SHARED DECISION MAKING
PATIENT INVOLVEMENT IN CLINICAL PRACTICE

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Shared decision making

Patient involvement in clinical practice

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Contents

For reasons of consistency within this thesis, some terms have been standardized throughout the text. As a consequence the text may differ from the articles that have been published.

Section 1

Literature review and conceptualisation of shared decision making

Chapter 1

Shared decision making and patient involvement in clinical practice: an introduction

Shared decision making

The work presented in this thesis examines decision making, one of the most complex aspects of human activity. It does so within the context of medical practice, specifically within the interaction between clinicians and patients widely known as the *consultation*, where problems are identified and plans made for their potential resolution and management. There can be no doubt that healthcare decisions have come under increased scrutiny, not only in terms of content, but also in the ways that decisions are made within medical consultations [1, 2]. Although there are similar shifts in power taking place in the relationship between clinical professionals and the managers of healthcare [3], this work does not address decision making at the macro level or organisation or policy, it fixes its gaze on the micro-communication processes within inter-personal interactions Uncertainty of medical outcomes, lack of empirical evidence, complex unpredictable interactions between human factors and medical interventions are inevitable features of clinical processes [4]. Moreover, recently, the role of human values and opinions — the patient perspective — has had an increasing influence on medicine [5]. The purely technical biomedical view of medical practice is often (but not necessarily or exclusively) encountered in specialist fields, where expertise is at its highest and sharpest focus Clinicians who deal with unspecified problems and particularly those who provide continuous care to patients (rather than single or episodic interventions) are typically more aware of Engel's description of the biopsychosocial construct that underpins a wider conceptualisation of medical practice [6] It is within this biopsychosocial paradigm that 'shared decision making' is situated, a consulting method proposing that patients and professionals engage in a detailed participative dialogue about healthcare interventions

The term 'shared decision making' is now used as a short hand for consultations where it is expected that clinicians actively involve patients in the decision making process [7] Questions have been asked about the extent to which the control over the process lies with the clinician or with the patient, and whether the responsibility for this process can be shared between the parties involved Box 1 describes an example of a situation where the shared decision making method is of particular relevance.

Box 1   Hormone replacement therapy

A 50-year-old woman consults her clinician about the discomfort she is experiencing as she enters the menopause She wants to discuss how to obtain relief from hot flushes, mood changes and other problems related to her oestrogen reduction She is also aware, but has not obtained any further details, about the potential of hormone replacement to have long-term effects, such as reducing the future risk of osteoporosis She is representative of many women who consult their clinicians every year to ask for guidance on this issue

Correspondingly, for the clinician, this is a common problem and clinicians are normally well acquainted with the facts on hormone replacement therapy, and are prepared to acknowledge that the therapy has both harms and benefits if taken over many years (5-10) It is, in other words, a good example of a situation in which 'professional equipoise' exists [8] The clinician has knowledge about the harms and benefits but is not professionally compelled to recommend one particular line of action as the prevailing 'best practice' Not all clinicians hold this view some are 'against' hormone replacement whilst others recommend it openly In most situations, however, clinicians usually keep an open mind about the therapy and for this reason, usually seek the views of their patients about the decision It is a situation where decision making has the potential to become a shared process

Before presenting a more detailed outline of the thesis, a brief account is provided of the relevant background in which the call to respect and augment the role of the patient as an autonomous decision maker has been made Box 2 lists some of the contextual factors that have led to the interest in shared decision making

Box 2   Contextual factors that have led to the interest in shared decision making

1970s	Biopsychosocial basis to medical practice put forward by Engel [6, 9]
1980s	Patient centredness concept proposed and described [10]
1990s	Evidence based medicine movement and debate [11]
1990s	Patients begin to be conceptualised as consumers and partners in care [12]
1990s	Individual autonomy becomes a dominant ethical principle [1]
1990s	Professional 'power' declines and the role of 'expertise' is questioned [13]
1990s	Patient choice policy is debated in the context of economic limitations [14]
1990s	Internet and information technology begins to change the way patients access information [15]
1990s	Debate regarding decision making models - rational or heuristic frameworks [16]
1990s	Shared decision making emerges as a concern in the medical literature [17]

At the core of shared decision making is the view that it is acceptable, indeed important (and perhaps beneficial), to offer patients a role in decision making This is a shift away from the more traditional stance of clinical professionals It is also a departure from the position of those who espouse the patient centred method Although the method advocated the need to explore the patients' agenda, ideas and concerns, it did not propose that the decision making process should be shared, and the method did not examine the concept of patient participation in decisions to any significant depth The evidence that enhancing the communication skills of clinicians leads to improved patient satisfaction and understanding of information is not generally disputed [18, 19] In addition, the ethical position of beneficence supports the view that clinicians should communicate as effectively as possible with patients Similar evidence exists for the consulting method known as patient centredness

To summarise, the literature on patient centredness has demonstrated that satisfaction increases when clinicians focus on patient perspectives and take their ideas, concerns and expectations into account [20, 21] Although most studies have demonstrated positive healthcare outcomes and reductions in health service utilisation [22-25], this effect is not large and has not been without equivocation [26] Patient centredness as a method has been criticised for being too broad, one that contains many domains and skill requirements, and as a consequence is one where the development of reliable measurement instruments has met many difficulties [27, 28] Trials of decision aids (information tools provided to patients in order to improve their understanding and participation in decisions) have demonstrated benefits [29, 30]. They are not widely used in clinical settings however, and early assessments of decision aids have revealed many obstacles to their

implementation, including some evidence that healthcare professionals may find the use of such technology to be at odds with their consulting patterns [31] Given, however, that asking patients to share the responsibility of decision making is a step beyond effective communication, and is a step which has potential disadvantages as well as benefits, it cannot be assumed that the results of studies that evaluated patient centredness hold true for shared decision making

Bekker conducted a systematic review of the research conducted into informed decision making [32] and provided an appraisal and bibliography of interventions that could reasonably be expected to affect informed decision making, such as changes in information provision, cost, or service provision It was interesting to note that the majority of studies in this area (85%) were not theory-driven, and that the vast majority of studies used interventions that were designed as additional aliquots of information or education for patients Studies that specifically set out to modify the skills (and by default) the attitude of professionals to the involvement of patients in decision making were not revealed in this report Bekker did report however, that the role of cognitive and social factors were evident, as demonstrated by an intervention that showed that a social skills intervention resulted in significant behaviour change [33]

This thesis therefore starts from the position that the effect of developing the ability of clinicians to involve patients in decisions has not been reported and that the effect of enhancing the role of patients in decision making processes has not been adequately evaluated [34, 35] It was to address this knowledge gap that studies in this thesis were designed It is only when the concept of shared decision making has been adequately defined, developed and implemented in practice, and exposed to accurate means of measurement can it be possible to answer the remaining key questions would involving patients lead to 'better decisions' (decisions that are consistent with personal values and beliefs even if they were contrary to official guidelines regarding 'best practice' or 'maximal effectiveness')? Would involving patients in decisions enhance the likelihood that they would adhere to management plans and, finally, would these steps enable researchers to test the conjecture that involving patients in healthcare decisions leads to improved health outcomes?

Having delineated the increasing interest in the premise, and potential future benefits, of involving patients in decisions, the details of the method, the intrinsic communication skills and required information formats, become pertinent issues for further consideration This thesis considers three aspects of shared decision making It first of all addresses the fundamental question what is shared decision making? Can it be accurately defined at conceptual, theoretical and (most importantly from the point of view of healthcare professionals), at a practical level? Although discussions about professional practice have increasingly recognised the role of patients in healthcare processes, the proposal to share decisions in consultations is a relatively recent development [2] A set of 'principles' for this method of consulting has been put forward [7,

36] but the concept had not been examined in any significant depth from the clinician's perspective. This thesis takes the stance that the principles of shared decision making were in need of substantiation in terms of conceptual validity and practical implementation. Is it, for instance, possible to 'share' decisions across the institutional settings met in general practice? Do clinicians agree that decisions can truly be *shared* or are there inevitable (and insurmountable) power imbalances in clinical encounters that militate against this proposal? If the concepts and suggested principles are validated, what are the views of clinicians about the feasibility of such consulting methods in service settings? Might they argue that they already undertake a participative approach to the management of clinical problems, having already espoused the patient centred approach as formulated during their apprenticeships in existing communication skills development programmes? It was also felt necessary to delineate the exact nature of the consultation skills required to facilitate a more equal partnership, and examine whether shared decision making was an equally valid consulting method across a wide range of clinical conditions. In short, the first task in this thesis was to clarify the concept of shared decision making, as applied to professional encounters in general practice.

Establishing a means of measuring shared decision making was the second area that required attention. Having established a clear definition of shared decision making and described its characteristics, it was necessary to ensure that the consultation method was measurable by a tool that was capable of achieving an acceptable level of validity and reliability, whilst also being as efficient as possible. It was not evident that any previous instrumentation existed in this field but this premise had to be systematically examined. If there was an identified need, an instrument would need to be developed and validated.

These two key steps — conceptualisation and measurement — led to the final aspect of shared decision making considered in this thesis whether it is possible to implement the shared decision making consulting method in clinical settings. It was important to establish whether clinicians were willing to consider the usefulness of these skills in their clinical practice, and whether it was possible to demonstrate a change in consulting patterns over time. It is important to stress therefore that the thesis examines the definition and development of shared decision making *skills*. The underlying model of skill development is based on Hargie's revision of Argyle's social skills construct [37], where it is considered that setting motivational goals (in this case 'involving patients in decisions'), leads to a process of performance monitoring and skill improvement by the individual concerned.

Theoretical and conceptual background

An assessment of dyadic decision making considers *how* a course of action is chosen. The focus in this work is on the external decision making *process* as witnessed by observers, and it is this visible, audible process that is examined in the thesis. Nevertheless, it should be recognised that the end point of all decision making processes is an individual cognitive activity. It is the clinician behaviours, and the factors that influence them

— the means by which clinicians explain the existence of options, the manner in which they describe them and their associated attributes — that are of prime concern. The details of individual cognitive decision making processes are beyond the scope of this work, but it is important to acknowledge the underlying significance of the debate that currently exists.

Three broad types of decision making theories exist. Normative theories describe the action of individuals who espouse rational decision making (they become fully informed and act in accordance with calculated preferences) in order to maximise 'expected utility'. The second type are known as the descriptive theories: they describe how people make decisions on a day to day basis, using simplifications and rules of thumb (heuristics). The third type are known as prescriptive theories, in that they recognise the possibility of poor decisions under the other approaches (people do not act as rational calculators and are prone to make poor decisions using heuristic mechanisms). Prescriptive theories recognise that decision making can be influenced by values, beliefs and other strategies. In essence, this theory proposes that decision making processes can be manipulated by introducing external interventions such as additional information, decision aids, different communication strategies and so forth. It is these theories that underpin the thesis: it is conjectured that developing the ability of clinicians to undertake shared decision making leads to changes in patient decision making processes, higher levels of patient involvement, and, in turn, influences the decision making outcomes.

In many situations, decisions are clear; the benefits of one option clearly outweigh the potential drawbacks. But decisions are often complex and outcomes uncertain, especially in disciplines such as medicine. There is also an additional problem in many circumstances. Information is scarce, either unavailable (i.e. cannot be found in time or, as is often the case in medicine, non-existent) or, as is the case in many consultations, not provided by the clinician, or, if it is provided, not presented in formats that can be readily assimilated by patients who may lack the background knowledge necessary to contextualise information.

Psychologists have revealed that human decision making is an amalgam of approaches, some based on rational calculation but mostly based on rules of thumb (heuristics) that help simplify the process [38, 39]. These heuristics include the *availability heuristic* (how easy is it to bring similar outcomes to mind) and the *representative heuristic* (making probability decisions on category characteristics rather than on base rate information) amongst others. They allow us to be 'cognitive misers'; which often allows us to make satisfactory decisions, but not decisions that conform to the rules of rationality [40].

Those in the rational school often approach decision making by proposing the expected utility theory [41], which assumes that we make choices by weighting our preferred outcomes by the probability that they will occur. But utility estimation (the usefulness or perceived usefulness or value of an outcome) is a complex

area. It has been shown for example that people feel worse about losing a certain amount than gaining a similar attribute. But the research has been based on assessing monetary-type issues. Asking patients to do similar tasks when faced with decisions about healthcare interventions raises unexplored issues: what would be the effect of experiencing a drug side effect and losing current health status for instance contrasted to the possibility of relieving a symptom? It is, in short, more difficult to apply the philosophy of *expected utility* to healthcare decisions. The customer in healthcare is normally a 'patient' — in other words — they have concerns regarding symptoms or problems and typically turn to others for guidance about decisions [1].

Studying the involvement of patients in clinical options should therefore recognise that the activity occurs in situations that are often emotionally charged. Decision making by individuals has been widely discussed in economic texts where the dominant theory is that of *rational choice* engaging in a free market environment. But this literature is subject to assumptions that are being challenged by theorists from cognitive science [16, 42]. Heap touches on these when he states that 'the typical autonomous agent seems like a sovereign customer with a coherent shopping list and a fat wallet in a well-stocked market' [43]. These assumptions are decidedly shaky when we consider images of patients, fearful for their well being, in awe of medical expertise, faced with difficult concepts, yet suspicious of motives as they become aware of the difficulty within healthcare systems to bridge the divide between patient demand and limited resources [1]. The concerns about the complexity of cognitive decision making issues do not devalue work on the observed components of participation between clinicians and patients. It may be that advocating a rational analytic model may not match what is feasible in practice, nor even necessary, in order to gain a greater involvement of patients in decision making [44].

Patient preference
It may well be that society at large promotes the ethic of autonomy, choice and free will (it is the political direction that most economies seem to be taking [45]), but the research shows that at the individual level patients have widely varying views about their wish to participate in medical decisions. Paternalism, informed choice and shared decision making are the terms now commonly used to describe the spectrum of patient involvement in decision making [7, 36]. But who exactly decides which decision making method should be used within the consultation process – should it be the clinician or the patient? Insisting that patients take decision making responsibility (an ethical position termed *mandatory autonomy*) leads to patients complaining that they feel abandoned [46, 47], and runs contrary to the other ethical principle of non-maleficence [48] (do no harm). Studies in this area have demonstrated that clinicians tend to underestimate both how much information patients wish to receive and the level of involvement they would prefer in decision making [49], but that as a general rule patients have a greater wish to receive information than to partake in treatment decisions. Three recent reviews summarise this area: Benbassat [50] conducted a review of published 'surveys' and noted that preference for passive roles correlated with increasing age, less education

and male sex but only explained 20% of the variability documented [50]. Guadagnoli [51] reviewed the literature 'for and against' patient participation in decision making [51]. In 1999-2000 Entwistle and O'Donnell conducted a review of instruments designed to determine patient roles in decision making [52].

The majority of this work has been done in North America and it is not known whether the findings can be applied directly to other contexts, for instance, in primary care in Europe. The studies suffer the weakness that patients have not had any previous experience of active involvement in decision making and are very unlikely to have met clinicians who are experienced at this consulting method, or in using decision aids, so the work suffers from being removed from situated experience of active involvement. How can patients know their preferences for roles they have not experienced? More sophisticated survey methods are now being utilised (e.g. conjoint analysis [53, 54]), and it is an area that requires further longitudinal research. For the purposes of this thesis, the view was taken that shared decision making should incorporate individual patient preferences as part of the negotiated process of involvement. Patients should in other words be encouraged and facilitated to become participants in decisions, but only to the extent that they themselves wish to do so.

Evidence based medicine

There is another comparatively recent development within medical practice that needs to be described because it provides an essential context for the shared decision making method. Modern medical practice is distinguished by the increasing emphasis placed on *evidence*, often at the expense of the patient perspective on illness. Note that the most often quoted definition of evidence based medicine (EBM) states that:

> [it is] the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgement that individual clinicians acquire through clinical experience and clinical practice. [55]

The five steps of EBM are, to quote:
- Conversion of information needs into 'answerable' questions
- Track down, with maximum efficiency, the best evidence to answer the questions
- Critically appraise the evidence for its validity and usefulness
- Apply the results in our clinical practice
- Evaluate our performance [56]

This description does not, explicitly at least, call upon the patient to have an active role in decision making. EBM was conceptualised as a method where professionals made decisions, based on a rigorous appraisal of 'evidence'. There was little in the early EBM publications that acknowledged the role of patient values or

opinions as contributory ingredients. Whatever the explanation, suffice it to say here, that EBM's doctor centredness ethos was noted by many commentators. In 1996, as part of the King's Fund *Promoting Patient Choice* series, a booklet was published in which Hope used the term 'evidence based patient choice' [14], thus providing a bridge between the world of evidence and patient perspectives. He defined 'evidence based patient choice' as follows: 'the use of evidence based information as a way of enhancing people's choices when those people are patients'. It is not the most elegant of titles, yet it does two things. It reveals the rather awkward engagement of these two concepts and sparks off further debate about the extent to which this trend is inevitable or impossible [57].

A concerted move to discuss increased patient involvement occurred in the late 1980s, at least in the developed world. Variations in medical practice were being examined and highlighted [58] and the potential conflict between individual benefit and societal priorities in collectively funded health systems were being debated [59]. Almost unnoticed in the UK's *Patients' Charter* was the statement that 'you (the patient) have a right to have any proposed treatment, including any risks involved in that treatment and any alternatives, clearly explained to you before you decide whether to agree to it'. In 1996, *Patient Partnership: building a collaborative strategy* [12] emphasised the intention to 'promote user involvement in their own care, as active partners with professionals'. These processes are not unique to medicine. The corporate world has long recognised the added value of what Prahalad has called 'co-opting customer competences' [60] so that individuals actively engage in the customisation of products in the just-in-time delivery systems that now characterise many modern systems.

Outline of the thesis
In summary, this thesis examines the proposal that 'clinicians should strive to involve patients in the decision making process' and does so by tackling three broad questions:
- What is shared decision making? (Chapters 2, 3 and 4)
- Can it be measured? (Chapters 5 and 6)
- Can it be implemented, and if so, how? (Chapters 7, 8 and 9)

The work considers the theoretical basis of shared decision making, before moving to suggest a skill framework and, subsequently, to design an instrument to measure empirical practice. As has been noted, the proposal to involve patients in decision making is still the subject of debate. Clinicians doubt whether patients can become truly involved by citing the inherent difficulties of understanding medical interventions, and are concerned lest the underlying uncertainty within many decisions would (if fully exposed) lead to unnecessary or unwelcome patient anxiety (as postulated by the clinicians). It is worth noting that very little parallel work has taken place from the patient perspective [61].

As the theoretical framework and clinical competences were clarified and tested for feasibility in the field, it became possible to use quantitative methods to examine empirical practice across larger samples of consultations, across many clinicians and over time Code-categorisation quantification was one method used to examine the validity of the theoretical competences proposed. The development of measurements scales is a well-described research area and this process was undertaken in the thesis, as a prelude to investigating the development of shared decision making skills of a group of clinicians within the context of a clinical trial. Table 1 summarises the research question and approach taken in each study

Table 1   Questions contained in the thesis and methods

Research Question	Method	Chapter
What evidence exists about shared decision making? Examine its relevance and effectiveness in primary care	A literature review	2
Is the shared decision making model equally valid in all clinical contexts?	Qualitative methods transcripts of consultations examined using discourse analysis	3
What can be observed when clinicians undertake 'shared decision making' in day-to-day practice?	Quantitative analysis of consultations using code-category analysis and linear chronological displays	4
Do measures of patient involvement in clinical decision making exist?	Systematic review methods adapted to search for existing instruments and to appraise their validity and reliability	5
Is it possible to develop and validate an instrument to measure involvement in decision making during routine general practice consultations?	Qualitative and quantitative methods used to develop and test a measure of the extent to which clinicians involve patients in decision making (psychometric testing on a sample of clinical consultations)	6
What skills do clinicians propose that are required to undertake shared decision making with patients?	Qualitative methods sequential focus groups using key informants selected by purposeful sampling	7
Do clinicians who are at an early stage in their careers in general practice consider that sharing decisions is a feasible task?	Qualitative methods reactions of registrars in general practice (using focus groups) to being asked to develop these skills with standardised scenarios and simulated patients	8
Can shared decision making skills be developed by clinicians?	Quantitative data from a programme evaluation using a specific instrument in the context of a randomised multiple interrupted-time series controlled trial	9

Chapter Outlines

Chapter 1
The introduction provides an outline of the thesis, provides a contextual background and a summary of the main research questions and methods used in the studies

Chapter 2
The literature review in this chapter examined both the theoretical background to this field and explored the conclusion of previous studies The aims of the work were to describe the inherent difficulties that make it problematic for clinicians, particularly general practitioners, to discuss treatments with their patients and to propose methods by which they could share information and achieve shared decision making The review examines the different models of decision making, the evidence in favour of patient centredness and the resulting move to increase the involvement of patients, the effect modifiers, the literature on patient role preferences, ethical and medicolegal issues, and the practical barriers to 'shared decision making'

Chapter 3
It was conjectured that 'shared decision making' was a consultation method that suited some clinical topics more than others It had been recognised that the concept of 'equipoise' led to situations where it was felt easier to 'involve' patients in clinical decisions It was considered important to investigate this issue in greater depth Consultations were examined where it was known that clinicians find decisions uncomfortable, e g. when patients present with viral upper respiratory tract infections and have differing views to clinicians about the appropriateness or otherwise of antibiotics The methods of *discourse analysis* were used to examine consultations of this nature

Chapter 4
This study examines consultations where 'equipoise' was more likely to pertain (at least to a degree) and where clinicians were purposively using the skills of shared decision making. We examined the resultant communication behaviours using code-category assessments of the discourse This empirical data was compared with the theoretical 'competences' derived for shared decision making in order to assess the complexity of the interaction and the recursive nature of the discussions between clinicians and patients This method contributed to the design of an instrument that was being developed to measure to what extent clinicians involve patients in decision making

Chapter 5

This chapter reports a systematic search for existing measures in this specific area of communication skills, i.e. an appraisal of instruments that had the remit of measuring to what extent clinicians involved patients in decision making processes The literature review had revealed that there was no agreed construct to describe patient 'involvement' [62]. Although involving patients is an important element of patient centred practice, patient participation in decision making had not been defined in sufficient detail to allow rigorous evaluation Identified instruments were then assessed to see if they had the ability to measure whether, and to what extent, clinicians were 'involving' patients in healthcare decisions A range of databases were searched for articles describing *methods of assessing the consultation*

Chapter 6

This chapter describes the process of developing an instrument to measure the extent to which clinicians involve patients in decisions, and designated the title OPTION, short for Observing Patient Involvement Scale. The consultation skills of explaining equipoise, portraying options, communicating risk and engaging patients sensitively in decisions are skills that need to be considered by an instrument that aims to assess this aspect of clinical interaction [8] over a wide range of topics and problems The instrument was designed to provide research data for empirical studies in this area

Chapter 7

This chapter describes a study designed to explore the clinician perspective regarding the involvement of patients in decision making. They were asked to consider previous theory in this field and to propose a set of competences (skills) and steps that would enable clinicians (generalists) to undertake 'shared decision making'. A qualitative study using sequential focus group interviews of key informants was designed

Chapter 8

It was important to explore the feasibility of developing the skills (competences) of shared decision making in practice, and the attitudes of clinicians to the methods being proposed Indeed, it could be conjectured that clinicians were already using these skills in their daily practice and were both knowledgeable and adept in this area The aim was to elicit the reactions of general practice registrars to being asked to consult using a suggested consulting method [63] with simulated patients in three specific disease areas (lower urinary tract obstructive symptoms (prostatism), menopausal symptoms and atrial fibrillation), using focus groups as a means of collecting data

Chapter 9

The final study in the thesis illustrates the use of the OPTION instrument in the context of a randomised controlled trial. The skills (competences) of shared decision making had been described [8, 63], but there were no studies evaluating attempts to develop these skills in a cohort of clinicians. The aim in this study of clinicians was to determine the effect of providing exposure to these concepts, to develop the skills using simulated patients, and to measure the extent to which the clinicians who participated in a randomised controlled trial increased their ability to involve patients in clinical decisions.

Chapter 10

The final chapter presents the conclusions and the recommendations that arise from the studies. The opportunity is taken to place the work in the context of the other literature in this area and to consider the implications for practice and further research.

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Chapter 2

Shared decision-making in primary care: the neglected second half of the consultation

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Abstract

The second half of the consultation is where decisions are made and future management agreed. We argue that this part of the clinical interaction has been 'neglected' during a time when communication skills development has been focused on uncovering and matching agendas. There are many factors, such as the increasing access to information and the emphasis on patient autonomy, which have led to the need to give more attention to both the skills and the information required to appropriately involve patients in the decision making process. This analysis, based on a literature review, considers the concept of 'shared decision making' and asks whether this approach is practical in the primary care setting. This study, and our ongoing research programme, indicates that future developments in this area depend on increasing the time available within consultations, require improved ways of communicating risk to patients, and an acquisition of new communication skills.

Introduction

The clinician-patient relationship is changing rapidly towards a more active partnership, fostered by the increasing access to information about treatments and the consumerist trends in modern society This shift towards *involvement* is also evident in policy statements 'Collaboration' and 'partnership' are the key political words of the late 1990s But it was earlier, as if to counter-balance the 'internal market' reforms, that the policy of involving patients in their healthcare decisions (both at individual and community levels) was published In 1991, the *Patients' Charter* [1] included the statement that 'you (the patient) have a right to have any proposed treatment, including any risks involved in that treatment and any alternatives, clearly explained to you before you decide whether to agree to it' In 1996, *Patient Partnership Building a Collaborative Strategy* [2] emphasised the intention to 'promote user involvement in their own care, as active partners with professionals '

Whilst it may be necessary to change the way the second half of the consultation is conducted to achieve these goals, how to do this within primary care encounters is less clear The aims of this paper, which is based on a literature review [3], are to describe the difficulties posed by the ways that clinicians currently discuss treatments with their patients and to propose alternative methods by which they could share information and achieve shared decision making We have not attempted to consider patient involvement in decision making at the macro level of policy-making and prioritising resources

The second half of the consultation

Byrne and Long [4] analysed over 2000 consultations and identified a general structure which consisted of 6 phases

1   establish relationship
2   reason for attendance
3   verbal / physical examination (solve problem)
4   consider the condition
5   detail further management
6   termination

Phases 1-3 cover the first half of the consultation up to the point when the clinician considers that he or she has reached a full understanding of the patient's problem Much emphasis has been placed on the importance of this task [5] and, if it is not achieved, it is unlikely that the consultation will have beneficial outcomes

However our focus with regard to information sharing and shared decision making is on phases 4 and 5 of the consultation. Byrne and Long reported that discussion of the patient's condition occurred in less than 25% of consultations and patients have been found to be dissatisfied with the explanations of their conditions and the information they receive [6]. Our own research [7] confirms the findings of others [4, 8, 9] that, in many consultations, there is little, meaningful dialogue between clinicians and patients about the nature of the problem and the possible therapeutic actions [10].

We believe that skills to enhance this 'second half of the consultation' have been neglected to date, and thus involvement and empowerment are at present distant fantasies. We will now describe conceptually and practically how these goals might be achieved, starting from a discussion of the different methods of decision making in a medical context.

Methods of decision making in a medical context

Methods of clinical decision making in the consultation can be represented as a spectrum from a paternalistic method at one end, to the informed choice method at the other end [4, 11]. In between these is the method of shared decision making (Figure 1).

Figure 1   Spectrum of patient-clinician interaction
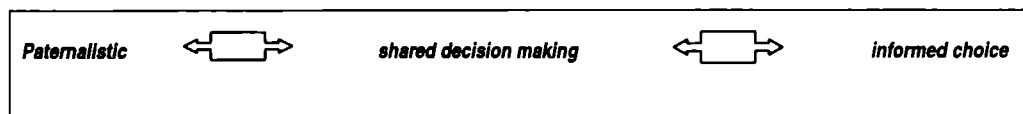
The paternalistic method is supported by Parson's [12] conceptualisation of the sick role. Specifically this obliges the patient to seek 'expert' help and comply with the medical regimen. It is a consulting style where the clinician does what is thought best for the patient without necessarily eliciting the latter's preferences. Byrne and Long [4] found this style of consultation to be used most frequently. By keeping the patient as passive recipient of the clinician's 'expert' advice, it clearly has the superficial attraction of maintaining the professional's status.

It is possible to argue that the logical opposite to the 'paternalistic' method is consumerism: where patients (well informed or otherwise) have predetermined views about preferred options. One extreme form is the patient who discharges himself or herself from care, despite advice to the contrary. However, the 'informed choice' decision making method is usually placed at the opposite end of the spectrum and describes a process whereby patients receive information from their clinicians about treatment choices, and are then left to make the decision. The information imbalance between patient and clinician is recognised: 'technical

knowledge resides in one party — the clinician, while preferences reside in the other — the patient' [11] and a concerted effort is made to fully inform the patient about the choices available. The patient now has both the information required and the personal preferences necessary for decision making. Indeed, the clinician may feel 'proscribed from giving a treatment recommendation for fear of imposing his or her will on the patient and thereby competing for the decision making control that has been given to the patient' [13]. There is concern that the 'informed choice' method, where control over decision making is vested entirely with the patient, may lead to increased anxiety; and if taken to its extreme form it may lead to patients feeling that they have been abandoned [14]. An illustration is the dilemma many feel when a clinician fully explains the risks and benefits of ante-natal screening for Down's syndrome, but steadfastly declines to guide the decision.

Sharing information and sharing decisions are not synonymous [15]. They are separate goals within the consultation and require different skills. Whilst it is possible for the sharing of information to occur alone (after which either the patient or the clinician makes the decision) shared decision making cannot occur unless preceded by the sharing of information. It also requires specific attention to be paid to how decisions are made in the consultation and the reaching of agreement over the treatment decision. It may even be the case that the agreement will be that one or other of the participants will make the decisions alone. Charles [11] points out that none of the methods explicitly describe 'a process in which both physicians and patients share in decision making, no matter how much information they share.'

It may well be that different types of health problems need different decision making methods and this requires further exploration. But if we were to share decision making with patients, what would be the characteristics of the process? Summarised, they are reported as follows [11]:

- Shared decision making involves at least two participants - the clinician and the patient - and often many more (their respective networks of family or professional colleagues)
- Both parties (clinicians and patients) take steps to participate in the process of treatment decision making
- Information sharing is a prerequisite to shared decision making
- A treatment decision (which may be to do nothing) is made, and both parties agree to the decision

Contained within each step are areas that can be expanded and discussed. For the purpose of this paper, the information sharing stage (which if it contains probabilistic data is often known as 'risk communication') requires an 'open two-way exchange of information and opinion' (i.e. preferences) about risk [16], so that management decisions can be based on a better understanding of the options and outcomes. This process cannot, by definition, occur within a clinician centred consultation and the process of shared decision making is integral to the wider concept of patient centred consulting [17].

Why should we share decisions?

'Sharing decisions' may be a desirable end in itself on humanistic grounds [18]. In addition, there is a growing body of evidence confirming the problems which occur due to poor communication between clinicians and patients and which contribute to non-adherence with therapy, advice or other management plans [19]. Because 'shared decision making' has previously been loosely and poorly defined there is no specific evidence to support shared decision making in practice. However, the benefits of effective communication on patient satisfaction have been clearly identified [8]. Studies of 'participatory consulting styles' and 'patient centred consulting styles' have provided confirmation of benefit [7]. Stewart [20] reports that where patients 'perceive' that they have achieved 'common ground' with clinicians there are fewer demands on laboratory and referral services. Her review [21] concluded that four key dimensions of communication were related to positive outcomes:

- the provision of clear information
- questions by patient
- willingness to share (discuss) decisions
- agreement between patient and clinician about the problem and the plan

It has also been found that if people take an active part in making decisions about their care, they have better health outcomes, as exemplified in the achievement of improved diabetic control in studies by Greenfield and Kaplan [22-24]. Recent work also reveals the complexity that underlies these apparent relationships between patient involvement and improved health outcomes. Street [25] found that the patient's *perception* of decision control is a key issue with both stable and dynamic characteristics, depending on the patient personality, their involvement within the consultation and the eventual health outcome. Huygen *et al.* [26] showed that certain types of consulting styles could improve the health of patients across a practice list. Confirmatory work is beginning to be published from the secondary care sector illustrating the benefits on patient satisfaction and long-term outcomes of 'participatory physician' styles [27]. There will also be times when patient preferences will be in direct conflict with clinical guidelines. The wish to receive antibiotics for viral illnesses is a classic example that can threaten both the clinician-patient relationship [28] and health outcomes [29]. Shared decision making will need to accommodate many such modifiers.

'Effect modifiers'

Despite this and the breadth of evidence accumulating about the benefits of 'effective' communication on patient satisfaction [8, 21], and on patient adherence to treatment [19, 30] there are some discordant notes from other studies [31]. These give an indication of the important 'effect modifiers' on benefit from patient involvement in their management — it is not always the most appropriate method for a consultation, depending on patient characteristics or the context of the consultation.

Savage and Armstrong [32] randomised 359 patients to receive 'directive' and 'sharing' consulting styles, verified by assessing a sub-sample of 40 recordings. The 'directing' style had a better effect on satisfaction levels but only in those with self-limiting illness or chronic conditions, echoing similar work by Thomas [33]. These results appear to indicate that if the 'sharing strategies' are followed mechanically or ritualistically they are insensitive to the situational context and will not produce improved health outcomes.

Other patient characteristics that are likely to be effect modifiers are lower educational status, severity of illness and advancing age (see scenario in Box 1). But no one variable, illness condition or sociodemographic, could be regarded as predictive [34]. It is also important that the imperative to 'share decisions' must not come out of the blue — if it is unexpected then it may cause anxiety rather than alleviate it, and fail to achieve the desired improvements in health outcomes.

Box 1   Case History

An elderly lady (aged 82) has been suffering from right upper quadrant pain for some two years and eventually consults her clinician He refers her to a surgeon who, with the aid of ultrasound findings confirms a diagnosis of cholecystitis The surgeon then suggests that cholecystectomy is an option, and that he would be happy to do this if the patient would like this This situation of contributing to the treatment decision is completely novel to this lady - she has been used to being told 'what treatment she should have' - and she now feels highly uncertain and anxious. She chooses to discuss the situation with her clinician again who has more of an understanding about her expectations for involvement in decision making, and is more positive about opting for cholecystectomy. She then informs the surgeon that she will have surgery.

This scenario illustrates how a long-term context of involvement in decision making is important, and that it cannot be imposed out of the blue Once introduced to the concept of involvement in decision making (whether suddenly or in the longer term) patients may still find it hard to participate in the decision making to the level expected by the clinician (A footnote to this scenario records that her gallbladder histology subsequently returned showing early stage carcinoma, thus showing that if the patient's participation in the decision had been to defer treatment this would have had major consequences. Truly sharing decisions means that clinicians must still retain responsibility to advise where necessary, and cannot opt out or 'abandon' the patient simply to an 'informed choice' without expecting negative consequences).

Do patients want to share decisions?

Most of the work evaluating patient preferences for participation has been done in North America and has been critically analysed by Deber [35, 36] and reviewed more recently by Guadagnoli [18]. It is not known whether these findings can be applied directly to other patients with different medical problems and contexts. Much of the research is based on surveys using different instruments, thus making comparisons difficult. It would appear that patients' desire for information is stronger than their desire to be involved in decision making [34, 37-39]. However, research done using hypothetical questions or scenarios may not truly reflect patients' views when they are actually taking part in a consultation. The link between 'patient preferences for participation' and actual participation is not that strong [11]. For example, a majority of healthy subjects stated that they would want to select their own treatment if they were to have cancer, however, only a minority of patients with cancer shared this view [40]. Again it should be questioned whether such findings can be

transferred to primary care where patients are most often likely to be involved in smaller decisions about less serious problems.

Although patients may dislike the clinician uncertainty that may be conveyed by shared decision making [41], clinicians tend to underestimate both how much information patients wish to receive and the level of involvement they prefer in decision making [42]. Clinicians are often unaware of patients' views on treatment [10] and may also lack the skills to elicit patients' preferred choices. Recent work has showed that prescribing decisions about antibiotics are guided by clinician perceptions of patient expectations rather than actual expectations [43].

Although many clinicians now subscribe to the view that patient preferences should be considered when treatment decisions are taken, the ability to elicit preferred choices is often lacking. A study [44] that followed up 425 women who consulted their clinician with menorrhagia found that half the clinicians were unaware of their patients' views. Other work in different settings [10, 39, 45] has demonstrated that patients, perhaps because they feel their clinicians are not interested, rarely make demands for information or for increased involvement. This tendency can be modified, and work demonstrates that patients can be 'trained' to increase their participation [46], although this approach is unlikely to be practical on a widespread basis.

Assumptions and generalisations clearly cannot be made and the literature points to the need to ascertain involvement preferences within consultations, and for the need to develop ways of accurately assessing preferred levels of participation. Methods to categorise the role patients wish to take in decision making have also been developed, and can be used in research to indicate which option patients favour [47].

The fact that the majority of patients indicate a desire for more information about their illness and potential treatment options, but a much smaller number express preferences to participate in treatment decisions, gives rise to interesting speculations. How are preferences affected by situational factors, or learnt behaviours? Recent developments in psychology indicate the existence in screening programmes of 'blunters' (avoidance behaviour) or 'monitors' (attenders) and points to the effect that personality has on levels of involvement [48]. The 'preference' studies consistently show that sociodemographic variables are not useful in predicting who wants more or less active roles in medical decision making, and there is a concern that hypothetical studies (the majority) do not accurately reflect 'actual' views. The principles of 'patient involvement' however should not override preferences for participation, assessed within the consultation. Clinicians largely determine communication styles: patients do not insist on shared decision making, however open they are about their preferences. Perhaps it is also illogical to ask about a patient's preferred role in decision making until they have realised the possible harms and benefits of the choices they

face, and the associated probabilities Then, and only then, can it be legitimate to ask an individual whether or not they wish to take an active part in deciding what is best for them The effects of well-defined and skilfully implemented 'shared decision making' processes in real clinical contexts clearly require assessment

Ethical and medicolegal perspectives

These variations between patients also raise ethical and medico-legal issues The law, as far as it concerns the clinician-patient relationship, has been static in the United Kingdom for a number of years [49], but there is increasing pressure on clinicians to address the issue of 'informed consent' [50] In the United States, consumer and patients' rights groups have been, and are still, changing the way in which patients and healthcare professionals arrive at decisions Many would argue that the move towards adopting the 'informed choice' method is a direct consequence of clinicians consulting defensively

The ethical position itself is not clear-cut because the principle of autonomy is not necessarily beneficial [51] and may conflict with the equally valid principle of beneficence In many ways, the recent developments in palliative care communication made explicit the duty of the clinician to respect patient choice [52] Lupton [53] has described the ambivalence patients feel between wanting to behave 'in a consumerist manner' and their equally strong desire 'at other times to take on the passive role' and invest their trust in professionals Shared decision making offers a balance to these opposing positions by actively involving patients in decision making but also requiring the professional to use his or her expertise and experience to guide the patient and make decisions if required Consequently, shared decision making would appear to be consistent with the new ethical principle of 'relationality' proposed by Bottorff *et al* [54] This principle promotes the provision of accurate honest information in the context of the individual situation, examining the ethics of care in terms of such factors as response, interpretation, accountability and social solidarity, often counterbalanced against other values such as truth and confidentiality

What problems prevent 'shared decision making' in the primary care context?

Studies of consultations [4, 8-10, 20] in general practice have consistently revealed that sharing information about the identified problems, identifying treatment options and sharing the decision about the preferred future management rarely occurs, and there do not seem to have been any significant changes since the mid 1970s [10] There are many proposed explanations for this, drawn from clinicians themselves [55] and from social science analysis

- it takes time
- it is threatening to the 'power' relationship between clinician and patient
- continuity of care means that treatment decisions are often coloured by prior experiences of both patient and clinician in that particular setting
- lack of training/experience/modelling

- lack of skill in 'sharing' and 'involving' patients in decision making
- lack of information about risks and benefits
- lack of skills and tools to convey information about risks and benefits [56]
- patients are perceived not to like the 'clinician uncertainty' it may convey [55]

Lack of time may be used as a reason for not giving patients information or involving them in decisions. However, Howie has demonstrated the benefits of providing patients with more time and has developed the concept of patient 'enablement' as an outcome in its own right. He has shown that time spent within consultations appears to be directly related to the quality of care: more time producing greater benefit and increasing the ability of patients to understand and cope with their health problems [57, 58]. Beisecker [39] found that the degree to which patients sought information from their clinicians depended, amongst other things, on how long the consultation lasted and whether they were invited to inquire. Street [59] confirms that participation in decision making is increased when clinicians exhibit patient centred behaviours. Although having enough time within consultations is important for 'shared decision making', perhaps time should be regarded as necessary, but not sufficient.

The proposal that there is a general lack of *time* will not be widely contested, but clinicians may not be as ready to admit that a lack of skills in sharing decisions and information are also significant obstacles [60, 61]. Pilot work we have undertaken with clinician registrars using simulated patients indicates that these clinicians are not familiar with the skills required to 'share decisions' and that patients are equally tentative about the process of involving themselves in decisions. This may occasionally backfire, deterring the clinician from continuing efforts to share decisions.

Traditional clinical skills enable clinicians to achieve working diagnoses, suggest treatment strategies and plan future management, but there has not been the same emphasis on the ability to share detailed information about the probabilities of the available treatment outcomes. It is very difficult to obtain and present data about risks and benefits to patients in a meaningful non-technical way. Only 10-30% of clinical decisions are backed up by evidence [62]. Furthermore, the information that is available is often not in a form that actually assists us [63]. Information about diagnoses, drug therapy and operative interventions are inevitably pooled data, and are therefore difficult to 'particularise'.

The 'average' patient is a rarity [41]. The patient in the consulting room may have heart failure, osteoarthritis, live alone, take warfarin and be at risk of falling down the stairs. Arriving at a 'shared decision' in this context involves more than obtaining information about the best way to treat heart failure in an elderly man. Developing risk communication tools for a course on 'shared decision making' [55] has illustrated how difficult it is to portray the risks and benefits of commonly met problems. Our pilot work indicates that *how* information

is presented (verbal, tabular, graphical versions) has a major influence on the depth of patient involvement in decision making. The development of decision aids such as leaflets [64], videos [65], boards [66], and web pages [67], needs to be undertaken in the light of this type of research and our findings also indicate that communication skills in shared decision making will need to be developed if professionals are to make appropriate use of these tools.

How might we achieve 'shared decision making' within consultations?

Shared decision making clearly rests in the paradigm of patient centred medicine [17]. Stewart has described the concept of finding 'common ground' and it is this component of the consultation that is being considered in detail. The conceptual clarification that has occurred recently [11, 68] has resulted in a set of 'competencies' [sic] to be described in a Canadian context [69]. Box 2 outlines the steps she suggests need to be taken in order for patients to share in the decision making process: it is assumed that the agenda matching and problem solving phases of the consultation have been successfully completed, and that patient 'role preferences' are respected.

Pilot work in clinical contexts suggests that this method will need to be modified [55]. We suggest a further competency to be included after the 'transfer of technical information' that concerns checking patient understanding of this information (W Rosenberg, personal communication 1998). The understanding of apparently simple information still varies enormously between individual patients and requires careful and sensitive clarification [70].

Box 2   Steps for patients to share in the decision making process [69]

- Establishing a context in which patients' views about treatment options are valued and necessary
- Eliciting patients' preferences so that appropriate treatment options are discussed
- Transferring technical information to the patient on treatment options, risks and their probable benefits in an unbiased, clear and simple way
- Clinician participation includes helping the patient conceptualise the weighing process of risks versus benefits, and ensuring that their preferences are based on fact and not misconception
- Shared decision making involves the clinician in sharing the treatment recommendation with the patient, and/or affirming the patient's treatment preference

Conclusion

Shared decision making offers a method for the management stage of the consultation, with the underlying aim of achieving an active partnership between patient and clinician. There is no specific evidence for the shared decision making method but the patient centred approach — in which it is embedded — has demonstrated improvements in short-term outcomes (patient understanding and satisfaction), patient adherence and a reduction in the use of resources (laboratory services and referral) [20].

As we have stated, shared decision making does not happen regularly. Some of the 'competences' required for shared decision making are being formulated, but a checklist of behaviours or steps taken during a consultation may never 'resonate with patients' methods of decision making or constructions of their illness experience' [11]. It should be possible to obtain observable evidence of shared decision making but we may need to go beyond the analysis techniques currently used to assess the clinician-patient interaction. Observation alone will not capture the process that takes place 'in the patient's head'—where ultimately decision making occurs. Neither will observation of interaction enable the longitudinal aspect of decision making to be determined: the effects of patients discussing options with family and others.

Having learnt to explore both the biomedical and personal agendas, clinicians are now faced with the challenge of providing patients with information and learning how to share decisions with them. How these skills are best developed and what tools should be deployed to share information about risks are areas that need further work. There will always be a concern that the clinician's view (mediated via the way the clinician frames the information [71]) will sway the patient.

A mood of questioning consumerism and the unprecedented electronic access to information is re-defining the role of the generalist. The clinician should be prepared to adapt to the patient's preferred role: to hand over, share, or take overall responsibility for, decision making. For the patient, involvement will bring new responsibilities — a requirement to evaluate risks and benefits. Clinicians are uniquely placed to share decisions with patients. It is an important task, best done before patients enter the potential bias of secondary care perspectives. We have for too long neglected the second half of the consultation.

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Chapter 3

Is 'shared decision-making' feasible in consultations for upper respiratory tract infections? Assessing the influence of antibiotic expectations using discourse analysis

Elwyn G, Gwyn R, Edwards AGK, Grol R.

Abstract

Objective: To examine the discourse of consultations in which conflict occurs between parents and clinicians about the necessity of antibiotics to treat an upper respiratory tract infection, aiming to appraise the feasibility of shared decision making.

Design: A qualitative study using discourse analysis techniques.

Setting: A general practice with 12,500 patients in an urban area of Cardiff, Wales.

Participants: Two consultations were purposively selected from a number of audiotaped sessions. The consultations took place during normal clinics in which appointments are booked at 7-minute intervals. The clinician is known to be interested in involving patients in treatment decisions.

Method: Discourse analysis was employed to examine the consultation transcripts. This analysis was then compared with the theoretical competences proposed for 'shared decision making'.

Results: The consultations exhibit less rational strategies than those suggested by the shared decision making method. Strong parental views are expressed (overtly and covertly) which seem derived from prior experiences of similar illnesses and prescribing behaviours. The clinician responds by emphasising the 'normality' of upper respiratory tract infections and their recurrence, accompanied by expressions that antibiotic treatment is ineffective in 'viral' illness — the suggested diagnosis. The competences of 'shared decision making' are not exhibited.

Conclusions: The current understanding of shared decision making needs to be developed for those situations where there are disagreements due to the strongly held views of the participants. Clinicians have limited strategies in situations where patient treatment preferences are opposed to professional views. Dispelling 'misconceptions' by sharing information and negotiating agreed management plans are recommended. But it seems that communication skills, information content and consultation length have to receive attention if such strategies are to be employed successfully.

Introduction

The encouragement of 'patient choice' has concentrated attention on decision making [1, 2], and how involvement can be achieved against a background of evidence based practice. It is becoming widely accepted that participation in decisions results in greater client satisfaction and leads to improved clinical outcomes, as measured by decision acceptance and treatment adherence [3, 4] Charles [5] has described the three broad methods of decision making: the paternalistic method, the informed choice method and the shared decision making method.

In the paternalistic method the clinician decides what he thinks is best for the patient, without eliciting the latter's preferences. The informed choice method describes a process whereby patients receive (usually from clinicians) information about the choices they have to make. In theory, decisions need not be 'shared' as the patient now has both components (information and preferences) necessary to reach a decision. Furthermore, the clinician "is proscribed from giving a treatment recommendation for fear of imposing his or her will on the patient and thereby competing for the decision making control that has been given to the patient" [6]. An argument has been put forward that the informed choice method leads to patient 'abandonment' [7]. Shared decision making (see box 1) is seen as the middle ground between these two positions, where both patient and clinician contribute to the final decision [5].

Box 1   Characteristics of shared decision making [5]

- Shared decision making involves at least two (often many more) participants—the clinician and the patient
- Both parties (clinicians and patients) take steps to participate in the process of treatment decision making
- Information sharing is a prerequisite to shared decision making
- A treatment decision is made and both parties agree to the decision

A list of skills for 'shared decision making' has also been proposed, based on qualitative work in a Canadian context [8]. But it is not known if these 'conceptual' 'competencies' [sic] resonate with the inherent variability of actual professional practice. We cannot assume that the shared decision making approach can be implemented when disagreement exists. But this is part of a wider issue: how should clinicians operate in a consumerist climate [9], which encourages patient autonomy and involvement in decision making, and yet remain true to the professional imperative to follow 'evidence based' guidelines [10]? Does this dilemma negate the shared decision making process, or enrich it, by admitting an element of responsibility (rather than paternalism) to the clinician's contribution?   Our specific aim is to examine the 'shared decision making' method in situations of conflict over preferred treatments and we use discourse analysis [11] to inspect the details of two consultations for upper respiratory tract infections.

Method

Discourse analysis is a form of textual microscopy — the study of language in context [11, 12]. Studies of how clinicians talk to patients at outpatient clinics [13], how health visitors discuss issues with their clients [14] and how HIV counsellors convey information and advice [15] are examples where the techniques of conversation analysis have revealed previously hidden perspectives. By focusing on its organisation and sequences, it is possible to discern the *rhetorical* organisation of everyday talk: how, for instance, is one version of events selected over any other? How is a familiar reality described in such a way as to lend it normative authority? On a broader front, discourse analysis is "concerned with examining discourse (whether spoken or written) to see how cognitive issues of knowledge and belief, fact and error, truth and explanation are conceived and expressed" [12]. The one essential thing about 'doing' discourse analysis is to stick to the text, which in many cases and in these examples, are pieces of talk. Transcription was undertaken by RGw and GE and a key to the symbols appears in Box 2.

Box 2   Key to transcript symbols

( )	brackets containing a stop indicate a pause of less than two seconds
(2)	numerals in round brackets indicate the length in seconds of other pauses
[ ]	square brackets contain relevant contextual information or unclear phrases
[ ]	italicized square brackets describe a non-verbal utterance
[	this symbol in between lines of dialogue indicates overlapping speech
<u>so</u>	underlining signifies emphasis
	a colon indicates elongation of the preceding sound
=	an equal sign means that the phrase is contiguous with the preceding phrase without pause
D	is the doctor
F	is the father
M	is the mother

Having analysed the discourse, we will compare the communication strategies used in the two consultations against the theoretical 'competences' for shared decision making [8]. Although these skills have not yet been observed in practice they are summarised in Box 3.

Box 3   Competences for shared decision making

- Establishing a context in which patients' views about treatment options are valued and necessary
- Eliciting patients' preferences so that appropriate treatment options are discussed
- Transferring technical information to the patient on treatment options, risks and their probable benefits in an unbiased, clear and simple way
- Clinician participation includes helping the patient conceptualise the weighing process of risks versus benefits, and ensuring that their preferences are based on fact and not misconception
- Shared decision making involves the clinician in sharing his treatment recommendation with the patient, and/or affirming the patient's treatment preference

The cases: two young children with an upper respiratory tract infection

The consultations took place within routine general practice sessions in an urban part of Cardiff. They represent actual episodes of care in a setting where patient appointments are booked every 7 minutes. The cases were purposively selected to highlight consultations where conflict occurs regarding the management of upper respiratory tract infection. To maintain confidentiality fictitious names are used. Consent was obtained for the recording and analysis, both before and after the consultations. The clinician is the same in both instances and is known to have an interest in the involvement of patients in treatment decisions. The transcript records the first encounter between this particular doctor and the clients involved.

Case 1 : Tracey

Tracey, who has evidently been suffering from repeated sore throats (003-4) is brought by her mother.

Normality

001	D	Tracey you're eight now is that right?
002		[inaudible sore throat evidently the matter]
003	M	she.'s suffering a lot from it um ( )
004		she always seems to be on antibiotics um (2.0)
005		Doctor A he's seen her last he gave her
006		one load lot of (.) antibiotics and then he gave me
007		a pre prescript repeat prescription then (2 0)
008		to have the other to get it right out of the system
009		[talks to child]
010	D	[to Tracey] you're eight now how many times have you had
011		what we say is tonsillitis?
012		(3 0)
013	M	I'd say (.) about every two and a half months
014	D	every two and a half months *[muttering]*
015		is it stopping you going to school? it is is it?
016		can I take a look in your throat ( ) please ( )
017		have you had this done before?
018		(6 0)
019	M	they said this when she went over for an examination
020		because she's seeing a speech therapist about her tonsils
021		being really enlarged
022	D	they are rather enlarged but nothing out of the ordinary
023		lots of children have got tonsils of this sort of size

[Further examination takes place]

024	D	yeah okay (.) okay well the first thing to emphasise I guess
025		is that this is a sore throat ( ) you're right to call it a tonsillitis
026		cos that's just a Latin name for a sore throat
027	M	right
028	D	okay (.) it's probably caused by repeated viruses (.) right=
		[
029	M	right

030	D	=like ( ) repeated colds
031	M	yes
032	D	y'know when you get a cold or a flu it's a virus
033		chicken pox measles they're viruses ( )
034		it's probably caused by repeated viruses coming and going
035		contact with other children contact with school
036		sometimes you leave a virus hanging around in your body
037		and reactivating ( ) the difficulty with viruses is
038		which I'm sure you know is that
039		antibiotics ( ) don't do a dickie bird for them
040		they don't ( ) wipe them out

This repeat episode of a 'sore throat' is accompanied with a seemingly overt complaint by M that her daughter has seen many others with the same problem (004). 'she always seems to be on antibiotics' One 'load' (006) was not enough, a repeat was needed, and then 'the other' in order to 'get it right out of the system' (008) This sequence contains two significant pauses. Are these to gauge reactions to what appears to be a statement of discontent? If so, D does not take these potential turns, does not comment, and proceeds with an attempt to engage the daughter (010-011), Tracey.

She does not reply and after a pause M responds by describing the two monthly frequency of attacks Acknowledging this information by means of an echo (line 014) D continues his engagement, his turns have been precursors to gaining consent, implicitly given by Tracey, for a physical examination (016), 'can I take a look in your throat (.) please ( )' Although M has attempted to distance his use of a medical term by asking how many times 'have you had *what we say* is tonsillitis' (011), M takes the opportunity during the ensuing silence to state a corroborating fact Tracey is 'seeing a speech therapist about her tonsils being really enlarged' (021), and thus M provides a clue as to *her* understanding of the 'real' nature of this problem The next turn marks a significant change in the discourse Whilst agreeing that there is enlargement, D emphasises the normality of this finding and completes the examination D then uses discourse markers and pauses to start an explanatory phase of turns (024-040) He suggests the 'sore throat' (his preferred term 026), and by inference the previous episodes, are 'probably caused by repeated viruses', and compares the problem to the common cold [16]. M acknowledges the turns using short agreements (027, 029, 031) and D goes on to list common viral problems where antibiotics are not associated with usual management (032-033). Having emphasised the normality of the condition, D mentions the inevitability of exposure to viral vectors, and the lack of effectiveness of antibiotics in such viral illnesses (035-040) This could be seen as an oblique way of providing advice and avoiding conflict Silverman noticed a similar pattern in HIV counselling and used the term 'advice as information' sequence [15]

Personal experience, views and 'evidence'

041	M	right (.) the trouble is (.)
042		I could go away from here tomorrow
043		I mean you're the doctor I'm not telling you your job
044		but I'd be guaranteed back tomorrow
045		because she seems to (.) this now is nothing
046		to how she she usually goes right down with it
047		as well you know second third
048		[
049	D	with a high temperature
050		becomes very ill=
051	M	=that's right
052	D	sure (.) yeah (.) and some people find that (.)
053		antibiotics help them through that illness
054		if they extend their
055		[
056	M	yes
057		(.)
058	D	what I'm saying I guess is that (.)
059		the best guess we can do is that this is a viral illness
060		that it won't respond to antibiotics
061		it'll just (.) take its time and get better (.)
062		some people like to have a course of antibiotics
063		because they feel it makes a difference (.) and (.)
064		the (.) science on this is a bit fifty fifty (.)
065		sometimes it does (.) sometimes it doesn't (.)
066		and as you've probably heard from the papers
067		people are a bit wary of giving antibiotics
068		[
069	M	that's right yes=

Despite reassurance and indeed attempts at persuasion by D, that viral illnesses should be regarded as self-limiting problems, M immediately counters. Using a discourse marker 'right' (041) to emphasise her turn, followed by a disclaimer 'I'm not telling you your job' (043), she feels able to provide a personal account of her daughter's previous illness patterns. By doing this she claims prior experience of the situation and locates herself as one with a certain limited knowledge. This strategy is known as 'category entitlement', by which individuals' experience entitles them to special knowledge about a topic [16], which in effect counters D's position. She says that 'I'd be guaranteed back tomorrow' (which constitutes a type of threat, since she will be wanting 'antibiotics' then, if they are not provided today). The graphic term 'she usually goes right down' elicits an interjection, a query inviting confirmation (049-050), which allows D to re-enter (058). He acknowledges the weakness of his position (it's his 'best guess' that this is a viral problem), proposes the illogicality of treating a viral illness with antibiotics yet concedes that the odds are 'fifty fifty', that sometimes they make a 'difference'. The interview seems to have coincided with a wave of publicity about the overuse of antibiotics [17], and this is brought in as added weight to the clinician's reluctance to prescribe (066-067).

Option portrayal

070	D	=yeah ( ) <u>so</u> ( ) we've got two choices ( ) all right now?
071		<u>these</u> are the two choices ( )
072		we'll give you plenty of paracetamol ( ) fluids
073		and let this illness carry on
074		and build up a <u>natural</u> immunity ( ) yeah?=
075	M	=all right
076	D	or we'll give you some antibiotics ( ) and ( )
077		treat it as we've treated it in the past
078		although as you <u>say</u> ( ) it ( ) keeps coming back
079		and I don't think we can stop that
080	M	<u>no</u> ( ) she certainly reacts better ( ) <u>I</u> would say so
081		out of experience
082	D	to?
083	M	the antibiotics really <u>do</u> seem to work on her
084		I ( ) <u>have</u> given her paracetamol I was sent away
085		going back a while ago ( ) to give her *[parroting]*
086		paracetamol plenty of fluids ( ) she was burnin up ( ) ah no ( )
087		she ( ) it seemed to drag along a long way you know

Turns take place in quick succession between D's reinforcement of his views about antibiotics, with the affirmations 'that's right yes' and 'yeah' (069-070) acting as turn controlling devices. The pauses after 'so' and 'we've got two choices', followed by the rhetorical device 'all right now' (070), similarly demonstrate the imposition of professional control on the turn and signify a deliberate attempt by the doctor to gain attention to his views about the choices available He goes on to outline two options, the use of time, fluids and paracetamol or treatment with 'some antibiotics', with the casual quantifier *some* used to undermine the way 'we've treated it in the past' This is underlined by a thinly veiled disparagement that the problem 'keeps coming back'. At this point D's turns are less intrusive M calls on her 'experience' and cites previous improvements (080). D interjects, but only to clarify that they are still talking about 'antibiotics' as the perceived agent of benefit D then frames a question in the plural inclusive form 'is that our preference' (088), a signal perhaps that D's view is not static, that he is prepared to meet M's perceived preference This attempt at arriving at a 'shared' view had been hinted at previously by the indication that both D and the patient had choices 'we've got two choices' (070).

The decision is then rapidly achieved, and seems to be made in the following brief exchange.

088	D	is that your preference? ( ) to have a go with some antibiotics
089		rather than try the paracetamol and= [telephone rings through following turn]
090	M	=I'd rather the antibiotics
091	D	yeah?
092	M	<u>real</u>ly ( ) I <u>wou</u>ld

This is followed by a turn in which M justifies her stance. But the justification is not by reference to an actual requirement for her daughter to have treatment, but by the fact that she is a 'busy person', whilst immediately reaffirming her view that 'antibiotics definitely do work better on her' (099).

093		I mean if there was a way I thought she was going to be all right
094		in a couple of days ( ) I know it sounds awful
095		if I've got the antibiotics into her
096		I'm ( ) a busy person myself I'm ( )
097		back and forward to jobs you know and I can't
098		[laughing] I know that sounds awful
099		but ( ) the antibiotics definitely do work better on her ( )
100		I would say so
101	D	excuse me a second [answers phone] yes okay um ( )
102		have you found any particular one to be more helpful
103		than any other?
104	M	umm ( ) the clear one

There is the clear implication ("I'm a *busy person* myself") in this turn that if M had more *time* to be with her daughter, then D's preferred strategy of using simpler measures could well have been accepted. M insists on her guilty feelings (094) about pursuing this preference, repeating the expression (after laughter) in line 98. However, the laughter re-frames the confession of 'guilt' as formulaic, an interpretation which is ratified by her next comment, a further and emphatic justification for her choice ("the antibiotics *definitely* do work better on her") From that point onwards, the consultation proceeds with checks about specific antibiotic suitability and closes with explicit expressions of gratitude by M.

Case 2: Ali

Ali, who has been suffering from a high temperature for a day or so is brought by his parents. The father, for whom English is a second language, does the talking. The doctor has completed his examination and has explained that Ali has got 'tonsillitis'. We enter the transcript at the point where the doctor is asking about the father's views (077)

Parental ideas about possible management

075	D	now (2 0)
076		did you have any ideas as to how we should
077		deal with this ( ) problem?
078	F	actually I have a ( ) other son [D mmm] ( )
079		six and a half years old [D mmm] ( ) he had
080		lots of problem ( ) about his tonsils ( )
081		the same problem ( ) actually he [all come?] now
082		he finished this problem (1 0) he's coming to age seven
083		( ) so ( ) I think it is better to keep the child from cold
084		( ) no cold drinks? something like that ( )
085		I don't know any more

Prior experience

F responds to D's question without surprise, and describes a similar previous event with another son However, the only course of treatment suggested is that the child should be "kept from cold drinks something like that", the partial disclaimer indicating that he is not expert in any *real* knowledge on this account This reticence suggests that F is treating D's invitation to contribute as rhetorical, as if he knows that D is the *real* purveyor of knowledge – even though he (F) has previous knowledge of the condition with another child

Normality

```
086    D    okay ( )  the the ways we deal with tonsillitis ( )  um ( )
087         it's quite normal for children to have this kind of problem
088         ( ) yeah? d'ya?
                              [
089    F    yes=
090    D    =it comes and goes it's usually a viral infection
091         a virus okay? ( )
092         which means that (1 0) I would like you to u_se ( )
093         either Disprol or Calpol to keep the temperature down
```

D's reaction is to 'normalise' the condition by emphasising its *regularity* [16] by reassuring the parents that "this kind of problem" is something that "comes and goes" This is 'advice as information' again [15] He also takes the opportunity to establish that it is a viral infection and explain why he doesn't want to prescribe antibiotics.

Personal views on risks and benefits of treatment

```
100    D    right? ( ) now ( ) some people then ( ) like to use ( )
101         antibiotics as well ( )
102         but ( ) I'm not so keen because
103         antibiotics don't deal with viruses ( )
104         they just ( ) are no use (1 0)
105         and they also cause some problems ( )
106         they sometimes cause diarrhoea and vomiting ( ) um ( )
107         and it means that you have ( ) problems for the future (1 0)
108         so ( ) those are the kind of possibilities (1 0)
109         which ( ) which way would you like to deal with the problem?
110         (1 0)
111    F    actually if I use antibiotics for my children ( )
112         the problem ( ) is ending in a short time ( )
113         which I ha ob observe ( ) but the the another way ( )
114         some paracetamol or things yeah (1 0)
115         it will end but a little bit more than the uh ( )
116    D    yes take a bit longer=
117    F    =yeah take longer
118    D    sure I understand ((yeah))
119         (1 0)
120    F    so it's it's uh ( ) family I mean the uh parents we don't (1 0)
```

121		want to see our children (.) going down I mean getting weak
122	D	[quietly] sure=
123	F	=so we want to take some (.) antibiotics

D enforces his position by mentioning harmful side effects ("diarrhoea and vomiting") as well as "problems for the future". After describing these possible effects, the question "which way would you like to deal with the problem" (line 109) would seem loaded – but F too has a clear stand on the issue of antibiotics, gained from his own experience of watching his children "going down".   On a superficial level, D has offered clear involvement, but the undercurrents are clear.

124		(1.0)
125	D	you would like to do that would you?
		[
126	F	yeah
127	D	yeah?
128	F	yeah ( ) it is too difficult to to explain but (2 0)
129		if we can uh (2 0) can be encouraged by doctors yeah
130		we can do some uh paracetamol
131	D	sure=
132	F	=we cannot lie
133		( )
134	D	my own feeling is that
135		you're probably better to use paracetamol and fluids
136		rather than use antibiotics
137		because you can cause sickness
138		and also resistance for the future
		[
139	F	I see
140		yeah I understand
141	D	um ( ) but if you feel strongly
142		that you would like to definitely have an antibiotic
143		we can do that as well ( )
144		um the other possibility's for me to give you
145		a prescription for an antibiotic
146		and for you to wait
147	F	I see ( ) yeah
		[
148	D	and and only use it
149		if things get worse
150		you can give me a telephone call or something
151	F	yeah ( )
152	D	so which one of these possibilities would you like to do?
153		(1.0)
154	F	okay [slight laughter in voice] let me ask my wife
155		[to M] which one paracetamol or ( ) antibiotics?
156		( ) antibiotics?

Presenting and perceiving the choices available

Ali's father, like Tracey's mother, would prefer to receive antibiotics but the doctor attempts to change F's opinion by listing potential problems (134-138). This is the 'firmest' position that D has taken so far, and it would have been interesting to see what might have happened had F remained strident in his request for antibiotics at this stage. He appears to back down, however, conceding, "I see yeah I understand" (line 139-140). D accommodates to this concession in F's stance by offering a compromise, stating that he is prepared to give a 'delayed prescription'. Three choices have now been offered: 1) paracetamol only; 2) paracetamol and antibiotics; and 3) paracetamol and the possibility of antibiotics in a few days. However F seems to consider only a straight choice between paracetamol and antibiotics, which is translated in F's version to his wife as "which one, paracetamol or (.) antibiotics?" he then repeats his preferred choice "antibiotics?" before M responds in their own language (inaudible on tape).

The husband and wife share a decision

		[After a subdued and brief laugh, M responds to F at some length in their own language, quietly and insistently]
157	F	yeah paracetamol this time please [M still talking quietly to F]
158	D	okay (2.0) Disprol or Calpol?
159	F	yeah
160	D	which one? doesn't matter
161	F	I see uh Calpol is uh eh better than paracetamol or euh which one?
		[M whispers to F throughout]
162	D	children like it a bit better than most stuff [laughing]
163	M	yeah=
164	F	=okay

The outcome of this brief interaction is surprising. In one short utterance (line 157), F states his new preference and (while his wife continues to speak to him in a quiet voice) offers no further contribution whatsoever to the decision, only giving his son's age, the family's address, some minimal feedback and a farewell. It is as though the entire preceding discussion has been wiped out. His wife meantime is busy thanking D and bidding him goodbye (175-182).

175	M	thank you very much
176	D	no problem and he's you know he'll be healthy fine
177	F	okay
178	D	okay no problem
179	M	thanks very much
180	D	bye bye now
181	F	bye bye
		[
182	M	bye

Comparison of the cases with suggested shared decision making competences
The cases are compared against each competency (see Box 3) in turn:

- *Establishing a context in which patients' views about treatment options are valued and necessary*
  Given that these are first consultations, a 'context for respecting views' cannot be assumed or easily achieved. Nevertheless, 'views' are elicited Tracey's mother clearly wants antibiotics. Ali's father is asked about his 'ideas', and although this is taken to be a rhetorical query, he declares his preference.

- *Eliciting patients' preferences so that appropriate treatment options are discussed*
  In both cases attempts are made to 'discuss' their preferred choice. It seems as if the defensive position prevents the doctor clarifying the parental expectations and to gauge reactions to the information provided about the undesirable effects of prescribing antibiotics.

- *Transferring technical information to the patient on treatment options, risks and their probable benefits in an unbiased, clear and simple way*
  The doctor does not transfer *detailed* information about the harms and benefits of the treatment options Perhaps uncertainty about the exact diagnosis and treatment outcomes makes this a difficult process to contemplate. There is however an attempt to convey 'normality' in both consultations, and that such episodes are self-limiting.

- *Clinician participation includes helping the patient conceptualise the weighing process of risks versus benefits, and ensuring that their preferences are based on fact and not misconception*
  There is no assessment of risk and benefit in either case. The emphasis is on obtaining parental acceptance of the self-limiting nature of the problem Weighing harms against benefits of the three options (no treatment, symptomatic treatment, and antibiotic provision), in terms that can be readily assimilated does not occur.

- *Shared decision making involves the clinician in sharing his treatment recommendation with the patient, and/or affirming the patient's treatment preference*
  The doctor has attempted to use the concept of 'normality' as a means of persuading the patients to accept symptomatic treatment. It is to be *expected* that young children will develop upper respiratory tract infections, and the doctor wants to avoid its medicalisation. But this 'normality' is in fact the unshared decision. The doctor tries to change Ali's father's preferred choice and this does not fit into the underlying tenet of the 'shared decision' method. It is noticeable that the conflict is suddenly resolved by the decisions to use or not use antibiotics. the haste, by both parties, to complete the

consultations after this point is clear. The doctor is unable to affirm the preferred option and we are left sensing an unacknowledged acceptance that one party has achieved their 'choice' at the expense of the other.

Discussion

Shared decision making [5] is made difficult when differing opinions about the 'best' treatments exist. Some components of the shared decision making method can be discerned, but they are incomplete. Albeit briefly, treatment preferences are explored but (from a professional perspective) 'misconceptions' remain, and the 'affirmation' stage is not convincing in either meeting. Perhaps the approach would succeed if more attention were given to the competences. If expectations and experiences were explored, if options and risks were fully explained, then it would be more likely that agreement and satisfaction with conservative management could be achieved. But it is rare for clinicians to carefully explore expectations [18, 19] and we also suspect that the stages of 'shared decisions' are rarely employed in general practice. They would at least double the consultation length. Employing such methods may be one way to successfully change prescribing patterns — we simply don't know. As matters stand within general practice in the United Kingdom [20], clinicians are prone to acquiesce to parental requests for antibiotics.

The other explanation is that the theoretical competences of shared decision making are flawed, so divorced from the realities of busy clinical environments as to be unworkable. Observed practice reveals that clinicians either acquiesce, take up positions of 'friendly persuasion' [21] or use other strategies, such as the mixed messages implicit in the offer of delayed prescriptions, in order to preserve their 'evidential' standpoint. These tactics have not succeeded in curtailing the inappropriate use of antimicrobial therapy.

These two consultations demonstrate the tension between 'best practice' and pragmatism [19, 22]. The scenario is recognised as one of the most 'uncomfortable' prescribing situations in which clinicians find themselves [23]. Providing an antibiotic for a viral illness is costly, illogical, contributes to the increasing levels of drug resistance [24], *rewards* attendance with viral illnesses and leads to a vicious circle of re-attendance, with the result that workload for self-limiting illness spirals over future family generations [25, 26].

Evidence based medicine promotes rational decision making but patient requests are influenced by many other factors and often deviate from the professional view [27]. One important constraint is uncertainty — there is always a worry that viral type symptoms may be precursors of more sinister illnesses, such as meningitis [28, 29]. The clinician's position is made yet more difficult by the fact that the parent's satisfaction seems to depend entirely on receiving the tangible representation of 'getting well' — an antibiotic [30].

Decision making: approaches and dimensions

Decision making within the medical consultation can be considered to have three dimensions: the locus of the decision, availability of information about the choice to be made, and value systems (the patient's experience, fears and expectations and the clinician's world view e.g. one based on empirical evidence). Two of these dimensions are illustrated in Figure 1 and the three decision making methods represented.

Figure 1 Decision making and the availability of information in consultations: a conceptual model
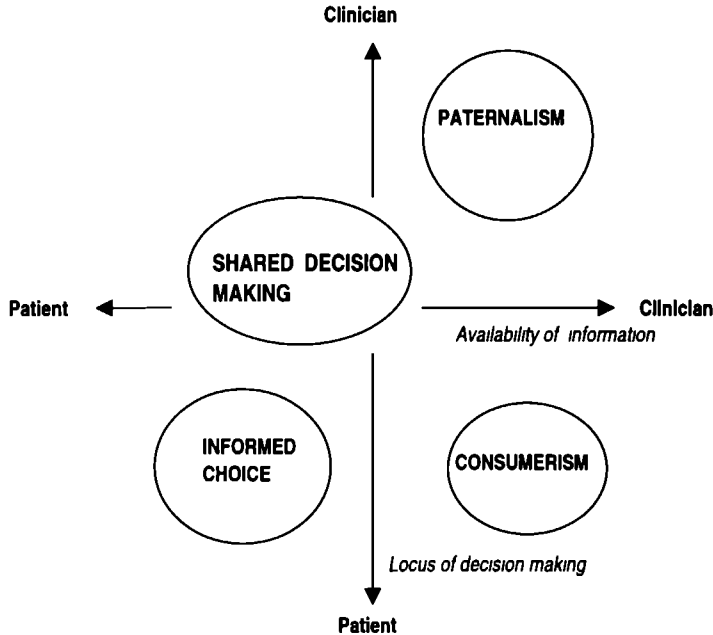
The model illustrates the tension within these consultations. Decisions were not made unilaterally by the clinician (paternalism). Tracey's mother was 'allowed' to take a decision but it could be argued that she was not well 'informed'. The 'shared decision making' approach does not fully encompass the cases either. The clinician retained the locus of decision making in Ali's case, but relinquished it in Tracey's situation. Information was *held* by the clinician in both cases but there was little attempt to share details, at least to the point where the parents are fully informed.

Perhaps the opposite of paternalism is consumerism, where the utility of 'evidence' is more precarious. This conceptual framework illustrates the fragility of a rational model when in fact decisions are influenced by so many different parameters [31]. Table 1 illustrates the pragmatic approaches that are available in these situations: acquiescence, negotiation, or paternalism.

Table 1   Potential consulting styles available when patient views differ from the 'evidence' of best treatment

	Patient held views or prior experience about treatment choices disagrees with (evidence based) views of clinician
Acquiescence	Provision of antibiotics is the 'easy' route to avoid conflict and achieve superficial patient satisfaction
Negotiation	'Friendly persuasion' may achieve conservative management if time is spent matching explanatory models, but conflict also possible
Paternalism	Paternalism: opportunities for discussion not provided

Contexts that favour shared decision making

Professional 'equipoise' about the outcomes of decisions is an important criterion that enables shared decision making to take place, and which is missing in these cases. It allows patients the 'freedom' to choose preferred options. Many decisions in medicine have this quality. But professionals cannot maintain 'equipoise' on all issues. It is also clear that concerns about power asymmetry in the clinical context need to be reformulated when such clear expressions of treatment preferences are witnessed. Similar findings in the private sector emphasise the need to re-examine assumptions in this field [32]. There is a large literature on the preferred roles of patients in clinical decision making [33, 34] which has been comprehensively reviewed by Guadagnoli [2]. The majority of the work to date is unfortunately based mainly on hypothetical scenarios. To examine patient preferences (or perceptions) about their involvement in decisions prior to an exposition of options pre-judges the issue. It is also important to understand how both parties in these consultations viewed their respective contributions to the decision making process, and exit interviews will be an important aspect of future research in this area.

Conclusion

The current understanding of shared decision making needs to be developed for those situations where there are disagreements due to the strongly held views of the participants. This is not to argue for 'paternalism'. There are many advantages to 'shared decisions' — they maintain the ethic of patient autonomy, meet the legal needs of informed consent, ensure that treatment choices are in line with individual values and preferences and are linked to improved health outcomes — but there are limits.

It could well be that training health professionals in the skills of sharing decisions will turn out to be the most successful way of achieving appropriate decisions, as judged against the criteria of 'effectiveness', patient agreement and satisfaction, both in situations of *equipoise* about 'correct' treatment choices and conflict between professional and patient preferences. But as yet we do not know if the shared decision making approach is either effective or practical. We suspect that more time is needed to explore, explain and enable the process [35], and that clinicians need to improve their communication skills and the content of the information they provide during the portrayal of options. Meanwhile, Tracey 'always seems to be on antibiotics'.

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Chapter 4

Shared decision making observed in clinical practice: visual displays of communication sequence and patterns

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Abstract

The aim of the study was to examine the communication strategies of clinicians attempting to involve patients in treatment or management decisions. This empirical data was then compared with theoretical 'competences' derived for 'shared decision making'. The subjects were four clinicians, who taped conducted consultations with the specific intent of involving patients in the decision making process. The consultations were transcribed, coded into skill categorisations and presented as visual display using a specifically devised sequential banding method.

The empirical data from these purposively selected consultations from clinicians who are experienced in shared decision making did not match suggested theoretical frameworks. The views of patients about treatment possibilities and their preferred role in decision making were not explored. The interactions were initiated by a problem-defining phase, statements of 'equipoise' consistently appeared and the portrayal of option information was often intermingled with opportunities to allow patients to question and reflect. A decision making stage occurred consistently after approximately 80% of the total consultation duration and arrangements were consistently made for follow-up and review. Eight of the ten consultations took more than 11 minutes — these specific consultations were characterised by significant proportions of time provided for information exchange and patient interaction.

The results demonstrate that some theoretical 'competences' are not distinguishable in practice and other stages, not previously described, such as the 'portrayal of equipoise', are observed. The suggested ideal of a shared decision making interaction will either require more time than currently allocated, or alternative strategies to enable information exchange outside the consultation.

Introduction

What should happen — and what actually happens — when clinicians actively attempt to involve patients in management decisions? There is an increasing interest in the effect of forming partnerships with patients, especially with regard to decision making and the positive effect that this is believed to have on health outcomes [1] Although there are theoretical descriptions of the stages and skills required for 'shared decision making' within clinical consultations [2-5] there is a scarcity of empirical work that examines actual practice and tests the conceptualised models [6]. A series of qualitative studies have identified specific competences for shared decision making (see Box 1) [4, 7] This conceptualisation of shared decision making has been partly confirmed by Towle, working in a different context [5] Towle's framework emphasises the need to make the process explicit at the outset by identifying the patient's preferred decision making style at the inception of the clinician-patient relationship and to explore the patient's preferred role in the decision making process before options and further information are provided Another similar theoretical construct — Dowell's 'concordant therapeutic alliance' model — is based on an agreement of jointly identified and negotiated goals [8]

Box 1   Stages and competences of involving patients in healthcare decisions [4]

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 (e g ideas, fears, and expectations of possible options)
6	Checking process Acceptance of process and decision making role preference, involving patients to the extent they wish to be involved
7	Make, discuss or defer decisions
8	Arrange follow-up

Yet both theorists and clinicians are aware of the inherent barriers to achieving 'involvement' — power and information imbalance, time limitations, variable motivations, attitudes and unknown preferred roles of both patient and clinician in the process — and are therefore ambivalent about the concept of defining professional skills [9], and suspect that the inherently unequal power dynamic within consultations may prevent a successful provision of options and information about risk [10, 11] Clinicians in particular, raise issues such as data accessibility, validity and complexity, and question the ability (or wish) of patients to become actively engaged in decisions [6, 12] Schneider similarly raises these concerns from the perspective of patients, particularly when they have other priorities, such as symptoms and anxieties foremost in their minds [10]

It is important therefore to consider how clinicians faced with the reality of service workloads undertake the task of involving patients in decisions. Can communication patterns be identified in these consultations? We were not aiming at this stage to make value judgements about the consultations and did not set out to assess whether some clinicians were more or less skilled than others [13]. The research aim was to identify the communication patterns within consultations where attempts were being made to involve patients in clinical decisions in order to, firstly, test the theoretical competences frameworks, secondly, to observe the effect on consultation duration, and thirdly, to analyse whether the proposed time order patterns suggested within the models are confirmed.

Method

The consultations, clinicians and practice

Consultations were purposefully selected for audio taping by anticipating those patients who would return for the results of investigations and discussions about future management. The clinicians had positive attitudes to the concept of 'sharing decisions' with patients. Two clinicians are researching this field (GE, AE), the others (SM, HJE) were familiar with, and motivated to use, the concept of 'sharing decisions' with patients. This ensured that consultations were obtained in which 'shared decision making' occurred — information-rich cases that are otherwise difficult to study because it is difficult to obtain the conditions of patient consent and clinician co-operation to obtain the specific empirical data. In all other respects, the consultations took place under normal conditions. It became clear that we were selecting conditions characterised by clinical 'equipoise'— situations where the clinician, fully informed about the problem, has no predetermined view about the preferred management or treatment that the patient should follow (Box 2).

Box 2   Conditions selected for recording and transcription

Atrial fibrillation Anticoagulation with warfarin offers more protection against thromboembolic events than the use of aspirin or no treatment [14]. But anticoagulation also poses significant risks [15]. Warfarin may be the most effective treatment—in terms of preventing strokes—but there is no certainty that all patients would 'prefer' this treatment if they were fully informed

Lower urinary tract obstruction symptoms In broad terms, three options exist to manage the symptoms of lower urinary tract obstruction —watchful waiting, medication or surgical interventions—and each has associated risks and benefits [16] Patients may prefer to take no action if their symptoms cause little 'bother'. Impotence is potential side effect of medication and retrograde ejaculation, impotence and incontinence can occur following surgery [17, 18].

Cholesterol The management of marginally raised cholesterol requires an interpretation of a wide range of risk factors (age, blood pressure, smoking status), and consideration given to the potential harms associated with the medication as well as the anticipated benefits [19]

Hormone replacement therapy Clinicians vary in the advice they provide about the pros and cons of hormone replacement therapy when used in the prevention of osteoporosis, especially about the weight given to the risk of developing breast cancer

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Clinicians perceive these situations as ones where 'legitimate' choices are available precisely because clear pros and cons exist for each option. In addition to the medical issues involved, such decisions are likely to require an exploration of the patient's likely experiences and perceptions, which are intimately related to the

quality of life and value judgements that are implicit within such decisions. (We recognise that 'equipoise' in this context is a professionally defined concept and that it is equally possible that some patients would like involvement in decision making in other clinical scenarios, thus extending the applicability of this characteristic.) The conditions selected are described in Table 1. The patients were from practices in South Wales.

**Table 1 Conditions discussed and patient details (C1-10)**

Consultation	Condition	Patient Age / Sex	Date	Clinician	Years in practice
C1	Atrial Fibrillation	69 Female	1998	AE	4
C 2	Lower urinary tract obstruction symptoms	63 Male	1998	SM	2
C 3	Lower urinary tract obstruction symptoms	52 Male	1998	AE	4
C 4	Cholesterol (raised blood levels)	73 Female	1999	HJE	1
C 5	Atrial Fibrillation	79 Female	1999	GE	13
C 6	Atrial Fibrillation	75 Female	1999	AE	4
C 7	Cholesterol (raised blood levels)	28 Male	1999	AE	4
C 8	Lower urinary tract obstruction symptoms	58 Male	1999	AE	4
C 9	Lower urinary tract obstruction symptoms	60 Male	1999	AE	4
C 10	Hormone replacement therapy	51 Female	1999	AE	4

Visual Display by Sequential Banding and Category Mapping

'Shared decision making' has been conceptualised as a series of interactive skills and stages and it was vital therefore to view consultations as sequences of meaningful stages and avoid techniques that could not distinguish these patterns by analysing the frequency coding of small speech units. A decision was therefore made to develop a visual format to display patterns within consultations.

Each consultation was transcribed using the line-numbering conventions of conversation analysis (the full transcripts are available from the authors). Copies were sent to three collaborators (GE, AE and MW) who, although they liaised and negotiated an agreed understanding of the banding categorisations, undertook the coding process independently of one another. At each coding cycle, banding decisions were discussed where disagreements occurred and the category definitions clarified. The assumption used for coding was that the clinician directs the consultation process or at least determines the time provided to differing stages within the interaction. The prime indicator to define a new coding for a sequence of text within the transcript was based on the questions: at what point in the consultation does the clinician move to a new task? The on-line transcripts are colour coded to delineate the banding segments. The duration (in seconds) of each band was calculated. Full agreement on the banding categorisations was achieved after three coding cycles. This categorisation data was converted into a visual display, termed sequential banding (Figure 1). This enabled the similarity, complexity and variation within interactions to be assimilated and compared to theoretical frameworks.

Figure 1 Banding Analysis: consultations 1- 10
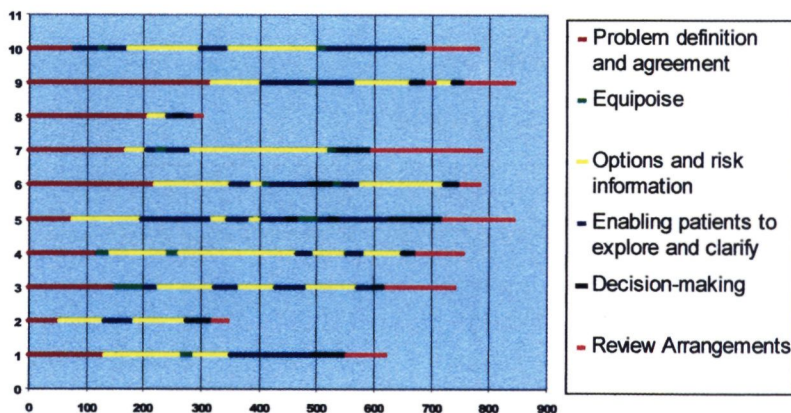
Results

Testing the theoretical model

In an earlier conceptualisation of 'shared decision making' we had listed 8 theoretical competences (Box 1) [4, 20]. Our initial attempts at coding using this framework were unsuccessful. During the iterative coding process we observed that the first activity in each consultation was one of 'problem definition' and decided that this stage should be categorised. The consultations consistently contained sequences where the clinicians were aiming to convey that the clinical problems could be managed in more than one way — that legitimate choices existed for patients — implying an active need for patient involvement. We termed and categorised examples of this *talk* as the portrayal of clinical 'equipoise'. During the early iterations of this process it also became clear that although 'option portrayal' and 'information provision' (risk communication) both occurred within the discourse, the processes are tightly interwoven and we were unable to agree code distinctions between these categories. The difference between a clinician checking for concerns and understanding (enabling a patient to become involved) and exploring a patient's preferred role in the decision making process was similarly difficult to distinguish. Therefore the categories of 'option portrayal' and 'information provision', and 'checking' and 'exploring', were respectively combined. By this adaptation of our initial framework, six coding categories (see Box 3) were agreed.

Box 3   Empirical model for involving patients: a coding categorisation for banding and mapping analysis

Transcript sections were coded as discrete categories by determining the clinician's main strategy during that section of the consultation.

1. *Problem definition*: this occurs when the professional is clarifying the reason for attendance and reaching an agreement with the patient about the problem for which a treatment or management plan needs to be considered. This section is deemed complete when the professional talk indicates that this task is completed and another stage is initiated.

2. *Equipoise*: this is defined as stating a position of equal balance. In the context of a consultation *equipoise* occurs when a clinician uses phrases to indicate to the patient that there are a number of management possibilities available. In other words, the clinician is explicit about the fact that there is no fixed professional view, and that it is legitimate to discuss choices in more detail. This explanation, if it occurs, sets the scene for listing options.

3. *Options and information about options (risk communication)*: in this stage a number (two or more of the management options) are listed and described. Whether a brief list of options is followed by more detailed information about each option in turn or whether detailed data is provided when each option is mentioned does not affect the coding of this stage.

4. *Enabling patients to explore their concerns and queries*: within this stage the clinician indicates the opportunity for patients to voice their concerns and questions about the choices and information provided, to declare their anxieties and to voice any difficulties or misunderstandings.

5. *Decision making*: at this point in the consultation, an indication is given that it is time to arrive at, or to agree to defer, a decision

6. *Review arrangements*: the clinician agrees with the patient's suggestion, or initiates strategies to review decisions at a further point in time.

The visual data displays of agreed categorisations

The sequential banding is shown in Figure 1. The process involved displaying the categories longitudinally in a chronological order according to their duration within the consultation. Actual timings rather than proportions of total duration are displayed and calculations made about the relative contributions of each stage to the overall interactions (Table 2).

Table 2   Proportion of total time coded by category (C1-10)

Category	Minimum %	Maximum %	Mean %
Problem definition	9	69	25
Option information	11	58	35
Enabling	6	37	18
Equipoise	0	7	3
Decision making	2	13	7
Reviewing	5	24	12

Tabulated categorisation data are provided in Table 3.

Table 3   Consultation banding and sequencing: categoriations durations

Consultation 1: Atrial Fibrillation	No of text lines	Time (seconds)	Consultation 2: LUTS	No of text lines	Time (seconds)
Problem definition and agreement	56	133	Problem definition and agreement	20	54
Options and risk information	54	128	Options and risk information	28	76
Equipoise	11	26	Enabling patients to explore and clarify	17	46
Options and risk information	26	62	Options and risk information	36	98
Enabling patients to explore and clarify	61	145	Decision making stage	17	46
Decision making stage	25	59	Reviewing arrangements	9	24
Reviewing arrangements	28	67			
	Total 261	**Total 620**		**Total 127**	**Total 345**

Consultation 3: Atrial Fibrillation	No of text lines	Time (seconds)	Consultation 4: Hypercholesterolaemia	No of text lines	Time (seconds)
Problem definition and agreement	51	152	Problem definition and agreement	46	119
Equipoise	17	51	Equipoise	8	21
Enabling patients to explore and clarify	5	15	Options and risk information	37	96
Options and risk information	35	104	Equipoise	9	23
Enabling patients to explore and clarify	12	36	Options and risk information	79	205
Options and risk information	24	72	Enabling patients to explore and clarify	9	23
Enabling patients to explore and clarify	16	48	Options and risk information	25	65
Options and risk information	32	96	Enabling patients to explore and clarify	10	26
Enabling patients to explore and clarify	9	27	Options and risk information	28	73
Decision making stage	4	12	Decision making stage	6	16
Reviewing arrangements	43	128	Reviewing arrangements	34	88
	Total 248	**Total 740**		**Total 291**	**Total 755**

Consultation 5: Atrial Fibrillation	No of text lines	Time (seconds)	Consultation 6: Atrial Fibrillation	No of text lines	Time (seconds)
Problem definition and agreement	33	77	Problem definition and agreement	66	219
Options and risk information	52	121	Options and risk information	40	133
Enabling patients to explore and clarify	49	114	Enabling patients to explore and clarify	9	30
Options and risk information	15	35	Options and risk information	7	23
Enabling patients to explore and clarify	17	39	Equipoise	1	3
Options and risk information	5	12	Enabling patients to explore and clarify	23	76
Enabling patients to explore and clarify	21	49	Decision making stage	12	40
Decision making stage	7	16	Equipoise	5	17
Equipoise	18	42	Enabling patients to explore and clarify	8	27
Enabling patients to explore and clarify	4	9	Options and risk information	47	156
Equipoise	4	9	Decision making stage	7	23
Decision making stage	3	7	Reviewing arrangements	11	37
Enabling patients to explore and clarify	43	100			
Decision making stage	39	91			
Reviewing arrangements	52	121			
	Total 362	**Total 840**		**Total 236**	**Total 783**

Consultation 7: Cholesterol/Blood Pressure	No of text lines	Time (seconds)	Consultation 8: LUTS	No of text lines	Time (seconds)
Problem definition and agreement	63	168	Problem definition and agreement	88	208
Options and risk information	13	35	Options and risk information	14	33
Enabling patients to explore and clarify	4	11	Enabling patients to explore and clarify	3	7
Equipoise	10	27	Decision making stage	9	21
Enabling patients to explore and clarify	12	32	Enabling patients to explore and clarify	5	12
Options and risk information	92	245	Reviewing arrangements	8	19
Equipoise	3	8			
Decision making stage	25	67			
Reviewing arrangements	71	189			
	Total 293	Total 780		Total 127	Total 300

Consultation 9: LUTS	No of text lines	Time (seconds)	Consultation 10: HRT	No of text lines	Time (seconds)
Problem definition and agreement	113	316	Problem definition and agreement	29	77
Options and risk information	31	87	Enabling patients to explore and clarify	15	40
Enabling patients to explore and clarify	30	84	Equipoise	7	19
Equipoise	3	8	Enabling patients to explore and clarify	11	29
Enabling patients to explore and clarify	23	64	Options and risk information	50	133
Options and risk information	37	104	Enabling patients to explore and clarify	15	40
Decision making stage	8	22	Options and risk information	61	162
Reviewing arrangements	6	17	Equipoise	3	8
Options and risk information	12	34	Enabling patients to explore and clarify	57	152
Decision making stage	4	11	Decision making stage	11	29
Reviewing arrangements	33	92	Reviewing arrangements	34	91
	Total 300	Total 840		Total 293	Total 780

Sequence and relative proportions

Clinicians devoted a substantial part of these consultations to formulating and agreeing a 'problem', spending on average 25% of the time on this task. The range was wide (9-69%) however and the transcripts reveal the variations in complexity and degree of clarification that are necessary at this stage. In a similar way, reviewing arrangements were consistently identified at the end of these consultations. This illustrates that these types of consultations are deemed to require follow-up appointments, and that ongoing aspects of the plan are typically monitored. On average 12% of the total time was devoted to this 'reviewing' stage.

Figure 1 demonstrates the patterns that are visible during the mid-phases of the consultations. When the problem definition component of the consultation is completed, clinicians in seven of these consultations take a definite turn within the interaction and set out 'options' to the patients. Interlinked closely with talk of choices is the provision of information about the associated risks and benefits. There was no clear pattern discernible: it did not appear that information about the pros and cons of options were not provided in any ordered sequence.

In two of the consultations, the clinician (AE) makes a statement about 'equipoise' (see Box 3) immediately after the 'problem definition' stage. In one other consultation (C10) a short passage of 'enabling' interaction occurs before the concept of 'equipoise' is explained. Equipoise talk is present within eight of these consultations in all, and occurs twice in four of them (C4-6 and C10). These are relatively short segments and, when present, take up on average 3% of the total time.

The mid-phase of these interactions illustrates the extent to which two-way interactions take place between patients and the clinicians. 'Patient enablement' follows talk about 'options'. Consultations C3-7, C9 and C10 contain numerous switches between these stages and demonstrate the interactive nature of the discussion. For these consultations the time provided for 'patient enablement' averages 18% of the total. Every consultation contains a stage where the clinician took a speech turn (or turns) in order to focus on a decision, even if the eventual outcome is one of decision deferral. There is a consistency to the timing of this stage, irrespective of the total consultation length. By calculating the start of the main decision making sequence within the consultations it was noted that this stage regularly occurs close to 80% of the total duration.

Duration of consultations

Eight of the consultations are longer than 10 minutes in length (mean 11 minutes 18 seconds, median 12 minutes 47 seconds). When the two shorter consultations (C2: 5 minutes and C8: 5 minutes 45 seconds) are compared to the others, the results demonstrate that 6% and 13% (respectively) of the total time is given to 'enabling' the patient to discuss issues within the consultation whereas the mean time proportions provided for 'enabling' within the other consultations is 19%.

Discussion

Principal findings

Designing a method of displaying the categorisations to be displayed in linear time using sequential colour banding facilitates the examination of complex patterns of communication, and the mechanism will be developed in further studies using a larger number of consultations. This in-depth study of motivated clinicians *intent* on 'sharing' decisions shows that their practice does not match existing theoretical frameworks, and that even within the practice of one clinician (AE), where 7 consultations were collected, extensive variation and adaptation can be seen within the communication patterns. Secondly, there are identifiable patterns (including new components) within their communication strategies. Thirdly, it appears likely that shared decision making interactions will either require more time than currently allocated in general practice [21], or alternative strategies devised for fulfilling the necessary amount of information exchange, either before or within face to face interactions. The fixed (in relative terms) point of the decision making stage within consultations indicates the extent to which the clinician remains in covert control.

The portrayal of 'equipoise' seems to be a technique that legitimatises patient participation. The following excerpt from C1 illustrates its use:

> **Doctor:** *'um (.) I think (.) as you say you don't want to have a stroke (.) there is a good case I would say to having some treatment (.) the question is which <u>one</u> and I think to be <u>honest</u> um many (.) doctors would be divided as to the best treatment to go for (.) so it (.) it's probably a case of (.) not just <u>me</u> deciding the treatment (.) it's a <u>joint</u> decision I would say because (.) I couldn't say (.) from the heart for <u>definite</u> which one is the best one (.)'*
>
> [Pauses of less than 2 seconds duration are indicated by (.), and emphasis by <u>underlining</u>].

'Equipoise' is a consultation component that has not been previously described. And although it does not take up a significant amount of time within the consultations it seems to play a pivotal role. The declaration by a clinician that uncertainty exists about the best choice of treatment opens the way for a more open exchange of information about future management. The clinician is enabled to portray pros and cons and patients are absolved of their typically passive roles. In other words, stating equipoise acts as a catalyst for a more equitable exchange of views and facts.

The behaviours listed below are advocated in many consultation skills models:

- exploration of patient ideas, concerns and expectations about possible management options during the early stages of consultations [22-25]
- explicitly exploring the patients' preferred role in decision making [5, 7]
- negotiating the format of information [5, 7];

but they were not identified in these cases. Clinicians presented options and information and left the involvement process to be *implicit* within the discourse, thereby allowing patients to determine their own preferred degrees of involvement. This is not the first time that these stages have been found wanting in actual practice [6, 7, 26, 27]. Clinicians find these 'explorations' difficult to accomplish. Patients commonly regard such attempts as either rhetorical or irrelevant — the process usually requires clinicians explaining *why* they are interested in this information, and the time constraints of most clinical situations militate against success. The retort from patients: 'why are you asking me, you're the doctor' is very familiar to clinicians. These 'exploratory' elements have become the unchallenged mantras of communication skills training but it may be time to de-bunk the aspired 'ideal'. Lindblom's contention that empirical practice is based on the science of 'muddling through' [28] echoes our findings that clinicians in the field 'explore' issues by presenting practical options and teasing out the resulting issues.

Strengths and weaknesses

A new method of displaying data was developed because we were aware of the inability of code-category interaction analysis — frequency counts of small sections of speech — to illustrate communication patterns [29]. The strength of this work is the intensity to which empirical practice is analysed and the way in which an initial theoretical model (Box 1) was adapted to achieve an applied framework. We recognise that this report is based on a small sample of consultations, and from a small group of clinicians who work together on 'shared decision making' [4, 7, 30-34]. We do not therefore claim generalisability but wish to draw attention to the *particular*, and claim that these consultations provide examples of shared decision making in a clinical context. They point to the complexity of the interactions and the necessary adaptations that take place in such consultations. This degree of focus is justified by the fact that this style of practice is difficult to record and has not been examined in such depth previously. It is also accepted that conclusions regarding the success or otherwise of such communication strategies should be correlated with patients' *perceptions* of such exchanges and cannot be claimed by this method.

Implications for clinicians and policymakers

Clinicians are encouraged to develop ways of involving patients in management decisions. But the gap between ethical ideals, theoretical competences and what is feasible in practice is wide, and has been demonstrated across cultural divides [35]. The development of effective communication skills should be based on a synthesis of theory and practice, and should involve a critical examination of how feasible it will be to conduct successful participative interactions.

Evidence is emerging that a participative approach works best where there are legitimate patient choices [36]. Other approaches will be necessary where there is a need to 'direct' patients to change behaviours or adopt screening procedures, or where there are differing views about treatment preferences [31, 36]. The study highlights the limitations that will impede progress, even where clinicians have the necessary skills and attitudes, such as the time constraints of service environments, and the lack of methods that achieve accurate and accessible information exchange.

Unexplored territory

Although this study illuminates the shared decision making process, many questions remain. Perhaps other clinicians 'share decisions' using different methods? Perhaps the individuals in these consultations are 'unskilled' compared to others who have had similar training?

The perceptions of patients as they exit, reflect and discuss such consultations with others are also an integral part of assessing the success or otherwise of such participative interactions. There was no apparent evidence in these consultations that patient anxiety was generated or that they were reluctant to participate

but this requires confirmation [37]. The patterns observed give rise to the speculation that a patient's perception of 'successful' consultations would be those where time is distributed equally between 'information provision' and 'enabling' (e.g. C10), and undertaken by a technique described as 'chunking and checking' [38] (as in C4). It is also pertinent to ask whether there is a *minimum* length that denotes *sufficient* time for successful involvement. Both hypotheses require corroboration from the patient's perspective by further empirical studies.

A tension exists between the ethical positions that advocate 'mandatory' autonomy (patient preferences are disregarded), 'optional' autonomy (patient preferences are respected) and the complex diversity of clinical practice in the 'real world' where participation seems a rare event. How much pressure should there be on clinicians to change their styles of consulting? Will legal inquiry into acceptable levels of patient informed understanding be the ultimate lever for change? In summary therefore, although this work sheds light on *how* clinicians actually perform, it does not define how they *should* conduct this type of consultation.

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Section 2

The measurement of shared decision making

Chapter 5

Measuring the involvement of patients in shared decision-making: a systematic review of instruments

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Abstract

We wanted to determine whether research instruments exist which focus on measuring to what extent health professionals involve patients in treatment and management decisions. A systematic search and appraisal of the relevant literature was conducted by electronic searching techniques, snowball sampling and correspondence with field specialists. The instruments had to concentrate on assessing patient involvement in decision making by observation techniques (either direct or using audio or videotaped data) and contain assessments of the core aspects of 'involvement', namely: evidence of patients being involved (explicitly or implicitly) in decision making processes, a portrayal of options and a decision making or deferring stage. Eight instruments met the inclusion criteria. But we did not find any instruments that had been specifically designed to measure the concept of 'involving patients' in decisions. The results reveal that little attention has been given to a detailed assessment of the processes of patient involvement in decision making. The existing instrumentation only includes these concepts as sub-units within broader assessments, and does not allow the construct of patient involvement to be measured accurately. Instruments developed to measure 'patient centredness' are unable to provide enough focus on 'involvement' because of their attempt to cover so many dimensions. The concept of patient involvement (shared decision making; informed collaborative choice) is emerging in the literature and requires an accurate method of assessment.

Introduction

Although there is increasing interest in the outcomes of involving patients in aspects of healthcare decisions, albeit with a recognition that a flexible approach is needed in practice [1], there is no agreed construct to describe 'involvement' [2]. 'Patient centredness' is proving to be too ill-defined, [3] a method that in reality contains many constructs, and a recent comparison of instruments designed to measure it revealed the difficulty of achieving reliable tools [3, 4]. Although involving patients is an important element of patient centred practice, patient participation in decision making has not been defined in sufficient detail to allow rigorous evaluation. Research into the roles patients prefer within decision making processes has been mostly based on hypothetical scenarios [5, 6] and reveals a spectrum of views. Hypothetical determinations may not equate with the views of patients who have experienced actual involvement in decision making. There is evidence from studies on screening that the wishes of patients who are initially uninformed change after they have become aware of the harms and benefits of different treatment options [7]. This is likely to be especially true if the clinician is skilled at providing information and is sensitive to anxieties that may be generated by the potential responsibility of decision making. It is also important to conceptualise patient involvement as a process that will inevitably vary from one consultation to another. We were unaware of a method to measure 'involvement', and therefore undertook a systematic search of the literature with the aim of appraising the instruments identified.

Patient involvement can be viewed as occurring along a spectrum, from paternalism at one end to complete autonomy at the other [8]. 'Shared decision making' involves both the patient and the clinician being explicit about their values and treatment preferences [9]. The approach involves arriving at an agreed decision, to which both parties have contributed their views. The stages and skills of 'shared decision making' are being investigated by firstly using qualitative methods to investigate how clinicians and patients conceptualise 'involvement', and secondly by an empirical study which analyses consultations that aim to 'share decisions' [10-12].

Two assumptions underpin this review. Firstly, that involvement in decision making is a negotiated event that occurs between a clinician and patient, either explicitly, or as is more common, implicitly. The second assumption is that choices legitimately exist in most clinical situations, and that it is acceptable — vital according to those who place autonomy first amongst ethical principles — to portray options to patients, at least to some level of detail (excepting extremis, intellectual impairment, unconsciousness and psychiatric risk). Any attempt to measure involvement in decision making should therefore consider to what degree (if any) a health professional portrays choices and invites patients to participate in the decisions, along with other processes that may be associated (such as an exploration of views, concerns, and fears). Involvement is not considered as a rhetorical gesture. Successful 'involvement' starts from the position of respecting a patient's right to autonomy and self-determination, even when a fully informed patient, aware of a contrary

professional viewpoint, decides a divergent treatment or management plan. The ethical stance assumed here is one of optional autonomy rather than mandatory autonomy (where patient involvement in decision making is a requirement) [13].

Decision making in a clinical setting involves many factors, including prior experience, existing knowledge, trust and confidence in the clinician, personality traits, exposure and access to information, satisfaction with the consultation process, and the influence of family and others [13]. Despite this complex context, we consider that patient involvement in the decision making process within the consultation is an important construct to measure accurately, for many reasons. It is necessary if we are to gauge how involvement contributes to determining adherence to treatment choices, and whether involvement *per se* contributes in other ways to potential health gain.

Objectives

Having first appraised the literature on how professionals should most appropriately involve patients in decision making processes [14], and completed a qualitative study on the 'competences' required [11], we undertook a systematic search for instruments that focused on an evaluation of the extent professionals involve patients in decision making (and the quality) as observed by a third party. This is not to dismiss the literature that has focused on perceived involvement (as viewed by clinician and patient) and which has an important predictive effect on patient outcome [15, 16]. We consciously excluded such tools because of our focus on actual behaviour within the consultation. This is justified by an argument that each perspective (i.e. observed participation and the views of clinicians and the patients), needs robust measures so that valid comparisons can be made, and conclusions drawn about the most effective 'participatory' behaviours. Exploratory qualitative work provided a framework for our conceptualisation of patient involvement in decision making — see Box 1 [11, 17].

Box 1   Stages and competences of involving patients in healthcare decisions [11, 17]

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 (e.g. ideas, fears, and expectations of possible options)
6	Checking process: Acceptance of process and decision making role preference, involving patients to the extent they wish to be involved
7	Make, discuss or defer decisions
8	Arrange follow-up

We wanted to establish whether existing instruments were capable of providing valid and reliable measurements of 'patient involvement' to a level that is satisfactory for quantitative research purposes.

Methods

The methods of systematic reviewing have been developed primarily to summarise research that investigates the effectiveness of interventions [18]. This review applies the concept of a systematic and explicit method of assessment to the area of instrumentation. There are agreed methods for both developing and confirming the validity and reliability of health measurement instruments, which will be used as the basis for assessing the quality of instruments in this review [19].

Search Strategy

We sought to identify studies that reported the development or use of instruments that aimed to evaluate clinical interactions. Identified instruments were then assessed to see if they had the ability to measure whether, and to what extent, clinicians were, in a broad sense, 'involving' patients in health care decisions.

We searched the following databases: Medline (1986-98) CinAHl (1986-1999) Psychlit (1986-1998), Embase (1986-1998), ASSIA (1986-1998). The search strategy for Medline required articles to match against (i) one or more MeSH or textword terms relating to *decision making* or *patient involvement*, and (ii) MeSH or textword terms describing *methods of assessing the consultation*. The MeSH terms were correspondingly modified for use in different databases. Full details of the search strategy are available.

This subject area is not well indexed. We therefore used a strategy designed to achieve high recall/sensitivity rather than precision/specificity. A large number of titles and abstracts were generated from these searches. Two authors independently assessed this output and retrieved relevant articles for further assessment. Forward searches for citations of papers reporting the development and first use of relevant instruments were conducted on the Science and Social Science Citation Indices. We checked the reference list of identified papers and corresponded with 60 experts in this research area, determined by the authors as experts in the field of health communication research (list available).

Criteria for considering studies

Two criteria had to be met for studies to be included in this review, and were based on the widely agreed premise that patients can only contribute to the decision making process if choices are explored within the communication process. The measures had to:

1 involve assessments made by direct or indirect observation of the consultation (i.e. by audio or videotape recording)

2   include assessment of the core aspects of 'involving' patients 'in the process of decision making', and
         therefore contain items that covered at least one of the following stages (Box 1):
         a)   involvement of patients in decision making processes
         b)   a portrayal of options
         c)   a decision making or decision-deferring stage.

The inclusion criteria were applied in two stages. The first stage involved the evaluation of all identified instruments that measure patient-clinician interaction (actual or simulated practice). It could then be ascertained whether aspects of the second criterion were met. Decisions regarding inclusion/exclusion were checked by a second author (AE). Instruments that met both criteria were appraised in depth against an agreed checklist by two assessors (GE and AE), and by correspondence with the original authors when it was necessary to obtain further details.

Data extraction
Data extraction was carried out by GE and checked by AE. Authors were contacted with requests for copies of their instruments if details or questions were missing from published reports. Data were extracted in order to examine two broad aspects of the instruments. Firstly, descriptive features for each instrument were collected (Table 1): the stated aim, the theoretical or conceptual basis (or the theoretical or conceptual framework of the paper, methods of assessment, reports of instrument development and/or first use); the scenario(s) or aspects of the concept to be considered, the setting in which it was first used; and the apparent scope of its use. Included in these descriptive categorisations is information about the means of data collection and the existence of a guidance manual. Instruments that met the inclusion criteria were compared against a conceptual framework which describes the competences which professionals consider to be key features of patient-participation in decision making (see Box 1).

Secondly, there are the methodological issues that determine the quality of instruments and these are covered in Table 2. They concern the development of the scale (and its items) and to what extent validity and reliability have been assessed (see footnotes to Table 2) [19].

Results
The searching strategy identified a total of 4,929 abstracts from the following databases: combined listing from Medline, Psychlit and Embase, 2,460; CinAHI, 2,395; ASSIA, 74. After dual and independent assessments, a total of 107 articles were retrieved for detailed appraisal. Information and articles were received from 29 of the 60 authors contacted (see acknowledgements); 52 consultation assessment instruments that met only the first inclusion criterion of this review are listed in Table 3.

Reporting of results
Eight instruments were found to include items that measured patient involvement in decision making as defined by the inclusion criteria Descriptive details and an analysis of their development, validity and reliability data are provided in Tables 1 and 2 respectively It will be noted that there are four scales that fulfilled the 'measure involvement' criteria (see table 3) that are not appraised. Pendleton's Consultation Rating Scale [20], the Royal Australian College of General Practitioners [21], the Royal College of General Practitioners (UK) examination criteria [22] either had items which only mentioned the concept of involvement or in the case of the examination criteria were checklists that have not been subjected to any validation exercises in a research setting The Leeds Rating Scale [23] was not included as the concept of involvement was mentioned only as a broad approach within the interaction Using these strict criteria we would have also excluded the Calgary-Cambridge Observation Guides (formative assessment tools) but we felt the detailed items included deserved comparison with other existing instruments Both tables are arranged alphabetically by instrument name.

Synthesis of results
An appraisal of these instruments reveals that there has been an initial interest in the 'second half' of the consultation [14] but that very little attention has been given to a detailed assessment of the processes of participation [2] It is clear that involving patients in decision making, either implicitly or explicitly, providing treatment options, information about choices and then engaging in a decision making stage are 'constructs' that have not been considered to any significant depth in clinical interaction analysis. To date, the existing instrumentation only includes these concepts as sub-units within broader comprehensive assessments.

Constructs which are apparent in the literature (italics indicate phrases or items within original instruments)
Six constructs (Table 1) underpin the instruments that meet the inclusion criteria. Four of these are more focused in nature, and are concerned respectively with *problem solving* [24], *exploration of patient concerns* [25], assessment of patient *reliance* [26] and *informed decision making* [27]. The other constructs have broader scopes two aim to assess communication skills in a global sense [28, 29], and two aim to assess components of *patient centredness* [4, 30].

Problem-Solving Instrument (Pridham, 1980) [24]
Pridham's work considered *problem solving* and the *construction of self-management plans* based on the analysis of five consultations [24]. The method however was to assign codes to each 10-second interval and calculate counts of categorisations, namely 'scanning, formulating, appraising, willingness to solve, planning, implementing' (all applied to problems within the consultation) The instrument was not based on worded items No further work has been published on this instrument

Levels of Physician Involvement (Marvel, 1994) [25]

Marvel's [25] adaptation of Doherty's levels of clinician involvement with families [31] is included but the instrument does not fully address patient involvement in decision making. The prime aim of the measure is to evaluate the range of skills that clinicians use to address the psychosocial concerns of patients (and their families). For example, at the second level (of 5 ascending stages) the rater is asked to consider:

Level 2: Individual focus

Orientating question: What information should be exchanged with the patient to make the correct diagnosis and to design and agree upon a treatment plan?

Although options and decision making are not specified, the design and agreement could be understood as a measure of patient involvement. The primary aim is not to consider patient involvement in decision making, as items at other stages indicate.

Decision making Checklist (Makoul, 1992) [26]

The aim of this instrument is to assess how the consultation influences patients' perceptions of control and correlates with observed behaviours. Makoul's work was undertaken as part of a research thesis using a large sample of general practice consultations in the United Kingdom. The Decision making Checklist [26] (binary responses) concentrate on information provision. Three items (from a total of 24) focus on decision making:

Item 17	*Did the MD (doctor) ever seem to give the PT (patient) any responsibility for deciding how to deal with the health problem?*
Item 18	*Did the MD ever explain possible treatments to the PT?*
	(over and above naming the treatment)
Item 19	*Did the MD ever involve the patient in choosing a treatment for the health problem? (e.g. "which alternative")*

Informed decision making (Braddock, 1997) [27]

The aim of this instrument is to characterise the consent and decision making process in consultations. Braddock's coding of consultations using an informed *decision making* method [27] is an approach which, although it requires validation, has the benefit of having a firm theoretical stance and mirrors sequences that professionals suggest are needed in order to involve patients in decision making [17].

MAAS-Global (van Thiel, 1991) [29]

The aim of this instrument is to determine the degree of proficiency of medical interviewing skills. Van Thiel's adaptation of earlier MAAS scoring lists has resulted in the current MAAS-Global instrument [32]. This scoring list is now designed for use in general practice consultations. The sixth phase (named 'management') contains the following four items:

- *shared decision making, discussing alternatives, risks and benefits*
- *discussing feasibility and adherence*
- *determining who will do what and where*
- *asking for patient response.*

Scores are given to each phase (scored '0' for absent, 6 for excellent). The manual (in translation) indicates that the criteria for 'excellent' require that the clinician discusses the treatment plan and *provides the patient [sic] the opportunity to share his or her views*, that *the advantages and disadvantages of the treatments are described*, and that depending on the condition, it may be necessary to *discuss alternatives*. The criteria continue by addressing the need to be *sensitive to patient preferences* and to make *adequate review arrangements*.

Calgary-Cambridge Observation Guides (Kurtz, 1996) [28]

The aim of the Calgary-Cambridge Observation Guides is to act as a basis for formative assessment. The guides provide the most extensive list of items but they are not designed to be research instruments [28]. Nevertheless, the second guide which covers the 'explanation and planning' stage of consultations provides converging confirmation of the 'construct' of patient involvement in decision making, as depicted by the items within the section on negotiating a 'mutual plan of action':

27 *Discusses options, e.g. no action, investigation, medication or surgery, non-drug treatments*
28 *Provides information on action or treatment offered*
   a) *name*
   b) *steps involved, how it works*
   c) *benefits and advantages*
   d) *possible side-effects*
29 *Elicits patient's understanding, reactions, and concerns about plans and treatments, including acceptability*
30 *Obtains patient's views of need for action, perceived benefits, barriers and motivation; accepts and advocates alternative viewpoint as necessary*
31 *Takes patient's lifestyle, beliefs, cultural background and abilities into consideration*

32   *Encourages patient to be involved in implementing plans, to take responsibility and to be self-reliant*

33   *Asks about patient support systems, discusses other support available*

Component 3 of the patient centredness (Stewart, 1995) [33]

Component 3 of the *patient centredness* scoring instrument (which covers the concept of 'finding common ground') provides spaces to list which *problems the doctor has clearly defined* and whether *opportunities for questions* were provided. Raters are also asked to assess whether patients have been involved in *mutual discussions* and in agreeing *goals for treatment and management*. Binary (yes/no) responses are possible. Total scores provide an overall index of *common ground*. Although the instrument can assess whether 'discussion' occurs, it cannot distinguish whether choice is provided and to what extent patients are involved in the decision making process.

Euro Communication Scale (Mead, 1999) [4]

This instrument was developed specifically for use in a current study and measures a doctor's patient centred behaviour across five dimensions. Preliminary validation work comparing it to two other instruments reveals that three of the dimensions cover aspects of patient involvement in decision making: problem definition, decision making, patient ambivalence.

Validity and Reliability Testing of Instruments

The development of instruments to evaluate professional communication skills has taken place mostly in a generalist clinical setting; the eight instruments in Table 1 exemplify that trend. The quality of the instruments that met the reviews' inclusion criteria, compared to the rigorous psychometric standards of validity and reliability testing (item development based on qualitative techniques, followed by quantitative refinement and selection, and determination of sensitivity and responsiveness) is generally low (Table 2). Evolution of the MAAS instrument for instance has moved from the assessment of basic communication skills of medical students to the formative development of doctors training in general practice. It is a global index of ability across many different facets of communication skills. The most cited instrument aims to assess 'patient centredness' but this is increasingly recognised to be a multi-dimensional construct. Braddock's tool was developed from ethical principles [27], and Makoul's instrument based on the construct of 'reliance' [26] but the path taken from theoretical concept to item formulation, refinement and selection is not described. Many of the identified instruments have not been validated and the results of concurrent validity of Stewart's instrument when conducted outside the original development setting point to the need for further refinements [4]. Braddock and Marvel report inter-rater agreements without adjusting for agreement by chance. The use of generalisability theory [19] as a means of providing reliability coefficients based on the number of raters and the number of consultations is limited to studies conducted on the MAAS-Global instrument.

Clustering of existing instrument items

It is possible however to match the items identified within these eight instruments against a suggested chronological staging of 'patient involvement', which we have based on the competences identified in Box 1 and on existing literature in the field [1, 9, 11, 34] (Box 2). This matching process illustrates how the identified instruments vary in the extent to which they contain items that cover the broad sequences described. This comparison of items has the potential, if combined with further inductive work, to guide the construction of a patient involvement instrument.

Discussion

Principal findings

Existing instrumentation in the field of professional-patient interaction research and evaluation does not enable the construct of patient involvement to be measured comprehensively. Although an important finding, it is not a surprising one. None of the instruments we found (and included) were designed specifically to measure 'patient involvement'. The study of interactive communication within clinical consultations was pioneered in the 1960s, and many instruments have been developed since to evaluate the clinician-patient interaction. Nevertheless, the majority of existing observational tools have been situated within a paternalistic paradigm of interpersonal communication. The instruments that met our criteria are generic tools, capable of considering all types of clinical decision making scenarios but they vary extensively in the detail to which they measure 'involvement'. The MAAS-Global and Decision making [26] checklists for example do not cover the issue of *mutual plan of action* in as much detail as the Calgary-Cambridge Observation Guides. Those tools that had some items on 'involvement' lacked a clear conceptual and theoretical underpinning. Instruments developed to measure 'patient centredness' are unable to provide enough focus on 'involvement', and their quality has been questioned, mainly because of their attempt to cover so many dimensions within consultations [3, 4, 36]. The concept of patient involvement (shared decision making [9, 37]; informed collaborative choice [38]) is emerging in the literature and demands an accurate method of assessment.

It is important to recognise that how a construct is defined and understood will determine efforts to design measurements. The principles of 'shared decision making' (where professional and patient values are integrated to arrive at a final decision) differ from those of the 'informed choice' method, where patients are regarded as fully autonomous, and expected to make their own decisions [9]. It is clear that active patient involvement in the decision making process was not part of the patient centred consultation method, at least within early conceptualisations. Measurements will either need to state which method they are assessing (state underlying assumptions) or be capable of taking neutral observational stances, whilst having items that determine empirically which method the clinician is following. It also seems clear that some of the stages and competences (see Box 1) will be easier to operationalise into items than others, and this is exemplified by the frequency of items within the instruments that were included in our detailed appraisal (see Table 1).

Box 2   Clustering of existing items into identifiable 'stages' of patient involvement in decision making (arranged alphabetically by instrument):

Stages of patient involvement	Items found in existing instruments
Involvement in decision making process (i e agreeing the problem and the need for a decision)	• *involving patients in problem definition* (Euro Communication) [4] • *the clinical issue and nature of decision* (Informed decision making) [27] • *problems the doctor has clearly defined* (Patient centredness) [30, 35]
Exploring ideas, fears and expectations	• *takes patient's lifestyle, beliefs, cultural background and abilities into consideration* (Calgary-Cambridge Observation Guides) [28] • *exploring issues of patient ambivalence* (Euro Communication) [4] • *discussion of uncertainties* (Informed decision making) [27] • *discussing feasibility and adherence* (MAAS-Global) [32] • *opportunities for questions* (Patient centredness) [33] • *mutual discussions* (Patient centredness) [30, 35] • *goals for treatment and management* (Patient centredness) [30, 35]
Option portrayal	• *discusses options, e g no action, investigation, medication or surgery, non drug treatments* (Calgary-Cambridge Observation Guides) [28] • *discussion of alternatives* (Informed decision making) [27] • *What information should be exchanged with the patient to design and agree a treatment plan?* (Levels of involvement) [25] • *shared decision making, discussing alternatives, risks and benefits* (MAAS-Global) [32]
Provide information (risk communication)	• *Provides information on action or treatment offered* (Calgary-Cambridge Observation Guides) [28] • *Did the MD ever explain possible treatments to the PT? (over and above naming the treatment)* (Communication and decision making) [26] • *Discussion of pros and cons of alternatives* (Informed decision making) [27] • *What information should be exchanged with the patient to design and agree a treatment plan?* (Levels of involvement) [25] • *shared decision making, discussing alternatives, risks and benefits* (MAAS-Global) [32]
Checking process: understanding of information and reactions	• *elicits patient's understanding, reactions, and concerns about plans and treatments, including acceptability* (Calgary-Cambridge Observation Guides) [28] • *Obtains patient's views of need for action, perceived benefits, barriers and motivation, accepts and advocates alternative viewpoint as necessary* (Calgary-Cambridge Observation Guides) [28] • *assessment of patient understanding* (Informed decision making) [27]
Acceptance of process and decision making role preference/making decisions	• *encourages patient to be involved in implementing plans, to take responsibility and to be self-reliant Asks about patient support systems Discusses other support available* (Calgary-Cambridge Observation Guides) [28] • *did the MD (doctor) ever seem to give the PT (patient) any responsibility for deciding how to deal with the health problem?* (Communication and decision making) [26] • *did the MD ever involve the patient in choosing a treatment for the health problem? (e g "which alternative")* (Communication and decision making) [26] • *involving patient in decision making regarding management* (Euro Communication) [4] • *asking patient to express a preference* (Informed decision making) [27] • *determining who will do what and where* (MAAS-Global) [32]
Opportunity to review decision making	• *asking for patient response* (MAAS-Global) [32]

Assessing 'implicit' involvement may be impossible to observe reliably, as would any aspects that depend on the assessment of patient perceptions. To attain reliability, instruments in this area will have to narrow their focus on behaviours that can be directly observed (e.g. providing options, data about harms and benefits, checking understanding and so forth) and to attain validity, be based on competences that are at least feasible in actual practice [10, 11].

Strengths and weaknesses

This systematic review of instruments in the field of professional-patient interaction examines for the first time the extent of psychometric development and testing which has underpinned existing instrumentation in this area. It provides an assessment of the degree to which validity and reliability issues have been considered when measurement tools are developed and provides a comparison of items within existing instruments. Although we made extensive use of the technique of snowball sampling and contacted over 60 cited authors we found that publications in this area are spread over many journals which are either not, or poorly, indexed and we would welcome information about any instruments that have escaped our attention. Although we were able to obtain translations of work done in the Netherlands and contacted colleagues in Germany, we may have omitted other work not published in English. Some extensively used instruments were excluded (e.g. the Roter Interaction Analysis System [39]). Although this instrument included items that code patient question-asking and information provision, its dependence on the summing of coding categories precluded it as a tool capable of identifying an involvement process [40].

Implications for researchers and policymakers

Existing instruments have not been specifically developed to measure 'patient involvement' in clinical interactions: the tools were developed for different purposes. Those that have items relevant to this construct are not well developed or validated. It remains to be decided whether the instruments described in this review should guide the design of a measure of patient involvement. Valid instrumentation should be derived from a well-defined construct with item selection based on qualitative inquiry, and then rigorously developed according to psychometric principles. To what extent the development of such an instrument should be guided by patient (consumer) or professional perspectives is a moot issue. The communication steps in Box 1 are derived from qualitative work on both patient and professional viewpoints and provide a firm basis for conceptualising how clinicians should approach this task, and could guide instrument development. As no 'gold standard' exists, construct validity should be determined by means of hypothesis testing (using extreme groups, convergent and discriminant validity testing methods) [19]. The list of items evident in these eight instruments (Box 2) provides at least a starting point for discussion with professionals and consumers [11].

Although there is work to suggest that patient perceptions of involvement are an important component of any 'effect' that increasing the participatory nature of the consultation might have, there is a parallel need to be able to 'identify' the communication skills that result in differing perceptions. Correlating empirical practice against high perceptions of 'involvement' may well be one method of identifying 'good practice'. But there is also a need to determine the construct of 'involvement', determine the contributory competences, and develop an acceptable instrument to determine the levels of proficiency attained. This study allows us to move closer to that possibility. Proposals to involve existing research groups who have an interest in this area in the development of an 'involvement' instrument would strengthen the work and avoid the duplication of under-used evaluation methods in the field of health communication research [41].

Table 1 Descriptive data for instruments that consider involvement in decision making

Instrument, first author, reference, Country	Conceptual or construct framework	Method of assessment	Aspects of decision making considered (Numbers correspond to skills and stages described in Box 1)	Types of decisions considered Context of first use	Manual availability Citation total (SCI/SSCI) of Index Publication
Calgary-Cambridge Observation Guides (Kurtz, 1996) [28] Canada	Communication skills derived by expert consensus	Checklist of defined behaviours and stages	Within the explanation and planning phase a section exists, which is called 'shared decision making' which lists key stages of offering choices, checking views and negotiating acceptable management plan (1,2,3,4,5,6,7,8)	All types Developed within the undergraduate communication course, University of Calgary	Published Observation Guides available Citations 2
Communication & Decision making Checklist (Makoul, 1992) [26] United States	Investigation of 'reliance' the degree to which patients rely on clinicians for decision making	Checklist of defined behaviours and stages (binary responses)	Is information provided about medication and involvement in decision making? Discussion about medication Equality in consultation Number of options mentioned Involvement in decision making (1,2,3,7)	All types Consultations in UK-based general practice	No manual available Citations 6
Elements of informed decision making (Braddock, 1997) [27] United States	Informed consent	Binary scoring of defined elements of informed decision making	Nature of decision, alternatives, pros/cons, uncertainties, patient understanding and preferences (1,2,3,4,5,6,7)	All types Family practice in United States	No manual available Citations 11
Euro-communication Scale (Mead, 1999) [4] United Kingdom	Patient-centred consulting style	Rating scale applied to 5 defined behavioural dimensions	Patient involvement in problem definition and management decision making, self-efficacy and clinician responsiveness (1, 2,6)	All types Consultations in UK-based general practice	No manual available Citations 0
Levels of Physician Involvement (Marvel, 1994) [25] United States	Exploration and management of patient and family concerns	Levels of involvement coded and quantified	Level 2 describes the competency of collaborative information exchange, i e 'what information should be exchanged to diagnose, design and agree a treatment plan' (1,3)	All types Family practice in United States	No manual available Citations 11
MAAS-Global, (van Thiel, 1991) [29] Netherlands	Communication skills derived and defined by expert consensus	Rating scales applied to defined behaviours and stages	Discussing alternatives, discussing risks/benefits, checking processes (1,2,3,5,6,8)	All types Communication skills of medical undergraduates	Dutch manual available Citations 11
Patient centredness Component 3 Finding common ground (Stewart, 1995) [30] Canada	Patient-centred consulting style	Checklist of defined behaviours and stages, with binary scoring Total score expressed	'Mutual' discussion about goals for treatment and management (1,2,3,5)	All types Family medicine in Canada	Instrument and guidance available from authors Citations 0
Problem-Solving Method (Pridham, 1980) [24] United States	Interpersonal problem-solving skills	Intervals (10-second duration) are coded according to itemised process sheet	Problem-solving, guiding further action, self-management plan development, evaluation of problem-solving process (1,2,3)	All types Family practice in United States	No manual available Citations 0

Citation data obtained from Science Citation Index (SCI), Social Science Citations Index (SSCI), BIDS ISI Service, 16/9/99

Table 2   The development, validity and reliability testing of instruments that met inclusion criteria †

Instrument, first author, reference	How was the instrument developed?	Reported Validity Assessments	Reported Reliability Assessments
Calgary-Cambridge Observation Guides (Kurtz, 1996) [28]	The guides were developed and refined over 20 years within the undergraduate communication course of the University of Calgary, and have been adapted by reference to the cumulative literature on doctor-patient communication [42]	Content validity confirmed by authors Other validity aspects not measured systematically as the guides are formative, not 'research' measures	No published data
Communication & Decision making Checklist (Makoul, 1992) [26]	No details are provided about how items were developed or selected for inclusion in the checklist [26]	Content validity confirmed by authors The thesis and publications to date do not provide further data apart from hypotheses testing within the thesis which support the validity of measuring 'reliance' (on self or on clinician)	Inter-rater reliability coefficient (K) = 0 97 [26]
Elements of informed decision making (Braddock, 1997) [27]	The authors 'synthesised' the ethical methods of informed consent as presented in the bioethical literature and devised a 6-item list 'elements of informed decision making'	Content validity confirmed by authors The publication does not provide data regarding further validation or construct hypothesis testing	Inter-rater 'agreement' 77%
Euro-communication Scale (Mead, 1999) [4]	The scale was devised specifically for use in the Euro-communication study No data available regarding its development but the authors of the index publication admit that it has been limited	Poor concurrent validity with two other measures of patient centredness Significant positive associations with GP acquaintance with patient, GP age, consultation length, proportion of eye contact and importance placed on psychological factors by GP [4]	Internal consistency (Cronbach's alpha) = 0 90 Inter-rater agreement intraclass correlation coefficient = 0 34
Levels of Physician Involvement (LPI) (Marvel, 1993) [25]	The LPI was developed from Doherty's 'levels of physician involvement with families' [31], but no details are provided regarding the adaptation of the group measure to an instrument designed for a dyad interaction	Content validity confirmed by authors The publications to date do not provide data regarding further validation or construct hypothesis testing	Inter-rater 'agreement' 79%
MAAS-Global, (van Thiel, 1992) [32]	The instrument has been extensively developed from an original checklist of history-taking and advice giving in a medical student training context (1987) Development took place within a series of iterative assessments of communication skills The revised version (MAAS-R, 1989) was modified by van Thiel in 1992 and is now known as MAAS-Global	Content validity confirmed by authors The instrument is used throughout the Netherlands for communication skill assessments in general practice (1999) van Thiel confirms that publications to date do not provide data regarding further validation or construct hypothesis testing (personal communication, 1999)	Use of generalisability coefficients Inter-rater reliability MAAS-Global (intraclass correlations) = 0 78
Patient centredness Component 3 Finding common ground (Stewart, 1995) [30]	The existing measurements of patient centredness were developed over the last 20 years by a research group in Ontario, Canada, and based on the conceptualisations of Levenstein, Henbest and McWhinney Development of the instruments took place within the studies into patient centredness conducted mostly within the context of family medicine in Canada by the Ontario group	Good concurrent validity with 'global scores of experienced communication researchers' (r=0 85) Associations found with patients' subjective perceptions of 'finding common ground' but not with perceptions that the 'doctor explored the illness experience' Construct validity not systematically tested [30]	Inter-rater reliability coefficient = 0 83, intra-rater r= 0 73 [30]
Problem-Solving Observation Method (Pridham, 1980) [24]	This was developed by the principal investigator to assign codes to each 10-second interval which differentiate whether participants in the clinical interaction were 'organising', 'formulating', 'orientating', 'guiding', and 'planning' within an overarching construct of 'problem-solving' No evidence exists that this instrument has been used subsequently	Content validity confirmed by authors The publication does not provide any further validity data or construct hypothesis testing	Only 5 consultations analysed and inappropriate statistical analysis performed

† Footnote to Table 2   **Assessing issues of validity and reliability** (it is important to emphasise that we are not assessing the ability of the instruments to measure 'involvement in decision making' (they were not developed to undertake that task) but reporting published data)

Validity: Face validity indicates whether an instrument 'appears' to either the users or designers to be assessing the correct qualities It is essentially a subjective judgement. Content validity is similarly a judgement by one or more 'experts' as to whether the instrument samples the relevant or important 'content' or 'domains' within the concept to be measured An explicit statement by an expert panel should be a minimum requirement for any instrument However, to ensure that the instrument is measuring what is intended, methods that go beyond peer judgements are usually required For this study, the instrument should reflect the understanding given to patient involvement in decision making agreement that a defined problem needing a management decision exists, that valid options are available, and that both information and opinions contribute to the process of decision making If similar instruments already exist it is possible to consider criterion validity and construct validity Criterion validity is usually defined as the correlation of a scale with some other measure of the trait of disorder under study (ideally a 'gold standard' in the field) Construct validity refers to the ability of the instrument to measure the 'hypothetical construct' which is at the heart of what is being measured (For example, in this review an ideal instrument should be capable of measuring the level of patient involvement in decision making achieved within the consultation) If, however, no other similar measure exists it is not possible to compare against another scale For example, it emerges that a 'gold standard' for measuring patient involvement in decision making is not available Construct validity is then determined by designing experiments which explore the ability of the instrument to 'measure' the construct in question This is often done by applying the scale to different populations, which are known to have differing amounts of the property to be assessed By conducting a series of converging studies the construct validity of the new instrument can be determined High correlation with aspects of 'patient centredness', global measures of communication skills or patient perceptions of 'having their views' considered could be postulated, and investigated for example An additional method would be to measure 'patient involvement' within a sample of consultations and to test hypotheses within that population e g that elderly patients, or patients from low educational or social class are involved to lesser extents than other groupings

Reliability: Internal consistency this assumes that the instrument is assessing one dimension or concept and that scores in individual items would be correlated with scores in all other items These correlations are usually calculated by comparing items (Cronbach's alpha, Kuder-Richardson, split halves) Instruments which assess 'the consultation' rarely focus on one concept and it is not usually possible to assess internal consistency (although different elements of 'good' consulting could be expected to correlate) Stability this is an assessment of the ability of the instrument to produce similar results when used by different observers (inter-rater reliability) or by the same observer on different occasions (intra-rater reliability) Does the instrument produce the same results if used on the same sample on two separate occasions (test-retest reliability)? The production of reliability coefficients by using generalisability theory is advocated where measurements are undertaken in complex interactions by multiple raters [43]

Table 3   Clinical interaction measures: a list of instruments identified and considered

Instrument, first author, reference	Description of instrument	Data collection	Addresses 'involvement'	Portrays options	Considers decision making
Type A Instruments that measure concepts, stages or defined tasks within consultations					
Arizona Clinical Interview Rating Scale, (Stillman,1977) [44, 45]	Assesses 16 interviewing skills using 5-point scale, under 6 headings Organisation, Timeline, Transitional Statements, Questioning Skills, Rapport and Documentation of Data	Direct or recorded data analysis	(-)	(-)	(-)
Assessment of videotapes (Cox, 1993) [46]	This 37-item rating scale aims to distinguish between 'good' and 'bad' consultations	Videotape analysis	(-)	(-)	(-)
Barrett-Lennard Relationship Inventory [47]	A 64-item inventory divided across four variables empathy, level of regard, unconditionality of regard and congruence	Direct or recorded data analysis	(-)	(-)	(-)
Bensing's General Consultation Judgement (Bensing, 1991) [48]	Measures the attention given by a clinician to the 'psychosocial care' provided within the consultation A general judgement is made (on a scale of 1 to 10) against a set of 5 items that describe psychosocial care qualities	Videotape analysis	(-)	(-)	(-)
Brown University Interpersonal Skill Evaluation (Burchard, 1990) [49]	Assesses the interpersonal skills of surgeons using a 40-item list divided into four sections 'establishing rapport', 'demonstrating skills and procedures', 'testing for feedback' and 'providing appropriate closing'	Direct or recorded data analysis	(-)	(-)	(-)
Calgary-Cambridge Observation Guides (Kurtz, 1996) [28]	The aim of the guide is to act as a basis for formative assessment Communication skills derived by expert consensus Checklist of defined behaviours and stages	Direct or recorded data analysis	(+)	(+)	(+)
Category Observation Scheme (Mazzuca, 1983) [50]	Eleven behaviours are categorised Although there is an explicit category named 'sharing medical data', the focus is on data transfer and patient understanding	Videotape analysis	(-)	(-)	(-)
Communication & Decision making Checklist (Makoul, 1992) [26]	This checklist has items that cover whether information was provided about medication and whether patients were involved in decision making within general practice consultations	Audio or videotape analysis	(+)	(+)	(+)
Consultation Rating Scale (Hays, 1990) [51]	This consultation tasks rating scale uses evaluations such as 'explanations were adequate' or 'trainee listened attentively'	Videotape analysis	(-)	(-)	(-)
Communication Rating System CRS (Hulsman, 1998) [52]	Based on the Utrecht Consultation Assessment Method the CRS assesses 7 behavioural categories Although information 'effectiveness' is itemised, no evaluation of involvement in decision making occurs	Audiotape analysis	(-)	(-)	(-)
Daily Rating Form of Student Clinical Performance (White 1991) [53]	This 6 section 17-item rating scale was developed to provide feedback to medical students on their interviewing skills	Direct analysis	(-)	(-)	(-)
Elements of Informed Decision Making (Braddock 1997) [27]	This 6-item list covers the elements of 'informed consent'	Videotape analysis	(+)	(+)	(+)
Euro Communication Scale (Mead, 1999) [4]	A 5-item (dimensions) rating scale to assess patient centredness	Videotape analysis	(+)	(+)	(+)

Instrument, first author, reference	Description of Instrument	Data collection	Addresses 'Involvement'	Portrays options	Considers decision making
General Practice Interview Rating Scale (Verby, 1979) [54]	A 17-item 4 point rating scale of interviewing skills	Audiotape analysis	(-)	(-)	(-)
Interpersonal and Communication Skills Checklist (Cohen, 1976) [55]	A 17-item checklist developed for use by simulated patients after consultations	Observation by simulated patients	(-)	(-)	(-)
Interpersonal Skills Rating Form (Schnabl, 1995) [56]	A 13-item graded checklist developed to be used by standardized patients to assess the interpersonal skills of 4th year medical students	Observation by simulated patients	(-)	(-)	(-)
Lehmann-Cote Checklist (Lehmann, 1990) [57]	A 41-item checklist assessed the 'presence' or 'absence' of tasks in chronological order within a consultation	Videotape analysis	(-)	(-)	(-)
Levels of Involvement (Marvel, 1994) [25]	This tool assesses the degree to which clinicians explore patient psychosocial concerns	Videotape analysis	(+)	(+)	(+)
Lovett's Techniques of Interviewing Peer-Assessment Form (Lovett, 1990) [58]	This is a peer-review checklist covering interviewing skills developed within a communication course in psychiatry	Direct analysis	(-)	(-)	(-)
MAAS-Global, (van Thiel, 1991) [29]	Communication skills derived by expert consensus Measurement of medical interviewing skills (student assessment originally, but now adapted for general practice)	Direct or recorded data analysis	(+)	(+)	(+)
Patient centredness Component 3 Finding common ground (Stewart, 1995) [30, 35]	Items assess the degree of 'common ground' achieved within consultations This is the third section of a 3-component instrument designed to measure patient centredness	Audio or videotape analysis	(+)	(-)	(+)
Pendleton's Consultation Rating Scale (Pendleton, 1984) [20]	A 14-item consultation rating scale Paired opposing statements are scored for agreement on a linear analogue scale One item asks if the 'patient is involved in management adequately and appropriately' but there is no further elaboration	Direct or recorded data analysis	(+)	(-)	(-)
Physician Behaviour Checklist (PBCL) (Blanchard, 1986) [59]	A checklist developed to assess the behaviours of oncologists during ward rounds Some items cover the discussion of tests and future treatment, but none that identify patient involvement in decision making process	Direct analysis	(-)	(-)	(-)
Royal Australian College of General Practitioners Evaluation (Nyman, 1997) [21]	A checklist developed to assess the consulting skills of trainee clinicians in Australia One item asks if the patient was 'involved' in decision making	Direct observation	(+)	(-)	(-)
Royal College of General Practitioners Examination Criteria (RCGP, 1998) [22]	Membership of the RCGP is by examination or by assessment The criteria for consulting skills include one item about sharing 'management options' with the patient	Videotape analysis	(-)	(+)	(-)

Instrument, first author, reference	Description of Instrument	Data collection	Addresses 'involvement'	Portrays options	Considers decision making
Standard Index of Communication and Discrimination (SIC/SID) Levels of Response Scale (LRS) (Carkuff, 1969) [60, 61]	This index aims to measure the concepts of 'empathy, respect, concreteness, genuineness and confrontation' in communication processes	Audiotape analysis	(-)	(-)	(-)
Summative Assessment of General Practitioners (Campbell, 1996) [62, 63]	Based on the Pendleton consultation 'tasks', the instrument uses a 6-point scale It is designed as a summative assessment of registrars in general practice	Videotape analysis	(-)	(-)	(-)
Interactional Styles Taylor (1989) [64]	Coding system devised to analyse interactional styles, including paternalism, maternalism, shared decision making, and mixed styles	Videotape analysis	(-)	(-)	(-)
Telephone Assessment of TALK (Kosower, 1995) [65]	TALK is an acronym for 'trust, assert, listen and KISS (know, inquire, solve and stroke) This instrument categorises 24 generic behaviours into a conceptual framework and items are scored on a 5-point Likert scale	Videotape analysis	(-)	(-)	(-)
Teaching Communication Behaviour Scale (Clark, 1997) [66]	10-item scale that lists behaviours associated with achieving compliance with long-term medication (e g asthma treatment)	Videotape analysis	(-)	(-)	(-)
University of Leeds Consultation Rating Scale (Stanley, 1985) [23]	Communication skills derived by expert consensus The aim of the guide is to act as a basis for formative assessment Rating scales applied to defined behaviours and stages UK-based general practice type consultations	Videotape analysis	(-)	(-)	(+)
Utrecht Consultation Assessment Method [67]	UCAM is a checklist (incorporating a rating scale) which is divided into two categories 'patient-centred approach' and 'doctor-patient interaction' No further development work is being conducted on this instrument (personal communication)	Videotape analysis	(-)	(-)	(-)
Type B Interaction analysis measures - instruments which assess interactions at the 'micro' level (coded utterances or segments)					
Byrne and Long's Checklist of Behaviours (Byrne, 1992) [68]	This method subdivided the consultations into 85 'units of sense' and categorised them into three sets (doctor-centered, patient-centered and negative behaviour) The units were counted and a total score calculated for the consultation	Audiotape analysis	(-)	(-)	(-)
Cancer Specific Interaction Analysis System (CN-LOGIT) (Butow, 1991) [69]	This is an interaction analysis which was developed to assess the relationship between satisfaction with the consultation and the process and contents of consultations with an oncologist	Audiotape analysis	(-)	(-)	(-)
Davis Observation Coding 1991 (Callahan, 1991) [70]	Assessment of 20 behaviours (e g chatting, structuring interaction and counselling) 15-second intervals are coded It is noteworthy that the operational definition for 'structuring interaction', a behaviour in which the patient's preferred and actual role in decision making could be considered, specifically 'excluded planning treatment'	Direct or recorded data analysis	(-)	(-)	(-)
Faulkner's Communication Rating Scale [71]	Assessment of psychological concern by analysis of individual 'utterances'	Transcript analysis	(-)	(-)	(-)

Instrument, first author, reference	Description of instrument	Data collection	Addresses 'involvement'	Portrays options	Considers decision making
Interaction System for Interview Evaluation (ISIE-81)[72]	Coding system developed by National Board of Medical Examiners for 2-second intervals or behaviour change (whichever comes first)	Videotape analysis	(-)	(-)	(-)
Multi-dimensional Interaction Analysis System [73]	An interactional analysis method that lists 36 content areas and scores 'questioning, informing and supportiveness'	Direct or recorded data analysis	(-)	(-)	(-)
Measurement of Physician-Patient Communication (Kaplan, 1989) [74]	This coding scheme (a modification of Bales' interaction analysis) aimed to assess the attempts by patients to 'control' the interaction and judged the pattern of the consultation by quantifying utterances by both doctor and patient	Audiotape analysis	(-)	(-)	(-)
Medical Communication Behaviour System (MBCS) (Wolraich, 1986) [75]	13 provider behaviours and 10 patient behaviours are itemised and quantified. Clinician behaviours are divided into 3 categories. Content, Affective and Negative Behaviours. The instrument is situated in the paternalistic paradigm. For instance, the item 'advice/suggestion' is explained as, 'statements providing advice or suggestion on what the patient should do' (Their italicisation)	Audio or videotape analysis	(-)	(-)	(-)
Method for the Interactional Analysis of Doctor / Patient Consultation (Butler, 1992) [76]	This instrument codes the consultation by 'floorholding units' that are defined in terms of the content and form of communication categories e.g. physical agenda, emotional agenda and social agenda	Videotape analysis	(-)	(-)	(-)
McGee's Coding Method (McGee, 1998) [77]	Coding for patient utterances according to type of questions and by category (illness, treatment regimen, medical procedure, non-medical). Emphasis on information elicitation and verification	Videotape analysis	(-)	(-)	(-)
Ockene's Counseling Assessment (Ockene, 1988) [78]	A 3-item rating scale measuring the elicitation of feelings and information, and the provision of information	Videotape analysis	(-)	(-)	(-)
Patient-Doctor Communication Instrument (Wartzkin, 1985) [79]	This instrument gauges the 'amount' (in terms of time) of information transmittal that occurs between clinicians and patients, and collects information about situational and sociodemographic variables that affect this area	Audiotape analysis	(-)	(-)	(-)
Physician-Patient Interaction Coding System (Makoul, 1992) [26]	This is an intricate coding scheme which assigns codes to 'events of interest' within speech turns (both patient and doctor utterances) Two phases are defined as 'problems' and 'solutions' Within these phases, subordinate codes are described	Audiotape analysis	(-)	(-)	(-)
Problem-Solving Observation Method (Pridham, 1980) [24]	Assesses the interactive problem-solving behaviour of clients and clinicians. Interpersonal problem-solving skills	Audio or videotape analysis	(+)	(+)	(+)
University of Leeds Consultation Rating Scale (Stanley, 1985) [23]	A 10-item rating scale designed for use within an undergraduate communication skills course	Videotape analysis	(+)	(+)	(-)

Instrument, first author, reference	Description of instrument	Data collection	Addresses 'involvement'	Portrays options	Considers decision making
Relational Communication Control Coding Scheme (Cecil, 1998) [80]	Adaptation of Rogers [81] scheme that determines whether statements are assertions, questions, statements, 'talk-overs' or other categories and determines overall 'control' within interactions.	Audio or videotape analysis.	(-)	(-)	(-)
Roter's Interaction Analysis System (RIAS) (Roter, 1989) [39, 82]	The RIAS is derived from Bales' work assessing small group processes [83] but applies to the dyad scenario (i.e. doctor and patient) and consists of means of categorising each verbal utterance (distinguished in task-related behaviour and socio-emotional behaviour) and a set of global affect-ratings. Examples of the utterance codes include: Agree (shows agreement); [?] Med (closed medical question); Gives-Med (gives information-medical condition). The instrument's perspective is revealed by the following question: 'Did the clinician summarise his/her recommendations near the end of the visit?'	Audio or videotape analysis.	(-)	(-)	(-)
Street's Coding Structure [84]	Utterances are coded into 9 categories.	Videotape analysis.	(-)	(-)	(-)
Verbal Response Mode (VRM) (Stiles, 1979) [85-87]	This system is based on work in psychotherapy that had developed (by observation) a framework of 'response' modes: Question, Advisement, Silence, Interpretation, Reflection, Edification, Acknowledgement, Confirmation and Unscorable.	Transcript analysis.	(-)	(-)	(-)
Verhaak [88]	This study used a coding system designed to observe the detection of psychological symptoms in primary care consultations One item covered patient-centred behaviour during the prescribing phase	Videotape analysis.	(-)	(-)	(-)

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Chapter 6

Fleeting glimpses: measuring shared decision making in primary care using the OPTION instrument

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Abstract

Background: A systematic review demonstrated that there is no existing measure of the extent to which healthcare professionals involve patients in decisions within clinical consultations despite the increasing interest in the benefits or otherwise of patient participation in these matters.

Aims: To describe the development of the instrument and to assess its ability to assess the extent to which clinicians involve patients in decision making processes.

Design: A new instrument was developed, named OPTION (observing patient involvement scale), and used by two independent raters to assess primary care consultations in order to evaluate the scale's psychometric qualities, validity and reliability.

Study sample: 186 Audiotaped consultations collected from the routine clinics of 21 clinicians in the United Kingdom.

Method: The following evaluations were completed: item response rates, Cronbach's alpha and the calculation of summed and scaled OPTION scores. Inter-item and item-total correlations were calculated and inter-rater agreements were calculated using Cohen's kappa. Classical inter-rater intraclass correlation coefficients and generalisability theory statistics were used to calculate inter-rater reliability coefficients. Content and construct validity hypothesis testing was conducted.

Results: The evaluations demonstrate that the OPTION scale provides reliable scores for the extent to which patients are involved in decision making processes in consultations, and justifies the use of the scale in further empirical studies. The inter-rater intraclass correlation coefficient (0.62), kappa scores for inter-rater agreement (0.71), and Cronbach's alpha (0.79) were all above acceptable thresholds. Based on a balanced design of 5 consultations per clinician, the inter-rater reliability generalisability coefficient was 0.68 (two raters) and the intra-rater reliability generalisability coefficient, 0.61. Although there is little overall variance between clinicians, there is considerable variability *within* clinicians illustrating that some clinicians have a relatively narrow range of scores whilst others have a much greater range of scores, indicating that they modify the degree of patient involvement achieved in decision making across different consultations.

Conclusions: Involvement in decision making is a key facet of patient participation in health care and this scale provides a validated outcome measure for future empirical studies.

Introduction

Sharing decisions with patients is the subject of considerable debate [1, 2], yet remains an area where few empirical studies have been conducted [3]. A systematic review demonstrated that there is no existing measure of the extent to which healthcare professionals involve patients in decisions within clinical consultations [4]. Although some instruments include some components of patient involvement [5-9], they were found to be insufficiently developed to accurately measure this facet of communication in patient-clinician interactions. There is increasing interest in this area from consumers, professionals and policymakers, and a research need to ascertain whether achieving greater involvement in decision making is associated with improved patient outcomes.

The area is however complex and the concept is not easy to measure. It is reported that only a proportion of patients wish to become involved in the decision making process [1, 10], despite the possibility that 'involvement' could have a positive effect on health outcomes [6, 11, 12]. Nevertheless, recent qualitative research conducted with a wide range of consumer and patient groups revealed only minor qualifications for participation in decision making processes [13]. Patients stated that professionals should definitely provide information about treatment options, but should respect the extent to which patients wish to take on decision making responsibilities in clinical settings. It is proposed that these are skills which can be developed and that they are composed of a set of competences that include the following steps — problem definition, explaining that legitimate choices exist in many clinical situations, a concept defined as professional equipoise [14], portraying options and communicating risk about a wide range of issues, (for example, entry to screening programmes or the acceptance of investigative procedures or treatment choices), and conducting the decision process or its deferment. These are all aspects of consultations that need to be considered by an instrument designed to assess whether clinicians engage patients in decisions [14]. This competence framework forms the theoretical basis for the OPTION Scale.

The OPTION scale (acronym for 'observing patient involvement') is an instrument that has been developed to evaluate shared decision making specifically in the context of general practice but it is intended to be generic enough for use in all types of consultations in clinical practice. The underlying principles of the shared decision making method are described elsewhere [15-17], and the specific competence framework for this instrument were the result of earlier qualitative studies [14, 18, 19] and literature review [4, 20]. The OPTION scale is designed to assess the overall 'shared decision making' process. In summary, it examines whether problems are well-defined, whether options are formulated, information provided, patient understanding and role preference evaluated and decisions examined from both the professional and patient perspectives.

The instrument considered in this study was designed to have two ultimate objectives: the first and main objective was to enable accurate assessments of the levels of involvement in shared decision making

achieved within consultations. This ability will help provide research data for empirical studies in this area. The second objective is to arrive at a position where a robust research instrument could then be adapted to act as an educational scale for formative feedback to clinicians. The aims of this paper are to describe the development of the research instrument and to assess its ability to discriminate involvement levels and the decision making methods used in consultations within and between differing clinicians. We do this by reporting key aspects of the tool's validity and reliability using a sample of consultations recorded in a general practice setting.

Method

The study examines the psychometric characteristics of the OPTION scale using a sample of audiotaped consultations, collected from the routine clinics of 21 clinicians, and rated by two independent observers. Validity issues are considered at both theoretical (construct emergence) and item formulation and design stages; construct validity was also investigated. The scale's reliability was calculated by assessing response rates, inter-item and item-total correlations, inter-rater agreement (kappa), inter- and intra-rater reliability coefficients, using both classical and generalisability theory statistical methods.

Overall design features

The content validity of the instrument was developed by appraising existing research instruments and undertaking qualitative studies to define the construct and detailed competences of patient involvement in shared decision making in clinical consultations [4, 14]. The skills and steps of *involvement* were considered to be an essential part of the process of shared decision making, where according to the described principles of shared decision making both the clinicians and the patients take action to inform each other of their views regarding the preferred choice of management or treatment [16, 21].

Content validity and concept mapping

The development process followed established guidelines [22]. The systematic review [4] allowed existing scales, especially measures of related concepts such as 'patient centredness' and 'informed decision making' [6, 23], to be considered critically. Qualitative studies using key informants to clarify and expand the *competences* revealed that clinicians have specific perceptions about what constitutes 'involvement in decision making' which are matched in part, but not entirely, by patient views [14]. Using many design and piloting iterations, both patient and clinical perspectives contributed to item formulation. In addition, a sample of consultations in which clinicians were *intent*, and experienced, at the tasks of involving patients in discussions and sharing decisions were purposively chosen and examined [18]. Thus, the theoretical construct was refined by an assessment of clinical practice [24, 25]. The synthesis of this body of quantitative and qualitative work enabled the development of a theoretical framework for patient involvement in decision making, and informed the design of the OPTION instrument.

Instrument and scale development

An 18-item pilot instrument was used by 5 clinician key informants and 1 non-clinical rater to assess 6 simulated audiotaped consultations; item refinement and scale development involved 3 iterative cycles over a 12-month interval [14]. These consultations had been modelled to contain differing levels of patient involvement and decision making methods. This process reduced item ambiguity, removed value-laden wordings and resulted in short and (where possible) positively worded items [22]. A 5-point scale, anchored at both ends with the words 'strongly agree' and 'strongly disagree', was used to avoid the loss of scoring efficiency in dichotomised measures [22]. Revisions included increasing the focus on observable 'clinician behaviour' rather than attempting to assess patient perceptions of the consultation and modifying item sequence.

This version was subjected to further piloting using a second calibration audiotape containing modelled consultations (2 'paternalistic' consultations, 3 'shared decision making' and 2 'informed choice' examples). These consultations were rated by 2 non-clinical raters using OPTION and two other scales, namely the determination of 'common ground' developed by the Ontario group [6], and Braddock's measure of 'informed decision making' [23], selected as they were the most comparable scales identified [4]. A modified pilot 16-item OPTION instrument was regarded as a more acceptable and feasible tool by the raters and achieved an inter-rater reliability correlation coefficient of 0.96, compared to a score of 0.76 for the Braddock and 0.4 for the Stewart 'common ground' scale. These initial results confirmed OPTION's ability to provide reliable scores for involvement levels. A stable version of the instrument (June 2000) was described in a manual for raters [26]. By participating in item revision and the instruction manual drafting the raters were integrated into a calibration process before applying the instrument to the series of naturally occurring consultations.

Data collection: clinician and patient samples

To test the instrument, recordings of consultations were taken from the pre-intervention phase of an explanatory trial of shared decision making and risk communication [27]. As part of the recruitment process clinicians in Gwent, South Wales, audiotaped all consecutive consultations during a routine consulting session in general practice. To be eligible for recruitment into the trial, the clinician had to be a principal in general practice for at least 1 year and less than 10 years. The potential sample pool of 104 clinicians in 49 practices (average age 41, 62% male and 38% female) was approached, initially by letter (followed by telephone contact) and asked to participate in a research trial. It should be noted that, as far as we are aware, these volunteer clinicians were naïve to the concepts that we were measuring and had not been exposed to any specific training or educational interventions that could have influenced their degree of patient involvement. Patients attending on the specified recording dates gave their consent using standardised procedures, and their age and gender recorded. Apart from these consent procedures, no other stipulations were imposed and the data collected contained recordings covering the range of conditions typically seen in

routine general practice sessions. These consultations were rated using the OPTION instrument by 2 calibrated raters that were independent to the main research team. A random sample of 21 consultations (1 per clinician) was selected for test-retest analysis.

Data Analysis

The data were analysed by taking the response rate to each point on the item scales and calculating a summed and scaled OPTION score. Inter-item and item-total correlations were calculated. Inter-rater agreements were calculated using Cohen's Kappa. As well as assessing classical inter-rater intraclass correlation coefficient, the inter-rater reliability coefficients of the instrument were calculated using the statistical techniques described in generalisability theory [28]. This theory uses modified analysis of variance techniques to generate 'generalisability coefficients' [22]. The methods enable multiple sources of error variance to be calculated, and subsequent 'generalisations' made about the degree to which these sources are contributing to the overall variability. This in turn allows decisions to be made about the effect of changing the characteristics of the measurement process required [22] in order to assess the instrument's quality at measuring the level of involvement within individual consultations. We also estimated whether consultation scores clustered within clinicians by calculating an intraclass correlation coefficient [29]. The homogeneity of the OPTION scale was tested by calculating Cronbach's alpha, a form of split-half reliability testing that is used when there are more than 2 response alternatives [30]. Inter-item correlations and item-total correlation were calculated and factor analysis performed to determine whether the scale could be legitimately considered as a measure of a single construct.

As there is no similar instrument available it was not possible to establish criterion (specifically concurrent) validity. Assessment of the instrument's 'construct validity' was conducted by testing the OPTION measure against hypothetical constructs. Four constructs were examined, namely that the OPTION score level would be influenced by patient age, clinician gender or qualification, and whether the clinical topic was one where clinical 'equipoise' existed. Studies have also examined the effect of clinician gender on communication within consultations. Although an area of debate [31], Hall found that female clinicians made more partnership statements than male clinicians [32] and Coates' critical review [33] reported a broad consensus that female language is generally more cooperative. The mean OPTION scores for the 8 female clinicians were compared to those of their 13 male colleagues (t-test). In 1995, the MRCGP examination introduced a video assessment and listed shared decision making as a merit criterion. It was conjectured that success in the examination (at any time, prior to 1995, or after 1995) might be associated with higher scores (t-test). It has been established that increasing patient age leads to decreasing wish for involvement by patients [10, 34] and we assessed the correlation (Pearson) between the mean involvement and shared decision making scores against patient age. It was also hypothesised from previous qualitative work that decisions were more likely to be shared in consultations that contained clinical problems characterised by professional equipoise,

such as hormone replacement therapy [14]. The consultations were differentiated according to this characteristic and any significant differences between the mean OPTION score determined (t-test).

Results

Sample characteristics

Out of the potential sample pool of 104 clinicians, 21 clinicians in separate practices agreed to take part in a research trial and provided a tape of a routine clinic prior to the provision of any further intervention. These clinicians represented a slightly younger group than the sampling frame: average age 38 years, the male to female ratio was identical (38% female); 76% (16/21) of the clinicians recruited had been successful in the membership examination of the Royal College of General Practitioners, compared with an overall membership level of 54% in the sampling frame. Of the 242 consecutive patients approached in all practices, 12 (5%) declined to have the consultation recorded (the maximum refusal in any one practice was 3 patients in a series of 15 patients). The remaining 230 consultations were assessed and after removing consultations where there were technical recording problems, 186 consultations were available for analysis (average of 8.8 consultations per clinician). There was no age and sex difference between the consultations excluded because of poor recordings to those included for further analysis. One clinician recorded 5 consultations but the majority recorded 8 or more consultations. Consultations with women were twice as frequent in the sample and 66% of the patients seen were between 30 and 70 years old. The demographic and clinical characteristics of the recorded consultations are summarised in Table 1.

Table 1   Demographic and clinical characteristics of the recorded consultations (186)

Male	Female	Age (years)	Duration (minutes)		Clinical problems	
60 (32%)	126 (68%)	4 months – 83 years, mean 43.3 (SD 20.6).	Mean Median Range	8.2 (SD 4.0) 7.3 22.5	Respiratory Musculoskeletal Dermatological Psychological Cardiovascular Hypertension HRT Other	28 27 21 13 12 11 11 63

Scale refinement

The performance of the 16-item scale was analysed in detail. Four of the items had been formulated to try and discriminate between decision methods used by the clinician, to distinguish between paternalism on one hand and the transfer of decisional responsibility to the patient on the other. The other 12 items had been constructed to determine performance within a construct of a defined set of steps and skills. Our psychometric results (reliability scores, item correlations and factor analysis) and reflections on the conceptual issues underlying these dimensions led to a decision to agree a final OPTION scale that was

composed of the items that specifically evaluate the theoretical competence framework. It is the reliability and construct validity of this 12-item scale that is reported here.

Response rates to OPTION items

A summary of the response rates is provided in Table 2. Items 1, 2, 3, 4 and 6 have a range of responses across the 5-point scale but with a skew towards low scores. Oversights in item completion led to an average of 0.9% missing values in the dataset that were distributed evenly across all items (see Table 2).

Table 2   Option item response, missing values rates (%), and Cohen's kappa

OPTION Item	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Missing values (%)	Kappa [§]
1 The clinician identifies problem(s) needing a decision making process.	49.5	33.1	11.0	4.3	1.3	0.8	0.61 (0.31)
2 The clinician *states* that there is more than one way to deal with an identified problem ('equipoise').	6.2	3.2	5.4	13.4	71.0	0.8	0.82 (0.50)
3 The clinician *lists* 'options', including the choice of 'no action' if feasible.	6.7	4.0	7.0	9.7	71.8	0.8	0.75 (0.51)
4 The clinician *explains* the pros and cons of options to the patient (taking 'no action' is an option).	3.5	3.2	9.4	11.6	71.5	0.8	0.68 (0.43)
5 The clinician checks the patient's preferred information format (words/numbers/visual display).	0	0	0.3	0.5	98.4	0.8	0.98 (0.98)
6 The clinician explores the patient's expectations (or ideas) about how the problem(s) are to be managed.	0.5	1.1	8.6	18.8	69.9	1.1	0.75 (0.34)
7 The clinician explores the patient's concerns (fears) about how problem(s) are to be managed.	1.3	4.6	12.1	22.0	59.1	0.8	0.53 (0.42)
8 The clinician checks that the patient has understood the information.	0.8	1.1	35.2	26.9	34.9	1.1	0.38 (0.10)
9 The clinician provides opportunities for the patient to ask questions.	1.9	3.2	40.1	17.2	36.0	1.6	0.20 (-0.08)
10 The clinician asks for the patient's preferred level of involvement in decision making.	0.8	1.3	4.0	8.1	84.9	0.8	0.86 (0.66)
11 An opportunity for deferring a decision is provided.	1.1	2.4	4.8	7.5	83.3	0.8	0.83 (0.66)
12 Arrangements are made to review the decision (or the deferment).	19.4	7.8	35.2	5.4	30.9	0.8	0.58 (0.44)

§   Kappa: scores are for agreement across sum of 'agree, neutral and disagree' scale points, scores in brackets are kappa scores for 5-point scale agreement

The results indicate that the clinicians generally did not portray 'equipoise' (71% strongly disagree); the clinicians did not usually list options (71.8% strongly disagree); they did not often explain the pros and cons of options (71.5% strongly disagree) and they did not explore patients' expectations about how the problems are to be managed (69.9% strongly disagree). Responses to items 7, 8, and 9 revealed most variation across scale points. Item 7 asked whether the clinician explored the patients' concerns (fears) about how the problem(s) were to be managed: the response was 81.1% 'disagreement' and 12.1% 'neutral'. A similar pattern of disagreement with the assertion that the clinician 'checks patient understanding' and provides 'opportunities for questions' (items 8 and 9) was obtained but with higher scores for the neutral scale point (35.2% and 40.1% respectively). Clinicians were infrequently observed to 'ask patients about their preferred level of involvement in decision making' (84.9% strongly disagree).

Opportunities for deferring decisions were rarely observed (item 11, 3.5% agreement) but an arrangement to review the decision in the consultation was made in over a quarter of the consultations (item 12, 27.2% agreement). To summarise, the responses obtained indicate that the consultations recorded during these routine surgeries are characterised by low levels of patient involvement in decision making, and a largely paternalistic approach is taken to decision making. This is confirmed by noting that the items that assess equipoise, option listing and information provision (items 2, 3 and 4) achieved a mean 'agreement' response rate of 8.6%.

Reliability of the OPTION score (summed and scaled score)
Kappa scores are provided in Table 2 where the scale was aggregated to 3 points (agree, neutral, disagree). Five point kappa scores are bracketed. For all 12 items, the mean Cohen kappa score was 0.66, indicating high inter-rater agreement after correcting for chance. Excluding item 9 (which requires further attention due to its low kappa score, increases the mean kappa score to 0.71. Coefficient α (Cronbach's α) was 0.79 indicating little redundancy in the scale (ignoring variation across raters). The inter-rater intraclass correlation coefficient for the OPTION score was 0.62. Based on a balanced design of 5 consultations per clinician, the inter-rater reliability generalisability coefficient was 0.68 (two raters) and the intra-rater reliability generalisability coefficient, 0.61. The corrected item-total correlations lay between 0.35 to 0.66, except items 1 and 5, which had correlations of 0.05 and 0.07 respectively. Kaiser-Meyer-Olkin measure of sampling adequacy was 0.82 indicating a very compact pattern of item correlation, justifying the use of factor analysis. Factor analysis (principal component method) revealed that variable loading scores (onto one factor) resulted in scores that were above 0.36 (the recommended thresholds for sample sizes of approximately 200) for all except items 1 and 5 (-0.10 and 0.09). It asked whether a 'problem' is identified by the clinician and could be regarded as a gateway item to the scale, i.e. if a problem is not identified then it is difficult to see how the other items can be scored effectively. Item 5 (checking preferred information format) had a low endorsement rate within this routine sample, which was predicted. Items 2 to 4 and 6 to 12 had a mean factor loading of

0.64. A total of 35.2% of the variance was explained by one latent component. Of a total of 66 possible inter-item correlations, 49 were above 0.25 (mean r = 0.40).

Given these reliability indicators, the overall mean score for OPTION level, averaged across both rater scores, on a scale of 0 to 100 across all clinicians was 16.9 (SD 7.7, 95% confidence interval 15.76 to 17.98), with a minimum consultation involvement score of 3.33 and a maximum of 44.17. The scores are skewed towards low values (see Figure 1).

Figure 1 Distribution of OPTION Scores
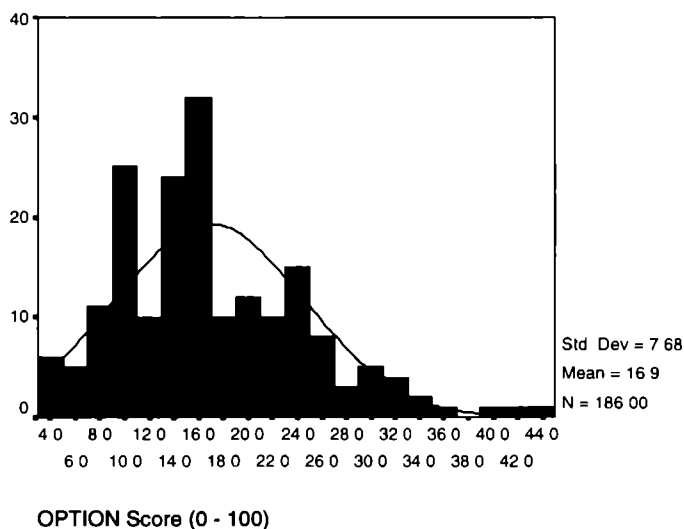
OPTION Score (0 - 100)

At the individual clinician level the mean OPTION scores lay between 8.8 to 23.8, with an intracluster correlation coefficient of 0.22 (across individual means), indicating significant clustering of consultation scores within clinicians. These scores and the 95% confidence intervals for each clinician are shown in Figure 2. Note that some clinicians have a much wider range of involvement score, indicating a more variable consulting style. The results show that the general level of patient involvement achieved in these consultations was low.

Figure 2 Mean Option Scores (0-100), showing 95 % Confidence Intervals
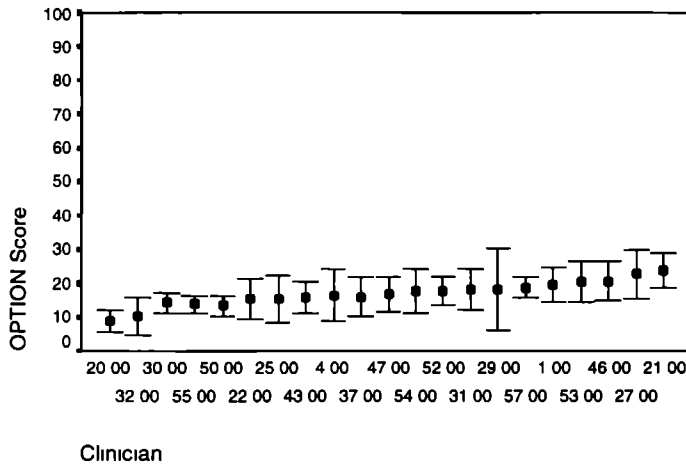
Construct validity

Two constructs were found to be correlated with increasing levels of involvement in decision making: patient age and the existence of a clinical topic where professional equipoise could be expected The correlation coefficient between the mean OPTION score and patient age (adult age range) was −0.144 (P < 0.01) and confirmed the hypothesis that involvement levels reduced as patient age increased. For consultations that contained clinical problems that are characterised by having a greater likelihood of professionals exhibiting *equipoise* about treatment choice (n=15, 8.1%), for example discussion of hormone replacement therapy and depression, the mean OPTION score was 21.6, this mean score was significantly different to mean scores achieved in consultations where equipoise topics did not occur (16 4, P < 0.01, t-test), confirming the hypothesis that involvement increases where this characteristic exists Clinician gender and success or otherwise in the MRCGP examination were not associated with differences in mean OPTION score (t-tests)

Discussion

Principal findings

The results of this study reveal that the OPTION scale provides reliable scores for involvement in a shared decision making process at the consultation level. Based on the psychometric characteristics reported we were satisfied that the scale could be used to provide a total score for the competence framework we had defined as shared decision making Although there is little overall variance between clinicians, there is considerable variability *within* clinicians as shown by the wide and differing confidence intervals around their mean scores (Figure 2). Some clinicians have a relatively narrow range of scores whilst others have scores

that indicate an ability to modify their involvement levels across different consultations and to adapt it to the preferred roles of patients in these interactions.

The content validity of the instrument was based on formulating the items from the existing literature; a combination of qualitative and quantitative studies designed to understand how patient involvement can be best achieved in professional practice; and subsequent development using an iterative design and assessment cycle. The results of using the instrument in this sample of consultations indicate that low levels of involvement in shared decision making are achieved by clinicians and that paternalism is by far the most common *modus operandi* in routine consultations.

The results indicate that OPTION achieves acceptable levels of measurement reliability for use in research settings where the aim is to assess the extent to which clinicians involve patients in decision making processes. By focusing on this specific aspect of patient centredness this scale has been demonstrated to be more reliable than existing measures in this field [35, 36]. Construct validity was supported by the determination of a correlation between involvement scores and patient age and the existence of clinical equipoise in the consultation, both hypotheses are supported by previous findings.

Strengths and weaknesses
The strength of this study lies in the method of instrument development. By taking full account of the existing literature, and rigorous application of scale development procedures many common risks in constructing instruments have been reduced [37]. Some weaknesses were however noted during the study. The majority of consultations in general practice contain more than one problem solving issue and it is impractical to apply the OPTION instrument to every single presenting problem. There is a requirement therefore for raters to agree an *index* problem. Guidance is given for this issue in a revised manual. In summary, the problem is chosen for which the prime attention is given during the consultation or for which the clinician achieves the greatest involvement score as the aim is to score demonstrated *ability* not to calculate involvement in all possible decisional issues. Secondly, parent and child consultations required additional guidelines (advising that the professional-adult interaction was assessed) and the raters to use judgement regarding the main patient participant where teenagers were being consulted. It was not possible to estimate concurrent validity (correlation of the measure with some other scale of the concept or trait to be assessed), as there was neither a 'gold standard' nor a comparable instrument available.

Psychometric assessment also revealed areas where further instrument refinement is necessary. Item 1 may need to be conceptualised as a 'gateway' item in that if no agreed problem can be identified then the assessment of involvement in decision making cannot continue. Although item 5 has a high kappa score, the response rate was highly skewed and the factor loading is low. The item is retained however as it asks about

a feature (use of risk communications tools) that is known not to occur in current service settings, although as interventions to change this situation are being introduced the results are likely to change with time as decision aids are introduced into clinical settings [38] [39]. Item 9 questions whether clinicians 'provide opportunities for the patient to ask questions' but it has low kappa scores and a factor loading score below 0.2. This item needs modification and further testing to overcome the variation in scoring judgement.

Implications for research and formative skill development
OPTION scores for these routine consultations taken from general practice in a UK setting are skewed towards the lower end of the scale. For some items, almost no responses were registered. For example, there was 98.9% disagreement with item 5 that asked if the clinician 'checks the patient's preferred information format'. These response rates were expected in this cohort yet it is theoretically important to retain this item in the instrument. Further research work in this area will involve presenting information in different formats and it is known that when clinicians develop the skills of involving patients there is a tendency for a pendulum effect. Retaining these items, and others that reveal skewed or 'floor' scores, will enhance the ability of the instrument to register change.

OPTION can therefore be used to determine a key issue within consultations in general practice, namely, the extent to which clinicians involve patients in clinical decisions by following a validated set of competences. It should be emphasised that the results revealed considerable variation of scores within individual clinicians, with some individuals having a wide scatter of scores than others as reflected in the difference in confidence intervals around mean scores. This result is congruent with the theoretical stance that clinicians should be flexible in their consulting style, and adapt to the nature of the problem and the patient preference for participation in clinical decisions. It is noteworthy however that these OPTION scores are low and it is anticipated that higher scores will be evident after periods of skill development. Nevertheless, we argue that it is important to retain reasonably wide confidence intervals around mean OPTION scores at the clinician level, as this is an indication of adaptation to context and patient interaction. In short, the instrument should be used to determine scores at group (mean scores) or at consultation levels and not to provide a definitive OPTION score that is taken to be characteristic of that clinician's ability, unless attention is given to case-mix, sample size and confidence interval estimation. The instrument results in a summed and scaled score that can be used for educational purposes, provided feedback is based not only on a clinician's ability to achieve high involvement scores but also to exhibit flexibility across patient problems and preferences. The validity of the instrument has been established by adhering to the principles of scale design and by using a defined set of consultations per clinician acceptable levels of reliability coefficients have been achieved, that comply with benchmarks in the literature. The responsiveness of the instrument to change (increased levels of patient involvement in decision making after skill development) and its behaviour in other clinical contexts and its reduction for use in educational contexts as OPTION*ed* will be validated in further evaluations.

Implications for practice

In the face of the widespread acceptance that patient centredness is a fundamental goal in clinical practice [40], and that sharing decisions is one of the key components of this approach, the result of this study confirms that the practice of clinicians, as represented by this sample (who are an 'above average' sample in terms of MRCGP membership and willingness to participate in this type of research), lies far away from espoused models in books and communication skills courses [41, 42], and indeed, the wishes of certain patients [43]. Does data from service contexts challenge these ideas: are the ideals of patient centredness and involvement in decision making completely unrealistic for day-to-day service contexts? Given that clinicians are consistently positive about the principles of patient centredness and patient participation in decision making processes, perhaps the issue of skill development is only a small obstacle and that the structural constraints, particularly the lack of time and readily accessible and relevant information about the harms and benefits of healthcare interventions, are the true limiting factors. These clinicians volunteered to have their consultations studied but even so the results reveal a very limited degree of patient participation. This study, among many others [44], provides additional evidence to the assertion that to successfully share information and involve patients in the consultation process demands more time than is allocated in the existing frameworks. Perhaps these results lend support to other changes, to the harnessing of technologies such as decision aids [39] and smart heuristics [45], that allow both patients and clinicians access to common sources of trusted information so that consultations are based on a firmer foundation for participation?

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Section 3

How should shared decision making be implemented?

Chapter 7

Shared decision making and the concept of equipoise: the competences of involving patients in healthcare choices

Elwyn G, Edwards A, Kinnersley P, Grol R.

Abstract

Background: Involving patients in healthcare decisions makes a potentially significant and enduring difference to healthcare outcomes. One difficulty (among many) is that the 'involvement' of apatients in decisions has been left undefined. It is usually conceptualised as 'patient centredness', which is a broad and variably interpreted concept that is difficult to assess using current tools. This paper attempts to gauge clinicians' attitudes to patient involvement in decision making and their views about the contextual factors, competences and stages required to achieve shared decisions within consultations.

Aim: To explore and understand what constitutes the appropriate involvement of patients in decision making within consultations, to consider previous theory in this field, and to propose a set of competences (skills) and steps that would enable clinicians (generalists) to undertake 'shared decision making' in their clinical environment.

Method: Qualitative study using focus group interviews of key informants.

Results: Experienced clinicians with educational roles have positive attitudes to the involvement of patients in decisions, provided the process matches the role individuals wish to play. They perceive some clinical problems as being more suited to a cooperative approach to decision making and conceptualised the existence of professional equipoise towards the existence of legitimate treatment options as an important facilitative factor. A sequence of skills was proposed as follows: 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 (e.g. ideas, fears, and expectations of possible options); 6) Checking process: Acceptance of process and decision making role preference; 7) Make, discuss or defer decisions; 8) Arrange follow-up.

Conclusions: These clinicians viewed involvement as an implicit ethos which should permeate medical practice, provided that clinicians respect and remain alert to patients' individual preferred roles in decision making. The interpersonal skills and the information requirements needed to successfully share decisions are major challenges to the clinical consultation process in medical practice. The benefits of patient involvement and the skills required to achieve this approach need to be given much higher priority at all levels, at policy, education and within further professional development strategies.

Introduction

The empirical evidence that involving patients in healthcare decisions makes a significant and enduring difference to healthcare outcomes [1-3] is not unequivocal, although there are some studies that support this hypothesis [1]. One difficulty (amongst many) is that the 'involvement' of patients in decisions has been left undefined. It is usually conceptualised as 'patient centredness' [4, 5], which is a broad and variably interpreted concept that is difficult to assess using current tools [6-8]. Nevertheless, the ethical need to respect autonomy and respond to the consumer demand for more involvement in decision making is becoming widely recognised [9-11]. However, apart from surveys (mostly hypothetical) of patient role preferences in decision making [12], the practical problems of involving patients in decisions have not been well investigated [13], although certain elements have been considered, such as the effectiveness of the risk communication stage [14].

The trend to place more decision making responsibility on the patient has led to the concern about potential 'abandonment' [15], where clinicians offer *information* about treatment choices but no guidance — a model known as 'informed choice'. Although this would seem to equate to 'unprofessional' behaviour in the eyes of some clinicians, this transfer of decisional responsibility is commonly reported by patients, and is commonly described in situations where clinicians are sensitive to medicolegal risks, such as in the United States [16]. This can result in patient anxiety in the face of uncertainty about the best course of action. For this reason, a middle ground is being advocated where decisions are shared — an approach often known as 'shared decision making'.

The key principles of 'shared decision making' have been conceptualised as a process that involves at least two participants — the patient and the clinician — and often many more (their respective networks of family or professional colleagues) [17]. Both parties take steps to participate in the process of decision making. Information sharing is a prerequisite to the process, a treatment decision (which may be to do nothing) is made, and both parties agree to the decision. Towle has proposed a list of competences based on work in Canada, which we used as a starting point for the study (Box 1) [18].

This possible approach has not been tested in clinical practice, although a study with simulated patients has explored its feasibility and suggested important modifications [13]. Future pragmatic trials will need definitions of the skills (competences) and stages in order to design measurable interventions. The question remains: what do clinicians perceive as the communication skills and stages that constitute the appropriate involvement of patients? The aim of this paper was to ask experienced clinicians to question these concepts, to consider the validity of existing proposals and suggest any modifications (or additions) that would enable the process to be realistically undertaken in their own clinical environment. This was done by conducting a series of key informant group interviews.

Box 1   Suggested steps for shared decision making [18]

- Develop a partnership with the patient
- Establish or review the patient's preference for information e.g. amount and format
- Establish or review the patient's preferences for role in decision making
- Ascertain, and respond to patient's ideas, concerns and expectations
- Identify choices and evaluate the research evidence in relation to the individual patient
- Present (or direct to) evidence, taking into account the above steps, and help the patient reflect upon and assess the impact of alternative decisions with regard to their values and lifestyles
- Make or negotiate a decision in partnership, manage conflict
- Agree upon an action plan and complete arrangements for follow up

Method

Six experienced clinicians actively involved in medical education attended three focus group interviews that focused on the skills required to involve patients in decisions (two to discuss the competences and a third interview to discuss and agree the results). They are regarded as the 'key informants' for this study. This technique is a recognised method for obtaining the views from within specific settings and situations [19]. The term originates from anthropological studies [20] where 'informants' are used to obtain opinions 'grounded' in specific experience and expertise [21]. They are chosen because they have special knowledge and skills and have access to perspectives otherwise denied to the researcher [22]. As they answer questions and provide explanations, they inevitably become engaged in the research process [23]. This straddling is important — theoretical constructs are thus tempered against field-based perceptions — and the relationship between informants and researchers contributes to a 'joint construction of reality' [24]. They are able to comment on the researcher's interpretations, expand, modify and clarify views as understanding increases as the process unfolds over time.

Study sample

Random selection procedures are not valid as it cannot be assumed that the characteristics of key informants are distributed equally in a population [25]. The sampling technique used is described as purposeful — a strategy which aims to yield a small number of informants who are judged able to provide specific insights [26]. It was decided that the informants should be able to think critically about the skills required for involving patients in decisions and had to meet the following criteria:

- be experienced clinicians who work in service settings
- have experience in assessing consulting skills competences
- have educational involvement at undergraduate or postgraduate levels

Informants meeting the above criteria in South Wales were identified and approached consecutively until we had achieved commitment from six clinicians (our preferred group size). One of the clinicians we approached declined the invitation; the clinicians who accepted the invitation attended each interview.

Key informant focus group interviews

Group interviews have been shown to be an effective technique for exploring opinions as well as defining consensus; the peer safety of group homogeneity promotes the exposition of hidden attitudes, a significant advantage over one to one interviews [27, 28]. By purposively selecting clinicians who had educational roles we were also emphasising the focus of the group, and making the most of their role as key informants. Before the first interview, participants were asked to read an overview of studies which evaluated the decision making roles that patients 'prefer' [29] and also a paper discussing the tasks facing clinicians in the 'explanatory' phase of the consultation [29, 30]. Before the second interview, informants were asked to read Charles' [17] discussion of the principles, and Towle's proposed steps, of 'shared decision making' [18]. No further information was provided. A resumé of our research aims was provided and the 2-hour long interviews were facilitated by one of the authors (GE). The interview questions are outlined in Box 2.

Box 2   Questions posed in the focus group interviews

First focus group: attitudes to patient involvement in decisions
• What are your views about the involvement of patients in clinical decisions?
• How important is it to consider the roles that patients prefer to play in decision making?
• What problems can be foreseen?
• What benefits might be anticipated?
Second focus group: skills required for involving patients in decisions
• What skills (if any) do clinicians need to involve patients in clinical decisions?
• What would constitute a successful 'shared decision' between a patient and a clinician?
• What stages could be identified and observed?
• Are there any other requirements?
Third focus group: results
• Discussion of pre-circulated report
• Agreement regarding amendments

Analysis

Transcripts of the recorded interviews were imported into NUD*IST (qualitative analysis software) [31]. The texts were coded into categories that corresponded with the emergent views about the skills of involving patients in decisions. Two authors (GE and AE) discussed the codes generated by this inductive approach, agreed descriptors, and compiled a logical sequence of stages for 'shared decision making' (Box 1). Quotes were selected on the basis that they were succinct examples of consensual views. Drafts of this paper were shared with the informants, both by correspondence (three cycles) and by discussion until there was agreement that both the 'quotes' and the text accurately summarised their views.

Results

The focus group finally recruited consisted of two GP vocational training scheme course organisers, two GP trainers, one continuing medical education tutor (who was also an examiner for the Royal College of General Practitioners), and one medical student tutor. These clinicians did not work in the same partnerships or share peer groups, and their practices were based in Llanrumney and Gabalfa (different areas of Cardiff), Bridgend, Swansea, Pontyclun (mid Glamorgan) and Abersychan (Gwent). The mean number of years in practice was 12 (range: 5-18 years) and the mean age 41 (range: 36-50). Based on the interviews, a list of 'competences' is proposed in Box 3.

Box 3   Stages and competences of involving patients in healthcare decisions

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 (e g ideas, fears, and expectations of possible options)
6	Checking process
	Acceptance of process and decision making role preference, involving patients to the extent they wish to be involved
7	Make, discuss or defer decisions
8	Arrange follow-up

Attitudes to involving patients in decision making

The overwhelming attitude to the concept of involving patients in decisions was 'yes, but'. The main proviso was that patient autonomy should be respected but not enforced Involvement should be achieved only to the patient's preferred level. The informants stressed the importance of maintaining flexibility: adherence to the 'informed choice' approach was considered 'another form of paternalism'. They supported the principle of involving patients, even if practical obstacles, such as the lack of time remained a major obstacle.

It is worth noting however that the informants expressed caution about the supposed wide applicability of 'shared decision making' The informants strongly agreed that some decisions lend themselves more naturally to the process of involvement. As one informant noted:

> Shared decision making is a tool I keep in my back pocket for those occasions when I really need to use it. (2nd interview)

Decisions where several legitimate treatment options were available were frequently cited as examples where the 'tool' was useful—situations such as atrial fibrillation, menorrhagia, early 'prostatism' and the consideration of hormone replacement therapy Whether all decisions in clinical practice can accommodate a 'shared' approach deserves to be explored in more depth [32] Nevertheless, even where legitimate options

clearly exist and co-operation is feasible, it was felt that clinicians must remain alert to any resistance and modify the communication process accordingly [33]. Despite these reservations, the clinicians agreed that the potential benefits (i.e. increased satisfaction and commitment to agreed management plans) outweighed possible problems.

Competency 1
Implicit or explicit involvement of patients in decision making process

The informants disagreed with Towle's first requirement—that clinicians should be explicit about the adoption of the shared decision making process at the start of a clinician-patient relationship [18]. This 'explicitness' was considered to reflect an insurance-based setting where patients take a more consumerist approach to healthcare. They did agree that patients should realise that they will be expected to take an active role in decisions, but this need not be expressed 'explicitly'— informants were aware that patient willingness to participate in decisions is often conveyed by non-verbal signals as much as by overt assent.

> ...it's about giving options and talking about them, not about actually saying "Hey ... this is [shared] decision making time... lets do this." I think patients would think I have gone barmy if I did that... (2nd interview)

Informants suggested the use of phrases such as:

> "There are several treatments that we could use here, and I'll run through them and see which one suits you best", rather than saying, "I'm involving you in a shared decision." (2nd interview)

The clinicians did however feel that it was important to frame the process so that patients fully understood that there was an opportunity to take part in a decision, and monitor non-verbal signals to check that patients had accepted the offer. An informant noted that involving patients cannot occur unless there is a 'trusting context' — a sense of:

> ... an equal relationship. [Patients] have to feel they are equal. If somebody feels they are equal with you and you're treating them as an equal... they will discuss [decisions] with you... (2nd interview)

Competency 2
Explore ideas, fears and expectations of problem and possible treatments

The informants confirmed that clinicians who are inexperienced at involving patients at the management stage of the consultation report that when they use phrases such as, 'What do you think we should do?', or, 'Did you have any views about the best thing to do?', they are commonly rebutted with responses such as, 'I don't know, you're the doctor' [13]. Exploring the 'patient's perspective on illness' is particularly difficult at this stage of the consultation, where the 'power' differential is clearly tipped towards clinicians. The informants

emphasised the need to achieve an understanding of this area by being open to the patient's contributions They suggested that by using mitigated phrases, deploying pauses and becoming sensitive to both verbal and non-verbal signals, it is possible to explore these issues without causing the impression that the enquiries are 'rhetorical' [32, 34] Another suggested ploy to draw out patients' views about possible choices was the use of 'listing'

> *[If] you ask [patients] what they think is wrong with them, then they won't tell you But if you give them a list of things that are in your mind then they will usually identify some of their concerns I think that's important bringing [the choices] up-front the patient [then] sees that the treatment options are valid '* (2nd interview)

Or alternatively, exposing the legitimacy of personal preferences by using phrases such as

> *I say, "Well actually, I might just do nothing here, but then I'm the kind of person who often does things like that I don't like taking tablets " and I explain that [to patients] '* (2nd interview)

Competency 3
Portrayal of equipoise and options

This was considered the pivotal stage of shared-decision making It consists of listing the options that are reasonably available, including, where relevant, the option of taking 'no action' Patients often find this a slightly surprising move, especially those who have previously encountered a paternalistic style As one informant noted

> *It depends how you put it to [patients], doesn't it? If you bluntly say, "Well, we could do A, B or C What do you think?" Then [patients] don't like it much Whereas if you say, "Well, you know, this isn't a black and white situation, Mrs Jones, there are a couple of options ", they will respond* (1st interview)

Although informants did not use the term themselves, they conceptualised what we term professional *equipoise* [14] i e in certain clinical scenarios the clinician can have no clear preference about the treatment choice to make This is where 'shared decision making' is most feasible Legitimate choices exist The following approach was suggested

> *Then if you discuss them [the options] briefly and say, "I'm not really sure which is the best one at the moment, do you have any view on it?" It's then very easy for them to say, "Well not really", and you can continue* (1st interview)

Equipoise was seen to be different to the 'uncertainty' that results from a lack of knowledge and it was felt to be essential that patients were aware of this distinction The informants readily admitted that variable (and genuine) levels of uncertainty clearly exist at times but expressing *equipoise* was perceived to be different

and seen as the skill of portraying options in a non-directive manner, that did lead to the patient developing a lack of confidence in a professional's ability.

it's the difference between doctor 'uncertainty' and the 'uncertainty' about the best treatment options They are two very different things aren't they? If you are confident telling them that you are uncertain which is the best treatment, [patients] are happy with that. That's a totally different thing to [the situation] where you are truly uncertain [due to] a lack of knowledge. (2nd interview)

Choice is always limited by the availability of specified options (unspecified options are discounted), and clinicians are in an influential position by the mere fact that they are able to decide which choices are described [35] This competency consists of making the correct range of options available, listing them in a logical sequence and in sufficient clarity so that patients perceive the opportunity to take part in the decision.

Competency 4
Identify preferred format and provide tailor-made information
Informants agreed that providing more information about each option was an indispensable step but drew attention to the need to identify the preferred 'data' format. Clinicians normally use verbal skills to convey information Patients may prefer the personal note that accompanies descriptions of this type [36]. But the increased emphasis on biostatistical outcomes offers the potential of giving numerical data in many circumstances—probabilities expressed as percentages, risk rates (relative, or absolute e.g. the 'number needed to treat') Clinicians need to be sensitive to these issues.

'I suppose we have to find out from the patient how much information they want, and how best to give it to them, really, and at what level.' (1st interview)

Informants emphasised the need for information accuracy [37] and the difficulty of extrapolating from population to individual risk As one informant noted:

it's complex because the knowledge sometimes isn't there and I don't know enough about the risks of the particular options I'm presenting [The data] also has to be patient centred, it has to be relevant to his or her particular concerns (1st interview)

It was felt impossible for generalists to recall detailed probabilistic information about a range of clinical problems and the informants noted the need to have rapid access to this type of data, preferably at the desktop

Competency 5

Checking process: understanding of information and reactions

Pausing and checking at regular intervals that an accurate understanding of both the treatment choices and associated information had been achieved was felt to be an essential skill. It was also felt that there was a need to review patient ideas, fears, misconceptions and expectations, which may have changed after the portrayal of treatment options. It was considered important to achieve:

> *a shared understanding of the problem and the choices, and the implications of each choice but also shared understanding about what's happening in the consultation [i.e. the decision making process].* (1st interview)

The most consistent theme in the transcripts was the emphasis given to the exploration of patient concerns and that the clinician understood the patient's perception of the relevant problem. Patients, they noted, are:

> *...afraid aren't they, they're afraid to come up with the ideas, concerns. Often they think we would see them as being silly concerns, or they're afraid that we [would regard them] as trying to dominate the consultation. We have to actively seek patients views, and often find [that] even by asking them directly they are very reluctant... Whereas if you say, "A lot of people in your position often wonder if so and so..." [Then they admit...] "Well actually yes, I am concerned about that..."* (2nd interview)

When asked about the checking process, the informants stated that:

> *You can't just do it once and say, I've done that, I can forget about it, because either the patient's ideas may develop during the consultation or the patient may be reticent to share their health beliefs, ideas and expectations... If you give them several opportunities, by checking throughout, they will come forward with their views.* (1st interview)

Competency 6

Checking process: acceptance of process and decision making role preference

It has been suggested that patients' preferences for 'involvement' in decision making should be ascertained prior to the actual process occurring [18]. Most of the published work reports hypothetical patient preferences for participation [12]. The informants disagreed and noted the impossibility of having informed views about preferred 'levels of involvement' before an actual consultation: in effect, before receiving information about the harms and benefits of the available options. The informants agreed that role preference should be ascertained after options have been described.

Informants stated that experienced clinicians are continually alert to signals that patients accept the level of 'involvement' being required of them, and adapt accordingly. The use of pauses, the technique of 'thinking out loud' and the monitoring of non-verbal cues were among the skills deployed:

> ..there's also the business about floating out cues to patients as well. They'll either pick up on them or not. If they don't, then perhaps you make the decision for them and if they do, then you might explore things a bit further. I suppose my sort of cues are that I think out loud with the patient in front of me and say, "Well there are a few options here..." They react in different ways, and often make me discuss the choices with them or just run them through myself. I might even say, "Well of the options, I think this is the best one, so perhaps that's what we'll do..." or involve them in it. It's like sending out a series of cues and see if they take the bait as it were...
> (1st interview)

'Checking acceptance of the decision making process' occurs without resorting to verbal utterances. Clinicians look for signs of:

> .. active listening... you know, they [patients] nod as we are talking and they encourage us to carry on , whereas the ones who don't want to know don't do that, they have very closed body language and don't encourage you...(2nd interview)

Competency 7
Make, discuss or defer decisions

This skill was described as the ability to make the transition from 'describing and checking' to the more active phase of achieving a decision, even if the result is to postpone the process. The competency is to convey that the 'decision making' or 'decision deferring' point has arrived and make it. Time pressure was perceived as a perpetual constraint for clinicians and the reality of short consultation lengths (in general practice particularly) led to an emphasis on the ability to bring discussions to a satisfactory close.

It was agreed however that the process should be perceived as open-ended: it is imperative to offer patients the opportunity to reflect and to discuss their concerns with others if needed. It was important to provide a 'cooling-off period' by using phrases such as:

> Do you want to talk further now or would you rather go away and come and see me next week,
> [so that you have an opportunity to involve] other people...(2nd interview)

It was noted that patients often seek guidance at this point by asking: 'What would you do doctor?' Even in a situation of equipoise, informants did not want to 'leave patients bereft of guidance'. In line with the description of 'shared decision making' as the middle ground between paternalism and 'informed choice', the

informants strongly agreed that it was acceptable to guide patients who requested assistance. The informants felt, 'it's a 60:40 situation patients want'. Clinicians should be:

> ...prepared to share [their] views about choices as well as taking into consideration patient's views about what is best for them... (2nd interview)

Competency 8
Arrange follow-up
Informants also felt that it was vital to offer an opportunity to reconsider issues on another occasion, even if, on the face of things, a firm decision had been made:

> ... if you are involving the patient it is important when the patient leaves, that they realise that the decision they've made on this particular occasion is not binding forever. (2nd interview)

Discussion
This qualitative study reveals that this group of experienced clinicians had positive attitudes to the concept of involving patients in decision making, was able to remain critical, and was able to suggest a list of skills that could be useful for others. These clinicians were not naïve to consultation skill texts, so this list of competences could not be developed de-novo, but was a result of a focused analysis of existing work. The competences developed here only mirror some aspects of Towle's framework [18]. New steps were proposed and fresh insights made. Checking that patients have understood the technical information provided is an important (and recurring) task. Towle's 'explicitness' stage (explaining that 'involvement in decision making was going to occur') was rejected by the informants as being 'too intrusive'. They felt that involvement was best done by using 'implicit' communication techniques, whilst maintaining surveillance that this was an acceptable process.

The most fundamental change to the previously proposed competences is that the timing of 'option portrayal' has been changed with respect to two other steps. The informants in this study stressed the importance of portraying options *before* checking whether the patient wishes to be actively involved in the decision. This is an important new facet to the shared decision making approach. The bulk of the literature to date has involved asking patients about their preferences for 'involvement in decision making' before an actual decision making experience [29, 38]. This study notes that asking patients about their *preferred* level of involvement before they have become aware of the possible choices they face is to pre-judge the interaction. In some consultations, where the choices are difficult and the issues painful, many patients will wish to withdraw from the decision making process. In others, they will wish to make active contributions. In many circumstances these preferences themselves depend as much on the skill of the clinician in 'sharing the decision' as on the actual problem faced, the personality type of the patient [39] or sociodemographic variables such as age or educational status.

The order agreed by the clinicians also confirms the value given by Katon and Kleinman [40] to an exploration of patient ideas (see their explanatory models) before professional views or options are portrayed so that the patient perspective is not contaminated by the clinician's assumptions

Two major challenges are apparent for a professional wishing to implement the shared decision making approach Firstly, involving patients appropriately requires the acquisition of a range of interpersonal skills, underpinned by a positive attitude towards the concept Secondly (and equally difficult) portraying options requires knowledge about the existence of the legitimate choices and access to technical information about the associated harms and benefits [41]

This study can be criticised for basing the definition of the skills and stages of involving patients in decision making on a small sample of informants who may be considered unrepresentative of the majority of clinicians On the other hand, collaborating with these 'key informants' over three consecutive discussion interviews was essential in order to explore these intricate communication skills in the intended depth and intensity Our aim was not to aim for a generalisable lowest common denominator but to tease out what is feasible in practice, as viewed by clinicians who subscribe to the highest potential standards within their discipline The results require confirmatory work, which should be undertaken from both professional and patient perspectives, particularly where patient involvement in the management of chronic conditions is likely to lead to significant pay-offs The process, in addition, inevitably contaminated the participants But the data reveals that they preserved their practical standpoints and remained critical of theoretical perspectives The principles of patient involvement are likely to be generic, although we recognise that further work needs to be done regarding their applicability in other clinical disciplines Taken in tandem with studies that reveal that clinicians in training do not regard themselves as well-equipped to share decision with patients [13], these results have important implications The benefits of patient involvement and the skills required to achieve this approach need to be given much higher priority at all levels, at policy, education and within further professional development strategies

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Chapter 8

Towards a feasible model for shared decision making: focus group study with general practice registrars

Elwyn G, Edwards A, Gwyn R, Grol R.

Abstract

Objectives: To explore the views of general practice registrars about involving patients in decisions and to assess the feasibility of using the shared decision making model by means of simulated general practice consultations

Design: Qualitative study based on focus group interviews.

Setting: General practice vocational training schemes in South Wales.

Participants: 39 General practice registrars and 8 course organisers (acting as observers) attended four sessions; 3 simulated patients attended each time.

Method: After an introduction to the principles and suggested stages of shared decision making the registrars conducted and observed a series of consultations about choices of treatment with simulated patients using verbal, numerical, and graphical data formats. Reactions were elicited using focus group interviews after each consultation and content analysis undertaken.

Results: Registrars in general practice report not being trained in the skills required to involve patients in clinical decisions. They had a wide range of opinions about 'involving patients in decisions', ranging from protective paternalism ('doctor knows best'), through enlightened self interest (lightening the load), to the potential rewards of a more egalitarian relationship with patients. The work points to three contextual precursors for the process: the availability of reliable information, appropriate timing of the decision making process, and the readiness of patients to accept an active role in their own management.

Conclusions: Sharing decisions involves sharing the uncertainties about the outcomes of medical processes and involves exposing the fact that data are often unavailable or not known: this can cause anxiety to both patient and clinician. Movement towards further patient involvement will depend on both the skills and the attitudes of professionals, and this work shows the steps that need to be taken if further progress is to be made in this direction.

Introduction

Involving patients in decision making is becoming an important clinical task [1, 2], particularly in general practice where health professionals can guide patients before they enter domains in which treatment bias may operate. Sharing information is not the same as sharing decisions [3] and there is no evidence that the available models for involving patients in decision making are feasible or that clinicians have the required skills [4]. In broad terms, three models of clinician-patient interaction — paternalism, informed choice and shared decision making — have been described, and their inherent assumptions debated [5] A paternalistic approach involves taking the responsibility for decision making. Informed choice is at the opposite end of the spectrum, where the patient is provided with 'sufficient' information and the clinician withdraws from the decision process. Shared decision making describes the middle ground [6]. But exactly how the principle of 'involving' patients resonates with practices has not been explored [7, 8]. Lists of competencies for involving patients have been proposed [9, 10] but not investigated (see Box 1).

Box 1   Towle's suggested steps for shared decision making [9]

- Develop a partnership with the patient
- Establish or review the patient's preference for information e.g. amount and format
- Establish or review the patient's preferences for role in decision making
- Ascertain and respond to patient's ideas, concerns and expectations
- Identify choices and evaluate the evidence from research in relation to the individual patient
- Present (or direct to) evidence, taking into account the above steps, and help the patient reflect on and assess the impact of alternative decisions with regard to his or her values and lifestyle
- Make or negotiate a decision in partnership, manage conflict
- Agree on an action plan and complete arrangements for follow up

It is therefore important to know if the theoretical constructs need to be adapted for use in clinical settings. We used focus groups to elicit the reactions of general practice registrars when they were asked to use a suggested model [9] in interactions with simulated patients in three specific disease areas (benign prostatic hypertrophy, menopausal symptoms and atrial fibrillation). In contrast with one to one interviewers, focus groups can explore differences in opinions as well as defining consensus and capitalise on group interaction to uncover hidden attitudes [12, 13].

Participants and Methods

Study sample

During 1998 four focus group interviews were held within the half day release sessions of vocational training schemes for general practice registrars in South Wales. Most researchers aim for homogeneity to gain peer group safety and the sample was purposefully selected to enable us to gauge the reactions of new clinicians to the concept of involving patients in decision making. All the registrars attending three vocational training schemes in South Wales were invited to take part in the study.

Interview structure

Participants were introduced to the concept of sharing decisions with patients and provided with an outline of suggested stages [9] and a description of the clinical problems they would encounter. Three small sets (3 or 4 people in each) were formed. Individuals volunteered in turn to consult with a simulated patient who had one of the three roles described in Box 2. The clinicians were asked to conduct the discourse as if they were a 'normal' consultation. The patients' roles and presentations were chosen, firstly, because they are typical of those seen in practice; secondly, because each clinical problem has treatment options that legitimately allow clinical *equipoise* — the patient's views can determine choice of treatment; and thirdly, because systematic review data are available regarding the options. The simulated patients were non-medically trained individuals with previous experience in undergraduate training in communication skills.

Box 2   Simulated patient roles

The vignettes described clinical situations in which the problem has been identified so that the participants could concentrate entirely on the decision making aspect of the consultation

Menopausal Symptoms
Patient undecided about hormone replacement therapy and anxious about the risk of breast cancer

Benign Prostatic Hypertrophy
Patient wishes to know more about the typical options that face a man who is told that he has 'prostatism', with no other risk factors

Atrial Fibrillation
Patient wishes to know about the pros and cons of warfarin and aspirin for prevention of stroke

Each set was assigned one clinical problem and the consultations conducted by different clinicians in turn while others observed. Before the first consultation, a short description of the risks of each treatment option was provided. Before the second consultation numerical data about the risks were provided, and before the third consultation the same data were provided in a graphical format. This staged introduction enabled us to gauge the effect it had on the registrars' methods of involving patients and is reported separately [14]

Focus group interviews

Group interviews were held after each consultation and reactions explored use of an interview schedule (see Box 3) The simulated patients were present and given opportunities to contribute The total duration of the interview was 80-90 minutes, and the proceedings were audiotaped and transcribed

Analysis

The transcripts were examined by three authors (GE, AE, RGw) to identify emergent themes [11] These were agreed by discussion and the data categorised independently by two authors (GE and AE), who

subsequently agreed an overall classification As our intention was to present viewpoints rather than achieve statistical generalisability, the data are not presented numerically Trends and majority agreements, however, are indicated The results were checked with the simulated patients and three of the course organisers and modified where required

Box 3   Interview schedule

Views on involving patients in decisions
- What do you think about the concept of 'shared decision making'?
- Have you been trained in anything similar?
- Is it important to consider patients' preferences for 'involvement'?
- What do you think about giving patients options?

Explore views on providing 'data' to patients
- Does it help?
- How much information is useful?
- Is it feasible to do this within the diversity of general practice?

Explore views on the skills required
- What problems do you anticipate in practice?
- Are there groups of patients in whom this approach would be difficult or inappropriate?
- Are these inherent skills or do they need development?

Results

Of 45 registrars within the training schemes during the study period, 39 (87%) attended one of four interviews in different parts of South Wales Eight course organisers acted as observers, taking the total number of clinicians involved to 47 Five themes were identified

Views about 'shared decision making'

Positive and negative views about involving patients

All the participants agreed that the concept of 'shared decision making' was novel

> *"It was new   Doing something different to the talk we normally do " (Heath)*

and a spectrum of opinions was elicited At one end was the view that no matter *how* data are presented it is unrealistic to expect patients to participate in decision making

> *"The patient has no information to make an informed choice At the end of the day it is a professional judgement " (Cwmbran)*
> *"They [the patients] haven't been to medical school for five years, how can we expect them to make a decision?" (Bridgend)*

There was also evidence of a professional reticence to undertake this approach:

> "I wouldn't have dreamed of showing you [the patient] the figures." (Roath)

Others were more receptive to the idea and the potential benefits of involving patients. This was tought to be particularly true when options are equally tenable.

> "It is more rewarding using them [the risk tools], because you feel you have informed the patient. They've got the information, and have some part in the decision rather than just listen to us talking to them." (Bridgend)

> "[sharing decisions] unburdens the doctor...[when] there's a lot of uncertainty about what is the best thing to do." (Cwmbran)

Barriers to sharing decisions:

Lack of information and a reluctance to share data

Most participants acknowledged the potential benefits and discussions revolved around the difficulty of actually involving patients. It was said that sharing decisions:

> "...is entirely content specific. You can't lay out options and their pros and cons if you don't know them." (Bridgend)

> "It threw into stark reality how often patients ask questions for which we don't have the information in the depth they require at our fingertips." (Roath)

Some thought that 'specialists' might be better placed than generalists on this task. Nevertheless, there was agreement that patients want information in 'depth'. All the participants agreed that the the data had to be robust.

> "it has got to be cast iron data".

Time and timing

Participants thought that it was very important to achieve the correct 'timing' for shared decisions. In their opinion only a few consultations contain problems for which it is feasible to provide options. Decision making in their view should not be imposed on patients who are anxious and not ready to consider choices. Lack of time was cited as a barrier, particularly the time it would take to find accurate data, though this was not overemphasised. The view emerged that it is unusual for decisions to be taken within one consultation, so the task could be staged. Further discussions are often necessary and the agreed view was that:

> "... sharing a decision is a process not an event." (Heath)

Contextual modifiers

Many participants emphasised the need to be sensitive to 'contextual' modifiers such as age and educational achievement It was widely thought that some patients would have difficulty in understanding outcome data presented as probabilities Presentations of choices, they said, often have to be simplified and at times omitted altogether Participants were also conscious that established consulting patterns within a long-standing professional relationship could militate against the introduction of a new approach to decision making

Types of decisions

Another obstacle was the nature of the decision itself Sharing decisions was considered particularly appropriate in situations of professional *equipoise* about the 'best' choice of treatment It was thought that situations that lacked equipoise (such as urgent or dangerous medical problems) or situations of conflict (where patient 'demand' is contrary to empirical evidence) needed different decision making approaches

Reported current practice

When they were asked to compared these techniques against their 'usual' practice most registrars stated that they normally bias their presentation of facts and consciously 'steer' patients

> *"You choose the data to help the patient make the decision you think they ought to make I'm sure I do that " (Bridgend)*

One clinician, talking about hormone replacement therapy, revealed a strategy of attempting to judge a patient's preferred choice before tailoring the data to reinforce the patient's view

> *"I try to establish what the patient really wants then I push the information in that direction " (Roath)*

Some of the participants, however, were not prepared to allow patients into the decision making arena

> *"If the doctor feels that one course of treatment is better than another course of treatment, then that should be strongly pressed home " (Cwmbran)*

There was also an unchallenged expression of irritation with the notion of the 'informed patient', and data were viewed as a method of enforcing the clinician's decision

> *"They've come in after reading the damn patient leaflet and are worried about side-effects There's no way they can assess in their head what the risks are, so they just don't take it [the medication] " (Cwmbran)*
> *"I spend a lot of my time telling people that they don't need whatever they've barged in and demanded so statistics could be quite useful for that " (Cwmbran)*

Training and skill implications

Although all the registrars had previously received training in communication skills, they all agreed that their previous experience of:

"... teaching had concentrated on the first part of the consultation. The emphasis has been on achieving rapport, matching agendas and problem-solving." (Heath)

Most participants were positive about the techniques being explored, which contrasted with their ambivalence about involving patients in decisions making.

Insights into the process of sharing decisions

Explicit about process

The registrars thought that an essential feature of successful patient involvement was explicitness about the decision process and indicated that a useful way of legitimising patient involvement was by the use of phrases such as:

"This is a problem on which doctors do not have one view." (Roath)

Many registrars recounted that when the phrase *"What would you like?"* is used as a ploy to explore patient views, the typical response is, *"I don't know, you're the doctor."* There was general agreement about the need to develop methods of involving patients that seem neither insincere or 'rhetorical'.

Portrayal of options

The participants noted that an important part of the process was a clear portrayal of choices. Some noted that they described options merely to undermine or dismiss them. Others noticed that they did not list all the options available—that there was a tendency not to describe the choice of 'no action' or of deferring a decision.

Patient role in decision making

The clinicians admitted that it was not their usual practice to ask patients about their preferred role in decision making. There was, however, an underlying assumption that most patients *do* want to be involved and that clinicians are good judges of their preferences.

"I think there is this kind of intuitive judgement [about preferred role] that I often make when I first talk to a patient in the first part of the consultation." (Heath)

Opinions about possible 'outcomes' of sharing decisions

For many participants a positive outcome of sharing decisions was the increased sense of confidence that resulted from the feeling of being *"protected by data"*. More commonplace in the discussion was the expression of concern about the potential anxiety in patients that could result from too much information and the added responsibility of decision making in the face of complex data about probabilities:

> *"It's clear on an intuitive level that 'doctor uncertainty' is likely to distress a lot of patients."* (Cwmbran)
>
> *"Telling people about small risks will probably cause more trouble than keeping quiet until problems crop up."* (Bridgend)

The simulated patients suggested that other more patient orientated outcomes were important and placed a high value on the availability of choices and the perception of involvement in decision making. The patients thought that a key characteristic of a 'successful' consultation would be the experience that information had been well presented, and therefore understood, and they were confident that greater understanding would lead to a greater commitment to a chosen management option.

Discussion

Our exploratory work shows that this group of junior clinicians had not developed the skills needed to involve patients in clinical decision making. These clinicians were in transition between the 'hospital based' clinical environment and the culture of general practice; experienced clinicians might react differently. The registrars were unaware of the benefits of patient participation in decision making and thought they did not have the information necessary to explain the risks and benefits of treatment choices. They admitted that 'friendly persuasion' [15] was their usual practice, justified on the grounds that the responsibility of being involved in decisions would lead to increased (and by implication unacceptable) anxiety in patients.

The use of simulated patients can be criticised for being one remove away from 'actual' practice [16]. Nevertheless, because our aim was to obtain views that were not based on abstract notions, this method was acceptable to the registrars and provided them with as close an experience as possible of the concepts of shared decision making within a peer group environment.

The stages of shared decision making suggested by Towle need modification to take into account the context, the type of decision, and the amount of control the patient prefers within the different stages of the interaction [10]. Population based surveys cannot predict role preference [17] and involvement needs to be tailored appropriately at every interaction [18]. This work illustrates the complexity of achieving partnership with patients and the illogicality of asking patients about their preferred role until they have realised the possible harms and benefits entailed and their associated probabilities. Then, and only then, can it be legitimate to ask whether individuals want to take an active role in decision making [10].

Box 4   Stages and competencies of involving patients in healthcare decisions

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 (e g ideas, fears, and expectations of possible options)
6	Checking process
	Acceptance of process and decision making role preference, involving patients to the extent they wish to be involved
7	Make, discuss or defer decisions
8	Arrange follow-up

Our results show that clinicians need to adapt to varying contexts, preferences of patients, and types of decisions [19]. To argue that patients should always be involved in clinical decisions is unwise. But as information becomes readily available to all, this work starts to identify some of the steps required to implement the process effectively

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Chapter 9

Shared decision making in primary care: a cluster randomised trial of practitioner skill development

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Abstract

Background: It has been proposed that involving patients in decision making processes could potentially lead to a range of improvements in affective, cognitive and medical outcomes. A consulting method known as 'shared decision making' has been described and operationalised and a specific process measure developed. This provides the opportunity to assess whether clinicians can develop these skills and implement them in service settings, as a prelude to examining the effect of involving patients in decision processes on other outcomes.

Aims. To evaluate the independent and combined impact of skill development workshops and risk communication tools on the ability of clinicians to involve patients in decision making processes.

Design: Cluster randomised controlled trial.

Study sample· 20 clinicians and 393 patients diagnosed as having four specified clinical conditions (nested within the clinician's organisation).

Method: Clinicians were randomised to two interventions — interpersonal skill development and the use of risk communication tools — in a cross over design. Patients were randomised within each practice, balanced for four clinical conditions across trial phases, and asked to attend for review-type consultations which were audiotaped Independent raters assessed the consultations using a validated scale — OPTION (observing patient involvement).

Results As a result of the interventions, the clinicians significantly increased their ability to involve patients in decision making in scheduled consultations in clinical settings with real patients Both interventions independently increased patient involvement levels The level of involvement achieved by the risk communication tools was significantly increased by the subsequent introduction of the skill development workshops. The alternative sequence (skills followed by risk communication tools) did not achieve this effect

Conclusions: The effectiveness of these interventions indicates the need to develop decision support technologies that provide easily utilised information for both clinicians and patients, within and outside the consultation. In addition, the results reinforce the need to develop communication skills during the postgraduate career, as it appears that decision aids only go part of the way towards delivering the overall potential benefit for patients.

Introduction

Shared decision making, a short hand term used for the process of involving patients in clinical decisions, has been the subject of debate in the recent literature on interpersonal communication in medicine [1, 2]. Although the principles of the method are described [3], the competences outlined [4] and a measure proposed [5], there is uncertainty about the proposal [6-8] and some doubt that the concept can be applied in clinical settings [9-11] Although there are feasibility studies reported [12] there is no agreement, or evidence, about how to implement shared decision making This uncertainty can be compared with a parallel situation regarding the patient centred method, whilst undoubtedly a worthy goal for clinicians, is not an approach that has been found exhibited in professional practice [5, 13-15] It is also a consulting method that has proved difficult to measure [16-18] For shared decision making, where the attention is more narrowly focused, the unanswered questions are twofold firstly, it is not clear whether clinicians working in everyday settings can improve their skills at involving patients in decisions, and, secondly, whether the model for developing shared decision making should be based on information provision or interpersonal skill development The study was therefore designed to explore Bensing's contention that evidence-based medicine [19] and patient-centred medicine [20] were separate worlds [21]

It should be emphasised however that involving patients in decisions (shared decision making) [22] does not equate to implementing the 'patient-centredness' method, which, to summarise, emphasises the importance of exploring patient agendas, ideas, concerns and expectations about presenting problems the conceptual distinctions centre on the onus in shared decision making for patients to take an active part in understanding and contributing to the decision process, provided they accept this role In essence, the idea of shared decision making is one where professionals should work to define problems with sufficient clarity and openness so that patients can comprehend the inevitable uncertainties that surround most decisions in medicine and therefore appreciate that choices have to be made between contesting options This is especially pertinent for generalist practice where the *pros* and *cons* of differing strategies can be considered using a broader set of biopsycholosocial evaluations, often informed by long-term relationships with patients. Very few studies have investigated shared decision making [23] and risk communication to any depth in actual clinical settings [24, 25] Hulsman and Bensing's review confirmed the inadequacy of the research designs reported to date [26], although the potential problems of taking a 'shared approach' to decision making have been well highlighted [9, 12, 27, 28] Despite the difficulties, it is important to investigate whether clinicians can achieve proficiency in the task on involving patients in decisions and, if so, how are the skills best developed, and most effectively *implemented* in everyday practice settings In summary, there are two broad schools of thought on how best to achieve patient participation in clinical decisions A widely promulgated view is the biostatistical model, known more recently as 'evidence based medicine' [19], where it is postulated that if clinicians are well informed about the risks and benefits of treatment choices, they will, as a consequence of their knowledge, impart harm and benefit information to patients and thereby involve them

in decision processes, particularly if they are given decision aids to assist the task of information provision [29]. An alternative approach is based on the development of interpersonal skills [30], emphasising the importance of communication skills as a means of ensuring patients participate in decision processes [20]. The current trial attempts to separate these two aspects and test their effect as single and combined interventions using a randomised cross over design in order to distinguish the contribution of each approach. Which intervention, if any, has the greatest effect? Perhaps the provision of well designed risk communication tools can achieve equivalent levels of patient involvement compared to skill development strategies, which are more expensive to deliver, and so future efforts should concentrate of providing easily available decision support materials.

As far as we are aware this is the first reported study to have operationalised *shared decision making* and *risk communication tools* as specific and comparable interventions. The aim was to investigate the hypothesis that the provision of these interventions, skill development workshops for shared decision making on the one hand and instruction in the use of risk communication tools on the other, would increase the ability of clinicians to involve patients in decision making processes, and in addition, to assess the contribution of each approach, both independently and in different sequences to delineate the best model for improving shared decision making with patients.

Design, participants and methods
Design
This study reports the results of a process measure applied within a cluster randomised controlled trial designed to study the impact of shared decision making and risk communication on patient involvement levels. Clinicians were randomised to two interventions; interpersonal skill development and the use of risk communication tools, in a cross over design see Figure 1. Patients were randomised in each practice, balanced for four clinical conditions across trial phases, and asked to attend for review-type consultations that were audiotaped and assessed using a specifically designed scale named OPTION (observing patient involvement). Clinicians consulted using consultations of typical length (approximately 10 minutes) about the specified condition, using 'normal practice' methods at baseline. They were allocated to one of the two interventions (see Box 1) and subsequently asked to implement their effect in consultations with selected patients. Randomisation was conducted by the trial statistician (KH) using a random number generator and implemented by the research officer (CA). Patients were randomised within practice samples after completing consent procedures. Ethical approval for the study was obtained from the Gwent Health Authority Local Research Ethical Committee and the work is reported according to current guidelines [31, 32].

Box 1   Trial interventions

Shared decision making

Clinicians randomised to this intervention attended two workshops where a standardised and previously piloted skill development process was undertaken using presentations, discussions and participation in consultations with simulated patients The theoretical basis underlying this skill development was the extended model of interpersonal interaction outlined by Hargie [30] which proposes that as skill 'perceptions' are translated into motor responses (speech and actions), a sequence of feedback loops ensure that performance is modified Repeated cycles lead to fluent skill acquisition. This is a widely accepted basis for communication skill development in clinical contexts [38] The background literature on shared decision making was outlined and participants asked to debate the relevance clinical practice. The skills (competences) of shared decision making [4] were described and demonstrated using simulated consultations (GE) This provided opportunities for all the participants to comment on the method, using an observational competence checklist Simulated patients were also encouraged to comment. Participants were asked to consult with the simulated patients using pre-prepared scenarios involving the study conditions At the second workshop, participants were asked to consider the competences in more depth. By the end of the workshop, all participants had conducted and received feedback from at least one consultation with a simulated patient

Risk communication tools

The risk communication tools consisted of tabulated data and visual displays of risk estimates using histograms and bar charts for the four study conditions The risk data were based on systematic reviews (or similar epidemiological sources) and presented as the best evidence available at the time of the trial Definitions of *risk communication* were provided in order to distinguish this concept from other terms in common use, such as risk *management* and risk *analysis* Recent research in this area was summarised [39] The participants were provided with treatment option information for the study conditions in the following range of formats summary statements, bar charts, numerical statistical information and abridged copies of source publications They were advised to choose the most appropriate format to use with individual patients Participants were told about the derivation of the risk tools, advised on how to use them in the consultation and then asked to incorporate them in simulated patient consultations. The consultations were conducted in pairs, where colleagues alternated roles This was repeated until each participant had received feedback after conducting two or three consultations using the risk communication tools across a range of conditions A plenary group discussion, which included the patient simulators, allowed the group to share learning points and consider the application of the materials in clinical practice

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Participants

Eligible clinicians in the Gwent Health Authority catchment (south east Wales) were identified for recruitment into the trial if they had been a principal in general practice for at least 1 year and less than 10 years. Four clinicians were excluded as they had been previously involved with the researchers on earlier studies. A total of 104 clinicians based in 49 practices fulfilled these criteria and they were all invited to participate by letter, followed by a telephone call. The study design allowed only one clinician per practice organisation. As an entry threshold to the trial, clinicians were required to provide an audiotape of a normal clinical session (recruitment tapes). This exercise was designed to determine their ability to undertake a study that depended on the use of audiotaped recordings to examine communication processes. These recordings were analysed using the OPTION scale to provide data about the patient involvement levels achieved by these clinicians in everyday practice settings [5].

The four clinical conditions were menorrhagia, hormone replacement therapy, 'prostatism' and atrial fibrillation, selected because they have more than one treatment option and as earlier studies have

demonstrated the successful use of risk communication tools [12]. Although patients with these problems can be found in all practices, the incidence of patients presenting these problems *de novo* is low. The trial therefore used a proactive method to identify previous attendees, circumventing the problems associated with clinician based patient recruitment. Computer reports (using disease codes and medication as identifiers) were generated where possible, augmented if necessary by hand searches. Inclusion and exclusion criteria are listed in Table 1. To maintain patient confidentiality, practice staff worked in liaison with the study research officer to send patients trial information and consent procedures. Patients were categorised into the four study conditions (for details see Figure 1), and asked to attend scheduled 10-minute consultations outside the clinicians' normal clinical sessions, with 20-minute spaces between appointments in order to create time for audiotaping and the administration of exit interviews and questionnaires to both patients and clinicians. The target sample was 24 patients per clinician: 6 attendances at baseline, 12 after the first intervention, and 6 after each clinician had received both interventions, giving a proposed clinician total of 24 audiotaped consultations. Patients unable to attend an allocated appointment were offered an alternative appointment (or excluded from the study if alternatives were inconvenient or if they did not attend). Both clinicians and patients were informed that the trial was investigating 'communication skills' but had not been told that we were specifically interested in decision making. The participating clinicians could not be 'blinded' in the trial but details about the interventions and the sequential cross over were not made explicit.

Table 1   Patient Inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
General	Consultation within previous 3 years	> 75 years of age
	Identification by computer codes and repeat medications	
Specific	Diagnosis of 'menorrhagia' (range of synonyms)	Hysterectomy
	Diagnosis of 'menopause' (range of synonyms)	
	Ages 45 – 55 current or previous users of HRT	
	Lower urinary tract obstruction: diagnosis of 'prostatism' (range of synonyms)	Prostate cancer
		Prostate surgery
		Raised prostatic specific antigen level
	Atrial fibrillation	

Outcome measure

Prior to the trial, it had been determined that there were no instruments available that could measure the extent to which clinicians involved patients in decision making with sufficient validity and reliability [33]. A scale known as OPTION (observing patient involvement) was therefore designed, evaluated and validated. The scale's psychometric properties are published elsewhere [5]: a synopsis is provided here. The scale consists of twelve 5-point items scored by two trained, calibrated lay raters who independently assessed recordings of clinical consultations, blinded to the trial phases. Potential scores range from 0 – 100, with high scores indicating increasing level of patient involvement in decision making (shared decision making).

Consultation timings were recorded and analysed Inter rater correlation coefficients (classical method) have been established in at 0 62, mean Cohen's kappa scores for inter-rater agreement level, 0 71 and Cronbach's alpha, 0 85 [5]

Statistical analysis

The study had sufficient power to detect a change of 6 6 points on the OPTION scale, equivalent to a moderate effect size [34] (0 6 of the standard deviation, corrected for clustering, in the OPTION scale when used to assess routine consultations [5]) A total sample size of 20 clinicians with 6 consultations measurements at each point was therefore needed, for a power of 0 80 and alpha of 0 05, taking into account consultation scores within clinician using an intracluster correlation (ICC) of 0 35 The actual ICC in routine consultations was 0 22, but we expected that it would be higher after the interventions To allow for equal comparisons of consultation numbers at each trial phase, the number of measurements after the first intervention was increased to 12 per clinician, which resulted in a proposed sample size of 480 patients

The mean OPTION scores (and 95% confidence intervals) for each clinician during the phases of the trial were calculated Where one rater had missing item scores (1 8%), these were substituted by valid rater scores, but only for aggregate data analysis Comparison of between and within group means (t tests) was corrected for clustering [35] To determine the predictive contribution of multiple variables whilst accounting for clustering, a hierarchical analysis (ratings nested within consultations within clinicians) was also performed using MLwiN, a multi-level modelling software [36, 37] Explanatory variables were entered as fixed effects in a regression model with the OPTION score as the dependent variable Using a reduction in the log likelihood of fit, the model was designed to assess the impact of rater, condition, patient age and interventions, with the intervention effect, either as a *single* or *combined* effect, or sequence *order* effect, entered as the last explanatory variable

Results

Recruitment and participant flow

A total of 21 clinicians, after they had provided an audiotape of a routine clinic, were recruited into the baseline phase, and 20 completed the study Figure 1 summarises the trial participant flow The clinicians represented a group that was slightly younger than the sampling frame average age 38 years compared to 41 years, the male to female ratio was identical (38% female), 80% of clinicians recruited had obtained membership of the Royal College of General Practitioners, compared with an overall membership level of 54% in the sample approached

Figure 1 Sequencing of Interventions and participation of clinicians and patients in trial of shared decision making skill development
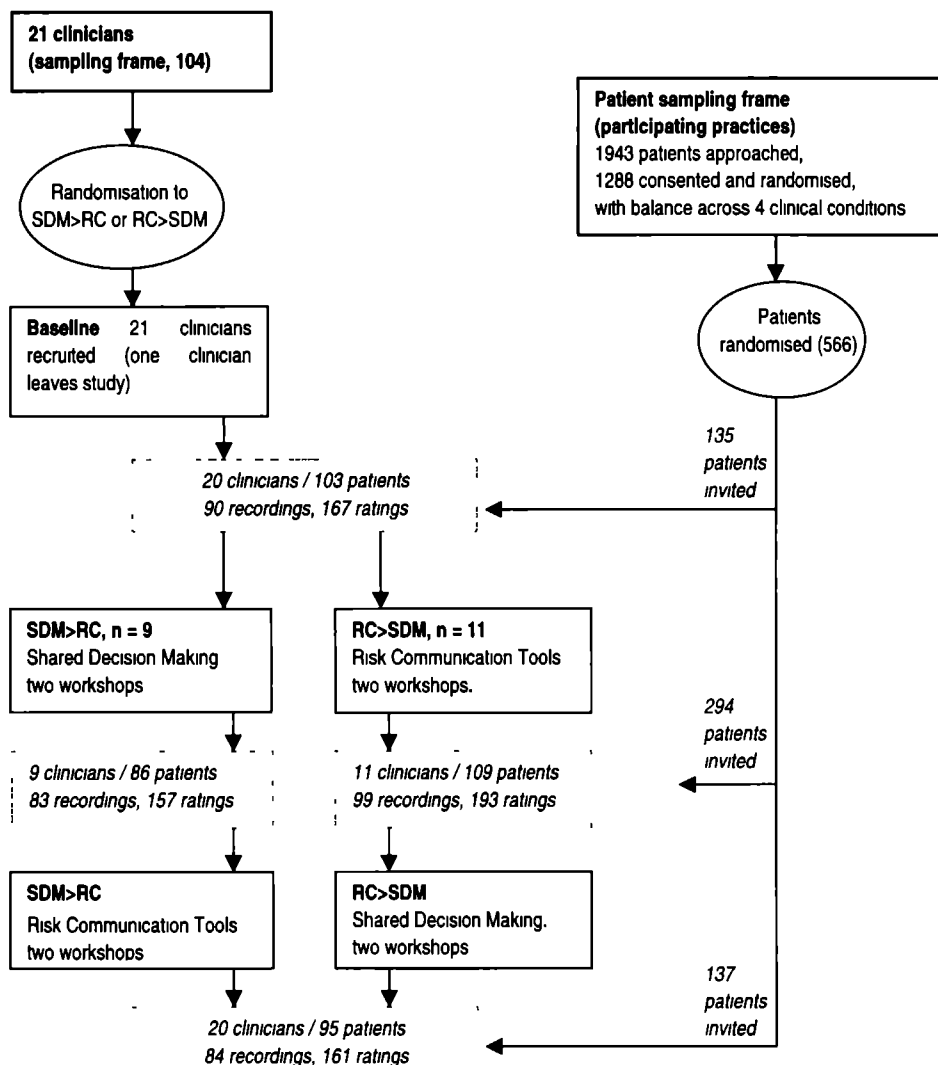
A total of 1943 patients in the participating practices were sent information about the proposed trial and 1288 (66%) gave their consent. The mean age of patients recruited in each condition category was as follows: menorrhagia 45, hormone replacement therapy 56, prostatic symptoms 63 and atrial fibrillation 65 years. Aiming for the proposed sample of 480, 566 patients were invited across the trial phases. Declined

appointments, non-availability to re-scheduled appointments and non-attendance resulted in 171 declined attendances, giving a total of 393 patient consultations and 356 successful recordings. There were no differences in age or condition type between attendees and non-attenders. The distribution of successful recordings and ratings across the trial phases is outlined in Table 2. Audiotaping was conducted within 4 weeks of completed intervention workshops. There was no significant difference between the duration of consultations in the trail phases (see Table 2).

Table 2   Data collection results, mean consultation duration across trial phases

Trial phase	Patient consultations	Recordings	Ratings	Mean duration, minutes, seconds	Menorrhagia	HRT	Prostate	AF
Routine	186	186	372	8,12				
Baseline	103	90	167	12,24	18	40	26	19
SDM>RC	86	83	157	12,37	16	29	24	16
RC>SDM	109	99	193	12,44	24	39	33	14
Combined	95	84	161	13,00	16	29	30	16
Trial totals	393	356	678		74	137	113	47

Outcomes

Mean option scores and ranges for each clinician across trial phases are presented in Table 3 and illustrated in Graph 1. The clinicians are grouped by their random allocation to the two sequences, shared decision making followed by risk communication (SDM>RC, n = 9), and risk communication followed by shared decision making (RC>SDM, n = 11). OPTION scores from consultations in routine practice showed no difference between groups (mean scores of 16.6 and 16 5 respectively) The difference in OPTION scores between the two groups at baseline (SDM>RC = 50.4 and RC>SDM = 44.8) was not significant (t-test, P < 0 1) There were significant within-group shifts after the first intervention, i e. after the skill development and risk communications workshop the group means changed from 50.4 (baseline) to 63.8 (SDM>RC) and from 44 8 (baseline) to 60.3 (RC>SDM) (t-test, P < 0.0005). The between group values at this point (63.8 and 60 3) were not significantly different (P < 0 1). After cross over, there was a significant difference between groups of 6 9 points (SDM>RC mean = 64 9, RC>SDM = 71.8 (t-test, P < 0.05). The ICC, corrected for variable cluster size, was 0 18 at the baseline phase.

Table 3   OPTION Scores for clinicians across study phases. Values are mean (range)

Clinician Groups	Recruitment	Baseline	Shared decision making	Risk Communication	After both interventions
SDM>RC Group					
1	19 6 (17 5)	44 3 (37 5)	57 0 (35 8)		60 8 (16 7)
2	16 5 (16 7)	45 0 (26 7)	68 2 (20 8)		60 8 (27 5)
3	15 5 (25 0)	52 3 (25 8)	66 9 (35 0)		61 4 (20 0)
4	22 6 (28 3)	44 3 (8 3)	69 8 (33 3)		78 3 (15 0)
5	14 4 (13 3)	67 5 (35 0)	68 7 (21 7)		66 3 (23 3)
6	10 2 (27 5)	55 0 (16 7)	60 0 (37 5)		62 7 (30 0)
7	15 9 (25 8)	57 5 (53 3)	59 6 (18 3)		73 1 (25 0)
8	20 6 (25 0)	48 3 (13 3)	67 0 (53 3)		61 3 (19 2)
9	13 8 (10 0)	43 5 (23 3)	58 4 (21 7)		61 3 (15 8)
Group Mean	**16.6**	**50.4**	**63.8**		**64.9**
RC>SDM Group					
10	8 8 (10 8)	29 2 (27 5)		52 7 (13 3)	65 7 (30 0)
11	15 4 (25 0)	Missing data		59 8 (27 5)	68 1 (19 2)
12	18 2 (39 2)	50 (12 5)		60 4 (35 8)	78 1 (26 7)
13	18 2 (25 8)	40 8 (25 8)		66 7 (35 8)	73 2 (19 2)
14	15 9 (19 2)	42 5 (37 5)		58 2 (18 3)	70 4 (25 0)
15	16 9 (15 8)	35 3 (14 2)		60 0 (40 8)	66 3 (10 8)
16	13 3 (15 0)	43 7 (14 2)		54 3 (41 7)	78 7 (38 3)
17	17 7 (17 5)	44 0 (57 5)		61 5 (24 2)	62 7 (15 8)
18	20 6 (30 0)	53 3 (30 8)		58 6 (11 7)	77 1 (13 3)
19	17 8 (25 0)	57 0 (29 2)		67 0 (29 2)	70 0 (13 3)
20	18 8 (13 3)	55 8 (35 8)		61 2 (15 0)	70 6 (35 0)
Group Mean	**16.5**	**44.8**		**60.3**	**71.8**
Overall Mean	**16.5**	**47.1**			**68.4**

Graph 1   Mean Clinician Option Scores across trial phases
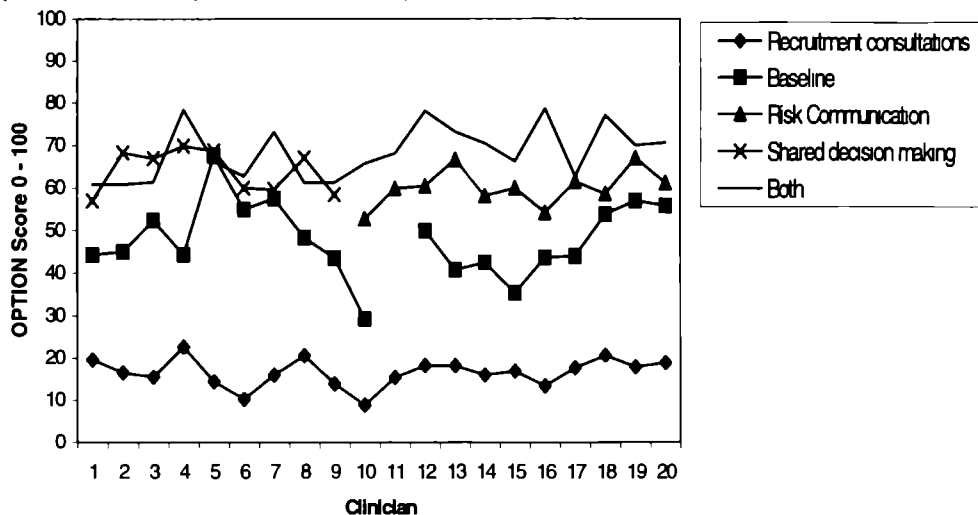
The results of the multilevel model are presented in Table 4. After data cleaning, 678 completed ratings were included in the analysis. A three level model was fitted with rating at level 1, consultation at level 2 and clinician at level 3. The model assessed the extent to which variability in OPTION could be explained by the rater, the medical condition (3 dummy variables) and the intervention (risk communication, shared decision making as single interventions, the effect of combining the interventions and the effect of the order in which they were received). All variables were entered as fixed effects initially, but the improvement of fit from allowing the effect to be random was also assessed. 'Condition' did not significantly improve the model fit and has therefore not been included. Only the effect of the raters was shown to have a random effect at the clinician level.

Table 4   Final Multilevel model results §

Fixed effects	Coefficients	Standard error
Constant	48.2	2.02
Rater	-12.5	1.03
Risk Communication (RC>SDM)	10.8	1.41
Shared decision making (SDM>RC)	12.8	1.51
Combined interventions	-10.9	2.34
Order (RC>SDM)	8.1	2.25
Random effects		
Level 3 Clinician		
Constant	44.7	21.06
Rater	13.4	6.64
Level 2 Consultation		
Constant	49.8	6.87
Level 1 Rating		
Constant	61.7	4.96

§ The basic model (only a constant included) had a −2 log likelihood log likelihood of 5507.09 which was reduced, after the addition of the variables and final iteration, to 5084.33.

To summarise, based on the results of the OPTION scale ratings, it can be stated that the trial has demonstrated:

- A significant increase in patient involvement as a result of both the risk communication and shared decision making skill development workshops
- A significant additional in patient involvement as a result of receiving both interventions was only seen in those who received risk communication intervention first then shared decision making skill development second (RC>SDM)
- Patient involvement levels did not vary across clinical conditions
- There was a significant difference between raters

It therefore appears that the most effective way to increase the ability of clinicians to involve patients is provide detailed information *before* discussing skill development techniques The ability of the clinicians to involve patients in decisions did not vary to any significance between conditions or patient age There were consistent differences between rater OPTION scores and the results remain significant when adjustment is made for this finding Initial analysis of patient outcomes, collected for a parallel study to be reported separately, indicates beneficial effects after both interventions These results require further assessment It is noted that during a debriefing interview (conducted on a small sample of the recorded consultations), one patient developed chest pain and was admitted for investigation The OPTION scores observed in the recruitment tapes are also presented for comparative purposes (see Graph 1 and Table 3)

Discussion
Principal findings
The clinicians recruited to this study significantly increased their ability to involve patients in decision making and integrated the risk communication tools into scheduled consultations in clinical settings with real patients Both interventions independently increased patient involvement levels The introduction of information designed to communicate options and associated harms and benefits increased patient involvement This level of involvement was significantly increased by the subsequent introduction of the skill development workshops The alternative sequence (skills followed by risk communication tools) did not achieve this additional effect

Strengths and weaknesses
The strength of this study is that it had operationalised 'shared decision making' as an increase in the ability of clinicians to involve patients in decisions and conducted a rigorous evaluation using a specific process measure This study focuses on clinicians in settings that were as near as possible to normal service conditions given the data collection requirements The interventions were piloted before implementation [12], delivered in practice contexts [40], and the clinicians reported that the methods were highly acceptable [41] An appropriate explanatory cluster randomised trial, with sufficient power, was designed [42] and the lack of a valid and reliable outcome measure in this field was recognised, and a scale specifically developed for use with the intervention Scores for the outcome measure were calculated in heterogeneous routine general practice interactions and during the study baseline phase in order to provide comparative scores for the different consultation characteristics evaluated in the trial

The clinicians recruited were remunerated for the disruption to their practices but it should be recognised that they represent motivated clinicians that are likely to have higher than average confidence in their interpersonal skills Although pre-intervention baseline assessments were conducted, a non-intervention control group was not included in the design Differing practice record systems led to variable patient

identification patterns but it is unlikely that this resulted in a systematic selection bias. Some patients in regular employment found it inconvenient to attend for consultation. Low educational or socio-economic statuses have been correlated with lower patient preference for involvement in decision making [43, 44]. It is likely that there is an association between these factors and employment status, which could have the effect of reducing the effect size. A reported difficulty was the requirement to conduct 'reviews' of problems where decisions had been taken at previous consultations. Although this issue had been anticipated, it is suggested that future work should examine 'new' decisions. As the clinicians worked in the same locality, it is possible that some contamination between groups could have occurred, although we do not think that a discussion of events at parallel workshops could have led to any significant impact on the outcome measured.

Interpretation within context of setting and intervention
No previous studies have examined the effect of providing these interventions and little was known about how to implement shared decision making in daily practice. The results demonstrate that the interventions led to significant clinician behaviour change, as detected by the OPTION scale. Further research is necessary to determine whether a large statistical effect size (set as 0.8 of the scale's standard deviation [34]) reflects a relevant clinical effect that is associated with improved patient outcomes. Nevertheless, the significant shifts in involvement levels after both interventions, with an additional additive effect when skills are provided *after* the introduction of risk communication tools, indicates that skill development and information provision can lead to changes in the clinical interaction. A suggested explanation for this sequential enhancement of OPTION scores is the possibility that clinicians were using the tools as devices to reinforce professional decisions after the risk communication workshops rather than as tools to portray equipoise and choice — a potential role that was only specifically emphasised during the skill development workshop. It is possible that the trial maximised its chances of achieving these results by concentrating on a set of clinical conditions where 'equipoise' was deemed to exist. However, the participants commented in a parallel qualitative study that the review-type nature of the consultations did not make it easy to conduct meaningful talk about choice [41].

Care needs to be taken about generalising these effects to routine clinical contexts as these clinicians were motivated and their behaviour reinforced by longitudinal measurement processes. Nevertheless, the results indicate that it is possible to significantly increase the involvement of patients in decision making processes by combining well-designed data formats with skill development courses. It is worth noting the large difference in OPTION scores achieved in routine consultations (16.5) and those achieved during the trial where the baseline mean was 47.1 and the final overall mean was 68.4. An increase the OPTION score was noted (21.6) when problems had 'equipoise' characteristics [5]. It is likely that the two explanatory variables for the difference between routine and trial baseline scores are the consultation characteristics (highly selected review-type interactions) and the additional time allocated between consultations.

Possible mechanisms and implications for clinicians and policymakers

It has been conjectured that involving patients in decision making may have significant benefits [45] but as yet existing studies do not provide a sufficient evidence base for this conjecture. Early reports from ongoing systematic reviews detail the heterogeneous operationalisation of 'patient-centredness' [16-18, 46, 47]. Studies that purport to implement patient centredness point to positive affective outcomes, such as higher patient satisfaction [48]. It has been concluded that clinicians who exhibit certain good communication methods (warmth and reassurance) achieve more effective health outcomes than those who omit these features in formal interactions [49]. But it is not yet clear that increasing patient centredness (and by implication, but not necessarily, patient involvement in decision making) leads to improved clinical outcomes [46, 48, 50, 51], although it should be acknowledged that biomedical outcomes are difficult to measure, not least because of the large number of contextual variables and confounders. A debate also exists about the most relevant and pertinent outcome measure of consultation processes [52].

In parallel with Bekker's review [25], where she noted that a social skill intervention resulted in significant behaviour change, this study demonstrates that clinicians are able to increase the extent of patient involvement in consultations. Further work needs to examine three aspects in particular: to assess the sustainability of these skills and to evaluate whether clinicians can apply these skills to 'new' decisions over an increased range of conditions. Having demonstrated that it is possible to achieve process change, the next task is to examine whether increasing involvement levels has an effect on a valid range of patient outcomes [52]. It is accepted that results from an explanatory trial of this nature have limited direct generalisability to routine service settings and it is not feasible to suggest that all clinicians should be given regular workshops on risk communication and shared decision making. However, the demonstrated effectiveness of these interventions indicates the need to develop decision support technologies that provide easily utilised information for both clinicians and patients, within and outside the consultation. In addition, the results reinforce the need to develop communication skills during the postgraduate career, as it appears that decision aids only go part of the way towards delivering the overall potential benefit for patients.

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Chapter 10

Discussion: conclusions and recommendations

Discussion

Shared decision making is a convenient short term to describe the process of increasing the involvement of patients in decision making and, accepting the term, the thesis has shown that the skills of involving patients in decision making can be identified, clarified and measured and that clinicians have the ability to develop these skills in health service settings As such the work has answered, in part at least, the three questions posed in the introduction to this thesis

- What is shared decision making? (Chapters 2, 3 and 4)
- Can it be measured? (Chapters 5 and 6)
- Can it be implemented, and if so, how? (Chapters 7, 8 and 9)

Whilst the studies in this thesis have demonstrated this to be a realistic aim they have also emphasised the fact this is a complex process that has many effect modifiers The results have generated a better understanding of the interaction between healthcare professionals and patients as they work together to arrive at agreements The thesis also reports the development of a new instrument to gauge the extent to which professionals involve patients in decision processes In this final chapter general conclusions are formulated and discussed

Conclusions

Three main conclusions can be formulated

1. Conceptual clarity which recognises the complexity of the decision making process

Shared decision making has become a widely used term to describe a consulting method where clinicians strive to involve patients in clinical decisions [1-4] The method has been discussed at the conceptual level (principles and aims) but little empirical evaluation of its application in practice has been conducted Closer examination of the concept by clinicians revealed that there are three main components to the involvement of patients in decision making firstly, patients need to be orientated to the intended process so that information sharing about options is made relevant and meaningful, secondly, skills are only part of the requirement — the availability of sufficient time within interactions is an important factor, thirdly, valid evidence in easy to understand formats are required by both clinicians and patients in order to provide a common platform of understanding In terms of identifying the perspective of patients, some advocate the process of asking patients explicitly for their preferred level of involvement in decision making (and thereafter deploy the relevant method) Other clinicians operate by employing an implicit process, and determine the preferred decision making model interactively within the consultation Further details about the exact process are provided The ethical debates associated with this flexible approach to determining the level of autonomy that clinicians expect patients to exhibit are discussed In sum, the thesis concludes that patients are encouraged to become involved in decisions to the degree that they would ideally *prefer*, or not to do so at all, if they so

wish; and that the *preference* should not be regarded as an enduring characteristic but as one that needs vigilant attention.

2. Measurement: validity and reliability

Arrival at an agreed competence framework enabled the design of a measurement scale. As chapter 5 reports, a systematic search for such a scale revealed that it was a justified endeavour. The development and psychometric assessment of the OPTION scale has provided a novel yet rigorous measure of the extent to which clinicians involve patients in decisions. Adherence to the recommended steps of instrument development ensured the scale's overall validity (see chapter 6 for details), and the reliability scores calculated using a number of statistical methods confirm its acceptability for use in research settings.

3. Competence framework which is feasible in routine professional practice

This thesis has contributed to the creation of a competence framework for the involvement of patients in healthcare decisions and the results of a cluster randomised trial have demonstrated that clinicians increased their ability to involve patients in decision making after focused training. The framework describes the steps that are proposed in order to orientate, engage, inform and involve patients in decisions. It is not put forward as a rigid formula but a guide to the deployment of a set of communication competences, with the proviso that the overriding ethical concern of *beneficence* should guide professional practice. Briefly stated, the framework delineates a process by which clinicians can engage patients in decisions whilst also aiming to avoid the creation of anxiety that the burden of additional information or unwelcome decisional responsibility could bring

Discussion

1. Conceptual clarifications: decision making models and their ethical dimensions

Many texts have outlined the three broad approaches to decision making between health professionals and patients, namely *paternalism*, *shared decision making* and *informed choice* [2, 5]. Paternalism describes a model where the decisional control lies with the professional. There are different varieties of this method Patients may indicate that they prefer the health professional to take decisional responsibility *after* having obtained details about the range of options and *after* providing the clinician with their personal views about the potential outcomes this approach has been described as the 'professional as agent', which is a form of modified paternalism Alternatively, paternalism can also describe a situation where hardly any information is shared and where clinicians make decisions unilaterally. At the other extreme, the *informed choice* is a term used to describe a method where patients are provided with as much information as is deemed feasible, or useful, and advised that the final decision is theirs and theirs alone. The clinician declines to offer any

professional guidance. Further details about these decisional approaches are available elsewhere [5]. Shared decision making advocates a more flexible approach [1, 2].

Shared decision making aims to make the patient fully aware of the advantages and disadvantages of available health interventions. It advocates that clinicians explore the patients' concerns about potential outcomes and check that the pertinent issues have been understood, i.e. that the patient has become *informed*. Confirming with certainty that patients also *understand* the information provided and the full nature and consequences of decisions is proving to be a difficult, perhaps impossible, aim. This thesis has been concerned with the clarification of how health professionals can make progress towards this goal by adapting their consultation methods. An assessment of whether patients have made truly informed choices is nevertheless important and needs to be pursued in parallel [6]

The shared decision making method does not insist that patients should make the final decisions, as would be expected under the *informed choice* method. Shared decision making recognises that patients often feel uncertain or ambivalent or overwhelmed by what can appear to be confusing or conflicting information, and, more often than not, seek to be guided about decisions This is not to suggest that clinicians should see shared decision making as another form of 'paternalism', where the only extra requirement is to provide detailed information about a range of options. Where feasible, shared decision making requires that clinicians enhance the ability of patients to engage in participative processes, recognise that this may be a novel experience for them, and increase their ability to comprehend the uncertainties that characterise much of medical practice. In short, shared decision making advocates a participative partnership. It proposes that sharing accurate information about the eventualities of interventions (tests and treatments) will increase patient confidence that the best possible decision was made, thus reducing the possibility of post-decision regret or complaint, and therefore increasing potential patient satisfaction and adherence to either lifestyle modifications or therapeutic interventions

It has to be remembered that shared decision making is a consulting method situated in a multi-dimensional, time-sensitive context. It is not a rigid method that can be advocated in a stereotypical manner. It is a method that requires clinicians to make tailor-made adaptations in order to account for modifiers such as patient preferences for involvement in decisions (including patient age, education, previous exposure to 'decision involvement' and health status), types of healthcare decisions, seriousness and certainty of outcomes, health domains, the recipient of the decision (child, unconscious or demented adult), the number of people consulted (family or others), and the impact of time and further reflection. The thesis specifically examined the nature of the shared decision making process within consultations where two types of conditions prevailed. The first type of conditions were examples of situations where clinicians would feel it legitimate to offer options about further investigations and treatment, a situation of professional *equipoise*, which is

described in more detail below The second type of situation considered was conditions where potential disagreement between clinicians and patients about management options was a common feature of the interaction (see chapter 3), for example, where parents present children with upper respiratory tract infections [2] Shared decision making is difficult when differing opinions about the 'best' treatments exist Some components of the shared decision making model could be discerned, but they were incompletely developed and many of the skills and consultation method did not seem immediately feasible in consultations where conflicting stances were taken regarding therapeutic interventions.

To summarise, a model of clinical decision making is proposed where the process is viewed as occurring between two dimensions: the locus of the decisional action and the location and use of information. This model is a further adaptation of a model proposed in an earlier publication [7]. These dimensions are illustrated in Figure 1 where four decision making methods are represented.

Figure 1   A conceptual model of decision making in consultations (Elwyn, Edwards, Wensing and Grol)
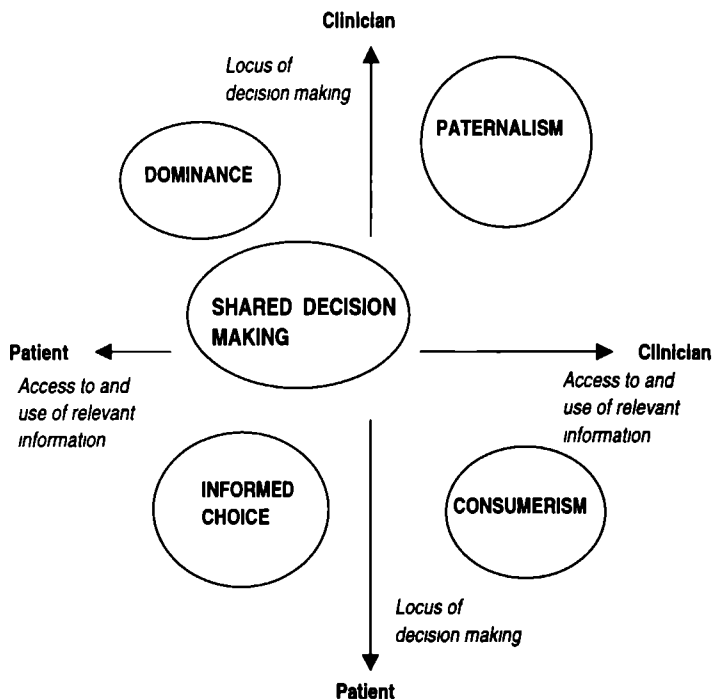
Paternalism locates the decision and the information in the professional quadrant. Informed choice is a term applied to a method where the decision and the information are placed in the patients' domain. Consumerism describes a situation where patient demand, uninformed by evidence of effectiveness, dominates the

decision making context. Professional dominance equates with situations where patients are well informed (maybe even better informed than the clinician) and where their preferences are clear. Nevertheless these patients are dominated by a clinician who does not take their views into account. Paternalism can have a friendly connotation; dominance however causes dissonance. Shared decision making straddles the middle ground, signifying that there is flexibility regarding the location of the final decision, i.e. an acceptance that this responsibility can be a negotiated process.

2. Measurement and the development of an instrument

Specific competences were defined and described as part of the iterative process described in this thesis. The early model is described in chapter 2 (see Box 1), but as a result of the studies conducted, the framework was significantly modified as the iterative processes led to the completion of a finalised process measure. The finally implemented competence framework is described in section 3 and was the basis for the construction of a measurement that is outlined in this section. The competences were introduced to a cohort of clinicians as part of a controlled trial where the impact of two interventions was evaluated (see chapter 9). The impact of the intervention on their consultations was examined by using a specific instrument named the OPTION scale, short for 'observing patient involvement'.

Box 1   Stages and competences of involving patients in healthcare decisions [4]

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 (e.g. ideas, fears, and expectations of possible options)
6	Checking process:
	Acceptance of process and decision making role preference, involving patients to the extent they wish to be involved
7	Make, discuss or defer decisions
8	Arrange follow-up

Preliminary searches did not reveal the existence of any research instruments that were capable of accurately measuring shared decision making. A systematic examination of the literature reported in the thesis (chapter 5) demonstrated that there was very little previous research in this area. Although an important finding, this was not a surprising one. The searches revealed the existence of many instruments designed to evaluate the clinician-patient interaction but the majority were situated in a paternalistic communication paradigm. The small number of instruments which were examined in closer detail (see chapter 5) were generic tools that did not specifically measure patient involvement. Instruments developed to measure patient centredness were unable to provide enough focus on involvement, and their reliability has

been questioned [8-10] It was our conclusion that the concept of patient involvement in decision making (often termed, shared decision making [2, 11, 12]) was emerging in the literature, and, given the lack of specific evaluation tools, it was necessary to develop a valid and reliable instrument

The thesis shows the importance of integrating both conceptual ideas and empirical findings into the design process of a measurement instrument, and its enhancement using a recursive development phase in which both researchers, health professionals and patients comment on item formulation and selection The instrument was designed according to a recognised sequence of construct validation, item formulation and scale design, using a combination of qualitative and quantitative methods Two calibrated raters, who had contributed to the construction of a rater manual, used the final version To maximise reliability, the instrument narrowed its focus on behaviours (competences) that could be directly observed, rather than on rater judgements about subjective issues such as perceived patient comfort within the consultation The design of the OPTION scale was the result of an iterative process that included feasibility studies and pilot evaluations The instrument employed in the studies and presented in this thesis contained 12 items based on the skills outlined in Box 2 Details are provided in the rater manual which is appended to this thesis (supplement) Detailed psychometric assessment is provided in chapter 6 The scale is available as a research tool and further work continues to adapt it for use in educational settings

3. Implementation: competence framework and the development of skills

It was largely assumed during the early phase of the thesis that clinicians did not involve patients in decision making to any significant extent Although this could have been a false premise, examination of the existing literature on clinician-patient interaction made this unlikely Nevertheless, it was important to formally examine whether clinicians were already skilled in the process of involving patients in decision making. When this issue was assessed in clinicians training to become generalists [13] and evaluated in a set of routine consultations from experienced general practitioners, it was found that the clinicians exhibited low levels of patient involvement in decision making processes (see chapters 6 and 8). These results were not surprising, given that other studies have already demonstrated that patient centredness (a related consultation method) does not feature when actual practice is evaluated [10] or when videotapes of material submitted for professional examinations is assessed (membership examination of the Royal College of General Practitioners (MRCGP) for example [14]). The patient centred approach, however, has been widely advocated in vocational training schemes in the UK and many other countries for many decades Since the early 1990s, the MRCGP has emphasised the importance of obtaining patient perspectives on illness, and has recently made shared decision making a merit criterion. In the face of this disparity between espoused teaching and empirical findings, it was necessary to examine what full-time clinicians in practice settings considered to be feasible processes to increase patient involvement in decision making in the real world of daily professional practice

This thesis therefore contains studies in which professionals were examined at close quarters using a range of methods, both qualitative (discourse analysis and focus groups) and quantitative (code-category analysis and observational assessments). By synthesising the results of a literature review, the examination of empirical practice and the reflective experience of clinicians at different stages of their professional careers, a concise formulation of the stages and skills of shared decision making was achieved (see Box 2 for a summary). Although the framework has overlaps and similarities to an alternative proposal [15], significant differences exist (see below)

Box 2   Shared decision making competences

- Problem definition
- Portray equipoise
- Portray options
- Check understanding
- Explore ideas, concerns, and expectations about intervention
- Role preference
- Decision making
- Deferment if necessary
- Review arrangements

Problem definition

Empirical examination of actual practice has revealed the importance of the first step in shared decision making, that of defining the problem Agreeing agendas is of course a basic feature of a patient centred approach but this distinct step of 'problem definition' takes on even more importance within decision making processes. Most problems have distinct features and different options that are part of their resolution or containment Providing information about options without first having exactly defined the scope and nature of the problem so that patients have fully understood the implications is a fundamental step and is often given too little attention by clinicians Decisions vary in the seriousness and certainty of their outcomes, and as we have speculated, some decisions are more amenable to being shared than others

For example, hormone replacement therapy requires patients to understand the difference between short and long-term treatment effects. Short-term hormone replacement therapy relieves symptoms in many patients without having significant harmful effects. Long-term treatment has a different aim, mainly preventative, as in the reduction of osteoporosis risk. These two different aims have to be distinguished for patients and the distinction emphasised that it is only long-term treatment with oestrogen replacement that carries an increased risk of breast cancer. The decision to take hormone replacement therapy depends on patients understanding the relative harms and benefits of using oestrogen, not for a year or two, but continuously over a 10-year period. This may seem blindingly obvious to clinicians but it is unlikely that patients realise the

implications of this distinction Until patients understand the relevant decisional issues, the latter stages of shared decision making are at risk of becoming wasted efforts The qualitative studies in particular provided the key finding that this first step, often bypassed, is probably the crux of shared decision making Time has to be spent clarifying the problem and defining its nature so that the *relevance* of sharing information about the available options is made obvious It is acknowledged that 'agenda setting' is also a key feature of the patient centred method and there is no argument with that requirement in terms of a diagnostic process The problem definition requirements for decision making are however different, and need to dwell on clarifying the decisional space, the inherent uncertainties and the possible outcomes of differing actions It is this problem structuring approach that is novel for many clinicians and is a skill that needs specific development

It is only when there is a shared problem that it is possible to consider the *process* required for shared decision making The studies in this thesis reveal the lack of attention given to this key step, one that is overlooked by professionals, who assume that their intent (to share the decision) is understood by the patient In fact, the reverse is often true Many patients have no experience of sharing decisions and find it strange to be drawn into such a requirement Secondly, when asked, many patients, according to the literature, declare a preference not to take part in decision making Although this literature has weaknesses in its methodology and assumptions (see chapter 1), the aggregate response of health professionals verifies that patients often decline an offer to provide their views about 'decisions' In particular, they do so when they have been inadequately orientated to the purpose and the process

Portray equipoise
The analysis of professional practice in this thesis has revealed that shared decision making interactions were characterised by a problem-defining phase as described above, albeit brief Consultations taken from clinicians who were aiming to share decisions (see chapter 4) also had phrases which have been described as statements of 'equipoise' Equipoise is a term typically used to describe a position of balance It was specifically chosen here to describe a feature found in consultations where clinicians were intent on sharing decisions Equipoise statements were identified in the talk of clinicians who wanted to contextualise the aim of sharing decisions, i e they wanted to make it clear that the process was being advocated not because the clinician was uncertain but because there was genuine room to discuss the patient's preferences and values regarding management decisions Here then was recognition that there were components outside the professional's remit that would influence the decision making process and that these required elaboration and integration

Many medical situations are characterised by uncertain long-term outcomes Menorrhagia, hypertension, lower urinary tract obstruction symptoms in men, atrial fibrillation and many other problems are characterised by having more than one treatment option These options all have associated harms and benefits and the

shared decision making method facilitates an open discussion about these issues. Patients, however, are unaccustomed to being asked about their views, and in general find it novel to be asked to participate in this way. There is therefore a need to pose problems as issues that need to be considered jointly: to be explicit that patient values must be fully integrated into the decision making process, even if it ultimately results in the health professional taking decisional responsibility. To facilitate this process, professionals must orientate patients to the concept of professional *equipoise* so that the options can be legitimately explained, and patients' reactions to the potential harms and benefits, considered. Statements that explain this requirement to patients are named *equipoise* statements, and help both the patient and the clinician achieve a joint understanding of the overall aims within the communication process. The thesis identified this component but noted that the time given to it was often very limited in consultations, even in the consultations of clinicians supposedly skilled in shared decision making. It is conjectured that, like problem definition, the orientation of the patient to a new role of greater participation is a critical step that requires further attention within interactions.

Portray options
It should therefore be clear that shared decision making requires a more elaborate process than a description of options, and the provision of information about those options. Choice however cannot be exercised without the presence of reasonable options, and to participate in decisions patients have to understand the nature of the problem and the clinician's underlying motive. The studies demonstrated that it is preferable to provide an outline of options first, before concentrating on the provision of detailed information. In other words, clinicians should state that 'for this particular problem, there are three possible options, A, B and C'. This process can be described as *option listing*, and it allows patients to grasp the nature and scope of the decision so that when further details about each option are provided, they can be considered within a constructed outline. The use of decision aids (various risk communication methods are available) has been shown to assist patients to assimilate information that can be difficult to convey using verbal descriptions alone. Most decision aids are based on graphical illustrations of option data [16] and proposals have been made to develop digital shared decision modules which are made available electronically [17]. Developments in this field will involve developing greater levels of interactivity to deliver personalised information given that a recent systematic review has revealed that risk communication is most effective when information is individualised, i.e. when risks are specific, and when treatment options are considered [18]. Risk communication strategies are not as effective when the aim is to modify lifestyle (e.g. stop smoking or recruit people to screening programmes). This information exchange stage is clearly very important within the overall process of patient involvement and the skill by which information is provided (pace, extent of detail, and the descriptions of both harms and benefits) will be a crucial part of the overall communication. Unless information of this nature is available and conveyed appropriately, then it is unacceptable to expect patients to become involved in decisions. Asking

patients to make choices without adequate information is akin to asking people to bet their fortunes using unknown probabilities.

Check understanding and conduct an exploration of ideas, concerns and expectations about the intervention
Checking that patients have understood information, and pausing at regular intervals to ascertain that they have done so, is a well-described element of effective communication in clinical settings. Kurtz advocates the method of 'chunking and checking' [19]. Exploring patient ideas, concerns and expectations (in this context pre-conceived notions and fears about interventions, not diagnoses) are a familiar part of the patient centred method. Nevertheless, these techniques ensure that professionals stay in touch with patients' perceptions as they become involved in decisions.

Role preference
There is a large literature that has explored patient views about their preferred role in decision making, ascertaining whether they wish to be active participants or passive recipients. Without describing that literature in detail here (comprehensive reviews are available [20, 21]), it can be summarised by stating that the majority of studies have asked patients to consider their 'preference' either in a hypothetical situation at a time shortly before engaging in a decision making process. However, it is clear that these methods are not ideal. One of the main difficulties is that an individual preferences regarding participation in decisions are probably not a stable constructs, especially if such views are collected using hypothetical situations. This is made more problematic by the fact that it is only when an individual has properly understood the scope and the nature of issues facing him or her that a decision about whether to participate in a decision can properly be taken. This is not to argue that all individuals automatically wish to take part in decisions when they are fully appraised of the harms and benefits. The reverse may well be the truth, as individuals retract from the responsibility of taking difficult decisions that could lead to post-decision regret or guilt [22]. It is also likely that there is a 'learning' or experiential component to such preferences and that a well-facilitated patient involvement which leads to a satisfactory outcome may well lead to higher preferences for such an approach in the future, despite hypothetical reluctance. Findings that support this contention have been found when evaluating the implementation of a try-out process before gaining formal consent from frail elderly patient to take part in clinical trials [23].

The health professionals we interviewed, and the consultations analysed, led us to two main conclusions. Firstly, it is only after options have been understood that patients should be asked about their preferred role in decision making. Secondly, and perhaps just as importantly, professionals found the task of role preference evaluation to be an awkward process, to the point of being impractical. Professionals reported that attempts to ask patients 'whether they wanted to take an active part in the decision' were often met with puzzlement. It was, they said, as if the question was superfluous. Patients (and professionals) assumed that

by communicating together, listening to information and taking part in an active dialogue that they were implicitly taking an active part in decision making. Making the process reliant on answering an *explicit* question about role preference was regarded as an unnecessary step. This step can be conceptualised as meta-communication (communication about the process of communication) and is a difficult leap in most circumstances, and more so it seems in an institutionalised interaction such as a clinical consultation. Nevertheless, the clinicians agreed that the step should be retained within the competence framework as a means of alerting professionals to the need to monitor patient acceptance and comfort with the communication process. Implicit engagement in the decision making process was regarded as a reasonable proxy for explicitly negotiated role preference *provided* the health professional remained sensitive to any signs of discomfort or reluctance. The ability to let the patient decide on their role preference by monitoring their comfort with the participation process is a skill that is at the core of the shared decision making method and relies heavily on the skills of interpreting and responding to non-verbal communication.

Decision making and possible deferment

It was demonstrated that, irrespective of the total consultation duration, clinicians typically start initiating the decision making part of the interaction when 80% of the total time has elapsed (see chapter 4). A more accurate way of stating this feature of consultations is that decision making talk appears when consultations are entering their final phases. Decision making talk seems to act as a cue to both parties to bring the interaction to a close. In service settings, where time is typically at a premium, bringing consultations to an end is an important skill and decision talk may well be recognised by both parties as a signal that discussions are approaching a time when they have to be concluded or re-scheduled. It follows therefore that the initiation of *decision talk* should be carefully planned and initiated only after the preliminary steps of the shared decision making process have been completed, i.e. *decision talk* must not be engaged prematurely and steps should be taken to ensure that the process is based on a good foundation of information about options.

At this point the location of the decision making *responsibility* will be of prime relevance. Whether clinicians explore this issue explicitly by asking patients if they feel able or willing to take the required decision or whether the process is part of a tacit process of evaluating the patient's comfort with the level of involvement, the clinician should match the degree of decisional responsibility with the patient's preferred role. In the absence of an urgent need to make decisions (which is the case for many chronic problems) clinicians can advise patients to deliberate and discuss options with a range of other people. In other words, deferment should be encouraged and patients told to investigate other sources of information and explore the implications of decisions with relatives and others.

Review arrangements

There is an accepted need to review a patient's progress in most clinical situations. This is particularly relevant when the patient has been asked to engage in a decision making process. The process itself may have been a novel experience and have generated uncertainty or burdensome decisional responsibility. An additional requirement is to obtain an explicit understanding that it is perfectly acceptable, and in many situations necessary, to review decisions. The clinician should ensure that the patient views this as a step that will be welcomed and not perceived as an implied criticism of his or her judgement or as an unnecessary re-opening of discussions.

Skill development and measurement

Chapter 5 reports the identified need to develop a valid and reliable instrument to measure the 'shared decision making' process in consultations and chapter 6 provides the assessment of a scale, named the OPTION scale, that was designed specifically for this purpose using a sample of consultations from routine clinics. Inter-rater reliability (correlation coefficients and kappa scores) was higher than for many similar scales. The results from a set of routine consultations in general practice revealed low 'involvement' scores, very little variation *between* clinicians but significant variation *within* clinicians. In other words, there was evidence of significant adaptation to presenting problems.

Chapter 9 reports the results of a trial where the OPTION scale was applied within a cluster randomised controlled trial of shared decision making and risk communication. The study was designed to examine the impact of these interventions on patient involvement levels achieved within consultations. The results demonstrated that the clinicians significantly increased their ability to involve patients in decision making in scheduled consultations in clinical settings with real patients. Both interventions independently increased patient involvement levels. The level of involvement achieved by the risk communication tools was significantly increased by the subsequent introduction of the skill development workshops. The alternative sequence (skills followed by risk communication tools) did not achieve this additional effect. The effectiveness of these interventions at increasing patient involvement indicates the need to develop decision support technologies that provide easily utilised information for both clinicians and patients, within and outside the consultation. In addition, the results reinforce the need to develop communication skills during the postgraduate career, as it appears that decision aids only go part of the way towards delivering the overall potential benefit for patients.

In summary then, it can stated that shared decision making can be implemented in clinical interactions by motivated clinicians and that focused training increases their competence levels. This is particularly true when clinicians are asked to conduct consultations in clinical situations where the concept of professional

equipoise legitimately exists. There are however other key ingredients, namely additional time and additional information. Although the clinicians were asked to consult the trial consultations in 10 minutes, the mean duration lay between 12 and 13 minutes at each phase. The effect of additional time increasing OPTION scores has also been witnessed in other parallel studies using simulated patients. Whether clinicians need to learn how to use risk communication tools before learning the specific skills of shared decision making, is, in the final analysis, an unimportant question. This thesis has demonstrated that both elements are required, and that the most important aspect of involving patients in decisions is to be able to communicate complex risk data in such a way that improvements occur in the levels of interpersonal communication achieved in clinical interactions; it is the ability to integrate these two components that is important.

Main methodological issues: strengths and weaknesses

A range of research methods were selected to examine the questions posed in this thesis. Two literature reviews were conducted. The first was a purposefully conducted wide-ranging review of the decision making literature, which encompassed ethical, medicolegal perspectives and appraised other developments such as the use of decision analysis and decision aids as an adjunct to face to face consultations. The review also considered studies already conducted into patient centred consultation styles and similar consultation approaches. The purpose of this work was to obtain as wide a canvas as possible for the remaining work, to explore the many disciplines and debates that exist in the field. The second literature review (appraisal of existing instruments to measure shared decision making) was based on the standard systematic approach of setting a focused research question and searching a defined set of sources using specific selection criteria. Nevertheless, a potential weakness of our approach lies in the fact that the literature in this field is diverse, not well indexed, and we were largely limited to examining studies published in English.

Given that one of the central aims of the thesis was to examine a relatively unexplored area of professional practice, it was decided to use qualitative methods to investigate the concept of shared decision making. The work was deliberately distanced from the theoretical discussions that had already occurred in the literature about participative decision making. This allowed the proposal that clinicians should share decisions with patients to be considered afresh by enlisting the perspectives of active clinicians. This method was chosen in order to bridge the theory-practice gap and narrow the potential disjuncture between those who advocate particular approaches and those who have to temper the idealism that this can often generate with the realities of professional practice. The ability of qualitative methods to obtain in-depth information, generate 'thick descriptions' of situated experience and multiple perspectives [24], seemed to be an ideal way of addressing these aims and are methods that are being increasing used to analyse interpersonal interactions [25-30]. The qualitative studies employed in the thesis (focus groups and the micro-analytic techniques of discourse analysis) use smaller samples as a consequence of their design, by being based on theoretical

sampling strategies. The sampling methods were purposive and inevitably contained bias. This characteristic of qualitative work limits the ability to generalise the results to larger populations. In other words, it is not possible to be confident, by depending on the results of the qualitative studies alone, that the views of the clinicians interviewed about the concept and feasibility of shared decision making were representative of all clinicians. Nevertheless, the consistency of our findings over multiple qualitative studies and the resonance of those results with detailed examination of empirical data taken from actual consultations provides adequate reassurance that the results are valid.

The quantitative studies in the thesis vary considerably in their aims and sample sizes. The code-categorisation of 10 consultations (chapter 4) is an example of methodological development [31]. A small number of consultations were coded using an innovative code-categorisation method which examined consultations in terms of the underlying communications intent of the clinicians – whether their statements were to do with defining problems, explaining the existence of options, providing information and so on. It allows consultations to be examined as sequences of clinician directed stages and provides patterns that illustrate the degree of interactivity that occurs within consultations. Although the work is not robust enough to allow firm generalisations to be drawn, the study significantly modified the construction of the OPTION tool (adding in the competence of problem definition and statement of equipoise) and the method will be used for further assessment of consultations in future studies. Code-categoriations methods have been criticised in the past because of their inability to portray the complexity and meaning of discourse by summing the aggregate of small speech sections, and the inherent low inter-rater reliability of most suggested systems [32]. The method developed in this thesis aimed to categorise wider sections of discourse, focusing on the main 'intent' of the speech section, and therefore arriving at broader patterns and greater rater agreement levels. The development of a new scale to measure patient involvement was based on the standard methods described in the measurement literature. The result is the production of a scale (and associated manual) for use in research contexts. Further work will be required to adapt the instrument to provide formative feedback in skill development settings. Using the background work on competence definition and scale development, a study was then developed to evaluate the effect of developing the skills in a cohort of clinicians recruited to study shared decision making. The strengths of the trial were the strict operationalisation of 'shared decision making', the use of a validated process measure and the application of an appropriate research design which comprised of a cluster randomised trial using crossed interventions. Interpretation of the work needs to take into account the recruitment bias for clinicians and selection bias for patients, which may have limited the representation of some characteristics. Other design effects, such as the possibility of contamination across groups were not considered to be significant influences.

Relation of findings to other existing literature

Although patient centredness has been advocated from the late 1970s onwards [33], interest in 'shared decision making' is a relatively recent development. Stewart et al reported an additional component to their group's evaluation of the patient centred method (measuring 'common ground') in the mid 1990s but the tool did not really focus on the decision making process [34]. Patient centredness is also proving to be too wide a concept to be operationalised and measured in practice [8, 9, 35]. Because this thesis has concentred on the competences of shared decision making, this discussion will compare those described here with others suggested in the literature. Examination of empirical practice has revealed that clinical practice is not easily categorised into the three types of interactions suggested by Charles (paternalism, informed choice and shared decision making), even though they have qualified their model with modifications and exceptions [1, 11]. Interpersonal interactions are more complex in reality and deciding where decisional agency rests at any given point in time may be an impossible goal, given the inherent instability of the interaction, multiple perspectives and hidden thought processes. Nevertheless, it is possible to observe whether clinicians are achieving a set of competences, if a sufficiently clear framework is provided for observational assessment

Towle published a suggested framework of *competencies* [sic] [15]. Her use of the word *competencies* was criticised by Greenhalgh who noted the distinction between the definition of skills (competences) and the description of personal attributes (competencies) [36]. Putting aside the debate about these distinctions, it is clear from the context that Towle was concerned with describing a set of skills (and steps) It seems reasonable therefore to compare her proposals against the framework outlined in this thesis There are two significant differences. Towle's *competencies* suggest that clinicians should start by 'develop[ing] a partnership with the patient', and secondly, before health professionals work at '*identifying choices*' (options), she suggests that patient preferences for information (amount and format) and role in decision making (risk taking and degree of involvement) are explored.

However, this thesis has revealed the impracticality (and illogicality) of exploring preferences in the abstract (i.e. before options are described and appraised). Asking patients about their preferred level of involvement before they have become aware of the possible choices they face is to pre-judge the interaction In some consultations, where the choices are difficult and the issues painful, many patients will wish to withdraw from the decision making process In others, they will wish to make active contributions In many circumstances these preferences themselves depend as much on the skill of the clinician in 'sharing the decision' as on the actual problem faced, the personality type of the patient [37] or socio-demographic variables such as age or educational status. The proposal to put information provision before an assessment of patient role preference also confirms the value given by Katon and Kleinman [38] to an exploration of patient ideas (see their explanatory models) before professional views or options are portrayed so that the patient perspective is not

contaminated by the clinician's assumptions. In addition, Towle did not specify the step of *problem definition* – a step which is considered within this thesis to be a fundamental first step in an effective participative decision making process.

It is also important to note that there are similar research groups working in this area, although often different nomenclatures are used [39]. The British Pharmaceutical Society for instance sponsors a web site on 'concordance' [40]. The term is used to describe: 'a new approach to the prescribing and taking of medicines. It is an agreement reached after negotiation between a patient and a healthcare professional that respects the beliefs and wishes of the patient in determining whether, when and how medicines are to be taken. Although reciprocal, this is an alliance in which the healthcare professionals recognise the primacy of the patient's decisions about taking the recommended medications' [40]. This concept has clear overlaps with shared decision making and Dowell is developing a scale to assess the levels of *concordance* achieved within consultations (J Dowell, personal communication). Braddock has devised a 6-item binary score scale to measure 'informed decision making' based on an assessment of the ethical principals of informed choice (see chapter 5) and has undertaken cross-sectional descriptive evaluations of audiotaped encounters in outpatient settings in the United States [41, 42]. A full appraisal of the scale's psychometric properties is awaited but the cross-sectional studies reveal very low levels of patient participation in the decision making process and the criteria for informed decision making were only met in a very small percentage of the consultations. Makoul and Schofield are part of another research group who are developing an instrument to measure 'evidence-based patient choice', building on their earlier work on the construct of patient 'reliance' in clinical consultations [43].

Implications for professional practice

Note that the thesis does not argue for or against the concept of involving patients in decision making. It is important to be aware that there are circumstances where patients are unable to participate in decisions or would not be expected to do so — unconscious and severe mental illness are obvious examples. On a slightly lesser scale, it also seems unwise that patients engage in decisions when they declare themselves anxious or frightened and state that they would prefer to be absolved of decisional responsibility. Although these are relatively rare situations it is nevertheless important to declare that the most appropriate professional stance seems to be that of assuming that patients should be involved in decisions, provided there are no contraindications or evidence to suggest that the individuals concerned have different role preferences.

Despite the increasing interest in patient participation in healthcare using self-management plans and efforts to teach communications skills and promote the patient centred consultation method across the

undergraduate and postgraduate curricula, the evidence speaks for itself: clinicians do not routinely use patient centred skills nor involve patients in decisions in their day to day practice [10, 41, 42, 44-46]. Yet, as the studies in this thesis demonstrate, many clinicians agree with the concept of patient involvement and are prepared to help devise a competence framework. When asked to develop these skills in a research context, they are able and willing to do so (see chapter 9). Researchers in this area cannot fail to notice the discrepancy between the espoused methods of shared decision making and the actual delivery of patient care in most settings. This discrepancy is a major tension in modern medical practice Clinicians increasingly faced with more informed patients, patients who have already investigated their symptoms or presumed diagnosis using web sites and other sources of information. They are exhorted to be increasingly sensitive to patient needs but, in common with other disciplines, general practice has to deal with the parallel demand of increasing expectations within time-limited consultations. High workloads and the short time 'bandwidths' allocated to most clinical interactions leave little room for detailed discussions about options. Morrison and Smith put it wonderfully when they said. 'Across the globe doctors are miserable because they feel like hamsters on a treadmill. They must run faster just to stand still [47]' They conclude that neither patients nor clinicians can tolerate a faster treadmill. The Institute of Medicine in the United States is apparently producing a report on redesigning health care, and Britain's Foresight report on healthcare contains many ideas including the creation of virtual cyber clinicians and rolling back healthcare into the community [48] Advocating shared decision making, which as we have noted, requires significant additional time and novel supportive technologies, needs to be part of this radical re-design. The shared decision making method, taken to its logical conclusion, like the internet, challenges the structure of medical practice [49]

Another important but perhaps slightly hidden implication of the results is the difficulty clinicians face when confronted with the ethical aspects of sharing decisions with patients. The thesis indicates that clinicians only feel comfortable if they are allowed to tailor their practice to individual patients. They instinctively voiced their anxiety about the thought of transferring the entire decisional responsibility to patients, knowing, as the literature confirms, that this is not what patients, in the main, wish. In other words, they rejected the principle described as *mandatory* autonomy [22]. They were prepared to enable *optional* autonomy, where the patient decides the extent of their decision making involvement, but emphasised that enquiring about role preference is an artificial, awkward and disrupting task within consultations, especially when the roles of both parties have been established over many consultations in previous encounters. It is also worth noting here, that the very notion of choice within modern medical practice is paradoxically becoming restricted Managed care, official guidelines, and third party decision makers (e g insurers or other payers) are increasingly defining the range of options available within healthcare systems and professionals may find themselves reducing rather than expanding the potential of patients to choose between options, and the debate about involvement levels will take on a different dimension.

Although this work has focused on the attitudinal changes and skill acquisition required of clinicians, this is not to underestimate the roles of patients Their contribution in terms of time, information processing and ability to engage in the additional responsibilities required will be fundamental to the success or otherwise of the clinicians strategies for increasing involvement. The patients' perception of these processes is a subject of further work in an additional research programme

Implications for medical education

On a more immediate and less ambitious front, the results of these studies are important for those who are concerned with the development of professional practice in educational contexts at under and postgraduate levels Jones has argued for a spiral curriculum in medical education, which helps to deliver a 'stem' doctor, i e one equipped with all the core communication competences and with enough core knowledge to develop into a well-rounded clinician in any selected discipline [50] The skills of shared decision making are one of the core components of that set of skills, made more essential as patients become web-literate For clinicians destined for disciplines that depend heavily on face-to-face meetings, the acquirement and deployment of advanced communication skills leads to higher levels of patient satisfaction and may contribute to improved health outcomes The development of an evaluative scale (OPTION) that can be adapted to provide formative feedback in skill development settings will add to the value of the work reported here, and could potentially be used to monitor the attainment of performance standards in selected settings

Further research and development

Valid and reliable methods of evaluating the extent to which clinicians involve patients in decision making had not been previously developed The OPTION scale has been shown to be valid and reliable in general practice settings and care has been taken to keep the instrument generic enough for use in different areas of clinical practice Work is however required to assess its responsiveness in different contexts such as hospital outpatient settings and genetic counselling interactions where different communication methods are typically employed and how it could be best adapted for use in educational events However, one of the important consequences of the work has been to reveal that the process of involvement can only be partly addressed by skill development Three other areas of further research and development are necessary

Patient role preferences in decision making processes
Clinicians find it difficult to ask patients about their preferred role in decision making in the midst of a consultation Asking patients about their preferences in advance of consultations, e g by using hypothetical situations may provide some guidance but there are concerns that measuring role preference in this way may be a pointless task It is known that role preference varies with age, education, social class, illness severity,

the topic considered and the duration and quality of relationship with the relevant professional [21]. These variables inevitably vary across consultations and the predictive value of measuring goal preference at a given point in time is questionable. In addition, it is possible to speculate that although role preference is an inherently unstable characteristic, it nevertheless could be modulated by a long-term patient-professional relationship. Developing a working partnership in other situations is clearly a process that takes time and so the development of a participative decision making process relationship is also likely to be dependent on continuity in healthcare settings. Further research using more sophisticated methods than those reported to date needs to be conducted.

Information transfer and decision support aids

Decisions are more confidently made when high quality information about the benefits and harms of possible interventions is available. It is not easy to understand probabilistic data and patients, like other individuals, have a limited perception of risk, and the difference between absolute (baseline) and relative risk [51]. Verbal descriptions of risk using terms like 'likely' and 'rare' and the forth give rise to many differing risk perceptions [18]. Visual representations of data (graphs or bar charts) show increasing promise but they can be modified significantly by positive or negative framing effects [52]. Cognitive science has demonstrated that rules of thumb (heuristics) are normally used to make decisions [53]. These heuristics (anchoring, availability, representiveness and so on) profoundly affect the judgement of people in situations of uncertainty [54]. Although there are no easy solutions to these issues, research into shared decision making should be aware of these problems and the promotion of promising risk communication technologies such as decision aids [16] must ensure that data designers balance the presentations to reduce the effect of these systematic influences.

Cognitive decision making processes

Clinician skill acquisition is a necessary step towards the goal of ensuring that shared decision making becomes an acceptable healthcare process. But the trial (chapter 9) also demonstrated that maximum patient involvement is also dependent on clinician familiarity with high quality risk data. It is widely accepted that the clinician by virtue of the professional status has an unassailable *role* in decision making interactions and can therefore be the agent that facilitates (or restricts access to) a participative process. But despite the emphasis in this thesis on the descriptions and measurement of these skills, it must be acknowledged that they are only part of the complex cognitive processes that must occur when decisions are made. Studying the *involvement* of patients in clinical options must also eventually pay attention to underlying mechanisms — the mental deliberations that underlie all decisions at the individual level — and recognise that this activity often has to occur in situations that are emotionally charged.

Decision making by individuals has been widely discussed in economic texts where the dominant theory is that of a human capable of *rational choice* engaging in a free market environment But this literature is subject to assumptions that are being challenged by alternative models proposed by theorists from cognitive science [53, 55] Heap touches on these when he states that 'the typical autonomous agent seems like a sovereign customer with a coherent shopping list and a fat wallet in a well-stocked market' [56] These assumptions of unbounded rationality are decidedly shaky when we consider patients, who are often fearful for their well being, in awe of medical expertise, faced with difficult concepts, yet suspicious in many circumstances of professional motives as they become increasingly aware of the difficulty all health systems have in closing the divide between patient needs and limited resources [22]

When the critique of the *rational choice* model as an explanatory framework for human decision making [53, 55] is added to the contextual difficulties inherent in healthcare situations, the necessity to appreciate the contested analysis of the interactive processes within consultations becomes obvious Shared decision making has not declared a position in this debate about decision making models, but it is certainly not supporting a *purely* rational or *purely* affective model It does however give priority to a rational model, and emphasises the role of evidence, provided that evidence is as rigorous as possible and is presented in ways that patients can readily assimilate In other words, shared decision making tries hard to bridge the divide between the worlds of evidence based medicine and patient centredness [57] Nevertheless, the shared decision making method acknowledges the complexity of this area and does not advocate one decision making theory over another Although this could be perceived as a theoretical weakness, it remains clear that shared decision making provides a pragmatic framework for clinicians who wish to increase patients' understanding of healthcare options, make existing evidence more readily available to them, and thereby generate a more participatory approach to decision making, whatever the underlying decision making processes Clarifying the skills of shared decision making, and providing a measure, is a step in the direction of greater patient participation, despite the difficulties being uncovered [25, 26]

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Summary

The work presented in this thesis examines decision making within the context of medical practice, specifically within the interaction between clinicians and patients widely known as the *consultation*, where problems are identified and plans made for their potential resolution and management. The term 'shared decision making' is now used as a short hand for consultations where it is expected that clinicians actively involve patients in the decision making process. Questions have been asked about the extent to which the control over the process lies with the clinician or with the patient, and whether the responsibility for this process can be shared between the parties involved. At the core of shared decision making is the view that it is acceptable, indeed important (and perhaps beneficial), to offer patients a role in decision making. This is a shift away from the more traditional stance of clinical professionals. The studies undertaken were designed to examine the concept of shared decision making and to test the feasibility of involving patients in clinical interaction. To summarise the conclusions of the thesis have shown that the skills of involving patients in decision making can be identified, clarified and measured and that clinicians have the ability to develop these skills in health service settings.

Chapter 1 introduces the subject area by providing definitions of shared decision making in the overall context of patient centredness, and describes how these concepts have become of increasing interest to clinical professionals over the last few decades. A summary is provided of how the discipline of decision making models in cognitive psychology, the influence of evidence based medicine and the research on patient preferences for involvement in decision making needs to be kept in mind in order to contextualise the results of the main focus of the thesis: that the observed communication skills of clinical professionals are important components in the endeavour to involve patients in decision making processes. The introduction summarised the three main research questions:

- What is shared decision making?
- Can it be measured?
- Can it be implemented, and if so, how?

Chapter 2 contains an overview of the literature on patient participation in clinical interactions. It was recognised that this research area was novel and that there was a lack of previous empirical studies to be examined. The review was therefore purposively designed to be a broadly based analysis of many different perspectives on the subject. Research studies were appraised, ethical, legal, theoretical and conceptual publications were also included in order to obtain a comprehensive view of the research area. The aims of the chapter were to describe the difficulties posed by the ways that clinicians currently discuss treatments with their patients and propose alternative methods for them to share information and achieve shared

decision making There was no attempt to consider patient involvement in decision making at the macro-level of policy-making and resources prioritisation

Three basic methods of clinical decision making in the consultation were described in the literature They could be represented as a spectrum from paternalism at one end, to 'informed choice' (full patient responsibility for decisions) at the other [4, 11] Shared decision making lay in-between these two methods and the principles had been described as follows

- Shared decision making involves at least two participants - the clinician and the patient — and often many more (their respective networks of family or professional colleagues)
- Both parties (clinicians and patients) take steps to participate in the process of treatment decision making
- Information sharing is a prerequisite to shared decision making
- A treatment decision (which may be to do nothing) is made, and both parties agree to the decision

However, when the literature review was conducted, no other publications had examined the concept of shared decision making in any depth, and no studies had explored the views of clinical professionals The chapter summarised the research that suggested that four key dimensions of communication are related to positive outcomes, namely the provision of clear information, enabling patients to ask questions, a willingness to share (discuss) decisions and an agreement between patient and clinician about the problem and the plan Nevertheless, the studies were evaluations of 'patient centredness' in the main and the more tightly defined concept of 'shared decision making' had not been evaluated The chapter debated the ethical and legal issues and considered the practical obstacles that professionals perceived would make it difficult to achieve patient participation in decision making It was found that shared decision making offered a method for the 'management stage' of the consultation Although there was no specific evidence to support patient involvement in decision making processes, the patient centred approach — in which shared decision making could be seen as being embedded — had demonstrated improvements in short term outcomes (patient understanding and satisfaction) despite a lack of consistent evidence to support positive long-term patient outcomes

Chapter 3 presents a qualitative study which uses the method known as discourse analysis, a fine grain textual assessment to examine the detail of communication processes in purposively chosen consultations where we hypothesised that a shared approach to decision making would be problematic, namely, discussions about the necessity of antibiotics to treat upper respiratory tract infections Two consultations were selected from the clinic of a clinician known to be interested in involving patients in decisions The analysis was compared with the theoretical competences proposed for 'shared decision making' It was

concluded that professional 'equipoise' about the outcomes of decisions is an important criterion which enables shared decision making and that it was missing in these cases. The existence of 'equipoise' allows patients the 'freedom' to choose preferred options. Many decisions in medicine have this quality. But professionals cannot maintain 'equipoise' on all issues and that the understanding of shared decision making needs to be developed for situations where there are disagreements due to the strongly held participant views.

In *chapter 4* a further assessment of actual practice was undertaken. The aim was to examine the communication strategies of clinicians attempting to involve patients in treatment decisions. The empirical data were then compared with a set of derived theoretical 'competences' for shared decision making. The subjects were four clinicians, who recorded consultations where they had the specific aim of involving patients in the decisions. Transcriptions were coded into skill categorisations and presented as visual displays. The data did not completely match proposed theoretical frameworks. The views of patients about treatment possibilities and their preferred role in decision making were not explored. The interactions were initiated by a problem-defining phase, statements of 'equipoise' consistently appeared and the portrayal of option information was often intermingled with opportunities to allow patients to question and reflect. The results demonstrate that some theoretical 'competences' are not distinguishable in practice. Other stages, not previously described, such as the 'portrayal of equipoise', were observed. These observations led to a reformulation of the skill framework which was then used to guide scale development.

Chapter 5 provides a foundation for the measurement of shared decision making. The aim was to determine whether research instruments existed that measured the extent to which health professionals involved patients in clinical decisions. A systematic search and appraisal of the relevant literature was conducted. Relevant instruments had to concentrate on assessing patient involvement in decision making using observational techniques (either direct or by using audio or videotaped data) and contain assessments of the core aspects of 'involvement', namely: evidence of patients being involved (explicitly or implicitly) in decision making processes, a portrayal of options and a decision making or deferring stage. The results revealed that little attention had been given to a detailed assessment of the processes of patient involvement in decision making. The existing instrumentation only included these concepts as sub-units within broader assessments, and did not allow the construct of patient involvement to be measured accurately. Instruments developed to measure 'patient-centredness' are unable to provide enough focus on 'involvement' because of their attempt to cover so many dimensions. It was concluded that the concept of patient involvement (shared decision making; informed collaborative choice) required the development of a valid and reliable assessment method.

Based on the results of the systematic review, the development of a scale to measure the extent to which clinicians involve patients in decision processes was initiated. *Chapter 6* reports the development (using a mixture of methods) and psychometric assessment of a scale, named as OPTION (short for observing patient involvement). The scale was used by two independent assessors to assess a set of 186 audiotaped consultations from 21 clinicians in the United Kingdom. The results demonstrate that the scale provided reliable scores for patient involvement at the consultation level with satisfactory levels of inter-rater reliability, justifying its use in further research. Although the scale found is little overall variance between clinicians, there was considerable variability *within* clinicians indicating that some clinicians have a relatively narrow range of scores whilst others have a much greater range of scores, demonstrating that they modify the degree of patient involvement achieved in decision making across different consultations.

Chapter 7 reports work that was done in parallel with the development of the OPTION scale in order to inform the construct validity of the measure. The aims of the study were to explore what constituted the appropriate involvement of patients in decision making within consultations, to consider previous theory in this field and to propose a set of competences (skills) and steps that would enable clinicians to undertake 'shared decision making' in their clinical environment. A qualitative study using sequential focus group interviews of key informants was designed. It was found that experienced clinicians have positive attitudes, provided the process synchronises with the role patients wish to play in decision making processes. They perceive some clinical problems as being more suited to a co-operative approach, and conceptualised the existence of professional 'equipoise' about treatment options to be an important facilitative factor. A sequence of skills was proposed. 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 (e g ideas, fears and expectations of possible options), 6) Checking process. Acceptance of process and decision making role preference, 7) Make, discuss or defer decisions, 8) Arrange follow-up. In summary, the clinicians viewed 'involvement' as an implicit ethos that should permeate medical practice, provided clinicians respect and remain alert to patients' individual preferred roles in decision making. They concluded that the interpersonal skills and the information requirements needed to successfully share decisions are major challenges to the consultation process in medical practice.

Having defined a competence framework and developed a measure, it became necessary to consider the problems of implementation. *Chapter 8* reports a qualitative study that examined the feasibility of performing an intervention study in this area, by examining the reactions of clinicians to workshops that aimed to develop skills and provide risk communication tools. A total of 39 general practice registrars (trainee clinicians) and 8 course organisers from vocational training schemes in South Wales attended group interviews to explore these interventions. The registrars conducted and observed a series of consultations about treatment choices

with simulated patients using verbal, numerical and graphical data formats. Reactions were elicited and the registrars reported having had no training in the skills required to involve patients in decisions. They exhibited a wide spectrum of opinions about 'involving patients in decisions', ranging from protective paternalism ('doctor knows best'), through self-interest (lightening the load), to the potential rewards of a more egalitarian relationship with patients. The work pointed to three contextual process precursors: the availability of reliable information, appropriate timing of the decision making process, and the readiness of patients to accept an active role in their own management. They agreed that sharing decisions involved sharing the uncertainties about the outcomes of medical processes and exposed the fact that data are often unavailable or not known, thus potentially causing anxiety to both clinician and patient. It appeared however that many clinicians were ready for this development and the interventions were refined for use in a further study.

Chapter 9 reports the result of a cluster randomised trial that was designed to evaluate the independent and combined impact of skill development workshops and risk communication tools on the ability of clinicians to involve patients in decision making processes. Twenty clinicians were randomised to two interventions (interpersonal skill development and the use of risk communication tools) in a cross over design. Patients were identified and randomised within each practice, balanced for four clinical conditions across trial phases, and asked to attend for audiotaped review consultations. Two independent raters assessed 371 consultations using the OPTION scale. The clinicians significantly increased their ability to involve patients in decision making in scheduled consultations with real patients in clinical settings. Both interventions independently increased patient involvement levels. The level of involvement achieved by the risk communication tools was significantly increased by the subsequent introduction of the skill development workshops. The alternative sequence (skills followed by risk communication tools) did not achieve this effect. The effectiveness of these interventions indicates the need to develop decision support technologies that provide easily utilised information for both clinicians and patients, within and outside the consultation. In addition, the results reinforce the need to develop communication skills during the postgraduate career, as it appears that decision aids only go part of the way towards delivering the overall potential benefit for patients.

Chapter 10 discusses the implications of the results and provides a set of recommendations for research and clinical practice. It notes that shared decision making has become a widely used term to describe a consulting method where clinicians strive to involve patients in clinical decisions. The method has been discussed at the conceptual level (principles and aims) but evaluations of its application in practice had not been previously conducted. Examination of the concept by clinicians revealed that there are two main components to the involvement of patients in decision making: firstly, patients need to be orientated to the intended process so that information sharing about options is made relevant and meaningful, and secondly, the potential use of one of three decision making models, which have been termed 'paternalism', 'shared decision making', and 'informed choice' need to be considered. Some advocate the process of asking

patients explicitly for their preferred level of involvement in decision making (and thereafter deploy the relevant method). Other clinicians operate by employing an implicit process, and determine the preferred decision making model interactively within the consultation. The ethical debates associated with this flexible approach to determining the level of autonomy that clinicians expect patients to exhibit are discussed. In sum, the thesis concludes that patients are encouraged to become involved in decisions to the degree that they would ideally *prefer*, or not to do so at all, if they so wish; and that the *preference* should not be regarded as an enduring characteristic but as one that needs vigilant attention.

The thesis proposes a competence framework for shared decision making and a means for measuring the extent to which clinicians involve patients in decision making. The framework describes the steps that are proposed in order to orientate, engage, inform and involve patients in decisions. It has also demonstrated the effectiveness of an intervention design to develop these skills. Further studies should examine the potential relationships between the shared decision making and patient outcomes. In conclusion, the competences are not proposed as a rigid formula but as a suggested guide to clinicians in service settings, with the proviso that the overriding ethical concern of *beneficence* should guide practice. Briefly stated, the framework delineates a process by which clinicians can engage patients in decisions whilst also aiming to avoid the creation of anxiety that the burden of additional information or unwelcome decisional responsibility could bring.

Samenvatting

Dit proefschrift betreft besluitvorming in een medische context, met name in de interactie tussen zorgverleners en patienten die algemeen bekend staat als het *consult* Hierin worden problemen geidentificeerd en plannen gemaakt gericht op hun aanpak De term 'gezamenlijke besluitvorming' (*shared decision making*) wordt tegenwoordig gebruikt als korte aanduiding voor consulten waarin zorgverleners patienten actief betrekken in het besluitvormingsproces Er bestaat onduidelijkheid over de mate waarin controle over het proces bij de zorgverlener dan wel bij de patient moet liggen, en in hoeverre de verantwoordelijkheid voor dit proces kan worden gedeeld tussen de betrokken partijen De essentie van gezamenlijke besluitvorming berust op de assumptie dat het acceptabel, zelfs belangrijk (en wellicht gunstig) is om patienten een rol in de besluitvorming aan te bieden Dit betekent een verschuiving ten opzichte van de meer traditionele kijk van professionals De uitgevoerde studies hadden tot doel het concept van gezamenlijke besluitvorming te onderzoeken en de haalbaarheid te bepalen van het betrekken van patienten in de klinische interactie Samenvattend wordt in dit proefschrift geconcludeerd dat specifieke vaardigheden voor het betrekken van patienten in de besluitvorming kunnen worden aangewezen, verhelderd en gemeten, en dat zorgverleners deze vaardigheden kunnen ontwikkelen in de patientenzorg

In *hoofdstuk 1* wordt het onderwerp geintroduceerd door definities van gezamenlijke besluitvorming te geven in de bredere context van patientgerichtheid Er wordt beschreven hoe deze concepten in toenemende mate de belangstelling van professionele zorgverleners hebben in de afgelopen tientallen jaren Er wordt in het kort weergegeven hoe rekening moet worden gehouden met besluitvormingsmodellen in de cognitieve psychologie, met de invloed van *evidence based practice* en met het onderzoek naar voorkeuren van patienten omtrent inbreng in besluitvorming, om de resultaten van het belangrijkste thema in dit proefschrift in de juiste context te kunnen plaatsen het thema dat observeerbare communicatievaardigheden van professionals belangrijke onderdelen zijn van het betrekken van patienten in besluitvormingsprocessen De inleiding vat de drie hoofdvragen samen

- Wat is gezamenlijke besluitvorming?
- Kan het worden gemeten?
- Kan het worden geimplementeerd, en zo ja, hoe?

Hoofdstuk 2 bevat een overzicht van de literatuur over patientparticipatie in klinische interacties Het was duidelijk dat dit onderzoeksterrein nieuw is en dat er betrekkelijk weinig empirische studies zijn gedaan Het overzicht was daarom bewust een breder opgezette analyse van de vele verschillende perspectieven op het onderwerp Studies werden meegenomen, maar ethische, wettelijke, theoretische en conceptuele publicaties

werden ook opgenomen om een volledig overzicht van het onderzoeksterrein te krijgen. Het doel van het hoofdstuk was om te beschrijven welke problemen verbonden zijn aan de manier waarop huisartsen momenteel met patiënten praten over therapieën en om alternatieve methoden voor te stellen om informatie te delen en gezamenlijke besluitvorming te realiseren. Inbreng van patiënten in besluitvorming op macro-niveau van beleidsvorming en verdeling van middelen viel buiten het bestek van dit hoofdstuk.

In de literatuur worden drie basale methoden van besluitvorming in het consult beschreven. Zij kunnen worden opgevat als een spectrum dat loopt van paternalisme aan de ene kant naar 'geïnformeerd beslissen' (*informed choice*: de patiënt is volledig verantwoordelijk voor beslissingen) aan de andere kant. Gezamenlijke besluitvorming ligt tussen deze twee methoden in. De uitgangspunten hiervan werden als volgt omschreven:

* Gezamenlijke besluitvorming betreft tenminste twee deelnemers - de arts en de patiënt - en vaak veel meer (hun familienetwerken of collega's).
* Beide partijen (artsen en patiënten) ondernemen stappen om deel te nemen in het besluitvormings-proces.
* Het delen van informatie is een voorwaarde voor gezamenlijke besluitvorming.
* Er wordt een beslissing genomen over het beleid (wat ook 'niets doen' kan zijn) en beide partijen stemmen in met de beslissing.

Toen het literatuuroverzicht werd gemaakt, waren er geen publicaties die het concept van gezamenlijke besluitvorming diepgaand hadden onderzocht en geen studies naar de visie van zorgverleners. Dit hoofdstuk vat het onderzoek samen dat suggereert dat vier aspecten van communicatie gerelateerd zijn aan positieve uitkomsten bij patiënten, namelijk het verstrekken van duidelijke informatie, patiënten in staat stellen om vragen te stellen, een bereidheid om beslissingen te delen (te bespreken), en overeenstemming tussen patiënt en arts over het probleem en het plan. De geïncludeerde studies betroffen echter 'patiëntgerichtheid' (*patient centredness*) in het algemeen, terwijl het meer beperkte concept 'gezamenlijke besluitvorming' niet werd onderzocht. Het hoofdstuk bespreekt verder ethische en wettelijke aspecten en de praktische barrières die volgens professionals de realisering van patiëntparticipatie in de besluitvorming bemoeilijken. Het bleek dat gezamenlijke besluitvorming vooral een methode is voor de 'beleidsfase' van het consult. Hoewel er geen specifiek bewijs is dat het belang van patiëntinbreng in besluitvormingsprocessen ondersteunt, is wel aangetoond dat een patiëntgerichte benadering - waarvan gezamenlijke besluitvorming onderdeel is - leidt tot verbetering van korte termijn uitkomsten (begrip en satisfactie bij de patiënt). Er is echter geen consistent bewijs voor gunstige lange termijn effecten op de patiënt.

In *hoofdstuk 3* wordt een kwalitatieve studie gepresenteerd waarin gebruik werd gemaakt van conversatie analyse (*discourse analysis*), een gedetailleerde tekstanalyse van communicatieprocessen in geselecteerde consulten waarin werd verwacht dat gezamenlijke besluitvorming moeilijk zou zijn, namelijk discussies over de noodzaak van antibiotica voor behandeling van infecties aan de bovenste luchtwegen. Er werden twee consulten geselecteerd uit de praktijk van een arts met belangstelling voor het betrekken van patiënten in beslissingen. De analyse werd afgezet tegen de theoretische competenties voor gezamenlijke besluitvorming. De conclusie was dat 'gelijkwaardigheid' (*equipoise*) van de uitkomsten van beslissingen in de visie van de professional een belangrijke factor is die gezamenlijke besluitvorming faciliteert en die ontbrak in deze casuïstiek. Het bestaan van gelijkwaardigheid gaf patiënten de 'vrijheid' om naar eigen voorkeur een optie te kiezen. Veel beslissingen in de geneeskunde hebben deze eigenschap, maar professionals kunnen niet in alle situaties gelijkwaardigheid veronderstellen. Het inzicht in gezamenlijke besluitvorming moet worden ontwikkeld voor situaties waarin meningsverschil bestaat door uitgesproken opvattingen van betrokkenen.

In *hoofdstuk 4* werd een verdere verkenning van de feitelijke consultvoeringspraktijk uitgevoerd. Het doel hiervan was om de communicatiestrategieën te onderzoeken van huisartsen die probeerden om patiënten feitelijk te betrekken bij behandelingsbeslissingen. De empirische gegevens werden vergeleken met een theoretische lijst van competenties voor gezamenlijke besluitvorming. De onderzochten waren vier huisartsen, die consulten waarin ze specifiek tot doel hadden om patiënten te betrekken bij beslissingen op audioband opnamen. De transcripten van de consulten werden gecodeerd en werden vervolgens visueel weergegeven. De resultaten bevestigden het voorgestelde theoretische raamwerk maar ten dele. De opvattingen van patiënten over mogelijkheden voor behandeling en de gewenste rol in de besluitvorming werden feitelijk in de praktijk niet nagegaan. De interacties werden meestal gestart met een fase van probleemdefinitie; uitspraken over 'gelijkwaardigheid' kwamen consistent voor; en het verstrekken van informatie over opties werd vaak afgewisseld met het geven van de gelegenheid aan patiënten om vragen te stellen en opmerkingen te maken. De studie liet zien dat bepaalde theoretische competenties niet onderscheiden kunnen worden in de praktijk en dat andere, niet eerder beschreven activiteiten in het consult werden gevonden, zoals het aangeven van de 'gelijkwaardigheid'. Dit leidde tot een herformulering van de lijst van vaardigheden, die vervolgens werd gebruikt voor de verdere ontwikkeling van een meetinstrument.

In *hoofdstuk 5* wordt een onderbouwing geleverd voor het meten van gezamenlijke besluitvorming. Het doel was om na te gaan of er instrumenten bestaan om te meten of en in hoeverre professionals patiënten werkelijk betrekken in klinische beslissingen. Relevante literatuur werd systematisch gezocht en beoordeeld. Instrumenten moesten betrekking hebben op het meten van patiëntinbreng in besluitvorming; gebruik maken van observationele technieken (directe observatie of audio/video opnamen); en de kernpunten van

betrokkenheid omvatten, namelijk· patienten zijn daadwerkelijk betrokken bij de besluitvorming (expliciet of impliciet), er wordt een overzicht van opties voor behandeling geboden, er is een besluitvormings- of planningsfase De resultaten lieten zien dat er in de beschikbare instrumenten slechts zeer beperkt sprake is van een gedetailleerde beoordeling van patientinbreng in besluitvorming De bestaande instrumenten bevatten dit concept slechts als een aspect van een bredere beoordeling Meetinstrumenten voor 'patientgerichtheid' zijn niet in staat om 'inbreng van patienten' voldoende specifiek in beeld te brengen, omdat zij veelal een groot aantal dimensies omvatten. De conclusie uit deze systematische literatuurstudie was dat het concept patiëntinbreng (*shared decision making, informed collaborative choice*) vereist dat er een nieuw, betrouwbaar en valide meetinstrument wordt ontwikkeld

Op basis van de resultaten van dit literatuuroverzicht werd gestart met de ontwikkeling van een meetinstrument voor de mate waarin zorgverleners patienten betrekken in besluitvormingsprocessen In *hoofdstuk 6* wordt gerapporteerd over de ontwikkeling (met behulp van een mix van methoden) en over psychometrisch eigenschappen van dit meetinstrument, genaamd OPTION (afkorting van *observing patient involvement*) Het instrument werd toegepast door twee onafhankelijke beoordelaars op een set van 186 consulten op audiotape, afkomstig van 21 huisartsen in Groot-Brittannie De studie liet zien dat het instrument betrouwbare scores voor patientinbreng gaf op het niveau van consulten, met een acceptabele interbeoordelaarsbetrouwbaarheid Hoewel het instrument weinig variatie tussen artsen liet zien, was er aanzienlijke variatie binnen artsen Sommige artsen hadden een relatief beperkte variatie van scores, anderen een veel grotere variatie Dit betekent dat sommige artsen de mate van patientinbreng in besluitvorming meer afwisselen tussen verschillende consulten dan andere

In *hoofdstuk 7* wordt gerapporteerd over onderzoek dat parallel aan de ontwikkeling van het OPTION instrument werd uitgevoerd om de constructvaliditeit van het instrument te onderbouwen Het doel van deze studie was om na te gaan wat een gepaste inbreng van patienten in besluitvorming in consulten bepaalt, om theorievorming op dit terrein te toetsen en om een lijst van competenties (vaardigheden) en stappen in een consult te bepalen op basis warvan zorgverleners gezamenlijke besluitvorming in hun klinische omgeving zouden kunnen realiseren Er werd een kwalitatieve studie uitgevoerd met focusgroep interviews met belangrijke informanten. Het bleek dat ervaren huisartsen een positieve houding ten aanzien van patiëntinbreng hadden, mits het proces paste bij de rol die patienten zelf wensten te spelen in het besluitvormingsproces Zij vonden bepaalde klinische problemen meer geschikt voor samenwerking en zij veronderstelden dat het bestaan van 'gelijkwaardigheid' van behandelingsopties in de ogen van professionals een belangrijke voorwaarde is Er werd een set van noodzakelijke vaardigheden voorgesteld 1) Impliciete of expliciete betrokkenheid van patienten in het besluitvormingsproces, 2) Nagaan van ideeen, angsten en verwachtingen ten aanzien van het probleem en mogelijke behandelingen, 3) Beschrijven van de

gelijkwaardigheid van verschillende opties, 4) Nagaan welke vorm van informatie wordt gewenst en verstrekken van informatie op maat, 5) Procescontrole: Begrip van informatie en reacties bij de patiënt (bijvoorbeeld ideeen, angsten en verwachtingen van mogelijke opties), 6) Procescontrole: Acceptatie van voorkeuren van de patient omtrent het proces en de eigen rol in de besluitvorming, 7) Beslissing nemen, bespreken of uitstellen, 8) Follow-up regelen Samengevat zagen de artsen 'betrokkenheid' als een impliciet ethos dat de medische praktijk zou moeten doordringen, mits artsen ook respect en aandacht zouden houden voor individuele voorkeuren van patiënten in de besluitvorming. Deelnemers concludeerden dat het aanbrengen van interpersoonlijke vaardigheden nodig voor het succesvol delen van beslissingen met de patient een grote uitdaging vormt voor het consultatieproces in de medische praktijk.

Nadat een lijst van competenties en een meetinstrument waren ontwikkeld, bleek het noodzakelijk om aandacht te besteden aan de problemen van implementatie. In *hoofdstuk 8* wordt een kwalitatieve studie beschreven waarin de toepasbaarheid van een interventie op dit gebied wordt onderzocht door het nagaan van de reacties van artsen op bijeenkomsten gericht op bevordering van shared decision making vaardigheden en verstrekking van hulpmiddelen voor risicocommunicatie. In totaal 39 huisartsen in opleiding en acht opleiders uit de beroepsopleiding in Zuid Wales namen deel aan groepsinterviews om ervaringen met deze interventies uit te wisselen De huisartsen in opleiding observeerden een reeks consulten wat betreft beleidsbeslissingen met simulatiepatienten met behulp van gegevens in verbale, numerieke en grafische vorm. De reacties werden gepeild en de artsen zeiden dat ze nooit training hadden gehad in de vaardigheden die nodig waren om patienten te betrekken in beslissingen. Zij hadden sterk uiteenlopende opvattingen over het 'betrekken van patienten in beslissingen', varierend van beschermend paternalisme ('de arts weet het het beste'), via eigenbelang (verlichting van werklast), tot mogelijke beloningen ten gevolge van een meer gelijkwaardige relatie met patienten. De studie vestigde de aandacht op drie voorwaardenscheppende contextuele processen: de beschikbaarheid van betrouwbare informatie, adequate timing van het besluitvormingsproces, en de bereidheid van patiënten om een actieve rol te accepteren in hun beleid Zij waren het erover eens dat het delen van beslissingen betekent dat onzekerheden over de uitkomsten van medische processen worden gedeeld en dat zij vaak werden geconfronteerd met het feit dat gegevens niet beschikbaar of onbekend zijn, hetgeen ongerustheid kan veroorzaken bij clinicus of patient. Het bleek echter dat veel zorgverleners open stonden voor deze nieuwe ontwikkeling ten aanzien van de communicatie met patienten De interventies werden verder uitgewerkt ten behoeve van verder onderzoek.

In *hoofdstuk 9* worden de resultaten beschreven van een cluster gerandomiseerd experiment gericht op evaluatie van het onafhankelijke en het gecombineerde effect van bijeenkomsten voor ontwikkeling van vaardigheden en het gebruik van hulpmiddelen voor risicocommunicatie op het vermogen van artsen om patienten in besluitvormingsprocessen te betrekken Twintig artsen werden op basis van toeval verdeeld

over twee interventies (ontwikkeling van interpersoonlijke vaardigheden enerzijds en gebruik van hulpmiddelen voor risicocommunciatie anderzijds) in een gekruiste opzet (*cross over design*). De patiënten werden geïdentificeerd en gerandomiseerd binnen elke praktijk, evenwichtig verdeeld over vier klinische condities en over de fasen van het experiment, en gevraagd om deel te nemen aan herhaalconsulten die werden opgenomen op audiotape. Twee onafhankelijke beoordelaars beoordeelden 371 consulten met behulp van het nieuwe OPTION instrument. De artsen verbeterden significant wat betreft hun vaardigheid om patiënten te betrekken in de besluitvorming in geplande consulten met echte patiënten in een klinische setting. Beide interventies verhoogden onafhankelijk de mate van patiëntinbreng. De mate van inbreng na de toepassing van hulpmiddelen voor risicocommunicatie werd significant verder verhoogd na voorafgaande bijeenkomsten voor de ontwikkeling van vaardigheden. De alternatieve volgorde (vaardighedenontwikkeling gevolgd door gebruik van risicocommunicatiehulpmiddelen) kende dit effect niet. De effectiviteit van deze interventies laat zien dat er behoefte is aan de ontwikkeling van beslissingsondersteunende hulpmiddelen, die gemakkelijk bruikbare informatie voor zowel zorgverleners als patiënten verschaffen, binnen en buiten het consult. Bovendien vormen de resultaten een prikkel om communicatievaardigheden te ontwikkelen tijdens de hele loopbaan, omdat beslissingsondersteunende hulpmiddelen (*decision aids*) slechts een deel van het totale mogelijk gunstige effect bij patiënt realiseren.

In *hoofdstuk 10* worden de implicaties van de studies besproken en wordt een reeks aanbevelingen voor verder onderzoek en voor de klinische praktijk gedaan. Het blijkt dat gezamenlijke besluitvorming *(shared decision making)* een breed gebruikte term is om een consultatiemethode te beschrijven waarin zorgverleners trachten patiënten te betrekken in klinische beslissingen. De methode is tot nu toe in de literatuur vooral besproken op conceptueel niveau (principes en doelen), maar echte evaluaties van de toepassing in de praktijk werden niet eerder uitgevoerd. Beschouwing van het concept door zorgverleners laat zien dat het twee belangrijke componenten heeft: ten eerste dat patiënten gericht moeten zijn op het beoogde proces, zodat het delen van informatie over opties relevant en betekenisvol is; ten tweede dat men gebruik kan maken van een van de drie besluitvormingsmodellen, die zijn benoemd als 'paternalisme', 'gezamenlijke besluitvorming' (*shared decision making*) en 'geïnformeerd beslissen' (*informed choice*). Sommigen hebben gepleit om expliciet te vragen aan patiënten welke mate van inbreng in de besluitvorming zij wensen (en dan de relevante methode toe te passen). Andere zorgverleners werken met een impliciet proces en zij bepalen het gewenste besluitvormingsmodel interactief in het consult. De ethische debatten ten aanzien van deze flexibele aanpak om de mate van autonomie te bepalen, die artsen van patiënten verwachten, worden besproken. Tenslotte wordt in het proefschrift geconcludeerd dat patiënten alleen aangemoedigd moeten worden om mee te beslissen voorzover zij dit zelf wensen. Deze voorkeur moet niet worden gezien als een blijvend kenmerk, maar als iets dat steeds aandacht behoeft.

Het proefschrift stelt een lijst van competenties ten aanzien van gezamenlijke besluitvorming (*shared decision making*) voor en een meetinstrument om de mate waarin zorgverleners patiënten betrekken in de besluitvorming vast te stellen. De lijst beschrijft de stappen die men moet nemen om patiënten te oriënteren, op te committeren, te informeren en te betrekken bij beslissingen.

Er is verder bewijs geleverd voor de effectiviteit van een interventie, gericht op de ontwikkeling bij professionals van deze vaardigheden. Verdere studies moeten nagaan welke mogelijke relaties bestaan tussen gezamenlijke besluitvorming (*shared decision making*) en patiëntuitkomsten. Concluderend: de competenties zijn niet bedoeld als een rigide formule, maar als een leidraad voor zorgverleners in de klinische praktijk, met als kanttekening dat het ethische principe van *beneficence* de praktijk moet leiden. Kort gezegd duidt de lijst op een proces waarmee zorgverleners patiënten kunnen betrekken bij beslissingen, terwijl ze tegelijkertijd proberen te vermijden dat er ongerustheid ontstaat over aanvullende informatie of de onwelkome verantwoordelijkheid voor beslissingen.

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Curriculum Vitae

Glyn Elwyn was born on the 24th of February 1955 He attended school at Ysgol Dyffryn Conwy, Llanrwst, and completed the following degrees at the University of Wales BA in Welsh and Drama (1978), MB BCh (1982) and MSc in Medical Education (1997) After practising general practice in a rural part of Africa (1985-1986) and in the inner city dockland area of Cardiff in the early 1990s he joined the Department of Postgraduate Education for General Practice in 1998 and was made a Fellow of the Royal College of General Practitioners in 2000 He attended INSEAD, the European Management School in 1998.

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Supplement

Option Scale Manual

OPTION

observing patient involvement scale

A manual for raters
June 2001

OPTION Development Group

Glyn Elwyn, Adrian Edwards, Michel Wensing, Chris Atwell, Cathy Lisles, Jill Bourne, Mike Robling, Kerry Hood, Richard Grol

Contents

Introduction

Over the last decade increasing importance has been placed on the concept of developing a partnership between health professionals and patients, especially when decisions have to be made about a range of possible interventions such as treatments, investigations or the benefits (or otherwise) of screening tests (e.g. cervical smears, breast mammography) [1, 2]. The ethical principle of respecting individual autonomy can be in conflict with the principle of 'not doing harm' if for instance a patient finds it too difficult to undertake the responsibility for decision making as a result of anxiety, stress or illness.

In broad terms, three decision making methods can be described, namely 'paternalism', 'shared decision making' and 'informed choice' [3]. The traditional 'doctor knows best' paternalistic method is a well-recognised consulting pattern. The 'informed choice' method is more recently described as one where the patient has overcome the problem of information deficit, either by having acquired the data independently or by having the information imparted directly by a health professional. The patient now possesses both information and personal preferences components, the components viewed as essential to a decision making task. In this method the decision making control is seen as vested in the patient and as Emanuel [4] noted the clinician "is proscribed from giving a treatment recommendation for fear of imposing his or her will on the patient and thereby competing for the decision making control that has been given to the patient". Full patient autonomy (as advocated by the 'informed choice' method) can lead to patient 'abandonment' where patients feel at a loss about the most appropriate course of action [5]. There is an increasing concern that placing all the decisional responsibility onto patients may not be acceptable, in either practical or ethical terms.

There is therefore interest in what has been termed the 'shared decision making' method [6], and in what Quill calls the concept of 'enhanced autonomy' [5, 7], where the views of both clinicians and patients are considered in the decision making process. The key characteristics of shared decision making have been described [3] as:

- it involves at least two participants
- both parties take steps to build a consensus about the preferred treatment
- information is shared
- agreement is reached on the treatment to be implemented

Although this approach to the clinical consultation could be viewed as being embedded in the broad concept of patient centred consulting method, it is focused much more on the decision making stage in consultations. This interaction typically occurs in the second half of the consultation or at review-type meeting interactions between clinician and patient, when the results of investigations are available for discussion. There has been very little research in this area. Although there are some instruments described for assessing patient centredness (albeit with a debate about their reliability), there are no validated tools available to measure the

extent to which clinicians involve patients in decision making [8]. It was therefore decided to design a new instrument, named the OPTION scale (observing patient involvement).

How the tool was developed

Based on a feasibility study with general practice registrars (a training grade) [9], we developed a set of 'competences' that constituted a framework for shared decision making [10]. Assessments of consultations using discourse analysis and quantitative code-category methods refined the conceptual framework that underpins the OPTION scale [11-13]. An early version of this instrument was developed in February 1999 and piloted with clinicians. Results from this phase informed the second version (mid to late 1999). The November 1999 version was piloted by three lay raters who were asked to score 7 simulated consultations. Using the inter-rater reliability results and discussions conducted in rater calibration meetings a further version was developed (June 2000). The June 2000 version (a 16-item scale) was evaluated using a set of routine consultations collected from 21 clinicians. The psychometric evaluation is reported elsewhere [14], but as a result of this assessment 4 items were removed, which results in a final scale consisting of 12 items. A small modification was made to item 12 as compared to the scale used in the studies presented in this thesis. This is the OPTION scale (June 2001) that is now available for wider use, in consultation with the team that developed the measure.

Description of the OPTION scale

The aim of the instrument is to measure the degree to which clinicians involve patients in decision making processes in consultations. It is not designed to evaluate patient reactions or behaviour in the consultation. It is therefore an observational tool to assess clinician behaviour. It should be emphasised that some of these items are derived from the point of view of achieving the highest possible standard of practice (and in ideal circumstances). We do not expect that clinicians will score highly across all these items in day-to-day practice, and the results of evaluation to date indicate that clinicians also vary widely in the score they achieve in different consultations.

Each item is scored on a five-point scale, with high scores indicating that the rater agrees strongly with the statement, and a low score indicating strong disagreement with the statement. The scores from the 12 items (minimum of 12, maximum of 60) are summed and scaled to provide a score that lies from 0 to 100. This manual describes the items and defines the mid-point of each item scale where this is necessary. When consultations take place with a parent and child, the interaction of the clinician with the *main protagonist* should be rated. In most circumstances, this will be the adult but it could be an older child or teenager.

The items: description and scoring

Item 1   Identification of problems

> 1   The clinician *identifies* problem(s) needing a decision making process.

Item 1 should be regarded as a 'gateway item'. If it is not possible to discern that the clinician has provided any scope for a decision making process within the consultation then the remainder of the scale is difficult to apply and disagreement should be registered on the item scale. It is anticipated that this would be a rare event and that most consultations have at least one problem identified at least in broad terms. Clear problem definition and structuring would indicate that this item is given the maximum score. Problems that are vague, assumed or left uncertain should be given a mid-point score and the rest of the scale completed where possible.

Often there is more than one problem in the consultation. This item can be scored highly provided at least one problem is identified in sufficient detail for the consultation to continue with a process of problem solving and decision making. This problem should be termed the *index problem* for the rating. It is important that the index problem is clearly identified by the first rater and a note made so that this 'index' problem can be verified (or rejected) by subsequent raters. An index problem is the problem where the highest degree of involvement occurs within the consultations, as the aim is to identify the *ability* to involve patients. Where there are more than two raters, agreement regarding the *index problem* should be achieved.

Item 1 is concerned with the level of clarity achieved within the consultation regarding the clinical problem or problems that need to have a decision made about them. The clinician typically achieves this task, unless the patient is assertive and helps the clinician to refine the problem definition by drawing attention to possible misunderstandings. For this purpose we are interested in the health problem (e.g. headache, menopausal symptoms, atrial fibrillation). This item does not attempt to cover the issue of diagnostic *concerns* – for example a patient with a headache may want to be reassured that this symptom is not due to a tumour (we expect that such tasks have been completed before a discussion about 'management' can occur). So in the instance of a patient with a headache, the ideal formulation would be along these lines:

> *"So I think you have a tension headache. Neither the history, the examination nor the tests performed suggest that the problem is due to a brain tumour or any other serious problem. We are dealing with a tension headache. There are many ways in which this problem could be managed..."*

This item does not cover whether the clinician explores the patient's ideas, concerns and expectations about the problem management. Subsequent items cover these issues.

Item 2   Equipoise statements

> 2   The clinician *states* that there is more than one way to deal with the identified problem ('equipoise').

More than one way of managing problems exist in many clinical situations, and as well as taking action the choice of acting conservatively is often a viable option as well as reviewing the need to intervene at a further consultation. Equipoise statements are those statements that convey to the patients that there is genuine professional uncertainly as to the 'best' way of managing the problem. The aim of these statements is not to convey that the clinician does not *know* the correct action to take, but to portray that there are legitimate options that require consideration. This item should be scored 'strongly agree' if the clinician uses phrases such as, 'there are many ways to manage this problem' or 'there are different possibilities' and so on, which indicate that the clinician is orientating the patient to the fact that choices exist.

Item 3   Listing options

> 3   The clinician *lists* 'options', including the choice of 'no action' if feasible.

Item 3 should be scored highly if the clinician *lists* options as distinct possibilities that are clearly available. An 'either/or' phrasing describing the existence of options should be scored highly. Listing is a way of orientating the patient to the number of options that are available, for example:

"There are three possibilities, A, B and C. Let me tell you more about A first.

Item 4   Explaining options

> 4   The clinician *explains* the pros and cons of options to the patient (taking 'no action' is an option).

Item 4 should be scored highly if the clinician *describes* or *explains* one or more of the options in detail. If no details are provided about the proposed intervention (or range of interventions listed) then the rater should

'strongly disagree' with the statement (score 1) The description of significant 'harms' associated with a potentially effective treatment should lead to this item being scored highly. A score of '3' would indicate that the clinician has described the proposed intervention (treatment or test and so on) but has not fully alerted the patient to the potential *pros* and *cons* For example, merely describing the advantages and not the disadvantages (or vice versa) of options would lead to a mid-point score

Item 5   Information format

> 5   The clinician *checks* the patient's preferred information *format* (words / numbers
>   / visual display).

Item 5 is an example where a high scores is not routinely expected The use of decision-aids (such as visual displays of data) is rare in routine consultations There are however occasions when formats of this kind are used and the item has therefore been retained Item 5 should be scored highly if the clinician asks patients about their preferred way of assimilating information If the patient's preferred method of assimilating information is not ascertained then this item should receive a low score A permission-seeking question such as

  "I've got this [decision aid of whatever type] to show you   ",

should be scored as a 3 More explicit permission or preference-seeking questions such as

  "What type of information format or type do you prefer?",

should be scored highly If no information is provided, then this item should be given a score of 1.

Item 6   Exploring expectations

> 6   The clinician explores the patient's *expectations* (or ideas) about how the
>   problem(s) are to be managed

Item 6 assesses proficiency in exploring the patient's expectations — what did the patient think was going to happen regarding the *management* of the problem These ideas are normally difficult to access Patients are reluctant to share their views about these issues, for a range of reasons Skilled, experienced clinicians are

however able to access these views using pauses and being alert to verbal and physical cues. For example, a patient who thought that she had a menopausal problem might have 'expected' further tests or to be prescribed some medication. This requires the clinician to ask the patient about prior conceptions regarding anticipated outcomes. If the clinician does not explicitly ascertain the patient's views then this item should receive a low score. Perfunctory (or unskilled) attempts to uncover a patient's ideas or expectations about management should be given a mid-point score.

Item 7   Exploring concerns

> 7 The clinician explores the patient's *concerns* (fears) about how problem(s) are to
>   be managed.

Asking about *concerns* and *fears* requires the clinician to ascertain fears, worries or anxieties that may be in the patient's mind. For example, a man who has 'prostatism' might have discussed the problem with peers and *fears* that his symptoms will lead to a surgical referral, and is therefore worried about the risks associated with operations. If the clinician does not explicitly ask about the patient's 'fears' or 'concerns' then this item should be given a low score. Unskilled or perfunctory attempts to explore a patient's fears and concerns about management should be given a mid-scale score.

Item 8   Checking understanding

> 8 The clinician checks that the patient has *understood* the information.

Item 8 should be scored highly if the clinician actively explores the patient's understanding of imparted information. To score highly on this item an explicit question needs to be posed or an opportunity provided where patients could ask questions to clarify information. Such questions would be formulated along the lines of:

> *"Is there any aspect of the information which I've given you which you would like to clarify or which you feel has been difficult to understand?"*

If patients volunteer that they have understood the information provided, this would indicate a high score. If no attempt is made to check comprehension, or to allow any opportunities for patients to *indicate* that they have understood the information, then the item should receive a low score.

Item 9   Opportunities for questions

> 9   The clinician provides the patient with *opportunities* to ask questions.

Item 9 should be scored highly if the clinician encourages the patient to *ask* questions and to *clarify* issues in the consultation. Patients would therefore be enabled to ask questions about any aspect of the problem and not directed to make enquires about the information provided. If the clinician specifically asks patients whether or not they have any questions then a high score should be given. Pauses and other opportunities for queries to be raised, such as providing pauses which are long enough for patients to feel able to take a turn should be scored positively. Low scores should be given where the clinician's communication style rules out opportunities for patients to pose questions.

Item 10   Preferred level of involvement

> 10 The clinician elicits the patient's *preferred level of involvement* in decision
>   making.

Item 10 should be scored highly if the clinician explores the patients' wishes about the role they want to play in decision making. It may be that patients want to be actively involved but are denied the opportunity, or that some patients do not wish to take any part in the decision making process but the clinician makes assumptions about their preferred role. It is impossible to assess a patient's preferred role by observation and the rater is not asked to make judgements about this. The item should be scored highly if the clinician specifically *asks* patients about their preferred role. If no attempt is made to ascertain the preferred role of the patient in decision making, then a low score should be given.

Item 11   Making (or deferring) a decision

> 11 An opportunity for *making* (or *deferring*) a decision is provided.

Item 11 should be scored highly if the clinician clearly provides an opportunity to make (or defer) a decision. Initiating the decision phase of the consultation usually requires the clinician to signal that this stage of the interaction should occur. This stage can involve a short summary of the options and perhaps an exchange of views about the best option, i.e. both clinician and patient views are made explicit. The observer is not required to make a judgement about the decisional agency (i.e. how the decision is made and who takes

control) but to indicate that a clear decision making phase is conducted. It is also possible the decision phase involves deferment; an acceptance that time is required for further discussion.

Item 12   Reviewing the decision

> 12 Arrangements are made to *review* the decision (or the deferment).

Item 12 should be scored highly if the clinician clearly provides an opportunity to review a decision, i.e to allow time for a decision to be reconsidered and if necessary revised or altered. A clear statement indicating that decisions are not final and can be reviewed and changed should be given a high score If review offers are not provided, a low score should be given.

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10   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, 50 892-899

11   Gwyn R, Elwyn G When is a shared decision not (quite) a shared decision? Negotiating preferences in a general practice encounter Social Science and Medicine 1999, 49 437-447

12   Gwyn R, Elwyn G, Edwards A "Let's have your honest opinion" dialogism and decision-making in primary care Submitted Social Science and Medicine, 2001

13   Elwyn G, Gwyn R, Edwards AGK, Grol R Is 'shared decision making' feasible in consultations for upper respiratory tract infections? Assessing the influence of antibiotic expectations using discourse analysis Health Expectations 1999, 2 105-117

14   Elwyn G, Edwards A, Wensing M, Hood K, Robling M, Smith C, Grol R Fleeting glimpses measuring shared decision making in primary care using the OPTION instrument For submission Medical Decision Making, 2001

Stellingen

behorende bij het proefschrift
"Shared decision making Patient involvement in clinical practice "
van Glyn Elwyn

1   We have for too long neglected the second half of the consultation *(dit proefschrift)*

2   Clinicians do not routinely use patient centred skills nor involve patients in decisions in their day-to-day practice *(dit proefschrift)*

3   Shared decision making recognises that patients often feel uncertain or ambivalent or overwhelmed by what can appear to be confusing or conflicting information, and, more often than not, seek to be guided about decisions *(dit proefschrift)*

4   The current understanding of shared decision making needs to be developed for those situations where there are disagreements due to the strongly held views of the participants *(dit proefschrift)*

5   Involvement in decision making is a key facet of patient participation in health care and the OPTION scale provides a validated outcome measure for future empirical studies *(dit proefschrift)*

6   The suggested ideal of a shared decision making interaction will either require more time than currently allocated, or alternative strategies to enable information exchange outside the consultation

7   The level of patient involvement achieved by using risk communication tools can be significantly increased by the subsequent introduction of communication skill development *(dit proefschrift)*

8   One might say that the learning of the medical role consists of a separation, almost an alienation, of the student from the lay medical world, passing through a mirror so that looks out on the world from behind it, and sees things in mirror writing
Hughes E The Sociological Eye New Brunswick Transaction, 1984

9   Respect for the autonomous choices of other persons runs as deep in common morality as any principle, but little agreement exists about its nature and strength or about specific rights of autonomy
Beauchamp TL, Childress JF Principles of Biomedical Ethics Oxford Oxford University Press,1994

10   The ability to define what may happen in the future and to choose among alternatives lies at the heart of contemporary societies
Bernstein PL Against the gods the remarkable story of risk New York John Wiley and Sons, 1996

11   Life can only be understood backwards but it must be lived forwards
Søren Kirkegaard

12   Remember when you are bemusing,
And daily decisions confusing,
     That for life existential,
     The thing that's essential
Is never the choice but the choosing