

# ○ Implementing patient decision aids in urology

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## GLOSSARY OF ABBREVIATIONS

BAUN	British Association of Urological Nurses
BAUS	British Association of Urological Surgeons
BPH	Benign Prostatic Hyperplasia
CNS	Clinical Nurse Specialist (also referred to as SN)
DQA	Decision Quality Assessment
DSA	Decision Support Aid
FIMDM	Foundation for Informed Medical Decision-Making
HIFU	High intensity focused ultrasound
LREC	Local research ethics committees
LUTS	Lower urinary tract symptoms
MA	Modernisation Agency
MDT	Multi-disciplinary team
MISR	Macmillan Information and Support Radiographer
MREC	Multi-site research ethics committee
MRSA	Methicillin-resistant staphylococcus aureus
NeLH	National Electronic Library for Health
NICE	National Institute for Health & Clinical Excellence
OHRI	Ottawa Health Research Institute
OP	Outpatient
PCPC	Primary care prostate clinic
SN	Specialist nurse
TRUS	Trans-rectal ultrasound scan
TURP	Transurethral resection of the prostate

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# 1 Executive Summary

## Introduction

The UK government is placing increasing emphasis on both the availability and quality of patient information, and the need to involve patients more in their care. Recent strategy from the Department of Health aims to improve information and provide and support choice (Department of Health 2004). Two of the many aims of this strategy are to:

- embed information as an integral part of delivering healthcare through the entire healthcare system; and
- help people to participate confidently in healthcare decisions.

*"Improving information for patients can empower them to take a more active role in their healthcare, improve relationships and communication with healthcare professionals, and increase their ability to take control of their health and participate more fully in decisions about their care and treatment"* (Department of Health 2004).

## The Innovatory Programme

This report describes and evaluates the implementation of an innovative programme to help patients diagnosed with either early-stage localised prostate cancer or Benign Prostatic Hyperplasia (BPH) to reach 'good quality' decisions about their treatment in partnership with healthcare professionals.

The programme was implemented in the urology departments of four NHS Hospital Trusts in England and was monitored and evaluated by researchers at Picker Institute Europe.

One site chose to implement the programme for both these groups of patients, one site concentrated just on BPH patients, and two sites implemented only the prostate cancer programme.

The programme was hosted by the Action On Urology Team (part of the NHS Modernisation Agency), who worked with a Programme Steering Group which included colleagues within the Department of Health, the Foundation for Informed Medical Decision-Making (FIMDM) in Boston USA, the Cochrane Institute of Ottawa and Ottawa University, and the Picker Institute.

The programme consisted of three elements:-

1. Nurse training provided by Professor Annette O'Connor from Ottawa University
2. Decision Support Aid (DSA) videos or DVDs provided by the FIMDM

3. Decision Quality Assessment (DQA) forms designed by programme partners and agreed by the steering group.

The implementation of the decision support programme was monitored and evaluated over a period of twelve months so that lessons could be learned for future national use of decision support programmes in the UK. The evaluation examined the situation before implementation in each of the participating sites, monitored the administrative implications, and explored professionals' and patients' experiences of participating in the scheme. Eighty-six patients with either BPH or prostate cancer took part in the scheme over a period of approximately six months; their knowledge, values and decisions were monitored and a sub-sample was interviewed. Medical and nursing staff in each site were also interviewed.

### Key Findings

- Overall, the programme was integrated into five different pathways with minimal disruption.
- The staff valued being able to give good quality, audio-visual information, and patients, on the whole, were grateful to receive it and found it useful and informative.
- Patients were willing to complete forms eliciting their values, preferences and knowledge about their condition.
- Findings suggest that men's knowledge about their condition and the implications of differing treatments improved after the DSA had been introduced, though there is still room for further improvement
- Patients' views about their symptoms and the available treatments are related to the decisions they make; thus those patients with BPH who said they were bothered by their current symptoms were more likely to choose surgery, whilst those who did not care for surgery were more likely to opt for watchful waiting or medication. The DQA therefore appears a valuable tool, though our findings need to be validated with larger samples of patients with BPH and also with prostate cancer.
- After initial doubts over the DQA, staff recognised its potential value; however, our findings suggest ways in which it could be improved.

As a result of this evaluation, a number of recommendations can be made for the future:

- any future programme and/or implementation strategy should include strong local leadership so that it takes into account the specific local pathway into which it is to be incorporated.
- the programme should be incorporated more effectively into routine procedures.
- widespread consensus should be reached amongst healthcare professionals on the evidence contained in the decision support aid before progressing with any future programme.

- a wide range of suggested improvements to the decision support aid, raised by professionals and patients involved in the programme, should be considered carefully before future use of the programme. These include the issue of whether or not to produce a UK English version, and versions in other languages; making it easier to view and review particular sections; and making it more interactive.
- a number of suggested improvements to the DQA used in this programme should be considered, including: making its purpose clearer; making it easier to incorporate into a consultation; clarifying the questions (and testing any proposed questions carefully before finalising the tool); making the answer format clearer for patients to use; and allowing for easier analysis of the results at a glance.
- the training should be made more widely available; opened up to clinicians other than nurses; and more appropriately geared towards the specific audience and programme tools, including more explicit guidance on how the DQA may be used in working with patients to reach treatment decisions. Its use should be evaluated.
- clear plans for sustainability should be built into the programme from the start, including issues associated with updating and replacement of DSAs.

We recommend that these issues be addressed before the programme is incorporated nationally in all urology departments.

The National Steering Group has already issued its short report on the Scheme (National Steering Group for DSAs in Urology, 2005). Our paper is the detailed research report. The sections which follow first set the context for the project (section 2), examining the policy background, the nature of urological conditions, patients' involvement in decisions about their care and the use of decision aids. section 3 describes the innovatory scheme and the research project. The next two sections present the findings: section 4 describes and discusses the implementation of the scheme and the views and perspectives of the staff; section 5 presents the views of the patients and discusses the outcomes for them of participating in the programme. Section 6 summarises, identifying a number of strengths and challenges for implementation of decision support programmes and making recommendations for future schemes.

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## 2 Background

### 2.1 Policy background

Improving access to information is an important part of government strategy to improve health and health services. The increasing emphasis on efficiency, evidence-based practice, and the involvement of patients in their care has brought about an increased reliance upon information. Good quality, timely and accessible information is needed for clinicians, to support professional standards and the best treatment and care; for managers, to support the best allocation of resources; for patients, to help them manage their condition, and to help them choose their treatment, and who will provide it; and the public, to inform health and lifestyle choices.

In 1998, the government published *The NHS Information Strategy: Information for Health*, which set out a programme for meeting the information needs of the whole NHS. The strategy document identifies access to the right information at the right time as a crucial ingredient of modern healthcare.

A number of important developments have occurred to improve access to information. These include the creation of NHS Direct, in which trained nurses deliver information and advice over the telephone, and NHS Direct Online, which provides a comprehensive on-line public gateway to health information.

A national consultation on choice, equity and responsiveness in 2003 highlighted the importance of improving quality and accessibility of information to enable people to make informed choices about their health and health care (DH 2003). This need to improve information was confirmed through the *Choosing Health?* consultation on public health. By way of response, the Department of Health published *Better information, better choices, better health: Putting information at the centre of health* in 2004 (DH 2004). This document builds on previous commitments and aims to bring together several strands of a wide-reaching strategy: to ensure information is available to disadvantaged and marginalised groups; to accredit information providers on the basis of the quality of their products so the information can be trusted; and to extend access to information in a range of media for everyone. A key focus in this document is providing the information and support needed by patients and the public to make difficult choices regarding their health and health care.

The importance of good information and support is also emphasised in guidelines produced by the National Institute for Health & Clinical Excellence (NICE) (see *Improving Outcomes in Urological Cancers: the Manual* 2002). These guidelines highlight the importance of involving patients in decision-making in urological cancer in general, and prostate cancer in particular. This can only work, they say, if patients are sufficiently well informed to understand the choices they face, and have sufficient time to consider the options carefully.

## 2.2 Decisions in urology

For some medical conditions there is a clear treatment option, based on scientific and clinical evidence, in which the balance of benefit over harm is large. For many others, however, the evidence is insufficient, or the ratio of benefit to harm is either uncertain or at least partially dependent on the patient's values, goals or preferred way of life. There are many cases, therefore, of uncertainty in clinical treatment. In these uncertain situations, patient involvement and patient choice are very important.

Prostate cancer and BPH are two such major preference-sensitive conditions, where taking the treatment decision may not be easy. Moreover, given the high prevalence of both prostate cancer and BPH, many men have to face these decisions each year. Prostate cancer is the most commonly diagnosed cancer in men in England, and estimates for the prevalence of BPH range from 10 to 30% for men in their early 70s, depending on how BPH is defined (Bosch et al 1995), although evidence from autopsies suggests that more than 90% of men older than 70 years have BPH (Sagalowski & Wilson 1998).

The range of treatments available for early-stage localised prostate cancer has grown significantly in recent years. Since approximately 80% of prostate cancers will grow slowly and may never cause harm if left untreated, watchful waiting (sometimes called active surveillance) is a legitimate option for many men to consider. Men who choose watchful waiting will be carefully monitored to check for any progression of the cancer, but will not receive active treatment until they and their clinician decide that it is warranted. The two other main treatment options, which are offered in most NHS hospitals in the UK, are radical prostatectomy and radiotherapy. There are two main types of radiotherapy – external beam radiotherapy and brachytherapy (seed implants).

For BPH too, there is a range of available treatment options. For men who are less bothered by the symptoms, watchful waiting is an option. For others, there is the option of medication (of which the main types are alpha blockers and reductase inhibitors), or several different types of surgical or device treatments.

Amongst these different treatment options for both prostate cancer and BPH, there is insufficient evidence to determine which is most suitable for which patient. There is, therefore, a high degree of 'professional equipoise', that is, where on clinical grounds a number of alternative treatments could equally well be advised (Elwyn et al 2000), making the involvement of patients in the decision extremely important. Each treatment has a range of different potential side effects to be considered carefully by the patient. The most common of these side effects include incontinence and impotence, which can have a significant impact on a man's life and identity.

## 2.3 Shared/informed decision-making

Whilst there is much discussion of shared decision-making, the concept is often rather poorly or loosely defined (Charles et al 1997). Despite this, it is increasingly advocated as an ideal model of treatment in the medical encounter. Charles et al (1997) make a distinction between three predominant models or approaches to decision-making: paternalistic, shared

and informed. They suggest four key characteristics of shared decision-making that make it different from the other two models:

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

In a later paper, the same authors revise their framework in order explicitly to identify different analytic steps in the treatment decision-making process, and decision-making approaches which lie between the three predominant models (Charles et al 1999). Their revised framework provides a dynamic view of treatment decision-making by recognising that the approach adopted at the outset of a medical encounter may change as the interaction evolves. Their paper highlights the complexity of decision-making approaches, and indicates that whilst several main types of approach can be identified, a rigid line cannot be drawn between them. Whilst differences between a paternalistic approach and a shared approach are perhaps more easily recognised, there are also differences between shared decision-making and informed decision-making. The informed decision-making model incorporates the idea of information-sharing (primarily from physician to patient), but does not necessarily lead to a sharing of the treatment decision-making process. Charles et al (1997) argue that "If the paternalistic model leaves the patient outside the decision-making process, the informed model leaves the physician outside by limiting the role of the physician to one of information transfer" (p 683). In practice, though, the terms 'shared' and 'informed' decision-making tend to be used interchangeably.

Each patient's preference regarding the degree to which he wants to be informed, and the degree to which he wants to be involved in making the decision, is an important consideration. Research has shown that while patients typically express high preferences for information about their illness and its treatment (Coulter & Magee 2003, Deber et al 1996), their preferences for participation in treatment decision-making are much more diversely distributed (Arora & McHorney 2000, Davison et al 1995, Ende et al 1989).

Rather than advocate a particular approach, Charles et al (1999) emphasise the importance of flexibility in the way physicians structure the decision-making process so that individual differences in patient preferences can be respected. The aim of a partnership approach to decision-making is that the decision reached is of 'good quality'. O'Connor et al (2003) suggest that making a good decision requires "a certain emotional readiness, information about options and uncertain outcomes, clarity about which trade-offs – among outcomes and over time – are acceptable, and a sense of confidence about the decision itself and its implementation" (p 570).

There is evidence to suggest that shared decision-making is not the norm within clinical practice. Doctors often fail to explore patients' values and preferences, tending to focus on the disease rather than the person (Corke et al 2005, Stevenson et al 2000). In Cohen and Britten's (2003) study in a British District General Hospital, qualitative interviews with men with localised prostate cancer suggest that existing practice is too paternalistic, with the interviews showing that respondents' treatment plans were mostly decided on their behalf by their clinicians. Although these men initially accepted this paternalistic approach, they often wanted to revisit the decision later. But the structure of patient follow-up did not afford the men an opportunity to discuss treatment decisions further (Cohen & Britten 2003).

Although physicians often describe the nature of decisions to their patients, they less often discuss risks and benefits and rarely assess patient understanding (Deyo 2001).

A recent report from the National Audit Office (2005) reported that prostate patients are almost twice as likely as other patients not to be informed about side-effects of their treatments, even though they can cause long-term problems including impotence and incontinence.

Making a good decision about treatment for conditions like prostate cancer or BPH is a complex and difficult task. The information provided needs to be of good quality, and risks need to be carefully explained (Coulter et al 1999, Godolphin 2003). Decision aids have been developed to assist doctor and patient in making good decisions together.

## 2.4 Decision Aids as tools in assisting shared decision-making

Patient decision aids have become increasingly popular, particularly in the USA and Canada. They can take many different forms, and vary considerably in levels of complexity and content. Deyo (2001) suggests that decision aids differ from other patient education materials in several ways: they make choices explicit, rather than imply a preferred choice; they use the best available evidence to quantify benefits and risks; most are interactive, allowing patients to obtain tailored information; and they often make use of media other than just print.

A Cochrane Review updated in 2003 identified over two hundred decision aids (O'Connor et al 2004), which can include conditions such as early stage breast cancer, knee osteoarthritis, hip osteoarthritis, uterine fibroids, abnormal uterine bleeding, low back pain, BPH, Prostate Cancer, and coronary heart disease.

Many decision aids have been evaluated for use in clinical practice. Evaluations have found that patients who participate in shared decision-making with the help of decision aids are more knowledgeable about treatment options and their benefits/risks, make decisions that are more consistent with their own attitudes toward these benefits/risks, have more informed discourse with their physicians, and choose options that are consistent with available scientific evidence (Barry et al 1997, Bekker et al 2003, see for example Billings 2004, Légaré et al 2002, Murray et al 2001, O'Connor et al 1999, Rostom et al 2002, Whelan et al 2004).

Despite this mounting evidence of the efficacy of decision aids, however, and their growing use in the USA and Canada, they have yet to be adopted routinely in the UK. This may be because, as O'Cathain and Thomas (2004) note, "the small amount of evidence available on decision aids in everyday practice shows that they face challenges in the real world". Billings (2004) suggests that further research into refining decision aids and promulgating their use is needed so that they may benefit more patients. Equally important is the monitoring and evaluation of implementation programmes to find out more about the challenges, and how they might be minimised.

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## 3 The Decision-making in Urology project: design and development

The project was hosted by the Action on Urology team (part of the NHS Modernisation Agency), working with colleagues in the Department of Health, the Foundation for Informed Medical Decision-Making in Boston, USA, the Cochrane Institute of Ottawa & Ottawa University, and the Picker Institute. The project took shape during 2004 and was implemented during 2005.

### 3.1 The Decision Aid Scheme

#### Aims and objectives

The decision aid programme is designed to provide patients with tailored, unbiased information about the benefits and possible risks of alternative treatments, and to engage patients in the decision-making process. It is designed to be an integral part of the clinical process of care, and to be incorporated into the treatment decision-making pathway.

The programme incorporates three elements:

- nurse training
- a video/DVD decision support aid
- a decision quality assessment form.

#### Nurse training

Nurse training was provided for members of each clinical team involved in implementing the programme. The training – entitled ‘Improving Skills in Supporting Patients’ Decisions in Urology’ – was delivered by Professor Annette O’Connor and Mary Jane Jacobsen, experts in the field of shared decision-making from the Ottawa Health Research Institute (OHRI), University of Ottawa. The objectives were to:

- Identify what makes decisions difficult for urology patients
- Understand concepts of decision support and decision quality
- Understand the role of patient decision aids
- Demonstrate skills in decision support using a clinical decision support protocol
- Develop self-appraisal skills in evaluating decision support provided to patients.

The training was delivered in two parts:

1. **Preparation for the skills-building workshop.** During the month before the workshop delegates were given access to a 3 hour internet-based auto-tutorial with quizzes and feedback to test their understanding of material plus a final quiz. During the auto-tutorial they learnt about a clinical protocol to structure their support (The Ottawa Guide:

Practitioner Worksheet). They were encouraged to try it out with someone they knew who was facing a tough decision (eg moving house, school or career planning, dealing with a health issue).

2. **Skills building workshop.** During this training day delegates had the opportunity to discuss the practical application of material learned in the auto-tutorial, including: using patient decision aids, role playing decision support using structured decision support protocols, and self-appraising their decision support skills.

### **Decision Support Aid (DSA)**

The videotapes and DVDs used in this project were produced by the Foundation for Informed Medical Decision-Making (FIMDM) in Boston, USA. The two programmes - one for early-stage localised prostate cancer treatment decisions, and one for BPH treatment decisions - are from a range of video-based tools developed by the Foundation to enhance patient involvement in decision-making. The video and DVD contain exactly the same content.

Each video lasts approximately 50 minutes. It includes information about:

- shared decision-making (what it is)
- the decision (why it is difficult)
- what you need to know about prostate cancer/BPH
- information on the treatment of prostate cancer/BPH
- making choices (table comparing treatments).

The Foundation states that its programmes:

- present the latest clinical evidence about the risks and benefits of treatment options in ways patients can understand
- explain why there is sometimes a lack of evidence to support one option over another
- include interviews with patients who have undergone treatments and experienced good and bad outcomes, illustrating the variety of patient perspectives and concerns
- focus on helping patients engage in high-quality decision-making with their doctors
- support patients in carrying out their choices with confidence and competence.

They state: "We offer a balanced presentation of each option, from both clinical and patient experience perspectives. Our goal is never to encourage any one treatment approach over the others, but rather to explain fairly and clearly the pros and cons of each option - and let patients, working with their doctors, decide which is best for them" (FIMDM 2002).

The FIMDM's videotapes go through a rigorous process of development, production, evaluation and revision. In addition, they are accompanied by a paper booklet that includes:

1. a verbal summary of the framing of the problem
2. all the statistical information that is presented in the tape
3. any other charts or graphs
4. and sometimes additional detail on general issues that are brought up in the programme.

The videos are reviewed every six months to ensure they are up to date and reflect current clinical practice. Updates may occur at any time if warranted by substantial advancements in

clinical knowledge. Every two years, the Foundation conducts an extensive review that involves outside clinical advisors, experts and patients. The Prostate Cancer video last had a major review eighteen months before this project started. The two-yearly review of the BPH video was completed shortly after the project began.

The video/DVD is a useful way of providing good audio-visual information in a way that does not increase demand on the clinicians' time. It is also in a format that can be watched as many times as the patient wishes, and with family or friends. The graphics enabled by the video/DVD format are designed to present statistics in a more understandable way. The video/DVD also incorporates interviews with patients who describe their own experiences. However, it is not suitable for those with severe hearing or visual impairments, or who cannot understand English.

The medium/format of the decision aid is an important consideration. Whilst DVDs are relatively cheap to reproduce (in large quantities), videos are more expensive. Whilst the Foundation for Informed Medical Decision Making takes on the responsibility for periodic updating of the content of their decision aids, any changes require production of new videos/DVDs. This requires a careful control of the product, to ensure that out-dated decision aids are replaced by updated ones.

### **Decision Quality Assessment (DQA) form**

One of the most interesting parts of the project is the DQA form, a new tool, which was designed for use in this programme, but which is guided by Sepucha et al's (2004) proposal for measuring decision quality. It is intended to form a part of the decision aid programme as a whole by:

- helping the clinician to gauge whether or not the information provided has been understood
- helping the patient to (re)consider some important aspects of this information, and some key values associated with the decision he must make
- helping the patient to communicate some of his values and preferences to the clinician.

The DQA is intended to help in the process of reaching a good quality decision by enabling a check to see whether the patient understands some key points, and by eliciting some of his values and preferences. It also gives the clinicians a new way of tracking values and decisions, so that these may be analysed in the future. This might enable them to make an assessment of decision quality amongst a population over a period of time, based on the patients' overall ability to answer questions correctly, and the overall concordance between their values and the treatment decisions made.

The DQA is made up of a small set of 'knowledge questions' (five for prostate cancer and four for BPH), followed by five 'values and preferences' questions or 'scaling tasks' (see appendices 1 and 2). The two DQAs were developed by the Decision-Making in Urology Steering Group, in collaboration with the FIMDM and the Picker Institute. Once an initial draft had been developed, Steering Group members (see below) were asked to comment and their suggestions were incorporated. A researcher at the Picker Institute then consulted four former prostate cancer patients for their views on the final draft.

There are concerns regarding the role and usefulness of such an instrument. Sepucha et al (2004) argue that, with responses to the knowledge and values/preferences questions, and documentation of the treatment chosen for a particular case, one can determine whether a man is well-informed about the key issues and can assess the level of value concordance within a population of men who receive their care from a particular provider or in a particular hospital. Ideally, the provider or hospital would be able to document that the men were well informed and those who, for instance, felt strongly about preserving their sexual functioning were less likely to undergo surgery for BPH, and those who were very bothered by their urinary symptoms were more likely to undergo surgery. These data, Sepucha et al suggest, would provide evidence that treatments were guided by patients' preferences, not by 'surgical signatures' or other unwarranted sources of variation.

In reality, it is very difficult to make sense of this kind of data. There are many potential factors that might be taken into account by a man in his decision-making process. Weighing up these factors is a complex process. For instance, a patient might report in the DQA that he is very bothered by his symptoms and that he does not feel strongly about preserving his sexual function (indicating that surgery might be a good option), but that he is particularly keen to avoid having surgery, for one reason or another. Such factors can be driven by a wide range of variables, for instance a self-employed patient might regard the recovery time from surgery as a strong negative, given the income he will lose during that time. Another patient, who has read stories about hospital-acquired infections like MRSA, might be scared away from any surgery (even though, in reality, the risk to him might be very small). Another patient, whose father perhaps died after having surgery, might have convinced himself that this was not an option for him. One problem with this DQA, then, is that it assumes that the decision-making process is entirely rational.

Sepucha et al (2004) contend that although an apparent mismatch between a well-informed patient's response to the values and the treatment chosen may not necessarily indicate poor quality choice, it would serve as a marker that further assessment may be needed. Moreover, they say, in the aggregate and controlling for other differences, the better the decisions, the more that the variance in the decisions can be explained by patients' reports of their preferences and concerns. "As a result, this measure of value concordance can be used to compare decision quality and patient-centredness of care across populations of patients, even if not for individuals" (p 58-59).

Charles et al (2004), however, further highlight the methodological complexities involved in measuring decision quality. Although the knowledge questions in the DQA act as a proxy measure for patients' understanding of the information they have been given, Charles et al point out that knowledge and understanding are different constructs. Careful attention should be paid to the underlying meaning of each. The measurement of knowledge might be undertaken fairly simply by asking if patients who are given some form of decision aid remember information contained in it, such as the percentage of patients who will survive beyond ten years if given a particular treatment. However, measurement of this type of knowledge acquisition gives us no indication of whether the patient understands how to use this information. For example, an understanding of probability statements would require both an understanding of their meaning at the aggregate level and their relevance to individual decision-making. These are issues of interpretation, rather than simply knowledge of facts. Interpretation of aggregate level probability statements can be

extremely complex. Further, it could be argued that knowledge questions test little more than recall or memory.

### 3.2 Implementing innovations in healthcare settings

The introduction of innovations such as our scheme into healthcare settings is widely recognised as a complex process (Fleuren et al 2004b). Previous experience of implementing changes can tell us a great deal about potential barriers and aids to the successful adoption and continuation of this project. Although there are regrettably few evaluative studies that report on the implementation process of innovations, several studies have identified a range of important factors to consider.

Fitzgerald, Ferlie and Hawkins (2003), for example, conducted a comparative case study to explore four innovations in different settings. Their findings underline the complex and interactive processes apparent in the diffusion and adoption of innovations. They found that implementation runs most smoothly if:

- there is robust scientific evidence to support the innovation
- *either* the innovation is applicable to many patients, *or* without the intervention, patients will suffer severely adverse outcomes
- there are neutral cost implications or savings
- the new intervention or treatment is not so complicated as to produce non-compliance in patients
- the new intervention raises patient satisfaction levels (Fitzgerald et al 2003:223).

Fleuren et al (2004a) conducted a literature review and Delphi study in order to obtain an overview of determinants of innovations in healthcare organisations. Their study identified fifty potentially relevant determinants of innovation processes, which they divided into four categories: characteristics of the environment, of the organisation, of the user (health professional), and of the innovation. Barriers can be both internal to the programme itself, and external, relating to the clinical environment and particular local circumstances or context. McCormack et al (2001), in examining the influence of 'context', that is "the environment or setting in which the proposed change is to be implemented" (p 96), comment that in health care, little research has been undertaken to explore the impact of the context of the practice environment on practice outcomes.

Dopson et al (1999) and Dunning et al (1999) evaluated the outcomes of implementation projects in 16 different clinical topics associated with a project on Promoting Action on Clinical Effectiveness based at the King's Fund, London. These studies highlight "the importance of understanding the local context for implementation, the identification of local clinical leaders, the need to understand 'culture' as a potential barrier to change and the adoption of a corporate approach to clinical effectiveness. Good team working was considered the critical element in the success of all 16 projects" (McCormack et al 2001:101).

Other studies have also highlighted the need for implementation strategies to be specific to local circumstances, taking into account any particular potential barriers (Eve et al 1997, eg Hodgkin et al 1996). These studies provide important pointers for this research and a

framework for data analysis. They also highlight the importance of evaluative research which monitors and critically examines both the process and the contexts of programme implementation.

In one of the few pragmatic trials of decision aids carried out so far, O’Cathain and Thomas (2004) identify various reasons for professionals (in this case midwives) not making use of the tools in practice, despite reporting that they approved of them. These reasons include: some midwives not agreeing with the content of the leaflets, some choices not being available locally, some midwives holding assumptions about women’s inability to participate in decision-making, some technological interventions such as ultrasound scans and foetal heart monitoring being considered so much a part of routine care that health professionals did not perceive a choice to be made on these issues.

In another pragmatic trial (Holmes-Rovner et al 2000), the pressure of work, and time as a scarce commodity for health professionals, was cited as a problem preventing the use of decision aids, and has been cited elsewhere as a barrier to the implementation of shared decision-making (O’Cathain et al 2004).

On the basis of the evidence we might anticipate a number of challenges for implementing decision support in urology. In particular, being a complex social intervention, this programme could be relatively difficult to implement, since a high degree of flexibility and sensitivity will be required on the part of those involved. It is unlikely that all patients will react in the same way to the information, or that all patients will be willing to accept the decision support aid. Healthcare professionals themselves may also respond differently to the innovation, which may affect the way it is implemented. On the other hand, decision-support is underpinned by robust scientific evidence and the innovation looked unlikely to be expensive to run.

### 3.3 The Evaluation

The Picker Institute monitored and evaluated the implementation of the innovation in four pilot sites.

#### Research Design

The intention of the evaluation was to describe and assess the progress of the intervention, and generate an understanding of how the intervention operates. This type of evaluation is more accurately described as project monitoring, but could also fall under the terms ‘formative’ or ‘developmental’ evaluation (Øvretveit 1998).

The research seeks to strengthen or improve the intervention by examining, amongst other things, the delivery of the programme, the nature of its implementation and the organisational context, personnel, structures and procedures. As a change-oriented evaluation approach, it is especially attuned to analysing strengths and weaknesses, to uncovering obstacles, barriers or unexpected opportunities, and to generating understandings about how the programme could be implemented better.

The decision aid programme is a complex social intervention. It is *complex* because it involves a number of interventions: nurse training, an intervention to inform patients, plus an intervention to influence the way the staff assess patients' knowledge and elicit their values and preferences during a consultation. The intervention is '*social*' since it is one which changes to adjust to changing conditions; it is 'evolving' rather than being 'implemented' in a linear fashion; and the organisations it is aimed at are social entities, constantly changing and involving sub-groups who interpret and respond to changes in different ways (Øvretveit 2004).

In such situations, it is neither easy, nor desirable, to use randomisation or control. The pilot sites cannot be compared with other sites, for instance, since each pilot site will implement the programme in a different way – in a way that fits with their local context – and in a way that might change regularly. The point of this research, however, is not to standardise the intervention but to describe it as it evolves.

The research aims, therefore, were to study the ways in which hospitals interpreted and carried through the decision aid programme, and to examine the views of both staff and patients on their experiences of participating in the programme.

The research objectives were to:

- help develop and then pilot the pathways and instruments to be used in the innovatory scheme
- assess the situation before implementation in each of the participating sites, examining particularly issues such as throughput, patient contact time, and patterns of decisions taken (via use of DQA and interviews with clinicians)
- monitor implementation: the administrative perspective; the professionals' perspective; and the patients' experience of participating in the scheme
- assess patients' perceptions of the value of the scheme in their decision-making process
- assess short-term outcomes, e.g. in terms of time, throughput, and change in practice or treatment options.

The research began in September 2004 and lasted for twelve months.

## **Methods**

An experienced researcher was allocated to the project full time for one year. During that time she accumulated a considerable amount of research data through:

- repeated visits to each site, where observations and detailed notes of discussions were made
- continuous e-mail communications with the project steering group, the management team, and the clinicians and administrators involved in implementing the programme
- detailed notes of project meetings
- qualitative interviews with staff involved in implementing the programme both at the start of the project, and six to eight months later
- in-depth interviews with a sample of patients who had used the innovative programme;
- collation and analysis of the completed DQAs.

All interviews were digitally recorded and transcribed with the participants' permission. All research material (except DQAs) was analysed through processes of thematic coding which was facilitated by the use of specialist software (NVIVO). The DQAs were analysed using SPSS (a statistical software package for social sciences).

### 3.4 Developing the scheme

All Action on Urology pilot sites (that is, departments of urology in England which had volunteered and been selected by the NHS Modernisation Agency's Action on Urology programme to pilot new approaches to delivery of care) were invited to participate in the Scheme. Five urology departments initially agreed to implement the prostate cancer and/or the BPH programme, but these were later reduced to four, due to the involvement of one of the sites in another prostate cancer research study. The four sites comprised two NHS Trusts in the east of the country (Essex Rivers/Colchester and Ipswich), one in the south-east (East Berkshire) and one in the north-west (Stockport). These were varied types of area, all with mixed economies and socio-economically diverse populations, two with significant rural or coastal hinterlands as well as urban centres, one with a sizeable migrant and mobile population, including a significant Asian community, and one a formerly-industrial urban area, but with a large affluent suburban commuter belt. Each site was asked to establish a project team to include, where possible, a patient representative, an urologist, a specialist nurse and project manager.

A national steering group was established to include urologists and specialist nurses from each site, as well as national and international leaders in the field, patient representatives, members of the Department of Health and the National Prostate Cancer Group, representatives from BAUS (British Association of Urological Surgeons) and BAUN (British Association of Urological Nurses) and the Prostate Cancer Charity. (See appendix 3 for steering group members).

The steering group played a key part in decisions about the content of the tools to be used in the innovation as well as in decisions about implementation. In particular it had a formative influence on the content and format of the DQA, and on the decision to include nurse-training as part of the scheme. In drafting the DQA, the 'framing' of the questions was felt to be extremely important. In particular, the nurses felt that the questions should be positively rather than negatively framed (eg by talking about living with cancer rather than dying from it). Another important consideration was to ensure that there was no real or perceived bias in the forms, for instance, by emphasising the possible side effects of one treatment more than those of another. A clinician's guide to each form was produced by the FIMDM (see appendix 4 for the clinician's guide to the BPH DQA), which detailed the correct answer to each knowledge question and the evidence behind it.

The steering group also considered key practical issues related to the project plan. These included:

1. **DVDs and videos.** It was decided that both DVDs and videos should be made available, and that each site should try to provide a space for viewing the decision aid, for those patients who do not have the appropriate equipment at home. It was decided that showing the video to groups of patients at a time was not ideal since strong personalities might influence the decision-making process for others in the group.

2. **National versus local data.** It was felt by some members of the steering group that the broad national picture presented in the video was not specific enough to each local site. The group agreed that local outcome data could continue to be given to the patient as a supplement to the video. It was reiterated that the decision aid would be complementary to existing practice, rather than a replacement of it.
3. **Staff workload pressures.** The group was concerned about the demand of the project on specialist nurses' time, which is already hard-pressed, and approved Action on Urology's provision of £7,000 per site to help cover administrative and other expenses.
4. **The lack of equivalent tools** for patients who cannot read or speak English, or who are visually or aurally impaired. The steering group agreed that while funds did not allow for the development of such tools in this programme, it was an important consideration and the project should help to gauge potential need in this area.
5. **National target waiting times for cancer treatment** (see section 4.1). The group sought advice from the Department of Health's Cancer Policy Team about the potential impact of the programme on the allowed time between referral/diagnosis and treatment for cancer. The Cancer Team advised that the programme would not be expected to require adjustment to the allowed time unless the patient specifically requested "some time to consider a diagnosis or proposed care plan away from the Trust and/or with relatives".

### 3.5 Conclusions

This pilot scheme is a decision-support project whose implementation was monitored and assessed in order to learn any necessary lessons before progressing to national implementation. The programme incorporates nurse training, a decision-support aid for patients and a decision-quality assessment form, whose operation is of particular interest as this is a new feature of a shared decision-making scheme. A key part in formulating the programme's implementation plan was played by a national steering group and by the four urology departments in England recruited to pilot the scheme. The main questions for the investigation are whether such a programme can be implemented with ease in varying urology care pathways; whether patients understand and find it useful; whether staff find it useful; and in particular whether the decision-quality assessment form works according to plan.

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## 4 Implementing the scheme: views and practices of professionals

### 4.1 Introduction: the national context

The project was put into place within a national (and international) context of rapid scientific, social and technological change. For both prostate cancer and BPH, new treatments are rapidly evolving and developing. Some departments in England offer wider ranges of innovative treatment than others. Whilst a patient is theoretically offered the choice of travelling elsewhere for a treatment not offered by his local hospital, the distance and inconvenience of travel will inevitably be a factor in his decision. Some newer treatments, like 'high intensity focused ultrasound' (HIFU), may only be available to a few patients within a local area. The variety of, and differential access to, treatment options makes the development and use of a general treatment decision aid difficult. The decision aids used in this intervention only covered the main treatments, rather than the wider range of additional options.

The existence of targets, particularly for waiting times, affects patient management. The NHS Cancer Plan stated that by 2005, for all cancers, there would be a maximum one-month wait from diagnosis to initiation of treatment and a maximum two-month wait from urgent GP referral to initiation of treatment (Department of Health 2000). While there is increasing pressure to speed up the pathway, shared decision-making can slow the process down. Patients will need time to absorb and understand information; to discuss the options with others; to deliberate; and finally to arrive at a treatment decision. It is recognised that with early stage localised prostate cancer, most patients have plenty of time to make a decision since these cancers are usually very slow growing. However, many clinicians and managers in this project were concerned about the programme's potentially negative effect on waiting times.

Whilst BPH treatment does not fall under the Cancer Plan's targets, the political drive for efficiency has led to a trend in the development of one-stop clinics, where specialist nurses and/or consultants can carry out numerous tests, reach a diagnosis, give information and support, and either treat or refer as appropriate, all in one appointment. Such a system might not allow sufficient time for the patient to consider different treatment options and reach an informed or shared decision.

The bewildering amount and variety of information now accessible to patients might influence the amount of time taken for a patient to decide on his treatment. Telephone information and support is available from, for instance, the Prostate Cancer Charity. There is an abundance of internet sites featuring information about prostate cancer and BPH; and hospitals increasingly have well-stocked and well-staffed information centres. Not all of this information is of good quality, and the patient has to be increasingly discerning. This abundance of information, and the variation in its quality, is an important feature of the context within which this programme was implemented.

These broader issues alerted us to some additional questions for the investigation: the impact of the scheme on waiting times, possible confusion over available treatment options, and potential information overload.

## 4.2 Implementing the scheme

All four sites involved in this project have well developed services for supporting patients diagnosed with prostate cancer/BPH. All the sites have at least one nurse specialist skilled in providing information and support to urology patients. One of the sites – Essex Rivers/Colchester – implemented both the prostate cancer and the BPH decision aids. Stockport and Ipswich implemented the prostate cancer decision aid, and East Berkshire focused on BPH.

When thinking about barriers to implementation, it is important to consider why three out of four sites in this pilot chose not to implement the programme in both prostate cancer and BPH pathways (since they were all offered this opportunity). Colchester is the only site to use both decision-making programmes. In East Berkshire, the urologists chose not to use the prostate cancer programme because they said they felt it was overly biased against surgery. They felt that local results were considerably better for prostate surgery than those detailed in the video. This is due principally to growing expertise in new techniques such as laparoscopic and, more recently, robotic surgery. This highlights the importance of generating a consensus on the information contained in the DSA and DQA. Ipswich and Stockport chose not to implement the BPH programme since they said pathways are more complex for this condition than for early stage prostate cancer. Ipswich also noted that the number of BPH patients is much higher than that of prostate cancer patients, so the administrative burden would be greater.

Implementation start dates were affected by: the timing of research ethics and local management approval; the need to resolve any clinician or nurse reservations or queries; the date of arrival of the videos and DVDs; and some local staff changes. Overall the project experienced some delay, but in all sites the scheme went into action either very late in 2004 or early in 2005. This section describes what happened in each site (diagrams showing how the scheme was incorporated into the pathways are given in appendix 5).

### Pathways before implementation

The healthcare pathway by which a patient is assessed, diagnosed, informed, supported and helped in reaching his treatment decision, varied somewhat between sites and according to whether the diagnosis was cancer or BPH.

#### a) BPH

In Colchester men first attend one of a number of community-based primary care prostate clinics (PCPCs), where a specialist nurse (who is employed by the PCT but clinically managed by the consultant urologist) conducts a series of tests and gives the patient information about his symptoms and possible causes. The consultant then reviews the cases and triages the patients *either* back into primary care (for management of mild symptoms), *or* to an outpatient clinic, which may be either a routine clinic where the results of further tests are

considered in the management of more moderate or severe symptoms, or an urgent outpatient department if prostate cancer is suspected.

In East Berkshire GPs refer their patients to a consultant urologist, who sometimes sees the patient himself, but typically streams him into one of a series of assessment clinics for LUTS (lower urinary tract symptoms) run by a specialist nurse. These clinics are run in outpatients, in two different locations, with the nurse seeing approximately four new patients and two follow-up patients in each clinic. In a single clinic appointment, a new patient undergoes a series of diagnostic tests. The nurse then gives the patient verbal information about his condition, and suggests a treatment, based on his symptoms and the degree to which they bother him. If she thinks the patient may benefit from medication, he is given a prescription at the end of the clinic appointment. The clinic is busy, and a new patient spends on average approximately 25-30 minutes with the nurse (for both discussion and tests).

#### **b) Prostate cancer**

The pathways for prostate cancer patients also vary by site, and are more complex than those for BPH. In Colchester one clinical nurse specialist (CNS) is responsible for providing information and support to prostate (and other) cancer patients. The nurse works alongside the consultant urologists in their clinics, and is usually present when the patient is given his diagnosis. After talking with the urologist the patient then has the option of talking with the specialist nurse. The amount of time spent with the nurse, and the amount of information he is given at this point, depends upon the patient and his emotional state. The nurse offers him support and provides him with the site's own local information folder, which is customised for each patient. The specialist nurse arranges to call the patient approximately one week (sometimes less) after the diagnosis, using this call to answer any of the patient's questions, and to offer him emotional support. Usually, the patient will make his decision and see the consultant when he is ready to confirm this decision. All patients are, however, offered the opportunity of being seen either in the out-patients department or on a home visit by the CNS, for further discussion and support in reaching a decision. The pathway is flexible (within reason) on numbers of visits and time spent with the patient. The urologist describes it as 'patient-led'. The nurse is able to support a large number of patients on her own by relying on telephone consultations. She emphasises her role in giving the patients emotional support and in being positive about the patient's outcome. She recognises that some patients may block information as a way of coping with their diagnosis, and says she feels she must respect that and not give them information they do not want.

The pathway in Ipswich was unusual in that it was undergoing a significant change at the same time as the programme was being introduced. The key aspect of this change was that the two specialist nurses and the Macmillan Information and Support Radiographer (MISR) were taking over the role of informing patients with early stage localised prostate cancer of the diagnosis. This was only to happen where the patient had already been discussed at the weekly multi-disciplinary team (MDT) meeting. Where a patient had not already been discussed in an MDT meeting, he would be informed of his diagnosis by the consultant urologist. The nurses say that the change in pathway is an improvement because they perceive themselves as more capable of giving balanced information on treatment options than a surgeon or oncologist. The new system also gives them more independence, and means that they can gauge more carefully when to give information, and how much to give, and allows them more time to support the patient.

Stockport includes hospitals in two locations<sup>1</sup>. Across both hospitals, the staff estimate that they have about six patients per month with early stage, localised prostate cancer. The pathway here is structured around a long-standing trial which encourages men diagnosed with early stage prostate cancer to discuss their condition and treatment with an urologist, an oncologist, and a specialist nurse (who is deemed to be independent from the urologist and oncologist) before deciding which treatment they would like. The patient is given his diagnosis by the urologist, who talks through the surgical option, and briefly introduces the other treatment options. The urologist usually gives the patient a booklet to take away, as well as the contact details of the specialist nurses. If the nurse is present at this time, she either spends time with the patient then, or arranges for him to come back. The nurse spends approximately an hour with the patient and goes through all the options in more detail. At the same visit the patient also goes to see the oncologist (either before or after seeing the nurse), where he is given more information about radiotherapy options. After going away to reflect on all the options, the patient telephones the nurse when he is ready to inform her of his decision. If the patient does not call the nurse, she will call him. Rarely, if a patient is having particular difficulty making a decision, he may come back for a second discussion with the nurse.

### **Pathways after implementation**

Because pathways vary, each site was left free to decide how and when to introduce the DSA and DQA. In the period prior to their introduction staff had had a number of concerns: whether patients should be asked to return to complete the DQA with the nurse after they had seen the video/DVD (that is, adding an extra step to the existing pathway); whether the DSA and DQA could be handed out after a treatment option had already been agreed/offered; whether the DSA and DQA should be handed out together; and whether the DSA and DQA could be given to all patients at the same point in the pathway rather than timed to fit in with patient-readiness. Although these are closely related issues, we discuss each in turn, showing how the sites dealt with them, and suggesting reasons why they varied.

#### **a) Adding an extra step to the pathway or not**

The biggest issue was whether or not to bring patients back in for a further appointment, after they had had an opportunity to watch the video, in order to complete the DQA and talk about their decision. In East Berkshire's BPH pathway the clinicians eventually decided not to bring the patient back. Their reasons were, first, the nurse's workload (it would add another four patients to each clinic), and secondly, anxiety about whether introducing a second appointment would mean a treatment could not be decided on at the first visit (see below). The chosen solution was to hand out the DSA and DQA at the single visit, and to get the patient to post them back using a pre-paid envelope.

In Colchester's existing BPH pathway patients routinely have two appointments, which one would think might make it easier for the decision support tools to be incorporated. Unfortunately the nurse could not hand out the DSA and DQA at the first of these appointments since all cases seen at the primary care clinic are then reviewed for further action by the consultant urologist. Only patients selected by the urologist for an

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<sup>1</sup> The oncologists and radiographers are based in a separate site and were not involved in this project.

outpatients' appointment to discuss possible treatment for their LUTS were considered eligible for the decision-support programme. What the nurse decided to do therefore was to telephone or write to all eligible patients (once the urologist had made the decision), inviting participation, and then send the DSA to those who agreed. The nurse then attended the outpatients clinic, and at that appointment, before patients saw the urologist, she asked them to complete the DQA. She sat with them, and answered any questions as they went through the form, which seemed to work well. This was the only site in which an extra step was added to the nurse's schedule, though it did not add any more steps to the patient's pathway. The reason why it happened here and nowhere else could be that the nurse's workload was less high than in other places or because it did not add to the patient's pathway, only the nurse's schedule.

In Colchester's prostate cancer pathway the nurse decided that it would be impossible - because of her heavy workload - to bring patients back a second time to go through the DQA with her after they had had a chance to watch the video/DVD. Despite her reservations, therefore, she incorporated the DQA into the pathway by asking patients to complete it on their own at home and to return it to her, along with the DVD/video, by post. In practice, this seemed to work well.

*"It's not been a problem usually, giving the patient the DSA and DQA at that initial meeting where they are given the diagnosis. The patient consents there and then ....."*  
*(clinical nurse specialist).*

In Stockport's prostate cancer pathway the nurses also initially felt that they would need to go through the DQA with patients because they saw the questions as difficult and possibly upsetting. Since they usually only saw the patient on one occasion, before he had made a decision (and they were happy to hand out the DSA then), again there was no obvious place for the DQA to be introduced into the pathway. Like other sites, they considered either introducing another step whereby the patient was invited back to complete the DQA, or going through the DQA with patients over the phone. But when they found that patients appeared happy to complete the DQA on their own at home their procedure was to ring the patient to see if he had made his decision and then send the DQA, asking him to return it by post.

In Ipswich, patients who were given their cancer diagnosis by the CNS/MISR were offered the decision support programme. The pathway includes two appointments with the CNSs/MISR. The first occurs in an outpatient clinic after diagnostic tests have been conducted, and the patient has been discussed at an MDT meeting. In this appointment, the nurses inform the patient of his diagnosis and give him any support he needs on hearing the news. At this meeting the patient was given the DSA. He then goes home to review the information and consider his decision. He can opt to see a consultant if he wishes. He is then asked to return at a date and time that suits him. The second appointment is more focused on information and decision support. The nurses answer any questions and discuss any misunderstandings or misconceptions the patient may have. The DQA was handed out at the end of the visit, with the patient asked to return it by post.

#### **b) Offering the aids after treatment had been agreed**

The only site where this was an issue was in the BPH pathway in East Berkshire, which was the only one where patients were seen in one single appointment and often given a treatment – such as medication or active surveillance – there and then. Despite the fact that it might seem odd to give the DSA and DQA to patients whose decision had already been taken it was eventually decided to do so because the nurse's busy workload made any other solution impractical. The staff justified the solution by saying that they could go on giving out the tablets, etc., and if the patient did not want to take them in light of watching the video, he need not.

#### **c) Offering the DSA and DQA together or on separate occasions**

There was considerable variation between the sites on this matter, and there are no obvious explanations. For example, one BPH site handed them out together, one sent the DSA and then gave out the DQA at a subsequent appointment. One cancer site gave them together and two offered them on separate occasions. The variation might be to do with whether the DQA was seen as an instrument which could only be completed when the patient's decision had been made or whether it was viewed as an aid to decision-making. For example in Ipswich at the patient's second visit (the DSA having been given at the first) the clinical nurse specialist and MISR discussed the patient's preferences and values and asked him which treatment he was leaning towards. If ready, the patient informed the nurses of his decision. The patient was then asked if he would take part in a research study by taking a DQA form home, completing it, and sending it back to the research office by post. In some of the other sites it was not seen as necessary for the DQA to wait until the later part of the patient pathway.

#### **d) Offering the DSA and DQA at the same point to all eligible patients**

In all three cancer pathways the nurses were particularly concerned about overloading the patient with information that he does not need or giving it before he is emotionally ready to absorb it. For example, in order to avoid information overload, in Ipswich the nurses only gave the DSA/DQA to patients who were eligible for all three main treatment options. They also talked about the importance of timing, gearing their information-giving very much around a particular patient and how much he can cope with, and when. They highlighted the differences between one patient and the next, and kept stressing that it "depends on the patient". In Colchester the nurse emphasised the importance of being flexible and gauging when each patient is emotionally able to cope with more information. Depending on her judgement, she offered some patients the video and the DQA at the first diagnosis meeting, and others during her later phone call with them (after which she offered to send the video and DQA).

#### **e) Patients selected to receive the DSA**

A key issue that provoked a great deal of discussion in each site was the question of which patients to include in this programme. Each site felt differently about this. Ipswich, for instance, felt that they should only offer the DSA/DQA to their prostate cancer patients who were eligible for all three main treatment options (not, for instance, those patients who for reasons of co-morbidity or age were not suitable candidates for surgery). Colchester, on the other hand, offered the DSA/DQA to early-stage localised prostate cancer patients who might not be suitable candidates for one or more of the options, but mentioned this to the patients at the time (that is, advised them that there was a section on surgery, for instance, but that this would not be relevant to them). This was also an issue for BPH patients, and

there was considerable discussion about whether the programme should be given just to those patients with symptoms severe enough to be considering surgery, or to all patients. The nurse and urologist in East Berkshire felt that the programme was of use to all patients, although the nurse said she used her discretion in deciding to whom she should give it. For example, a judgement was made as to whether or not the DSA and DQA were likely to be comprehensible and useful. For instance, those patients whose English was not considered to be good enough, or who were deemed unable to handle the information, were not offered the video or DQA. There is a large Indian population in the East Berkshire area and patients often bring relatives to translate for them. These patients are, at the moment, not getting an opportunity to see the video. In Colchester, the BPH programme was given only to those patients whose condition was seen as sufficiently serious as to warrant an outpatient clinic appointment following their being seen in the PCPC.

#### **f) Offering the Video/DVD Decision Support Aid (DSA) and Decision Quality Assessment (DQA) Form**

The DSA was found to be relatively easy to introduce as long as the patient has either a DVD or video player at home. The clinicians only met a very few patients without a DVD or video player. For these patients, the staff said they could provide a space to watch the DSA at the clinic. But in practice the length of the DSA, and the inconvenience for the patient in having to return another time, meant that this offer was never taken up.

Once the clinicians had decided at what point to offer it (see above), the implementation of the paper-based DQA used in this pilot was found to be straightforward. The DQAs require no additional technology, and little cost (the only costs are for photocopying and, where required, postage). As described above, the clinicians found patients in this pilot on the whole happy and able to complete it on their own at home, and to send it back.

#### **g) Time spent in consultation with patients**

The nurses did not consider the implementation of the decision support programme to have shortened the time they spent in consultation with the patient. Most said they needed to spend a small amount of extra time explaining the project and gaining the patient's consent (this was related to the research element of the programme), but that this was not problematic. However, it was suggested in some sites that consultant urologists were able to have shorter consultations with patients who had seen the video/DVD. This was only the case with urologists who knew about, and were supportive of, the decision-making programme. The BPH nurse in Colchester commented that those urologists who were not familiar with the programme were complaining that patients who had watched the video/DVD were asking more questions, and therefore were taking longer appointments.

One nurse specialist (in East Berkshire) said that although she did not spend less time with her patients as a result of having the DSA, she felt she was more confident that the patient would be getting comprehensive general information. She was able to focus her discussion on more personalised information, rather than spending a lot of time explaining the different treatment options.

#### **Administration of the programme**

The central programme manager at the Modernisation Agency carried much of the administrative burden of programme development and implementation. She was responsible for getting the videos/DVDs made, collecting and sending out all the 'products'

associated with the programme and its evaluation, such as booklets, patient information leaflets, consent forms, clinician's guides, and so on, and administering the finances.

The local sites also had to carry out administrative tasks. Some of these were specific to the pilot phase and would not be incurred in routine implementation, including: receiving and sending DQAs to the research team; writing to patients' GPs to inform them of the programme; recording the involvement of patients in their files so that follow up interviews could be arranged; dealing with the research-related paperwork necessary to comply with ethical requirements (consent forms, information sheets, letters to patients, and so on).

Other administrative tasks are likely to be permanent:

- localising documents by inserting hospital name and address and printing out on hospital headed paper
- photocopying a number of documents
- receiving and storing the videos/DVDs
- logging videos out to patients and back in. The FIMDM are keen not to have the decision aids in general circulation, in case they are viewed by a patient for whom they are not appropriate, or in case they remain in circulation after they have gone out of date. It also makes sense from a financial point of view to try to ensure the return of the decision aids. However, tracking the videos/DVDs requires some administrative time.

In all sites, these tasks fell primarily to the specialist nurses. Some nurses were able to draw informally on secretarial support within their department - for instance, for photocopying or printing. The nurses in Ipswich considered themselves extremely fortunate to have a research co-ordinator who took on all administrative duties associated with the project. They felt that without him carrying out that role:

*“it could have been an absolute nightmare. In fact, I don't think we would have been able to do it, to be honest with you”.*

Action on Urology gave £7,000 to each site to be spent as they saw fit. This was used to pay for administrative assistance in one of the sites where the nurse was under particular pressure as she was implementing the programme single-handed. Nurses in others sites commented that the paper work was too disjointed to make it easy to buy in specific secretarial support. For example, in Colchester the nurse for the BPH pathway described the administrative tasks (eg photocopying, composing and sending letters, posting out videos and DVDs) as quite a lot of work, but 'bitty' and not adding up to too much when the patient numbers were quite small.

Again in East Berkshire's BPH programme and Stockport's prostate cancer programme the consultants had little to do with the implementation of the programme. The nurses saw themselves as able to cope with the administrative burden, and in East Berkshire were able to ask secretaries to help with photocopying and printing. The biggest task was ordering and organising postage-paid packs to send out to patients. Other issues, like carrying around the videos and associated paper work to the clinics, were inconveniences, but not considerable hindrances to implementation.

### 4.3 Professionals' views about the scheme

*"It's made me think more about how do we test someone's knowledge of how informed they are about their decision, and also about what's important to them. That's what I like about it" (cancer specialist nurse).*

All four sites were visited several times before and during programme implementation. Initial interviews were conducted with (primarily nursing) staff from each site. The interviews and visits sought to establish a picture of the context at each site, and gather information on the ways in which each site implemented the programme. The interviews explored:

- roles of different members of staff in informing and supporting urology patients;
- details of the patient pathway from diagnosis to treatment
- the kinds of information patients currently receive about treatment options, prognoses and the implications of different treatments
- amount of time spent by staff on informing and supporting patients about treatment options
- practitioners' views on the information and support currently offered
- ways in which information and support is currently delivered
- other sources of information and support for patients
- ways in which patients differ in their decision-making behaviour.

When each site had been using the programme for between two and four months, those staff most involved in the implementation (mainly nurses) were interviewed again. In addition, an interview was conducted with the temporary programme manager with Action On Urology, and the acting programme manager. In total, sixteen qualitative interviews were conducted with members of staff, and a considerable amount of additional data was collated through email, telephone discussions and site visits. We discuss first their views about the three elements of the programme and then summarise their overall views.

#### **Nurse Training**

The nurse training was advocated by the Steering Group and seen by all key participants as an essential preliminary part of the programme, designed to train the nurses in how to support and work with the patients to reach treatment decisions. Staff availability and budget constraints only allowed one face-to-face training day. Inevitably its timing and location were not likely to be suitable for all, and as it was delivered as one single training day, during the early stages of the programme's development, its impact was reduced. For instance, some of the nurses who attended were much less familiar with the proposed scheme than others; some who went to the training day moved jobs before the scheme was implemented; and several of the nurses who were subsequently responsible for implementing the programme were not able to attend. In addition, delays in start-up led to several months between training and implementation, causing key messages of the training to be diluted.

The training was only intended for nurses (though one urologist attended), and it is interesting to speculate about the training needs of other clinicians.

## Views about the DSA

The staff involved in the scheme perceived the video as a useful addition to their repertoire of resources for patients. When asked about the benefits of the programme as a whole, most staff replied that the patients benefit from the video, since it goes through the information in more detail, and in a different format. They also felt being able to give the video was an advantage to them as healthcare professionals, knowing that the information would be covered in considerable detail. One nurse, who gave the video to BPH patients, said:

*“It makes me feel better, doing my clinic, knowing that you’re giving them a lot of information in a short period of time, I feel better that I can actually give them a video which covers the whole lot. It makes me feel like I’m not missing out, they’re not missing out on anything from a rushed consultation.”*

The urologist in one area also suggested that he benefits from the knowledge that the patient has received a considerable amount of in-depth information about his condition and the treatment options, and that this can lead to a more informed discussion between doctor and patient.

Most saw the video simply as patient information. Few talked about its more complex potential role as a patient decision aid. One exception was a specialist nurse, who felt that the video *might* help the patients to think a bit more about the choices they make. Whilst she considered that patients are likely to do this anyway, she felt that the video made it clearer for them, and perhaps acted as a balance against the information or advice from other sources, such as their friends or family:

*“maybe it makes them think a bit more about why they choose what they choose. They’re having to think about what is important to them”*

Some nurses felt the DSA was too long and complex, particularly for less literate or articulate patients. In addition, some nurses expressed a reluctance to give a lot of information to patients they thought were not ready to cope with it.

The staff in Ipswich value their locally produced information and talked about the importance of being able to individualise it for each patient, discussing the balance between volume of information and specificity. For instance, they criticised some of the nationally-produced booklets for having too much general information. They had the same concern about the video:

*“My only concerns about this video is it’s a bit like the CancerBACUP book. It’s got everything on it, and he might not be eligible for everything”.*

Having said that, the team were keen on having a video, since they had identified a need for good quality audio-visual information, and had already thought about procuring or producing one of their own. The nurses described, however, how some patients had declined the offer of a video since they either felt they already had enough information, or the format of a video did not particularly appeal.

A further issue that was carefully considered by the project sites was the degree to which the decision aid complements or even, perhaps, contradicts locally produced information. For instance, whilst the video might describe radiotherapy lasting a course of eight weeks, a local site might only run courses up to six weeks. This issue was raised as a concern by one of the sites early on in the project's development. Several staff also felt that the video was already out of date, since it does not mention newer treatment options such as HIFU or cryotherapy.

The view was also expressed that the DSA needs customising. For example, in Ipswich the nurses said that although they liked being able to offer the video, they would prefer it to be split up into short, fifteen minute slots, either indexed or as separate videos, so that they can be customised for the patient. Nurses in other sites also mentioned the importance of tailoring information for the individual patient.

It is perhaps not surprising that overall strong support – albeit with some criticisms – was expressed for the DSA, since the professionals we interviewed had all agreed to participate in the scheme.

### **Views about the DQA**

Whilst self-completion of the DQA at home provides the most practical solution to implementing this element of the programme, it might not be the best in terms of ensuring the quality of the patient's decision. The DQA was rarely, if at all, used as a tool to check that the patient had understood the information and had thought about his values and preferences in relation to his treatment decision. This was partly due to lack of time, and partly because the healthcare professionals did not, on the whole – at least at first, appreciate the potential value of the DQA in this regard. The form suffered from being seen as a research questionnaire, rather than as a clinician's tool. Clearer guidance as to how it might be used would probably have helped both patients and clinicians.

There was some variation between sites. For example in Colchester, the nurse and urologist did not look at the completed forms for the first few patients with a cancer diagnosis. However, they later started to examine the forms as they were returned, to check that patients had been able to answer the knowledge questions correctly. The nurse felt that this was a useful thing to do, and that it had started to change her mindset:

*“It does make you more aware of whether the patient's got a good understanding of what their treatment options are, and the side effects of those options”.*

She said that if she felt a patient had not understood the information, she was able to call him and discuss the issues further. However, in Ipswich the nurses did not see the completed DQAs unless their local research officer specifically showed them. The nurses said they found some of the completed forms interesting, but would not contact the patient to discuss them. And when the patient saw the consultant to agree and act on the treatment decision the DQA was not used in this consultation.

Despite some appreciation of its value there was much criticism of the DQA and a feeling that it needed revising and making more patient-friendly. Criticisms were to do with feelings that the questions were biased, that they might upset patients, or that the form was badly worded and difficult for people to understand.

For example, several of the urologists and oncologists were concerned that the questions in the prostate cancer DQA painted either surgery or radiotherapy in a poor light and were worried that the tool might put patients off having surgery or radiotherapy. They were keen to remove questions that highlighted the potential shortcomings of their particular treatment. The nurses, though, were generally concerned about patient reactions to the DQA, particularly about upsetting the patients, or 'opening a can of worms' - that is, prompting a patient to think further about a decision he has already made if it seems from the professional's point of view to be based on misconceptions or misunderstandings. For some nurses there was an important issue of the degree to which they should challenge a patient's decision, if it could be perceived to be of 'poor quality'. In Ipswich, for instance, although the nurses recognise the importance of values clarification, and checking the understanding of patients, one nurse commented that there is a dilemma about how much information should be given, and to what extent misconceptions should be challenged:

*"because, at the end of the day, any decision is a good decision".*

This concern might be interpreted as a somewhat paternalistic approach towards the patients. A nurse in Colchester (who left her post before the implementation began) expressed a great deal of reluctance in giving the form to what she called 'her boys' in case they might be worried by it, and was keen to defend the way she currently practised. A cancer specialist nurse commented that "All of the nurses, the initial fear when we read the DQA was:

*"Oh my god, have we got to give this to patients?"*

After beginning to use the DQA however, they were generally reassured, though some remained unconvinced about the DQA's ability either to help ensure a good quality decision, or to audit decision quality, with some nurses asserting that the knowledge questions are not the kind of questions men ask.

The cancer diagnosis was more likely to prompt feelings of concern and criticism of the DQA than BPH. The nurses' strong empathy with the patients deliberating complex options at such a difficult time is clearly important, but it could be translated into a caring collusion between the patients and professionals in which there is a spoken or unspoken agreement not to confront the more negative aspects of the diagnosis or treatment. This caring collusion might not always fit comfortably with the promotion and support of truly informed decision-making.

### **Views about the programme as a whole**

Overall, most of the healthcare professionals found participation in the programme a positive experience, with no negative consequences, such as exacerbation of their workloads or heightened patient anxiety. Despite some considerable concern and even scepticism at the early stages, most gave very favourable verdicts later on.

One of the nurses said that the programme, and particularly the training, had been useful:

*“I think we’re less focused on the information, and more focused on the support, now”*

The perceived added value of the programme was an important factor in getting the support of clinicians. Staff in local sites, however, often identified one particular aspect of the programme that they felt was most useful. For instance, one site was particularly pleased to be able to hand out the leaflet that goes with the video, since it is much more comprehensive than anything they had previously. Two sites commented that they had already identified a need for information on video, so were attracted to that aspect of this intervention. The nurses in Ipswich found the nurse training very helpful in helping them to re-think their clinics. They said that the tools produced by the Ottawa Health Research Institute helped them to structure their clinic appointments and to think more about the decision support they give, rather than simply the information. However, whilst they went through the process of ensuring understanding and assessing values and preferences with their patients, they did not find the DQA a helpful tool in this. Where there is enthusiasm for just one aspect of the programme, the impact of the intervention as a whole on developing shared decision-making might be reduced.

#### 4.4 Conclusions

We expected the introduction of a decision-support programme to be challenging, given its complexity as well as the complexity of organisational structures and clinical pathways. In the event, despite varying – and quite complex – pathways, the programme was implemented with minimal disruption in all pilot sites and with limited impact on staff time or waiting time. In fact it appeared to lead to very little change in pathways, the videos and DQAs being incorporated mainly by post. This suggests that the sites had a limited ability to be flexible; rather that they found a fairly straightforward way – that of using the postal system – of circumventing a need for flexibility.

The programme was implemented mainly by the specialist nurses, sometimes working single-handed. Team-working therefore was not always an issue at the practical implementation stage, though undoubtedly it had been crucial at the level of site approval and endorsement.

From what the nurses told us, there was clearly some capacity for flexibility over who was offered the decision-support, but we were unable to collect evidence about those patients who were not offered the DSA and DQA (or those who refused it). Patient-readiness, particularly in the case of cancer patients, is an important consideration, and staff feel the need to retain discretion over who should be offered or not offered the support aids.

Whilst the DSA was clearly offered as an additional and welcome decision-aid, there was little evidence from the provider side that the programme enhanced the decision-making process; that is, there was only limited reporting of staff having further discussions with patients about their queries resulting from watching the video/DVD, and very little incorporation of DQA answers into the decision-consultation. However, most pilot sites already had relatively sophisticated in-house processes. The DSA was certainly praised and seen as helpful, but the DQA was only occasionally reported as being helpful to staff or to patients, and was not really used in the way its designers had expected.

While the nurse-training was appreciated and praised, this part of the programme was not systematically evaluated. It was a modest exercise, did not involve all implementation-staff, and did not focus extensively on incorporating the DSA and DQA into local decision-making pathways and using them to full advantage.

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## 5 Participating in the scheme: patients' views and outcomes

### 5.1 Introduction

In this section we turn from the professionals to the patient-participants. The first sections focus on men's own subjective perspectives and perceptions of the programme and of their decision-process. Section 5.4 reports on the question of whether or not we can tell if the scheme made an objective difference to patients' knowledge, value concordance and choices.

The findings presented here are taken both from patients' answers to questions in the DQA and from a series of in-depth one-to-one interviews. Sixty-six BPH patients and 20 prostate cancer patients both took home the video/DVD and completed the DQA. The 66 BPH patients ranged in age from 44 to 84 years, with a mean age of 65.5. Of the 15 prostate cancer patients whose age was reported on their DQAs, the minimum age was 55 years, the maximum 72, and the mean was 63.7 years.

In-depth interviews were conducted with a sub-sample of these patients. Whilst the initial aim was to interview six patients from each site/pathway, the delayed start-up of the project, and the refusal of some patients either to take the decision support aid, or to partake in an interview, meant that this target was not quite reached. However, the researchers considered that in the interviews conducted all key themes were identified (ie towards the end of the fieldwork no new perspectives or topics were being presented in the interviews). A total of twelve BPH patients (six from each site), and eight prostate cancer patients (five from Colchester, one from Ipswich, two from Stockport) were interviewed.

### 5.2 Patients' views about involvement and outcomes

We report in this section on the kind of outcomes the men wanted, their views about involvement in the decision-making process, and their attitudes to the DSA and the DQA.

#### **Preferred outcomes**

The views of cancer patients about the values and preferences raised in the DQA varied. Whilst 37% of the 38 men responded that it was either important or very important that they retain their ability to have sexual erections, 26% felt that it was unimportant. The majority of patients reported that it was either important or very important for them to avoid incontinence (87%) and bowel problems (89%). However, 97% said that it was either important or very important to live as long as possible, even if that meant living with side effects.

For patients with BPH views were very mixed: 23% felt it was important to avoid medication, 20% felt it was neither important nor unimportant, and 58% felt that it was unimportant. Forty-two percent felt it was important to avoid surgery, 21% felt it was neither important nor unimportant, and 37% felt it was unimportant. Thirty percent felt it was important to be able to ejaculate normally with sexual activity, 28% felt it was neither important nor unimportant, and 42% felt it was unimportant.

Whilst these data give an insight into the men's values and preferences, the DQAs do not give any indication of value trade-offs – that is, which variable each man would value over another. They do, however, point to the difficult nature of treatment decision-making and to the importance of finding out what kind of outcomes men want to achieve.

### **Involvement in treatment decisions**

We were interested in finding out whether the decision-support programme appealed equally to men in differing circumstances and with different approaches to involvement in decision-making.

#### **i) Patients with prostate cancer**

As one might expect, given that our sample consisted of men who had agreed to participate in the decision-support scheme, the large majority said they wanted to be involved in the treatment decision. For example, 93% of the prostate cancer patients who completed the values and preferences section of the DQA (N=38) felt that it was either important or very important to be involved in making the decision about which treatment to have.

Nonetheless the men differed greatly in their approach to the treatment decision, with some wanting – and having – more involvement than others. We found three main types of approach among the patients with cancer: men who wanted to play a leading role in the decision and found it straightforward, those who wanted someone else to make the decision, and those who wanted to be involved in the decision but found it difficult to choose between the options.

First were those who reported taking the decision themselves and finding it straightforward. Albert<sup>2</sup>, for instance, a 71 year old patient with a small tumour in the very early stages, was definite, both before and after receiving information, that he wanted surgery:

*“I opted for surgery. He [the urologist] said ‘oh, you don’t need to take it’, and I said ‘no, that’s what I want to do’. I’d read about the other treatments, and then the nurse gave us the video, and I watched that two or three times, but I still had my mind made up on surgery, to get rid of it altogether”.*

Bill, who initially had all the options open to him except watchful waiting, also found the decision fairly straightforward, and felt that he had “an entirely free choice”:

*“I twigged from the statistics they all, whatever treatment you had, they all had about the same level of side-effects, the same level of recurrence, and therefore, to me, it was*

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<sup>2</sup> All names of patients in this document have been changed to protect anonymity.

*simply a question of which one I would prefer to undergo for treatment. It wasn't confusing. It was simply, well, it didn't really matter which one you had, it was the same result at the end of the day".*

Whilst they found taking the decision relatively easy, these patients felt that the video/DVD had been very useful in helping them to think more carefully about the different options. Albert, for instance, whose mind was set on surgery as soon as he heard his diagnosis, watched the video two or three times with his wife and said he found it extremely helpful.

Other patients did not want to be responsible for taking the decision and therefore found involvement much more difficult. Christopher, for instance, who was told he had an aggressive tumour and was offered a choice of either surgery or radiotherapy, said:

*"What I don't want is to have to make the decision, because I wouldn't know if that's the right or the wrong decision. I know nothing about operations, and cancer. I'm in your good hands, all you people, and if you say that is the right road to go down, I will take that road".*

This patient felt that the overwhelming piece of advice from the video and elsewhere was to get a second opinion. He did this, and went to see a private urologist ("one of the top men in the world") who took the decision out of his hands:

*"He was superb. Superb. He straight away said 'the right treatment for you ... is external beam radiation'. He said 'go back and see [the oncologist] and get him to start the treatment straight away'" ... He made no bones about it ... so I couldn't argue one way or another".*

Christopher was very happy to have his decision made for him. The private urologist conferred with the consultant back at Christopher's local hospital, and they agreed that radiotherapy would be the best option for him. For people like him the DSA appears to offer some guidance but not to help with treatment-decision-taking.

Other patients found it difficult because although, unlike Christopher, they wanted to be involved in the decision, they were not sure which option to choose. Edward for instance found the decision very difficult to make for this reason, and the DSA did not really help. He was told that since his tumour was moderately aggressive, he had all options open except watchful waiting. At the time of interview he was waiting for an assessment for brachytherapy to find out whether or not it is a valid option. He talked about the decision he was trying to reach:

*"At the moment brachytherapy is the most appealing to me in as much as I don't fancy external beam therapy for four weeks every day. Surgery, well, MRSA, and six weeks recovery, and catheters. So brachytherapy, which is obviously an overnight job, seems the most appealing. However, surgery is well, there it is, take it out, chuck it in the bin. But there are serious side effects. So it's very hard. Nobody's going to say 'go for that one.'"*

Whilst Edward understood why his involvement in the treatment decision was important, he felt that he needed more personalised advice from the urologist, about what it is best to do,

given his particular clinical circumstances. For such patients decision-support schemes look likely to prolong consultation and waiting times.

Another patient, Michael, was upset by his meeting with a urologist prior to having his biopsy (that is, before cancer was confirmed). He described the encounter:

*“[He] was more or less saying ‘look, you’ve got it, these are the options, you’re going to have to have it chopped out’. ... at that time I said, you know, are there no other things?, and he said ‘oh, you can discount them’. But actually, when you see the video, and you realise the probable side effects of surgery, I thought ‘not bloody likely!’”*

Michael found the decision difficult, but was very keen to make it himself. After watching the video, talking to other people, and finding out a great deal more information from other sources, he decided to try alternative therapies before reviewing the situation again in a few months time. The DSA clearly helps people who feel they are being pressured in one particular direction.

## **ii) Patients with BPH**

The picture is similar for men who completed the BPH DQAs, although a slightly smaller percentage felt it was important or very important to be involved in decision-making (79%). This may be because a treatment decision for BPH is a less crucial event than for cancer, given that the condition is not life threatening. A patient can revisit his decision several times, over many years, and the treatment options are generally seen as a progression from a minimalist option (watchful waiting), through medication, to the more invasive surgical options. Whilst there are some potential side effects of medication, they stop when medication is halted. Patients will often, therefore, drift into taking medication, without really realising that a treatment decision has been made.

We found two additional categories of treatment-decision-involvement among men with BPH (to add to the three found among men with cancer). First, was the case of men who were confused about their diagnosis and were unsure that a decision about treatment had actually been made. This may be because the diagnosis and treatment decision is sometimes obscured by the nature of the condition; lower urinary tract symptoms may be due to a number of different causes, and BPH is sometimes difficult to pin down. James for instance, after seeing the nurse, said

*“I think she more or less just said it was just a normal age thing”.*

For Philip, this confused the issue of treatment. When asked if the video helped him to decide which treatment he preferred, he replied:

*“No. It didn’t help me at all because I’m, because I don’t exactly know what is my present condition”.*

Then there were men who wanted to play a key role in the treatment decision, but found themselves being strongly advised to have one particular form of treatment, and thus in the end not really having much of a choice. Peter, whose only real concern was cancer, said that he could have continued to live with his symptoms, which weren’t causing him any real

concern. However, once he was seen by the nurse, he very quickly ended up having surgical treatment for BPH:

*“The nurse said well, you could leave it, but it’s only going to get worse, and by delaying it it could, it depends on how long you delay it for, but it’s probably going to have some adverse affect on your kidneys as well, if you continue to have trouble passing water. So I said ok, yeah, I’ll have the surgery”.*

For him therefore the video was not an aid to decision-making, but of course it may have aided his understanding or acceptance of the treatment offered. Peter’s case also highlights one of the ways in which the decision-making process could be complicated. Although Peter was not overly bothered by his symptoms, he was advised, for medical reasons, to have the surgery to prevent complications later. Another patient, Daniel, faced a similar situation. Daniel watched the video and felt that he had a pretty good idea of the situation, and had put the treatment options into order of preference. As a result of watching the DVD, he had decided that he was no longer in favour of the medical option, and was also less in favour of the surgical option:

*“I basically went to the consultant thinking for the moment, we have nothing much to lose by waiting”.*

When he saw the urologist, and was asked what he thought, he explained his favoured option. However, the urologist introduced important information to Daniel, that he felt had not been covered in the DVD. The urologist explained that he thought Daniel should have surgery sometime soon:

*“And the reason he gave ... was that the longer I wait, the more my bladder gets weakened, by always retaining a quarter of a litre or so in it. And the more I let that happen, the less my bladder will be able to operate properly after surgery. ... If I remember rightly, I think his actual words were ‘I don’t think your bladder can take thirty years of this’”.*

So having gone through the process of making what he felt to be an informed decision, Daniel was confronted with new information at a late stage, and the decision was ultimately made by the urologist. Daniel, Peter, and other men like them felt that they did not really have much choice, since they did not want to ignore the advice of the consultant. Peter said:

*“Yeah, it was an easy decision, yeah. Because I didn’t see as I had much choice.”*

Many of the men described the ways in which they saw the treatment decision having been made for them - often during the clinic, before they had had an opportunity to watch the DSA (as detailed in the previous chapter). James, for instance, described his appointment with the nurse specialist:

*“Yeah well, you know, she said there’s operations, and there’s laser things, and, or watching and waiting, or tablets. Which probably, she said, I think you’ll just go on the tablets for now and see how you get on with them” ... she said try the medication, so I thought I’d have a go. I don’t like, I take quite a few pills here and there, and I’m never keen on taking more but, er, I seem to have got on with it reasonably well”.*

Similarly, when Derek saw the urologist after having watched the video, he described:

*“About three quarters of the way through the interview, I thought it would be best to go on the wait and watch thing, and then the urologist said that he wanted to put me on one of the tablets ... And I said, well, alright then, we’ll do that, so he put me on the tablets”.*

Richard also watched the video and made his own mind up about which treatment would best suit him. He described his subsequent meeting with the urologist, in which he was surprised to be told which treatment he should have:

*“he said I think as far as you’re concerned, we’ll put you on these blockers, and I said ‘oh!’. And he said ‘what’s up?’ And I said ‘well, if you’d have asked me, that was the option that I would have chosen!”*

These reported incidents may look like paternalism (as found by Cohen & Britten, 2003), but of course they may be examples of cases where on clinical grounds one treatment is clearly preferable to another.

Other patients were similar to some of those with cancer who played a key role in the decision and found it straightforward. Duncan, for instance, explained that:

*“I really had made up my own mind what I would like ... and I didn’t feel any pressure to think any way, I mean, it really was up to me ... I think the information I got helped me make the decision”.*

Some of these men talked about how they made their decision, describing how they weighed up their values and preferences in relation to treatment options. John, for instance, explained:

*“Although it was suggested that there are tablets and things ... I think I would prefer to have an operation because I’m not so keen on taking tablets, because I sometimes think they may have side-effects. And I, looking at the video, I can see that maybe there could be a five percent problem area with regards to your sex life, but erm, five percent doesn’t seem too bad a, to take a chance on”.*

Whilst some men based their decision on deeply held feelings for or against either surgery or medication, others had their initial feelings challenged by the video. Jason, for instance, said that it totally changed his mind:

*“[before watching the video] I did not like the idea of an operation, and I even more didn’t like the idea of medication. So I was thinking that I would just sort of put up with things. But it totally changed my thoughts about it. One, that I’d be prepared to take medication, so long as it wasn’t for the rest of my life. And two, I’d be happy to have the operation”.*

When asked what factors changed his mind, he replied:

*“I think probably it was the testimonies, of the people on the video. The fact that it was relatively safe, but they were realistic about it ... I thought that was very honest. But it was people talking about actually having that operation”.*

Clearly the decision aid had been very useful to men like John and Jason.

## 5.3 Patients' views about the video/DVD and the DQA

### The Video/DVD

The previous section has showed how the video/DVD was used by the patients, whichever type of involvement they had. Many patients gave useful feedback on the ways in which they used the video, and the extent to which it helped them to take part in the decision-making process<sup>3</sup>. It is not surprising therefore that patients were, on the whole very complimentary about it.

#### i) Patients with prostate cancer

The patients interviewed were unanimous in finding the video/DVD and booklet interesting and informative. Most felt that it helped them to make (or affirm) their decision. Comments included:

*“with the notes that I got ... and the tape, that was enough for me to decide. To take in and decide what I did want. So I don't think you need any more. That tape should be enough for anyone in my opinion” (Albert).*

*“the video was most useful, because that's a better way of, a more impressive way of, it impresses on your memory better than just reading. But I found that summary useful in the back of the book so you can compare across” (Bill).*

Whilst a few of the interviewees sought out additional information themselves (from the Prostate Cancer Charity, CancerBACUP, or the internet), most did not. Several patients who either found, or were given, information from the internet were bewildered by the amount of it and the technical language used, and said that they found the video more useful.

The main reservation about the video was that it was not specific to their own circumstances or condition. Several men and their partners raised the desire for more personalised information. For example, Edward was one of several who said they found it difficult to

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<sup>3</sup> The video/DVD was given in some sites only to men who had all options (watchful waiting, surgery, external beam radiation or brachytherapy) open to them. In other sites, however, it was also given to men who might have been told that one of the options was not suitable for him. Several of the men interviewed, for instance, had been told that watchful waiting was not a good option given the aggressiveness of their cancer (as indicated by the Gleason score). Another was told that surgery would not be a good option for him since he was taking warfarin (a medication that thins the blood), after having had a heart operation some years ago.

relate to the men in the video, because of a lack of information about age at diagnosis and treatment, and indications of longer-term prognosis. Edward, amongst others, felt that he needed more information related to specific age groups of men. He felt that the video was informative, but was not useful in making a decision. He needed, he said, "somebody saying 'in my opinion I'd go for that for these reasons'".

Stephen also found it hard to relate to the men in the video:

*"It's difficult because of the age. I'm 77, and this video ... doesn't directly relate to the age at which you discover something is wrong. ... I thought a lot of it I could rule out in my own mind because I didn't think they applied to me directly ... the immediate radical surgery and things like that" ... they weren't exactly in my situation ... they were younger, generally speaking, and obviously having more advanced stages of the condition. ...*

A few patients commented on the fact that the video is American. Whilst that did not bother most patients, several felt it would be improved if it were to be anglicised. On the whole, however, the patients were complimentary of the DSA, and did not offer any more suggestions for improvement.

## ii) Patients with BPH

*"I think it is excellent. I hope they roll it out into other disease areas as well. Whatever I go down with next, I hope there is something like this available for it. Having this kind of thing is really really good" (BPH patient).*

*"The video and everything else meant that I had to spend much less time with [the urologist], and I was able to make the decision, and think about it, and discuss it with my wife" (BPH patient)*

Like the men with cancer, the BPH patients generally felt the video was useful and interesting. It was described as well balanced, comprehensive and a great way of conveying the information. Some patients felt that it was important to have the video and booklet together – the video for the pictures, the interviews with patients, and the expert explanation; the booklet so that they could re-read sections and flick through at a later date. A few patients felt that the booklet was easier to use than the video, since they could skip backwards and forwards and review particular sections again more easily.

Some patients watched the video just once, some with a partner, and some watched it several times. Jason watched it just once, but in three sections:

*"What I did was watch a section, then refer to the booklet, then watch another section and refer to the booklet. And that took place over about a week".*

For the BPH patients the video seemed to be more useful for those who went on to have an appointment with the consultant to discuss the possibility of surgery. For other patients, whose treatment decision had been made in the clinic appointment with the nurse, and who did not go on to see the consultant, the video seemed less relevant. However, some of these patients still found it to be useful. Harold, for instance, who was given medication in his

appointment with the nurse, found it interesting being able to check up on what tablets he was taking, and learn more about them from the video.

Again praise for the video was frequently tempered by comments on its Americanism, and also on its 'long windedness'. Comments include:

*"I thought it was alright. Americanised wasn't it, but."* (James)

*"It's very well done. I mean, clearly it's American. ... I thought it ... was a bit long winded, but it's probably better to explain it in extreme depth than try and skip it ... It just got a little bit, I wouldn't say too technical in some places, but ... I think if they could condense it a bit it would be useful"* (Peter).

*"I have to confess that the booklet was easier to handle than the video. I fell asleep during the video ... it was heavy going ... and it was quite slow I thought"* (Duncan).

*"I thought it had gone into everything in almost excruciating detail. It does drag as it goes along. But that said, I went to see the specialist with a fair idea of where I thought I was coming from, with a fair idea of what I thought would be a good thing to do ..."* (Daniel).

The fact that the video was American did not bother many men (although the majority commented on it). However, some did dislike it and a few were confused by it. For instance, Paul, who was asked whether he found the interview clips with patients helpful, replied:

*"Erm, yeah, I suppose it was. They were American, so they're different".*

This patient was also confused by the surgical options presented by the video. He believed, having been given an information sheet on the TURP procedure by the hospital, that only this option was being offered to him – he assumed that because the film was American, the other options were only offered in America:

*"It tells you everything, but whether you could actually have the treatment they were saying, I don't know. They were talking about the laser one, which sounded the best. ... It seemed as if that type was in America only at the moment, but over here you was just able to have the drilling out one"* (Paul).

During the course of the scheme's implementation some patients of course declined the video or did not watch it when they had it. For them we cannot know the key factors except through the eyes of those few men interviewed who had either not watched it or had put off watching it for a while, or from the nurses. For example some of the nurses suggested that refusal was rarely to do with not having a video player but more to do with a man having already made his decision and not wanting any more information. And sometimes patients made assumptions about it. Christopher had put off watching it because he assumed it was going to contain graphic pictures. Carlos, who had not watched it, said that it was partly for this reason ("who really wants to watch somebody going into your stomach?"), but also because he felt that he already knew enough:

*"I'm not really interested in looking at it. I know what it's all about".*

Thirdly, a patient might simply not want to invest the time required to watch the video (particularly for BPH, which is perceived to be less 'crucial'). And finally, one nurse suggested that some patients just did not like the audiovisual format (one patient refused to take the video because he said he would only fall asleep if he tried to watch it). In further piloting it will be important to ask those patients who choose not to take the video to give their reasons.

## The DQA

The DQA did not appear to present many problems to the patients; none of the patients interviewed said they found it difficult or distressing. However, very few found it particularly useful – most did not feel it helped them in considering their values or making their decision. This may reflect the fact that patients were largely asked to complete it once the decision had already been agreed. Many patients were completing the form to 'be helpful', which probably reflects the way in which it was presented to the patient as part of a research study. Whilst some patients joked about being tested, they were not bothered by this. Several patients added little notes on the form as they completed it. For instance, by one of the scaling tasks on the prostate cancer DQA, which asks 'How important is it for you to live as long as possible, even if you suffer side effects from your treatment', one patient circled 'very important', but added on the side 'this would depend on my quality of life'. This was one of a number of 'yes, if ...' answers to the questions. This indicates that the questions would benefit from some revision and clarification.

Several patients talked about elements of the DQA that confused them. Some were confused by the questions themselves, others by the answer format for the scaling tasks (for instance, not knowing whether to tick a point on the line or circle a whole number). Philip talked about how he was particularly confused by the first knowledge question on the BPH DQA:

Without treatment, the severity of urinary symptoms of BPH:

- a. vary from day to day and from week to week
- b. vary with how much liquid a man consumes
- c. usually get gradually worse over the years
- d. can do all of the above
- e. I don't know

Philip's response was to try to relate the question to himself, rather than answer more generally. He replied:

*"I don't know that because I haven't stopped the treatment. You see? To answer this first question there, I need to stop the treatment for a certain amount of time, to know if the symptoms have changed ... and I don't want to do that".*

Others, too, felt they needed further clarification to be able to answer the knowledge questions – such as the age of the (fictional 100) patients at time of diagnosis, the physical fitness of patients prior to surgery, and so on.

## 5.4 Outcomes

It is important to reiterate that this project was not a controlled trial, but a study of the implementation of an innovatory scheme. Nonetheless it is interesting to see if we can discern – however crudely – whether the scheme made a difference.

There are three main questions we can ask:

- Do men who have received decision support have more accurate knowledge about treatment outcomes than men who have not?
- When men are given the opportunity to consider and state their values and preferences do they make choices which accord with them?
- Do men who have received decision support make different choices from men who have not?

We can address these questions because before implementing the full decision support programme, each site used the DQA form with patients for a period of four to six weeks ('Before' phase). This was to help the sites look more reflexively at their information-giving processes, and to try the tool out in their pathways. Data from the DQA enabled us to examine men's knowledge and their values and preferences.

The BPH DQA was completed by 114 men, 48 before and 66 after the introduction of the programme. Of the two sites who implemented the programme for BPH patients Colchester had 5 patients completing the DQA in the 'before' phase and 25 in the 'after', whereas in East Berkshire the split was more even, with 43 in the 'before' phase and 41 in the 'after'<sup>4</sup>.

The prostate cancer DQA was completed by 43 men, 23 before the DSA was introduced and 20 afterwards. They were split more-or-less evenly between the three sites implementing the programme for cancer patients, except that in one site only two men completed the DQA in the 'after' phase.

The DQA might of course be considered an intervention in its own right because it encourages men to consider their values and preferences. However, we have no way of telling whether without a DQA men consider them just as well, because we did not examine the treatment decisions of men who did not use a DQA.

### **Knowledge about treatment outcomes**

Analysis of the completed DQAs before and after the DSA was incorporated into the pathway shows that men who took part in the programme were more likely to give correct answers to the knowledge questions than those who did not.

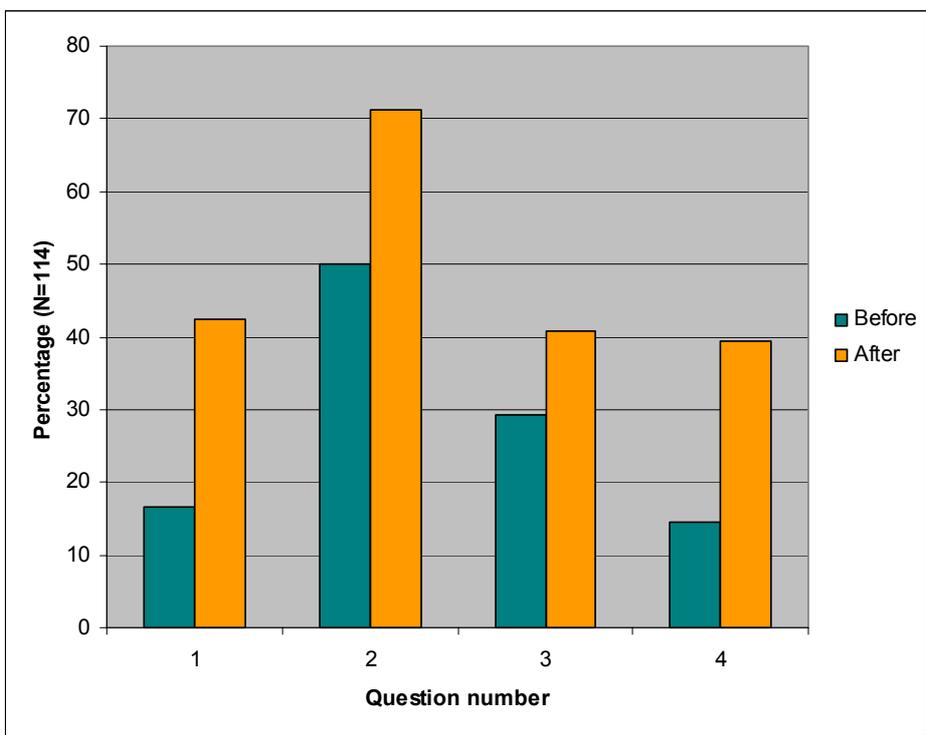
Figures one and two show the percentages of patients in the 'before' phase (before the DSA was introduced) and the 'after' phase (after the DSA was introduced) answering each

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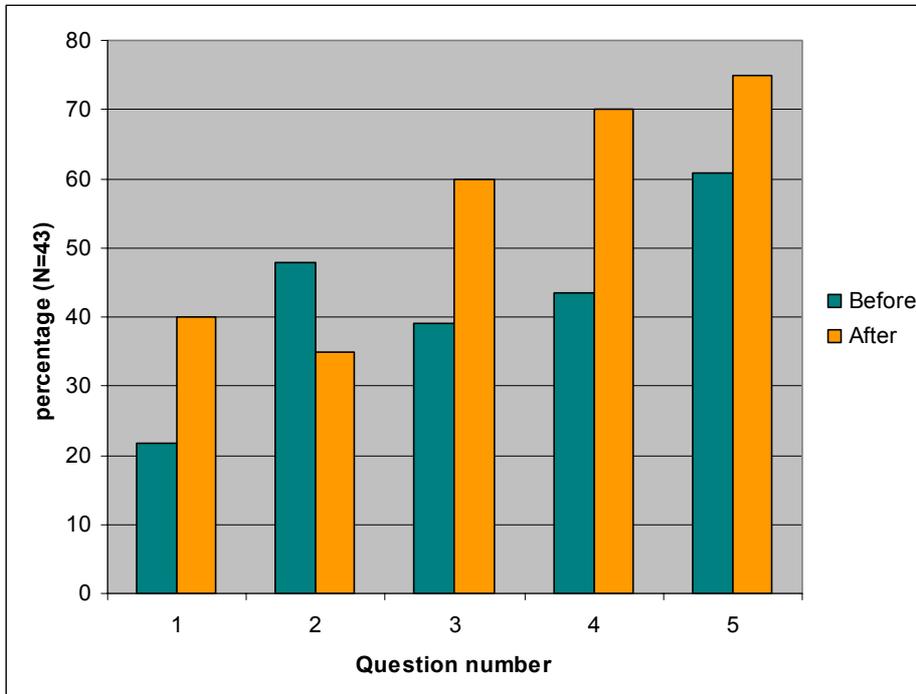
<sup>4</sup> Of these 114 BPH patients, 42.1% had received no previous treatment for their LUTS; 50.9% had received some kind of medication; 3.5% had already had a surgical procedure; and 3.5% did not specify what, if any treatment they had had.

knowledge question correctly. It is gratifying to see that there are improvements in correct knowledge scores for each question except one (question 2 in the prostate cancer DQA), between the two phases. However, it is important to be cautious about interpretation; we cannot with certainty attribute these improvements to the introduction of the DSA, since other factors were not controlled, and the total number of patients is small. There is also still room for improvement, with many of the men still giving the incorrect answer even after taking part in the programme. Also, of course, as discussed in section 3.1, knowledge of the correct answer to a question is not the same thing as understanding what it means.

**Figure one: percentage of BPH patients in each phase correctly answering the knowledge questions**



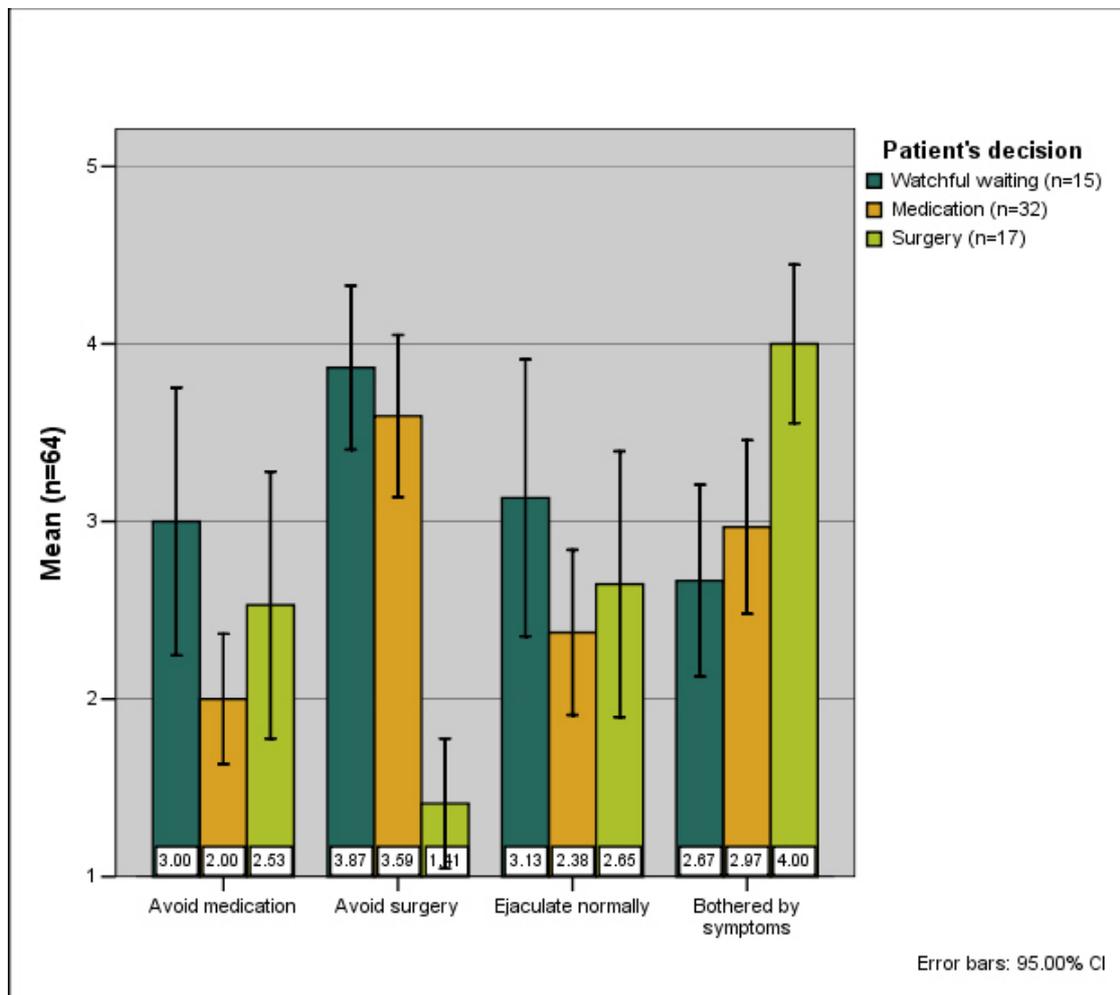
**Figure two: percentage of Prostate Cancer patients in each phase correctly answering the knowledge questions**



### **Concordance between treatment choice and values and preferences**

Here we look only at the values and preferences of men who took part in the programme, because knowledge scores are too low in the 'before' phase for us to be able to consider them as 'informed values'. We also look only at results from men with BPH as the DQA results for men with cancer involve very small numbers (only 20). Looking therefore just at the men with BPH who participated in the programme (figure three) we see an association between values and treatment choices. Thus patients who reported being bothered by their symptoms were significantly more likely to choose surgery than other groups. More patients whose final decision was 'watchful waiting' or medication rated 'avoiding surgery' as important in their decision. There was a trend for more patients whose final decision was surgery to report that they would be unhappy or bothered if their symptoms stayed as they were. These results are similar to previous studies that showed how decision aids ensure that decisions are based on informed patients' values. Despite these encouraging results, caution in interpretation is needed, and the DQA needs further validation with larger numbers (and with cancer patients).

**Figure three: BPH patients' values and their personal treatment decision**



### Decision support and treatment choices

The final question on the DQA asks the patients to record which treatment they have chosen. Their replies are shown in tables 1 and 2 <sup>5</sup>.

Table one shows that in the 'before' phase, the number of men with BPH opting for surgery was very low (just three out of 47). In the 'after' phase, 14 out of 61 men opted for surgery, and there was a drop in the proportion opting for medication or watchful waiting. Again caution must be used in interpretation, since other factors were not controlled, the samples were not matched and the numbers are fairly small.

<sup>5</sup> It is unclear from the DQAs whether each patient ended up having his chosen option, since the clinician did not always fill out the final treatment decision on the back page of the DQA.

**Table one: treatment decisions in ‘before’ and ‘after’ phases of men with BPH**

	<i>‘Before’ Phase</i>	<i>‘After’ Phase</i>	<i>Total</i>
<i>Surgery</i>	3 (6.4%)	14 (23.0%)	17 (15.7%)
<i>Medication</i>	34 (72.3%)	38 (62.3%)	72 (66.7%)
<i>Watchful waiting</i>	10 (21.3%)	9 (14.8%)	19 (17.6%)
<i>Total</i>	47 (100%)	61 (100%)	108 (100%)

For men with cancer table two shows that under the innovatory programme more men chose radiotherapy and fewer chose surgery. Again, however, one must be cautious about interpretation.

**Table two: treatment decisions in ‘before’ and ‘after’ phases of men with prostate cancer**

	<i>‘Before’ Phase</i>	<i>‘After’ Phase</i>	<i>Total</i>
<i>Surgery</i>	10 (43.5%)	7 (35.0%)	17 (39.5%)
<i>Radiotherapy</i>	6 (26.1%)	9 (45.0%)	15 (34.9%)
<i>Watchful waiting</i>	6 (26.1%)	4 (20.0%)	10 (23.3%)
<i>Void answer</i>	1 (4.3%)	0	1 (2.3%)
<i>Total</i>	23 (100%)	20 (100%)	43 (100%)

## 5.5 Conclusions

For patients with BPH or prostate cancer the process of decision-making is complex and was found to vary not only by condition but also by the kind of involvement men want in decision-making (which in itself may change during the process). The DSA was used in a variety of different ways and at different stages in the process (suggesting the need for flexibility in the point along the pathways at which it is offered and discussed). The DQA did not appear to help in patients’ decision-making, nor was it seen as intended for that purpose. But men certainly did bring their values and preferences to bear on their decision.

From the patients’ perspective, there is mixed evidence about whether the programme helped clinicians to involve patients more – some of the patients still reported apparently paternalistic approaches by doctors, though others described clear attempts to involve patients fully.

Decision-support was found helpful, and did appear to influence choices, though patients who found themselves in a state of patient-equipose (as opposed to professional equipose), that is, they were torn between competing values and preferences, continued to find decisions difficult. Indeed patients’ decisions did not always match their stated values

and preferences, though there was a tendency for them to do so. Numbers are, however, too small for firm conclusions to be drawn.

Patients were better informed after the programme, though there is still room for improvement. A minority of patients found themselves confused by the options and their implications, and for some there was a sense of information-overload (more particularly in the case of men with BPH).

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## 6 Discussion and Recommendations

### 6.1 Introduction

Overall, the implementation of the decision support programme has been very positive. The different elements of the programme have been integrated into five quite different pathways with minimal disruption. The urology staff have valued being able to give good quality, audio-visual information, and the patients have on the whole been very grateful to receive it. Most of the patients who were interviewed agreed that the DSA is a useful resource that should be made more widely available.

There are however, a number of issues which need further consideration. We discuss only those with implications for future use of the programme. This innovatory phase faced some particular challenges which would not affect further implementation. For example, the programme was a long while in gestation while instruments were developed and refined, sites and staff signed up, and financial and administrative implications considered. There was also the fact that the programme was being evaluated. The presence of external researchers meant that the laborious process of obtaining research ethics approval and management agreement from all the local research and development departments, had to be accepted. Importantly, the research also inevitably affected those involved in the programme, who were of course aware that their practices were being scrutinised.

The issues we consider below need to be set within the wider national and international context, which may threaten or support a programme's success, such as the increasingly complex information landscape into which the programme must fit. Short-termism and changing structures at strategic level have been demonstrated to weaken leadership and support. This may be particularly important given the cultural change required for successful implementation. In addition, existing structures and processes (such as one-stop clinics), can challenge implementation of new processes. And the introduction of new treatments threatens but also confirms the usefulness of decision-support programmes.

### 6.2 Issues in programme implementation, participation and benefit

#### **The three parts of the programme**

Overall, the three elements of the programme did not fit seamlessly together as a complete package.

The training, for instance, did not relate specifically to the DSA and DQA, and was not sufficiently focused on practical implementation issues. Having been brought from Canada, it could not be very well geared towards its specific audience and their current knowledge and experience. It would also have been beneficial to have included doctors, to raise their awareness of the programme, and to help them understand how and why decision support tools can be used. The training day would be expensive to repeat, and its benefits cannot be proved without a proper evaluation.

It was not always possible to offer the DVD/video at a time when it could have maximum benefit, nor could the healthcare pathways always accommodate patients' potential need for further discussions about its content. Nonetheless the DSA was found very useful, providing good, audio-visual information, which the patients can share with their family, and which can be watched many times. The information contained in it is evidence-based, and the statistics are clearly presented. It also includes good examples of other patients' experiences. The high level of ownership of DVD/video players in the population is an important factor facilitating the implementation of this programme. Having to provide space for patients to watch the video at hospital would have been problematic for most sites.

There were some criticisms of the content and form of the instrument. The lack of interactivity within the video/DVD format was identified as a weakness that might reduce the acceptability to the patients. The interviews with patients in this programme demonstrated how difficult it is to make one programme that 'fits all'. Some patients, for instance, wanted more information, some less. A more obvious consideration is that the programme is in English. It is also not suitable for people who are profoundly deaf and/or blind. The nurse in East Berkshire, where there is a large Southern Asian population, described how she made a judgement, when seeing the patients, as to whether or not they might be able to understand the video/DVD.

The decision quality assessment form (DOA) was one element which really did not work according to plan, and needs to be considered much more fully as part of the whole programme. Whilst patients did not mind completing the form, its purpose was not well understood, even by professionals. There were also a number of suggestions for improvement in its content and form.

Whilst the programme did not have any major unanticipated consequences for staff or patients, the different and often non-rational ways in which patients make their decisions can raise a number of dilemmas for professionals. The encouragement of shared decision-making may prompt difficult situations where, for instance, a competent patient makes an irrational choice. Brock and Wartman (1990) discuss irrational choices and their causes, describing an irrational decision as one that satisfies the patient's "aims and values less completely than other available choices" (p 1596). Understanding irrational decisions and their causes is important because healthcare professionals must decide when to accept patients' decisions (including those that seem not to be in their best medical interest), and when to try to persuade patients to change them. Brock and Wartman suggest that while healthcare professionals have a responsibility to try to change the irrational decisions of competent patients, in the end, such decisions must be respected if the patient is competent and cannot be persuaded non-coercively to change them.

### **The need for flexibility in implementation**

Whilst the decision aid programme overall is relatively flexible, and can be incorporated into varied pathways, and used by patients in a wide variety of circumstances, there are a number of important challenges that have been highlighted during the course of this pilot programme.

Although the programme was incorporated into existing pathways, it was not always possible for the various parts of the programme to be offered at the point patients or professionals thought as optimum. For instance, our study shows that second or additional appointments might need to be made with some patients, but workload pressures or the demands of the pathway made this impossible; it might entail a fairly major overhaul of the patient pathway. Nor did it appear that the programme was always used to maximum effect. For example, professionals differ in the degree to which they are willing to relinquish control over the decision; in their willingness to give full, unbiased information to all patients; and in their willingness to 'open a can of worms', challenge the misconceptions that some patients may hold, and encourage those patients who 'block' information to take more.

There is a need for more flexibility in the instruments themselves. An issue raised by several of the specialist nurses was the interaction between the DSA and other, more local information. The fact that the DSA did not incorporate local information could be seen as a weakness, since it may lead to repetition of, and/or contradiction with, other information. The programme is also limited in terms of treatment options. Charles et al (2004) discuss the value assumptions which, they argue, underlie all forms of decision aids. By comparing only three treatment options and their benefits and risks when there are, in reality, more than three, the programme authors are assuming first that only three options are worth considering, and second, that the only relevant information worth reviewing in order to make the decision is information on treatment benefits and risks. A practical implication is that the nurses must provide a range of further information on other treatments (such as HIFU and laparoscopic surgery), in addition to giving the video.

The DSA is not tailored to specific types of patient. The pilot project highlighted the differences between patients in terms of their preferred amount/type of information, and their preferred level of involvement in the decision-making process. And in the DQA other types of value or preference might need to be included for some patients.

### **Barriers to implementation**

There are many potential challenges to further successful implementation of this programme. First, the intervention is very dependent on the presence of specialist nurses with an information and support role. The administrative burden on nurses must also be considered, since it could threaten to overwhelm already over-worked staff.

As far as patients are concerned, not all will accept the decision support programme, and will continue to need other kinds of information source or decision-support. The evaluation of this pilot project, like other research, has suggested that patients' preferences for receiving information on treatments and for taking responsibility for treatment decisions varies.

Not all professionals will accept the programme, or not all of it. There is also evidence to suggest that clinicians are poor at assessing their patients' preferences for involvement in decision-making or their ability to benefit from it. Robinson and Thomson (2001) in a discussion of these issues suggest that more should be done to assess patients' preferences for participation in decision-making in order to predict who will benefit from the use of decision support tools and who will not. Clinicians using decision support tools need to be

familiar with these issues, and to think about how to deal with patients who do not want to be involved.

Variations in local contexts means that implementation must be locally-led, rather than top-down. For example, where there are one-stop clinics, implementation may be difficult because they do not naturally support the incorporation of shared decision-making, since there is insufficient time for a patient to absorb information, weigh up his values and preferences, and consider his options, before a decision is made. Implementation will require local leadership, as well as more lead-in time, for engaging professionals in the discussion of how best to implement the programme and how to work together to do so. More practically, the implementation of the programme depends on there being sufficient time, and its sustainability will depend on there being sufficient money available.

The willingness of each member of staff to change practice or embrace innovation is key to implementing any new project. This programme benefited from the fact that it was implemented in sites that were already the focus of service improvements and innovative practice through the NHS Action On Urology Programme, which had facilitated strong clinical and managerial networks and 'engaged' clinicians. In other sites and departments, it may be more difficult and/or time consuming to establish the support and commitment needed for implementation.

When thinking about barriers to implementation, research from elsewhere may be helpful. Graham et al for instance (2003) summarise several barriers and facilitators to implementation in general. They suggest that practitioners need to be aware that decision aids exist, and accessibility needs to be smooth, automatic, and timely. Decision aids need to be compatible with practitioners' practices and personal beliefs, up-to-date, attractive, easy to use, and not require additional cost, time or equipment. Finally, they report that practitioners need to feel motivated to use decision aids by factors such as time saving, avoidance of repetition, the potential to decrease liability, and improved decision quality with the possibility of reducing waiting lists. Uptake of decision aids may be facilitated if physicians have an opportunity to examine and try them, and if they can have unfettered access to them for distribution purposes.

### **Different programmes for different conditions**

In considering all these issues, and the feasibility of rolling the programme out in other urology departments, and beyond that to other medical specialties, it is important to consider the potential differences between the implementation of a BPH programme and that of a prostate cancer programme. Our research found that patients differ in their preferences for information and involvement in decision-making. Charles et al (2004) suggest that disease severity may influence the amount and type of support patients want in the clinical encounter, and the role of decision aids in this process. For example, for prostate cancer, it may be important to ensure that the decision aids can be used in the medical encounter as an integral part of the communication and support process undertaken to help men express their treatment preferences as part of a shared process of decision-making. Where the clinical problem is less severe in its health consequences, for instance BPH, it may be less important to embed the use of the decision aid within the context of the medical encounter. This is particularly relevant if the patient prefers an informed approach to treatment decision-making and wants to make the decision himself without the physician input.

## 6.3 Recommendations

It is clear both from this pilot and from other research that decision support tools that help patients and healthcare professionals to share information, think about values and preferences, and reach good quality decisions are needed more widely within the NHS. The informed decision-making in urology pilot project has been an important learning experience which will help those planning similar programmes to think more carefully about how to progress.

From the analysis of the research data, particularly taking into consideration the perspectives of staff and patients involved in the implementation, we make the following recommendations.

### **1. The importance of flexibility and responsiveness to local context**

The development of any future programme and/or implementation strategy should take full account of the specific local pathway into which it is to be incorporated. Any proposed programme needs to be flexible so that it will suit a range of pathways and contexts. The local team needs to develop a sense of ownership, and ensure that the whole team (especially the nurses), as well as other key staff, are involved in the process from the start.

### **2. Incorporation into routine practice**

The programme would benefit from being embedded more securely into routine procedures. Given the current emphasis on electronic patient records, and on IT developments such as Health Space and Connecting for Health, any new programme must look ahead and plan to incorporate and make use of these emerging systems.

A number of programmes in Canada and the US show that tools can be incorporated into electronic systems and routine practices with little additional burden on staff. The Dartmouth-Hitchcock Medical Centre, for instance, has integrated decision support and computerised assessment into their routine pathway for women with early stage breast cancer. Evaluation of the programme has demonstrated that, for those women involved, decision conflict is significantly reduced, and there is a high concordance between personal preference and post-video choices (Collins et al 2005). The development of electronic prescriptions could also pave the way for the introduction of information prescriptions in the form of information therapy.

### **3. The need for consensus on the content of the DSA**

There needs to be a consensus on the information and evidence contained in the decision support aid. In order to reach this consensus, some thought may need to be given to the possible customisation of information for local sites and the amalgamation of a centrally produced DSA with locally produced information.

Other improvements to the DSA should also be considered. Patients and staff included in this research suggested that a decision support aid could be improved by:

- a) making it easier to view and review particular sections, for instance through indexing or by separating sections out
- b) making it shorter (or ideally more interactive so that those requiring more information have the option of going to it)
- c) anglicising it. Most of the patients interviewed commented on the fact that it is American. Although they said that this is not a problem for them (they broadly agree that they value the information wherever it is coming from), they recommend that if it is to be used more widely we should think about making an English version.
- d) making it available in other languages
- e) making it easier to update.

These issues, however, must be balanced against other factors, such as increases in cost or lengthy time delays.

#### **4. A decision quality assessment that can be used both as an audit tool and a clinician's tool**

It is important to include some form of decision quality assessment that helps the patient to think about and share his values and preferences; helps the healthcare professional to gauge the patient's level of understanding of the information materials; and that can be used as an audit of decision quality at a population level (see Sepucha et al 2004). However, the DQA used in this pilot, and the way it was used, needs revision. Patients and staff made a number of points that could be considered in producing a revised DQA:

- a) Most importantly, its purpose should be considered fully and agreed. It should then be appropriate to that purpose. For instance, if it is to encourage men to consider values and make value trade-offs in choosing a treatment, it might need to be more interactive and more complete
- b) There should be more guidance as to how it should be incorporated into a consultation
- c) There is a need to re-structure and re-word the form. For example, some questions need to be more understandable, the answer format should be clearer for the patient to use, it should look less like a test. Any revisions should be tested via cognitive interviewing
- d) The results should be easier to analyse at a glance.

#### **5. Improvements in content and availability of training**

The training provided by the Ottawa Health Research Institute on the concepts and practice of shared decision-making was appreciated, and should be considered an important aspect of any future programme. However, this training should be seen as an element of the programme as a whole, and should include practical advice on how to implement both the DSA and DQA. In order to build wide-spread understanding and support of the programme within departments, it may be important to include other healthcare professionals, in addition to the nurses. The training would then need to be designed with that audience in mind.

## 6. Clear plans for sustainability

It is important that issues which might affect future sustainability of the programme are identified, and that plans are made, where possible, to mitigate any such problems. The issue of updating and replacing the DSAs is an obvious example. The programme plan should identify which organisations are responsible for updating the content, and funding the replacement of the decision tools.

## 7. Further piloting

Overall, we recommend a more extensive pilot before any national roll out. This pilot should provide an opportunity to:

- revise the DSA, DQA and training
- build the tools into electronic systems as far as possible, thinking about the future context, and making the most of what is already there.
- identify sites carefully so that potential barriers to implementation are considered in a broader range of sites (for instance, in sites that were not previously involved in Action On Urology, that do not have urology specialist nurses, and that have populations more varied in socio-economic background and ethnic origin).

Lessons learned from the current pilot project should be considered carefully when planning any future project.

## 6.4 Finally

When patients have to take complex healthcare treatment decisions they need: involved and informed staff, smooth-functioning care pathways, knowledge of their options, understanding of the evidence, appreciation of the risks and likely outcomes, and of the implications for them and their way of life. Only then will patients be optimally placed to reach their decisions. Decision-support programmes can help to ensure that all these come together when they are most needed.

The increased focus in government policy on information and involvement, and on choice and patients' perspectives, represent an important opportunity for decision support programmes. The decision-making in urology programme has the potential to prompt a much-needed general spread of interest in decision support within clinical and political arenas.

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## 8 Appendices

### Appendix 1

#### **Decision Quality Assessment for Early Stage Prostate Cancer Treatment**

Dear Patient

This form is intended to help you, your doctor and the nurses to come to a treatment decision for your early prostate cancer that best suits you.

Firstly, we would like to check that we have given you enough information about the major aspects of your condition and its treatment. We would like to see how well we are doing our job of giving you information. This is done through 'knowledge questions'.

Secondly, we want to make sure we have understood what is most important to you and your preferred way of life. This is done through 'values and preferences' questions.

We would like you to fill in this form before the decision about your treatment is agreed with your doctor or nurse. You can complete the form by yourself or with assistance from your nurse. In either case, your nurse or doctor will be prepared to discuss with you the answers to the knowledge questions as well as your personal values and preferences.

Thank you for taking the time to complete this form. This is our way of making sure that the treatment you do receive is the right treatment for you.

(Hospital) Urology Team

## Knowledge Questions

*The following questions are related to early prostate cancer including possible outcomes of three different treatments. For each question, please answer by ticking the relevant box.*

1. If 100 men with early prostate cancer have no treatment, about how many of them will live 10 or more years, unless they die from some other cause?
  - a. between 76 and 100
  - b. between 51 and 75
  - c. between 26 and 50
  - d. between 0 and 25
  - e. I don't know
  
2. Which treatment generally results in more men being alive 10 years after early prostate cancer is diagnosed?
  - a. surgery
  - b. radiation therapy (either external beam or radioactive seeds)
  - c. watchful waiting
  - d. all three are about equal
  - e. I don't know
  
3. Which treatment will result in the most men able to have sexual erections?
  - a. surgery
  - b. radiation therapy (either external beam or radioactive seeds)
  - c. watchful waiting
  - d. I don't know
  
4. Which treatment will result in the most men wearing pads to deal with leaking urine?
  - a. surgery
  - b. radiation therapy (either external beam or radioactive seeds)
  - c. both are about equal
  - d. I don't know
  
5. Which treatment will result in the most men having problems with the bowel?
  - a. surgery
  - b. radiation therapy (external beam)
  - c. both are about equal
  - d. I don't know





## Appendix 2

### **Decision Quality Assessment for Lower Urinary Tract Symptoms (LUTS) attributable to Benign Prostatic Hyperplasia (BPH)**

Dear Patient

This form is intended to help you, your doctor and the nurses to come to a treatment decision for your lower urinary tract symptoms that best suits you.

Firstly, we would like to check that we have given you enough information about the major aspects of your condition and its treatment. We would like to see how well we are doing our job of giving you information. This is done through 'knowledge questions'.

Secondly, we want to make sure we have understood what is most important to you and your preferred way of life. This is done through 'values and preferences' questions.

We would like you to fill in this form before the decision about your treatment is agreed with your doctor or nurse. You can complete the form by yourself or with assistance from your nurse. In either case, your nurse or doctor will be prepared to discuss with you the answers to the knowledge questions as well as your personal values and preferences.

Thank you for taking the time to complete this form. This is our way of making sure that the treatment you do receive is the right treatment for you.

(Hospital) Urology Team

Before you begin the questions, could you please check below any treatments you have had so far for your lower urinary tract symptoms?

- No treatment.
- Medical treatment
  - alpha blocker.
  - finasteride.
  - I'm not sure what kind of medicine I've had.
- Surgical treatment
  - transurethral resection of the prostate (TURP).
  - something other than a TURP.
  - I'm not sure what kind of surgical treatment I've had.

## Knowledge Questions

*The following questions are related to Benign Prostatic Hyperplasia (BPH) including possible side effects and outcomes of three different treatments. For each question, please answer by ticking the relevant box.*

1. Without treatment, the severity of urinary symptoms of BPH:
  - a. vary from day to day and from week to week.
  - b. vary with how much liquid a man consumes.
  - c. usually get gradually worse over the years.
  - d. can do all of the above
  - e. I don't know
  
2. Which treatment approach reduces urinary symptoms of BPH the most?
  - a. surgery
  - b. medicine
  - c. watchful waiting
  - d. all are equally effective
  - e. I don't know

3. Medical treatment for BPH can:

- a. reduce urinary symptoms
- b. prevent later complications like urinary blockage
- c. do both of the above
- d. I don't know

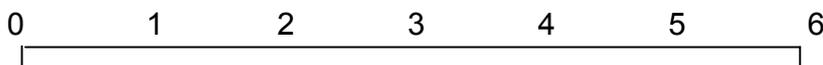
4. Of 100 men who have a transurethral prostatectomy (also known as TURP), about how many will not be able to ejaculate normally with sexual activity?

- a. between 0 and 25
- b. between 26 and 50
- c. over 50
- d. I don't know

## Values and Preferences Questions

This part of the form is to help us understand what is important to you. For the following questions, please mark your views on the scale below each question. There are no correct (or incorrect) answers.

5. How would you feel if your current urinary symptoms stayed just the way they are now for the rest of your life?



*I'd feel delighted*

*I'd feel terrible*

6. How important is it to you to **avoid** taking medicine?



*not important  
at all*

*very important*

7. How important is it to you to **avoid** having surgery?



*not important  
at all*

*very important*



## Appendix 3

### Steering Group Membership

**Chair:** Dr Mary Archer

**National Patient Groups:** Roy Williams; Colin Sloane; Peter Hurrell

**The Deputy Chief Medical Officer:** Dr Paul Whatling, Medical Lead National IT Strategy

**The National Electronic Library for Health:** Sir Muir Gray

**The National Prostate Cancer Group:** *Treatment Sub Group:* Professor David Neal, Chairman; *Information Sub Group:* Dr Chris Parker, Chairman & Tim Elliott, DOH Policy Team

**The Foundation for Informed Medical Decision-making:** Dr Al Mulley & Dr Michael Barry

**Cochrane Institute:** Professor Annette O'Connor

**The National Strategy Group (incorporating The informed Patient, CHOICE & and other initiatives):** Dr Tim Wilson & David Mowat

**NHS Direct On line:** Dr Adrian Reyes-Hughes, Clinical Director

**The NHS Modernisation Agency (Clinical Governance):** Cathy Green.

**The King's Fund:** Dr Jennifer Dixon.

**The Prostate Cancer Charity,** Tania Ross, Lead Nurse Helpline Services

**BAUS:** Mr Paddy O'Reilly

**BAUN:** Lyn Kirkwood

**Picker Institute Europe:** Professor Angela Coulter; Professor Janet Askham & Dr Erica Wirmann

**Action On Urology:** Jennifer Fenelon, National Programme Director; Mr Mark Fordham & Mr Mark Harrison, Clinical Leads; Ruth Cowley, Project Manager; Dr John Connolly, GP & AOU Steering Group Member & Nick Evans, AO Team

**The participating sites:** *Clinical leads:* Mr Graeme Urwin (York), Mr Rick Brough (Stockport & Tameside), Mr John Parry (Ipswich); Professor Chris Booth (Colchester); Mr Omer Karim (East Berks); Mr Mike Flannigan (Bradford). *Specialist nurses:* Lucy Powell & Judy Cecil (Colchester); Chris Garlick (Ipswich); Linda Martin (Stockport & Tameside); Janette Garden (East Berks).

**Observers:** Tet Yap, Urologist and researcher, RCS; Matthew Kershaw, DH Orthopaedic Programme

## Appendix 4

### **Decision Quality Assessment Measure for Lower Urinary Tract Symptoms (LUTS) attributable to Benign Prostatic Hyperplasia (BPH)**

#### **Clinician's Guide**

It is the clinician's professional responsibility to inform patients about their medical conditions including various treatment options, and to help them to take the most appropriate decision to suit both their clinical condition and their values, goals or preferred way of life. This is especially true when the decisions are complex because of high clinical uncertainty and high variation of patients' wants and needs.

Decision aids have been developed to assist clinicians in meeting this responsibility. Evaluations throughout the world have demonstrated that decision aids can improve decision quality and make patients more informed and clearer about the personal values and preferences (BMJ 1999; 319:731-4 and Cochrane Library 2004;3).

The Decision Quality Assessment (DQA) is a practical tool to assess patient knowledge and values relevant to treatment of early stage prostate cancer, or symptoms attributable to BPH, thereby giving clinicians the opportunity to measurably improve decision quality for men with prostate cancer or BPH.

The DQA consists of a series of multiple-choice questions chosen to assure relevant knowledge, and a series of scaling tasks to facilitate clarification and assessment of relevant values. Relevant knowledge pertains to the natural history of prostate cancer including prognostic variables, the effectiveness of treatment options, and the possible harms of each. The rationale for question selection and explanation for 'correct' answers can be described briefly.

#### Knowledge Questions

##### The natural history of BPH

The natural history of BPH is highly variable. It may vary from day to day and from week to week. Some men experience symptom improvement from one year to the next, but symptoms generally get worse over an extended period. A good decision about treatment begins with an understanding of what will happen without treatment as reflected in the answer to the first question.

1. Without treatment, the severity of urinary symptoms of BPH:
  - a. Vary from day to day
  - b. Vary with how much liquid a man consumes
  - c. Usually get gradually worse over the years
  - d. All of the above
  - e. I don't know

Correct answer is d. Answers a. and b. are self-evident, and natural history studies document slow progression of symptoms over time for populations.

##### The effectiveness of treatment for BPH

2. Which treatment approach reduced urinary symptoms of BPH the most?
  - a. Surgery

- b. Medication
- c. Watchful waiting
- d. All are equally effective
- e. I don't know

Correct answer is a. In the meta-analysis conducted by the AUA Guideline Panel, average drops in symptom scores from the IPSS were much more dramatic for TURP and related procedures than for any of the medical therapies or watchful waiting. Symptom relief with medical therapy was intermediate between watchful waiting (or placebo) and surgery. (J Urol 2003;170:530).

3. Medical treatment for BPH can:
- a. Reduce urinary symptoms
  - b. Prevent later complications like urinary blockage
  - c. Do both of the above
  - d. I don't know

Correct answer is c. Both alpha-blockers and 5-alpha reductase inhibitors reduce symptoms, while the latter drug class reduces the risk of acute urinary retention and progression to surgery (J Urol 2003;170:530).

Potential harms of treatment for BPH

4. Of 100 men who have a transurethral prostatectomy (also known as TURP) about how many will not be able to ejaculate normally with sexual activity?
- a. Between 0 and 25
  - b. Between 26 and 50
  - c. Over 50
  - d. I don't know.

Correct answer is c. In the Guideline Panel meta-analysis referenced above, the point estimate of the risk of retrograde ejaculation after TURP was 65%, with a 95% confidence interval of 56-72% (J Urol 2003;170:530).

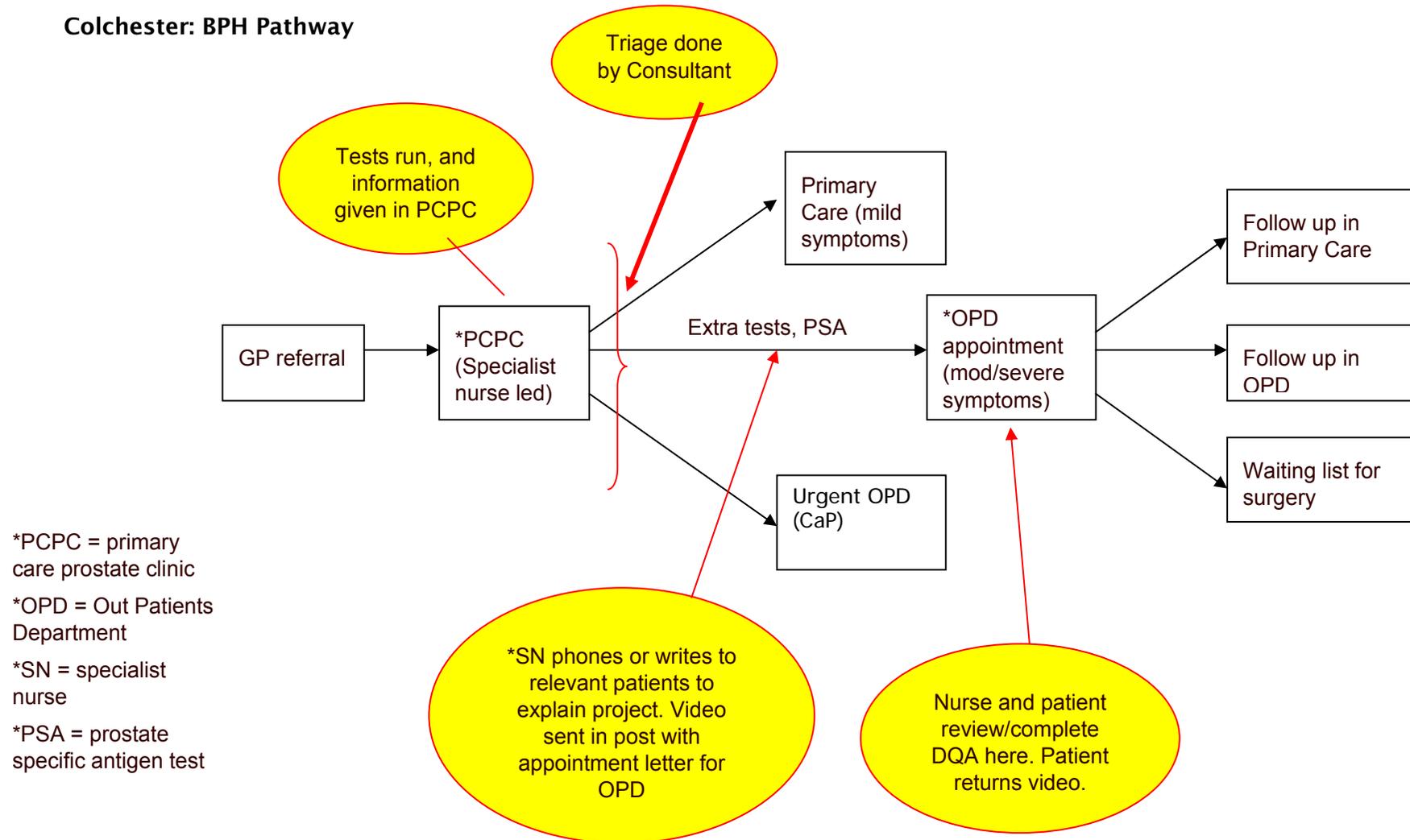
Values and preferences questions

As noted, different men often feel very differently about precisely the same health status. They are also more or less willing to take the same risks, and more or less willing to make the same trade-off between known harms in the near future and uncertain benefits in the distant future (Med Care 1989;27:S269-281). Different men are also more or less comfortable with decision-making and with the experience of being treated one way or another. The second part of the DQA is meant to assess these kinds of values and preferences of patients. There are not correct (or incorrect) answers. Nonetheless, decision quality depends on patients having the opportunity to gain insight about what is important to them as they look to the future as it will be affected by choice of treatment. This element of decision quality can be measured among populations of patients by quantifying the association between the values and preferences expressed by patients and the treatments they receive (Health Affairs 2004; October 7:57-64).

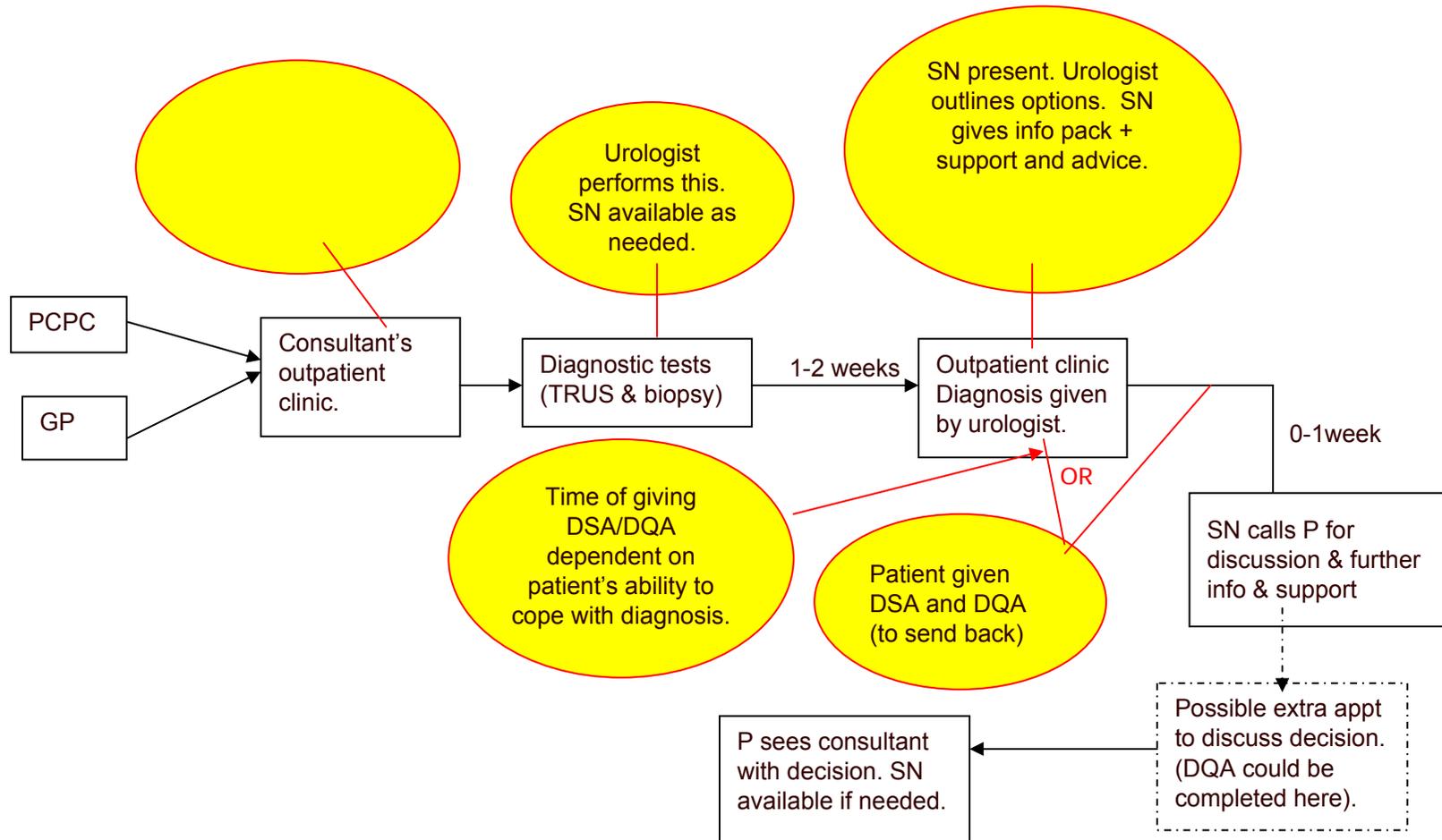
## Appendix 5

### Patient pathways in each site, Incorporating decision support scheme

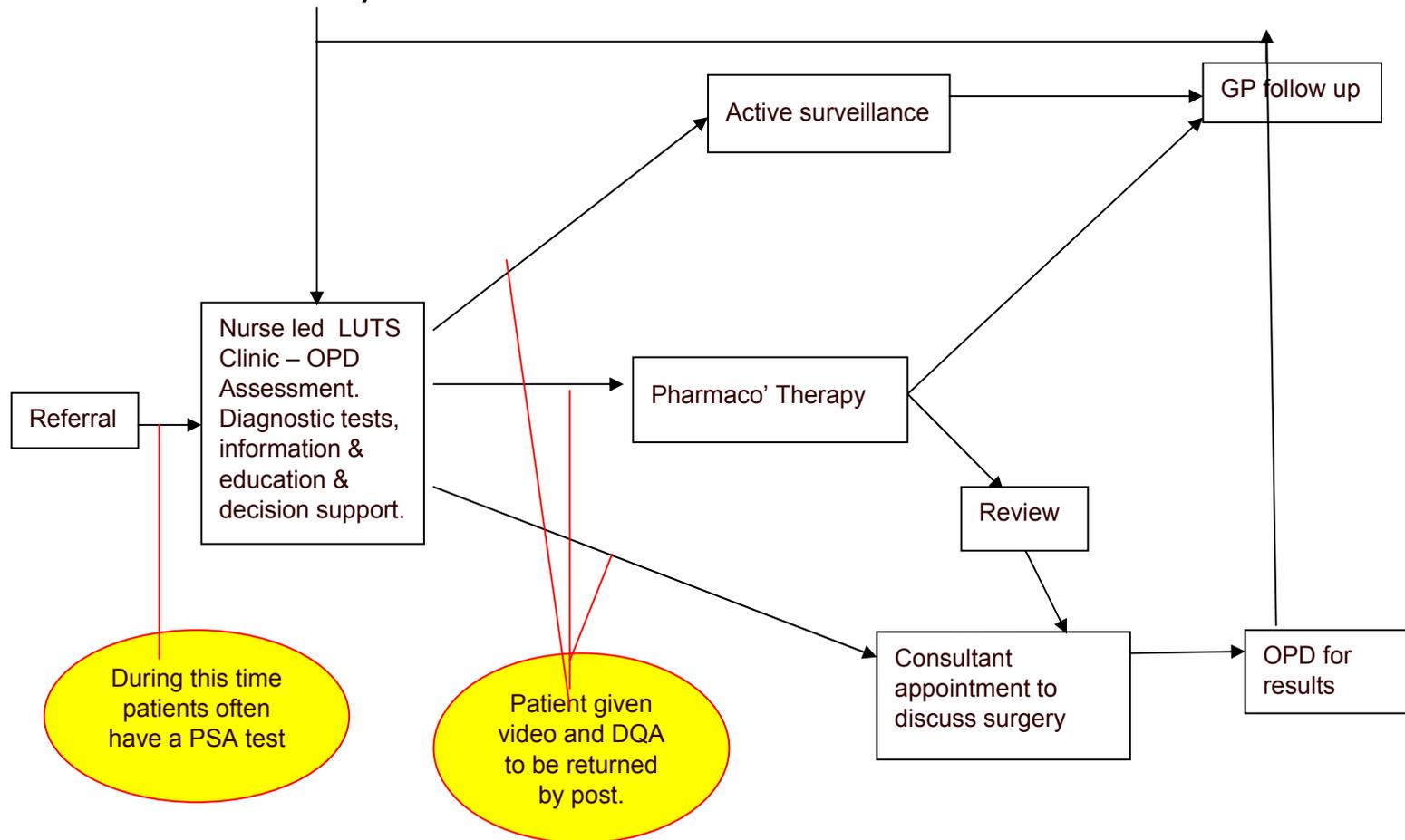
#### Colchester: BPH Pathway



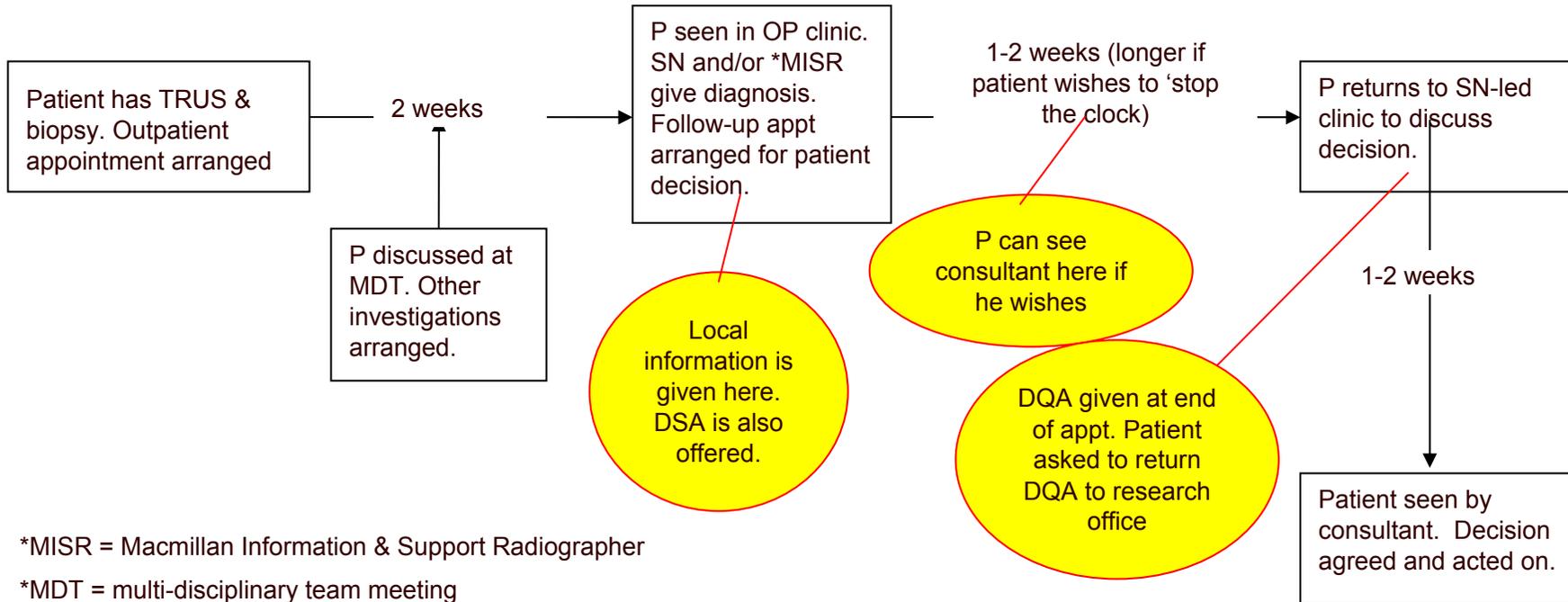
**Colchester: Prostate Cancer Pathway**



### East Berkshire: BPH Pathway



## Ipswich: Prostate Cancer Pathway

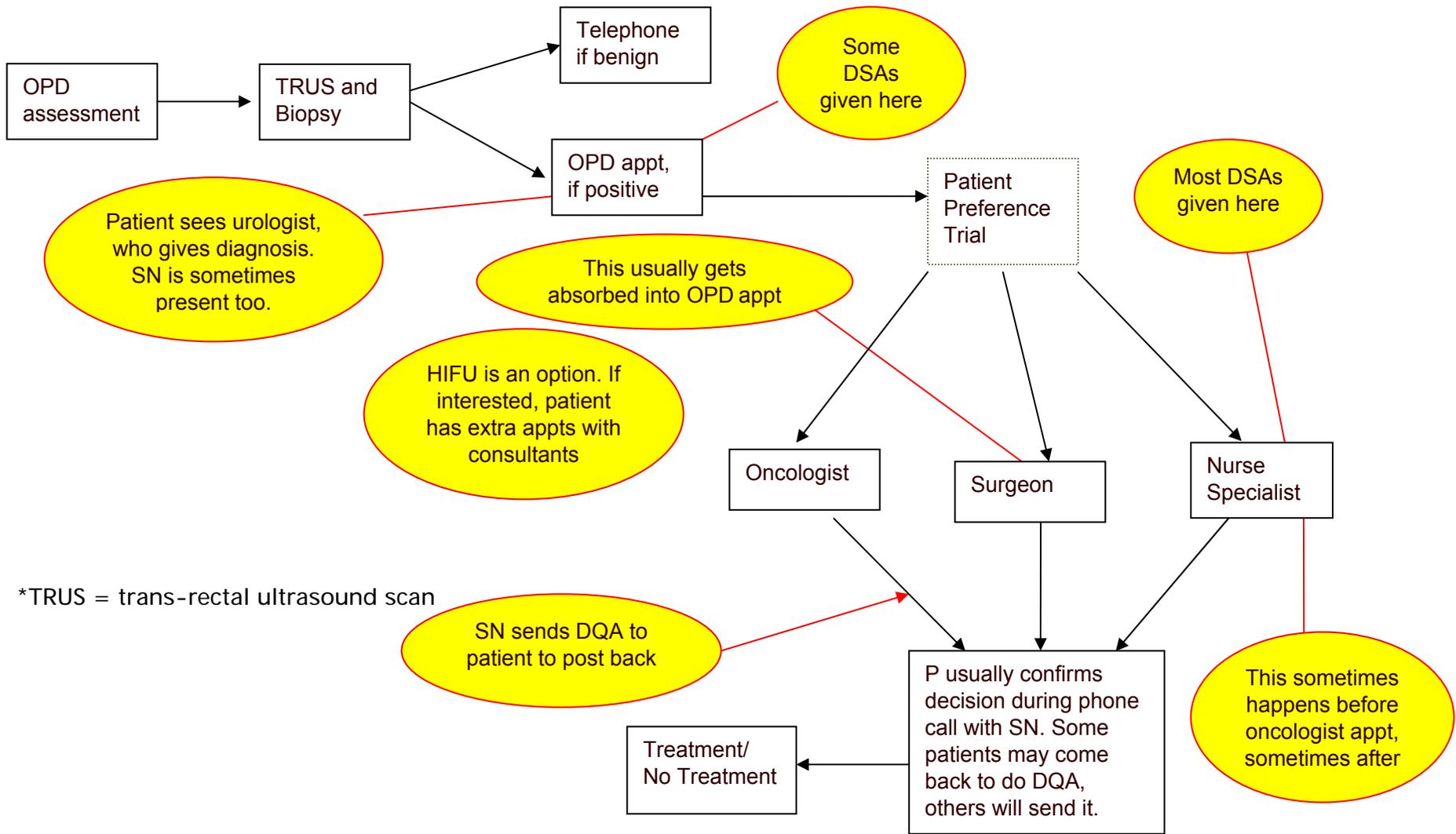


\*MISR = Macmillan Information & Support Radiographer

\*MDT = multi-disciplinary team meeting

\* OP = outpatient

### Stockport: Prostate Cancer Pathway



\*TRUS = trans-rectal ultrasound scan

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