been reviewed by the Scientific Review Board of Sheffield PCT to ensure the study is suitable. The study has been reviewed and given a favourable ethical opinion by the South Yorkshire Ethics Committee.

**Contact for further information**

Thank you for reading this information sheet. If you would like to ask anything about this research project then please don't hesitate to contact us. We will be more than happy to answer your questions.

Dr. Alastair Bradley

Telephone: 01142269786

E-mail: [a.bradley@sheffield.ac.uk](mailto:a.bradley@sheffield.ac.uk)

Address: Academic Unit of Primary Medical Care  
University of Sheffield  
Samuel Fox House  
Northern General Hospital  
Herries Road  
Sheffield  
S5 7AU

Who you should approach if unhappy with the study

Professor Nigel Mathers  
Academic Unit of Primary Medical Care  
University of Sheffield  
Samuel Fox House  
Northern General Hospital  
Herries Road  
Sheffield  
S5 7AU

Telephone: 01142715922  
Fax: 0114 2422136  
E-mail: [n.mathers@sheffield.ac.uk](mailto:n.mathers@sheffield.ac.uk)

## **Patient Informed Consent Trial**

### **Patient Interview Information Sheet**

We are inviting you to take part in a research project, supported by The University of Sheffield, to investigate your experiences after being referred for a possible hip replacement. We are interested in your views even if you decide not to have surgery. Before you decide to take part, please take time to read this information and discuss it with other people if you wish. Please don't hesitate to contact us, using the details below, if there is anything that is not clear or you would like more information about.

#### **The purpose of the research project**

Having any operation requires the patient to consent (agree) to let the surgeon carry out the procedure. Guidelines on consent have been given by the Department of Health and the General Medical Council.

Other studies have shown that, by improving the amount and content of information given to patients, the results from treatment are better. However, a lot of this information comes from studying doctors' experiences and we want to find out about patients' experiences of getting information before an operation and how that experience affected them when recovering from their operation. Some patients may decide that they don't want surgery after getting this information, but their views are still important to us. We are looking for people with these experiences to tell us about them in two (2) interviews.

#### **Why have I been chosen?**

People who have recently been referred by their General Practitioner (GP) to the Orthopaedic Department of the Northern General Hospital for a possible hip replacement are being asked to take part in this research project. This is the only reason you are being asked to take part. We are trying to get a wide range of views of people's experience, even if they decide not to have surgery.

#### **Do I have to take part?**

You do not have to take part- it is voluntary. Whatever you decide, it will not affect your medical care or legal rights.

#### **What will happen to me if I take part?**

If you decide to take part in the research project you will be asked to take part **in two (2)** separate interviews. The first interview would take place approximately 2 weeks after you have seen the orthopaedic surgeon at a place that suits you. The second interview would occur about three

months after the operation, again at a place and time that suits you. For people who decide not to have an operation we would want to interview them at similar time gaps.

Each interview will last about 40 minutes. The researcher is not a member of staff in the orthopaedic department so we hope this will help you to speak frankly about your experiences and views. The medical care that you receive will not be affected in any way by anything you say or do not say in the interviews.

The orthopaedic department may ask you to fill in some forms for them, one of which is a Patient Reported Outcome Measure (PROMs). The information on this form is routinely collected by hospitals for certain operations and seeing this information would help the researcher to understand your illness. We would like to repeat the PROMs questionnaire with you at the second interview to review what change, if any has occurred since the first interview. If you agree to take part in the study you will be asked if the researcher can have access to this information purely for the project.

If you do take part, you will be given a £15 shopping voucher at the end of the study to compensate you for your time.

You are free to withdraw from the project at any time, even if you have already been interviewed. You can withdraw by contacting us using the details below without having to give any reason. We will then cancel any appointments already made.

### **Will my taking part in this research project be kept confidential?**

Yes. All of your information will be kept anonymously. We will replace your name with an ID number and only members of the research team will have access to your information. Staff at the orthopaedic department will not be told any answers that you give during the interviews. All the tapes, computer files and documents will be kept locked away.

The only time that we would have to tell anyone else about something you say would be if we thought that you or another person was at serious risk and needed help- even then we would discuss this with you first.

The researcher will ask if they can tape the interview to make sure no important information is lost, but your interview doesn't have to be taped. The researcher can take notes instead if that is more comfortable for you. If you do agree to being taped, the research team will type up the conversation and remove any information that might identify you. No other use will be made of the tape without your written permission and no-one outside the research team will be allowed access to the recording.

### **What will happen to the results of the research project?**

The researchers will write reports on the project and its findings. The results will be presented at meetings and published in medical journals. Any data used will be anonymous, so you will not be identified at any time. Any quotations used will also be anonymous. If you wish we will send you a copy of the final report once the project has been completed.

**Will the research be used for educational purposes?**

Yes, part of the data from this research will be used for an MPhil.

**What if there is a problem?**

If you have a concern about any aspect of the study, you should ask to speak to the researchers who will do their best to answer your questions. Contact Dr. Alastair Bradley on 0114 2222094 OR Professor Nigel Mathers on 0114 2222200. If you remain unhappy and wish to make a formal complaint, you can do this through the University of Sheffield's Registrar and Secretary.

You can withdraw from the study at any time without giving a reason. This will not affect your medical care or legal rights.

**Who is organising and funding the research?**

The University of Sheffield is the sponsor of the project and the Royal College of General Practitioners will be funding the research.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people. The study has been reviewed by the Scientific Review Board of Sheffield PCT to ensure the study is suitable. The study has been reviewed and received a favourable ethical opinion by the South Yorkshire Ethics Committee to protect your safety, rights, well-being and dignity.

**Further information and independent advice.**

If you would like further independent advice about participating in research please contact:

Patient Advice & Liaison Service  
Northern General Hospital  
C floor  
Huntsman Building  
Herries Road  
Sheffield  
South Yorkshire  
S5 9JU  
Tel. **0114 2715759**

**Or visit the website: <http://www.pals.nhs.uk/>**

**Contact for further information**

Thank you for reading this information sheet. If you would like to ask anything about this research project then please don't hesitate to contact us. We will be more than happy to answer your questions.

**Dr. Alastair Bradley**

**Telephone:** 01142222094

**E-mail:** [a.bradley@sheffield.ac.uk](mailto:a.bradley@sheffield.ac.uk)

**Address:** Academic Unit of Primary Medical Care  
University of Sheffield  
Samuel Fox House  
Northern General Hospital  
Herries Road  
Sheffield  
S5 7AU

**Who you should approach if unhappy with the study**

Professor Nigel Mathers  
Academic Unit of Primary Medical Care  
University of Sheffield  
Samuel Fox House  
Northern General Hospital  
Herries Road  
Sheffield  
S5 7AU

**Telephone:** 01142222200

**Fax:** 0114 2422136

**E-mail:** n.mathers@sheffield.ac.uk

**Lower Limb Arthroplasty Unit**

**Northern General Hospital**

**Herries Road**

Mr. X Sheffield

**Consultant Orthopaedic Surgeon**

**S5 7AU**

**Direct Line: 0114 226 6259**

**Fax: 0114 271 5982**

X/DG

Dear

Invitation to participate in a research study Patient Informed Consent Trial (PICT)

We would like to invite you to take part in a research study for people with osteoarthritis of the hip. This project is conducted jointly by the Orthopaedic Department of the Northern General and the University of Sheffield.

The PICT study is designed to find out how and when patients make decisions about operations. In particular we are looking to interview patients who have been referred to the Orthopaedic Department for consideration of a hip replacement. We would like to interview people on two(2) separate occasions, whether or not they decide to have the operation, for their views and opinions about consent to an operation.

We have attached the Participant Information Sheet to this letter which will explain to you the full details of this study. If you are interested in taking part in the study, please complete and return the attached reply form to us within a week, using the envelope provided. Once the research team receives your reply, they will contact you and arrange to meet with you when you attend the Orthopaedic Outpatient Department for your appointment with the surgeon. If you would like to know more about this study, please do not hesitate to call us on 0114 2222094

Thank you

Yours sincerely

Mr .X

Consultant Orthopaedic Surgeon

Specialist in Hip and Knee Arthroplasty Surgery

Reply

**PICT study: Patient Informed Consent Trial**

Dr Alastair Bradley  
Academic Unit of Primary Medical Care  
School of Medicine and Biomedical Sciences  
University of Sheffield  
Sam Fox House  
Northern General Hospital  
Herries Road  
Sheffield  
S5 7AU

Tel: 0114 2222094  
Fax: 0114 2715915

Name :

I am willing/ **not willing** to participate in this study.

If you are willing to take part in this study, please tell us how you would like to be contacted:

Telephone (Tel. No. \_\_\_\_\_)

Post (Address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_)

E-mail (E-mail address: \_\_\_\_\_)

Please return this reply form using the Freepost envelope provided

Thank you

---



# PICT 1st Patient Interview Topic Guide

## Aims and Objectives

The aim of this interview is to explore patients' experiences of getting and receiving information relating to arthritis of the hip.

This will involve exploring:-

Physical symptoms

Understanding of process of osteoarthritis

Understanding of treatment options

Sources of information

Views/values attached to that information.

## Introduction

---

Introduce self and AUPMC

Introduce PICT study – Who is it for, What is it about

Talk through key points:

-Purpose of interview

-Length of interview

-Voluntary nature and right to withdraw

-Reason for recording interview

-Confidentiality and how findings will be reported

Any questions

## 1. Background and Personal circumstances

---

Aim: To introduce the respondent and highlight any background issues relevant to their arthritis and treatment decision.

Age

Household circumstances

Activity

Working

Hobbies

Medication

How much importance do they attach to their:- health

Mobility

Aware of any organisations (ARC)

## 2. Knowledge of condition

---

Arthritis – What do you understand about it?

Joints affected  
How long have they had symptoms  
Xray diagnosis  
Visit to GP – recent or long-term

### 3. Treatment options

---

Have options for treatment been discussed and by whom?

Do nothing  
Simple analgesia  
NSAIDs  
Physiotherapy  
Injections  
Surgery

### 4. Sources of information

---

What sources of information has the patient accessed and when in relation to signed consent?

Medical      GP  
                 Practice Nurse  
                 District Nurse  
                 Pharmacist  
                 Physiotherapist  
                 Orthopaedic surgeon  
                 Others

Non-medical      Friends  
                         Family  
                         Neighbours  
                         People with similar experiences  
                         Other people at clinics  
                         On-line chat forums  
                         DVD  
                         Books/leaflets

### 5. Values Attached to sources of information

---

Anything they didn't understand or would have liked to ask more questions

Which sources did the patient find most valuable and why

- More relevant to them
- Valued the persons opinion more
- Provided more information than other sources
- Accessibility – eg.

- web based info
- Reading
- Watching DVD

## **6. Decision**

---

Have they made a decision about surgery?

If Yes- what was decision?

when was decision made?

If No - why

What has prevented them making decision

– Lack of information

- Unsure about physical disability

- Unsure about benefits of surgery

- Unsure about options

What other options have they considered?

### **6a. Patient has decided to undergo surgery**

---

Why?

Do they consider they have had enough information to undergo surgery?

Anything they didn't understand or would have liked to ask more questions

Procedure

Alternatives

Risk

- Surgical procedure
- Time in hospital
- Recovery period
- Physio/OT
- Levels of activity post-op

### **6b. Patient declined surgery**

---

Why?

- Advised by surgeon
- Symptoms not severe enough

- Other reasons

Anything they didn't understand or would have liked to ask more questions

Have they altered their lifestyle in any way?

## **7. Views about consent (Procedure/Alternatives/Risk)**

---

Are patients aware what consent involves – informed

- Agree to have procedure done
- Aware of aftercare and recovery
- Risks of having/declining surgery
- What will happen if you do nothing

Have they received enough information yet to make decision.

If not

- what further information or sources do they wish
  - How are they going to find information.
  - More time to think
  - Further consultation with surgeon/specialist nurse

In what way do you think the consent process so far meets your needs or could be improved upon?

## **8. Facilitators and Barriers to Decision**

---

Who or what has helped you most in your decision

Why?

Who or what has helped you least with your decision

Why?

What could have been done better?

Why?

## PICT 2<sup>nd</sup> Patient Interview Topic Guide

### **Aims and objectives**

- i) To review previous interview
- ii) To explore patients experiences of surgery and post-operative period
- iii) To explore recovery from the operation if they have had it.
- iv) To explore experiences after surgery including contact with Primary/secondary care.
- v) To explore the delivery of information to the patient and how this influenced the decision making process.

### **Introduction**

---

Re-introduce self and study

Purpose of this interview

Length of interview

Confidentiality

Need to recap on previous interview

Any questions

### **1. Recall from previous interview**

---

Have they persevered with decision?

### **2. Change in physical symptoms**

---

Review PROMs data and complete further PROMs questionnaire.

Compare with current circumstances

What changes have occurred since last meeting?

- Had surgery
- Taken one of the other treatment options

Have your symptoms altered?

- In what way – better or worse
- Is this related to your decision about treatment option

Has your lifestyle/daily routine altered since last time?

- In what way

### **3. Contact with Medical Services**

---

What contact have you had with hospital since we last met?

- Surgeon
- Nurses
- Physio
- OT

What contact have you had with primary care?

- GP
- Practice nurse
- District nurse
- Pharmacist

More or less than expected?

Any further contact planned in terms of hip problem?

### **4. Patients perceptions of care**

---

How was your experience in hospital?

- Outpatient
- Inpatient

Why?

### **5. Patients perception of information giving**

---

Did the information you received help you to reach a decision about treatment?

- Procedure
- Alternatives
- Risk

At what stage if ever did you consider you had enough information to make your decision?

Anything they didn't understand or would have liked to ask more questions.

What information or source did you value the – most?

- least?

What method of information giving did you find most/least useful?

Oral

Paper

DVD

Web based

**6. Any suggestions to improve the Informed Consent process**

---

## PICT (Patient Informed Consent Trial)

### Orthopaedic Surgeon Topic Guide

#### Aims and Objectives

The aim of this focus group/interview is to explore Orthopaedic Surgeon's use of the informed consent process when patients are undergoing primary unilateral hip arthroplasty.

This will involve exploring;

- How they explain pathophysiology of osteoarthritis to their patients
- How the topic of surgery was approached
- How other treatment options were described
- Information supplied to the patient
- Sources of that information and how it was presented

#### Introduction

Introduce self, including level of training and AUPMC

Introduce PICT

Talk through key points of focus group schedule

- Length of focus group
- Purpose of focus group
- Facilitators role
- Voluntary nature, right to withdraw/ get involved as much or as little as they wish
- Reason for recording
- Confidentiality
- Need to sign consent forms

#### 1. Background

- How long have they been qualified?
- How long have they been practising in Sheffield?
- What is their position within Sheffield Orthopaedic department?

#### 2. Routes of referral into the orthopaedic department

GP

Musculoskeletal services

Rheumatology



## 2. Explanation of condition

- Do they check patient understanding before they start
- How they introduce the topic of osteoarthritis?
- How they explain it? E.g. what simple terms do they use?
- How/do they explain the x ray to the patient?
- If so how do they link this explanation to the patient's symptoms?

## 3. Treatment options

- Do they explain all the treatment options/risks to the patient?
- Do patients normally come already with a diagnosis or do they diagnose the patient?
- How do they make sure the patient understands? eg talkback technique
- How do they feel they could improve this discussion?

## 4. Information

- What sort of information do they supply/ suggest to the patient? oral/visual aids
- Where does the limit of their provision of information lie and what do they rely on Pre-op Assessment clinic and Joint clinic to provide?
- Do they view these clinics as part of the Informed consent process?
- Do they offer these to every patient? E.g limitations of age?
- What limitations do they feel these have? E.g age, internet access
- What types would they like to use in these consultations?
- Do they use their own opinions in these consultations?
- Do they feel the timing of the information is appropriate or is it too late/early?

## 5. Surgeons values

- What values do the surgeons attach to these forms of information?
- Do they direct patients to other sources of information
- Preference for written/ oral information or DVD/Websites eg. NHS Choices
- When do they get patient to sign consent form and why?

## 6. Decision

- Do they feel they aid the patient in the final decision?
- Do they feel the consent process is enough to inform the surgical pathway?

## 7. What could be done better? Why?



School  
Of  
Medicine  
& Biomedical Sciences.

Study Number:

Patient Identification Number for this trial:

## Patient CONSENT FORM

**Title of Project: Patient Informed Consent Trial**

**Name of Researcher: Dr. Alastair Bradley/Professor Nigel Mathers**

**Please initial box**

1. I confirm that I have read and understand the information sheet dated .....  
(version .....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw   
at any time, without giving any reason. This will not affect my legal rights or clinical care in any way.
3. I understand that the data collected during the study may be made available to responsible individuals from the NHS , the University of Sheffield, regulatory authorities or the NHS Trust, where it is relevant to my taking part in the research.
4. I agree to have my interview recorded and the recording transcribed by the project secretaries.
5. I agree to permit the researchers to access my hospital orthopaedic records solely for the purpose of the current research project.
6. I understand that the information from this study may be published in research journals and anonymous quotes may be used

\_\_\_\_\_

Name of Participant

\_\_\_\_\_

Date

Signature

\_\_\_\_\_

Name of Person taking consent

\_\_\_\_\_

Date

Signature

When completed, 1 copy for patient; 1 copy for researcher site file; 1 (original) to be kept in medical notes



School  
Of  
Medicine

Study Number:

Surgeon Identification Number for this trial:

## Surgeon CONSENT FORM

**Title of Project: Patient Informed Consent Trial**

**Name of Researcher: Miss Alex Ward/Dr. Alastair Bradley/Professor Nigel Mathers**

**Please initial box**

1. I confirm that I have read and understand the Surgeon Focus Group information sheet dated ..... (Version .....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. This will not affect my legal rights in any way.
3. I understand that the data collected during the study may be made available to responsible individuals from the NHS , the University of Sheffield, regulatory authorities or the NHS Trust, where it is relevant to my taking part in the research.
4. I agree to have my interview recorded and the recording transcribed by the project secretaries.
5. I understand that the information from this study may be published in research journals and anonymous quotes may be used

\_\_\_\_\_  
Name of Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name of Person taking consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

When completed, 1 copy for surgeon, 1 copy for researcher site file