

The REFER Project: Realistic Effective Facilitation of Elective Referral for elective surgical assessment

Research Report

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The Report

1 Executive summary

The REFER project was carried out to improve the process of referral from primary to secondary care for patients with non-urgent conditions who may benefit from surgical treatment. General practitioners have to respond to two potentially conflicting policy developments: the growing emphasis on managing demand for specialist services and the increasing political pressure to allow patients choice

1.1 Aims and objectives

The project was carried out in two phases. The aim of the first phase was to characterise the current use of referral guidelines by general practitioners in the NHS. The specific objectives of this phase were:

1. To systematically assess the referral guidelines that are currently available
2. To undertake an analysis of the current national and local policy context relevant for the development and implementation of referral guidelines
3. To undertake a national cross-sectional survey of general practitioners to establish the current use of referral guidelines

The aim of the second phase of the REFER project was to demonstrate how referral guidelines can be developed that explicitly incorporate patients' preferences for referral. Two referral guidelines were developed:

1. A referral guideline for osteoarthritis of the knee
2. A referral guideline for lower urinary tract symptoms in men

We also carried out a survey of general practitioners, surgeons and members of the public to establish the representativeness of the guideline development groups' views on referral appropriateness.

1.2 Results of REFER Project Phase 1

Systematic review of effectiveness of referral guidelines

This review addressed the following questions:

1. Do referral guidelines increase general practitioners' knowledge and awareness of appropriateness of referral?
2. Do referral guidelines increase appropriateness of referral?
3. What is the impact of referral guidelines on costs and health outcomes?
4. Are aspects of the guideline development process associated with the outcome of interest?

Medline, EMBASE and CINAHL databases were searched. 20 papers met the inclusion criteria.

There was some evidence that referral guidelines improve referral appropriateness but all studies addressing this effect were poorly designed. No studies reported on the effects of referral guidelines on general practitioners' knowledge of appropriateness of referral, rates of referral, or on health outcomes or costs. Neither were studies available on the association between aspect of the guideline development process and the outcome of interest.

Policy analysis: context for the use of referral guidelines

The aim of this policy analysis was to develop an overview of the current national and local policy context for the use of referral guidelines.

The analysis was based on policy documents, interviews with experts and stakeholders, and qualitative survey of five primary care trusts.

This policy analysis confirmed that unprecedented change is occurring in the NHS. Unevaluated methods for demand management are being introduced in many primary care trusts. For example, all primary care trusts had adopted intermediary clinical assessment and treatment services to manage referrals. Referral guidelines were not commonly used. There was strong support for the involvement of patients in the referral process. There was a discrepancy between the views of managers and clinicians on the extent and nature of inappropriate referrals. Managers emphasised the high numbers of inappropriate referrals whereas general practitioners and consultants did not believe that this was a problem.

Survey of general practitioners' views and use of referral guidelines

The aims of this survey were:

1. To undertake a national survey of general practitioners to inform the development of new referral guidelines

2. To establish whether, how and why general practitioners use guidelines for patients with non-urgent conditions who may benefit from surgical treatment
3. To examine general practitioners' attitudes to patient involvement in the referral process

A questionnaire was mailed to 324 general practitioners who were randomly selected from the list of 10 representative primary care trusts in England. 40% responded.

Although there was overall support for referral guidelines, they were rarely used in practice. Over a fifth of respondents indicated that they were expected to use referral guidelines by their local hospital or primary care trust. They indicated that referral guidelines would be most useful for patients with osteoarthritis of hip and knee, prostate problems, stress incontinence, infertility, back pain and menorrhagia. The notion that patients should be involved in deciding whether they should be referred or not was strongly supported.

1.3 REFER Project Phase 2

Referral guideline for osteoarthritis of the knee

Our aim was to develop a referral guideline for patients with osteoarthritis of the knee that explicitly incorporates the patients' own preferences for referral.

The guideline was developed by a group of 12 stakeholders (patient representatives, general practitioners, orthopaedic surgeons, and other health care professionals) who used a formal consensus development method. Recommendations were formulated on good primary care practice and on the appropriateness of referral.

The guideline development group recommended that general practitioners should take a detailed medical history and carry out a physical examination to verify the origin of the knee pain. They do not need to consider the results of a knee X-ray. There was consensus that the appropriateness of referral only depends on the severity of the knee symptoms and the patients' referral preferences and not on age, comorbidity or body mass.

There was consensus that patients with severe knee symptoms who want to be referred should be referred and that patients with moderate or mild symptoms and strong preference against referral should not be referred.

Preferences had a greater impact on the groups' ratings of referral appropriateness when symptoms were moderate or severe than when symptoms were mild.

Lower urinary tract symptoms

Referral guidelines were developed for men with uncomplicated lower urinary tract symptoms. Similar methods were used as for the osteoarthritis guideline.

It was recommended that general practitioners confirm that patients have uncomplicated lower urinary tract symptoms by taking a medical history to rule out previous acute urinary retention and by carrying out a digital rectal examination to assess the prostate for signs of cancer. Patients with uncomplicated lower urinary tract symptoms should be offered lifestyle advice before a referral is considered.

There was consensus on the appropriateness of referral for men with severe symptoms who want to be referred and the inappropriateness of referral for men with mild symptoms and either no preference or a strong preference against referral.

The groups' judgements seemed to be more responsive to symptom severity when patients did not have a referral preference than when patients had a strong preference for or against referral.

Representativeness of guideline development groups' view

A survey was carried out to determine the representativeness of the guideline development groups' ratings of referral appropriateness.

Questionnaires were mailed to 602 general practitioners, 200 orthopaedic surgeons, 200 urologists, and 134 members of the public. Response rates were 12% among the general practitioners, 28% among the surgeons and 79% among members of the public.

The views of general practitioners, specialists and the public correspond closely with those of the two guideline development groups. Furthermore, in all three groups the referral preference of patients had a strong impact on the ratings of referral appropriateness and its impact depended on the severity of the symptoms.

1.4 Conclusions

REFER Project Phase 1

1. Referral guidelines need to be developed as part of a more general referral and management package. This could involve the development of structured management sheets or educational interventional material which would strengthen the general practitioners awareness of the intervention. Also, one stop-services and direct access to waiting list could be considered.
2. Current policy developments regarding referral from primary to secondary care within primary care trusts need to be taken into account, including Practice Based Commissioning as well as the

establishment of intermediary services to manage demand for specialist services and secondary care.

3. Referral guidelines should allow for local variation in the available secondary care services.
4. Referral guidelines should help general practitioners to communicate with their patients about the risk and benefits of referral.
5. Referral guidelines should be concise and contain key message that are memorable.
6. Referral guidelines should be produced in a language that general practitioners can share with patients.

REFER Project Phase 2

1. The appropriateness of referral for patients with non-urgent conditions depends on the severity of their symptoms as well as their preferences as to whether they want to be referred or not. The appropriateness of a referral depends on the extent to which it is likely that the referral will have a beneficial effect on a patient's health.
2. Patient characteristics such as age and comorbidity have relatively little impact on referral appropriateness.
3. Referral guidelines should acknowledge that there can be an interaction between the impact that symptom severity and patient preferences have on referral appropriateness. The impact of patients' preferences on the guideline development groups' rating of referral appropriateness was on average smaller in patients with mild symptoms than in those with severe symptoms.
4. Decisions on the appropriateness of referral should balance the interests of individual patients (protection of patient autonomy; benefits and harms of specialist management) and those of the population in general population (efficient use of limited resources).
5. Developers of referral guidelines should take into account that there is a potential conflict between the general practitioners' roles of "patient advocate" and "gate keeper".
6. Formal consensus development methods can be used to elicit explicit statements on the appropriateness of referral of patients with non-urgent conditions according to symptom severity and their referral preference.

1.5 Implication for policy and practice

1. Referral guidelines should be developed as part of a wider package (e.g. structured management sheets, educational material) that can support general practitioners.

2. Intermediary services set up to manage demand for specialist services should consider using explicit referral guidelines.
3. Patients' preferences should be incorporated in referral guidelines for non-urgent conditions.
4. Formal consensus development methods should be used to develop referral guidelines that incorporate patients' preferences.
5. Referral of patients with non-urgent conditions such as osteoarthritis of the knee and lower urinary tract symptoms should not depend on age or comorbidity.
6. Referral guidelines for patients with non-urgent conditions should allow the impact of patients' referral preferences to vary according to symptom severity.
7. Referral guideline for patients with osteoarthritis of the knee:
 - Patients should be referred if they have severe knee symptoms and have a strong preference in favour of referral
 - Patients should not be referred if they have mild knee symptoms and have a strong preference against referral or no referral preference either way.
 - For all other patient groups, defined according to symptom severity and referral preference, there was no consensus with regard referral.
 - Age, comorbidity, and body mass do not affect the appropriateness of referral.
8. Referral guideline for patients with lower urinary tract symptoms:
 - Patients should be referred if they have severe uncomplicated LUTS and have a strong preference in favour of referral.
 - Patients should not be referred if they have mild uncomplicated LUTS and have a strong preference against referral or no referral preference either way.
 - For all other patient groups, defined according to symptom severity and referral preference, there was no consensus with regard referral.
 - Age and prostate size do not affect the appropriateness of referral.

2 Introduction to the REFER Project

The REFER project (Realistic Effective Facilitation of Elective Referral) is concerned with the development of guidelines for general practitioners so that they can ensure appropriate referral of adults with non-urgent conditions to surgical outpatients, taking into account patients' own preferences. The study was commissioned by the NIHR Service Delivery and Organisation (SDO) Programme of Research on Access to Health Care, in July 2004. It was granted ethical approval by Scotland MREC; reference MREC/03/0/108.

People are referred from primary to secondary care for a number of different reasons: including diagnosis, reassurance, further assessment of a known condition and often specifically for assessment for surgery (Rosen *et al.*, 2001; Gulliford *et al.*, 2001). The impetus for the SDO in commissioning this work was that a report from the Health Services Management Centre (Kipping *et al.*, 2002) which suggested that priority scoring tools were being implemented with little attention to reliability and validity. Tools developed elsewhere, were being modified or calibrated to incorporate locally perceived relevant elements, sometimes changing their purpose. Furthermore, the report suggested that tools designed for urgency assessment (priority scoring tools) might be inappropriate for assessment for referral (referral tools). It was also noted that such tools did not incorporate patients' own views, for example preferences, health status or quality of life.

One of the key determinants of demand in the NHS remains the general practitioners' gate keeper role, whereby decisions about referral for further opinion, investigation or treatment are taken by general practitioners (Kipping *et al.*, 2002). Access to secondary care is still restricted within the NHS to those whom the primary care practitioner consider appropriate for specialist care. However, there is substantial variation in referral rates in the UK (Reynolds *et al.*, 1991; Coulter and Roland, 1992; O'Donnell, 2000). NHS Trusts are seeking to decrease time between referral and surgery to a maximum of 18 weeks (Department of Health, 2006 (b)). Within the NHS there is therefore a constant tension between the systematic management of demand and the desire to ensure that individual patient preferences are taken into account (Darzi, 2008).

General practitioners themselves have expressed a need for a more systematic approach (McColl *et al.*, 1994). There is a need to improve the appropriateness of referral for elective surgery and to introduce guidance so that both over- and under- referral are reduced. There are important developments in this area which include the introduction of NICE guidance, particularly referral guidelines for use nationally throughout the NHS (National Institute for Clinical Excellence, 2001), along with the Patient Choice initiative and the Darzi next stage review (Darzi, 2008), all of which act in different ways to affect demand management and referral practice.

Our working definition of a referral guideline is that it is a systematic guide that should be based as much as possible on evidence and is used to assist those in primary care in making the decision whether a patient should be referred to secondary care or not.

2.1 Changes in project compared to original application

The actual research presented in this report differs from that proposed in the original application. First, in the original application the concept of patient preferences is used in two different ways: either as the wish expressed by patients to be referred or as the expression of the values that patients assign to certain health states or their quality of life. We explain in 2.4.1 that the Project Team decided that the focus of the project should be solely on preferences for referral.

Second, we proposed in the original application to carry out a large number of in-depth interviews with patients, general practitioners, nurse specialists, and consultants to identify items that should be included in the referral guideline. However, the Project Team felt after having considered the findings of the first phase of the REFER project that these interviews should not be carried out as they would add little to the work that was already completed.

Third, it was also decided that the pilot of the referral guidelines needed strengthening. Instead of piloting the referral guidelines in small samples of general practitioners, nurse specialists, patients, consultants and commissioners in the participating primary care trusts as proposed in the original application, we carried out a larger survey to determine the representativeness of the guideline development groups' ratings of referral appropriateness. These changes also reflect that the project was now focused solely on patients' preferences for referral.

As a consequence, we did not evaluate the reliability and validity of the referral tools, but compared the impact of disease severity and patients' preferences on the appropriateness ratings of referral observed in the guideline development groups and in the larger survey.

Also, we did not investigate in the survey the impact that other factors such as age, comorbidity and body mass have on the ratings of referral appropriateness. This was a pragmatic decision given that we had found that these factors did not influence the guideline development groups' views on the appropriateness of referral. Inclusion of these factors would have required that the survey questionnaire would have been considerably longer and the background information more substantial both of which might have reduced the response rate even further.

Fourth, we reduced the number of topic areas from three to two. The most important reason to do so was that the Project Team felt that we should spend as much of our resources as possible on answering the project's fundamental question of how referral guidelines can be developed that

explicitly incorporate patients' preferences rather than on the development of a third referral guideline.

2.2 Structure of the REFER project

The REFER project was divided into two phases. In the first phase of the project, we aimed to describe the context for the development of referral guidelines by undertaking a systematic review of the effectiveness of referral guidelines, a policy analysis detailing the context for the use of referral guidelines in the UK, and a survey of general practitioners' attitudes to use of referral guidelines.

In the second phase, we developed two referral guidelines taking forward the results of the first phase as much as possible.

2.3 About this report

The results of the first phase of the REFER project are described in chapters 3, 4 and 5. This work was carried out by Naomi Le Maistre and Aileen Clarke, with a major contribution from Ian Forde.

Chapters 6 and 7 describe the development of two referral guidelines, one for patients with osteoarthritis of the knee and one for men with lower urinary tract symptoms. Chapter 8 describes the representativeness of the views of the guideline development groups in members of the public and in wider groups of general practitioners and surgeons. The work in this phase was carried out by Nyokabi Musila and Jan van der Meulen, with major contributions from Aileen Clarke, Naomi Le Maistre, and Nick Black.

Chapter 9 contains a general discussion and presents overall conclusions.

Throughout the project, all members of the Project Team commented on drafts of protocols, research tools and reports. The REFER project was furthermore supported by a Steering Group. Membership of Project Team and Steering Group is presented in the Acknowledgements section.

2.4 Aims and objectives of REFER Project Phase 1

The aim of the first phase of the REFER project was to describe and assess referral tools and guidelines currently in use for referral from primary care to surgical specialties in secondary care, and to characterise their current use by general practitioners in the NHS. The specific objectives were:

1. To systematically assess referral tools or guidelines in use, in terms of their content, method of development, and effectiveness
2. To undertake an analysis of policies and initiatives, and a preliminary qualitative scoping exercise at local primary care trust level of the use of guidelines for referral from primary to secondary care in the NHS
3. To undertake a national cross-sectional survey of general practitioners using a stratified random sample to establish the current use of

guidelines for referral from primary to secondary care including the use of priority scoring tools in this context

4. To analyse and collate the findings from the policy context, the qualitative scoping exercise and the survey to produce an interim report and map for further dissemination and use in development of guidelines in Phase 2 of the REFER project

These objectives were translated into three separate pieces of work:

1. Systematic review of effectiveness of referral guidelines (Chapter 3)
2. Policy analysis of the context for the use of referral tools (Chapter 4)
3. Survey of general practitioners' attitudes to, and current use of, referral guidelines (Chapter 5)

2.5 Aims and objectives of REFER Project Phase 2

The aim of the second phase of the REFER project was to demonstrate how referral guidelines can be developed for patients with non-urgent conditions that can be treated with surgery that explicitly incorporate patients' preferences for referral. The topics of these guidelines were chosen based on the following criteria:

1. Demand from general practitioners for a referral guideline on specific topics (informed by the results of the first phase of the REFER project):
2. Availability of evidence to support the development of the guideline
3. Lack of authoritative guidance
4. Frequency of the condition
5. Uncertainty about the appropriateness of referral

On the basis of these criteria, and also considering that it is important to involve different surgical specialties, it was decided to develop

1. A referral guideline for osteoarthritis of the knee (chapter 6)
2. A referral guideline for lower urinary tract symptoms in men (chapter 7)

These guidelines were developed by groups including patients, general practitioners, surgeons and other healthcare professionals. To determine the representativeness of the views of these small groups of stakeholder and to examine the differences between the groups, we carried out a survey in wider groups of general practitioners, surgeons and members of the public (chapter 8).

2.5.1 Key definitions

Guided by the results of the first phase of the REFER project, the Project Team and Steering Group discussed the definitions of an "appropriate referral" and "patient preference".

Appropriate referral

The interviews with healthcare professionals and managers that were carried out in the policy analysis (see chapter 4) suggested that the appropriateness of a referral varies according to the “necessity”, the “direction” and the “quality” of the referral. In this context, the necessity of a referral is related to whether a patient with specific characteristics is believed to be *suitable* for referral to specialist. The direction specifies *where* or *to whom* the patient is referred. The quality depends on *how* the referral is carried out, including factors such as care provided before referral, the referral letter and the level of patient involvement.

The outcome of this discussion was that the Project Team and the Steering Group felt that the referral guideline should help general practitioners to identify those patients who are likely to benefit from a referral. Therefore, it was decided that the definition of an appropriate referral should be based on the extent to which it is likely that the referral will have a beneficial effect on a patient’s health.

Patient preferences

A further issue was that the term “preference” needed clarification. It is often poorly defined. It may reflect a patient’s view on a *health outcome*, a *healthcare process*, or a *treatment strategy* (Krahn, 2008). It was decided that the referral guidelines that were going to be developed should focus on the preferences of patients for treatment within primary care or for referral. It was felt that it was the only realistic option given that it is impossible for general practitioners and their patients to consider the preferences for all relevant healthcare processes and possible health outcomes as well as the probabilities that these may occur. Furthermore, there is hardly any research evidence on the differences in outcomes of patients with non-urgent conditions treated in primary or secondary care.

3 Systematic review of effectiveness of referral guidelines

3.1 Introduction

We undertook a systematic review of studies assessing the effectiveness of guidelines for the referral of adults with non-urgent conditions to surgical specialties in secondary care. The review was intended to inform the development of new referral guidelines in Phase 2 of the REFER project.

The gate keeper role of the general practitioner is an important determinant of demand for secondary care services. Decisions about referral to a specialist for further opinion are taken by general practitioners, and therefore access to specialist care is restricted to those whom a general practitioner considers to be appropriate. However, evidence shows that there continues to be substantial variation in general practitioner referral rates in the UK, indicating that access to surgery is not equitable (O'Donnell, 2000; Reynolds *et al.*, 1991; Wilkin *et al.*, 1987).

The implementation of standard guidance has the potential to ensure that both over and under referral are reduced. However, national guidance for the referral of common conditions to surgical specialties, such as the Referral Advice booklet published by NICE in December 2001, has not been rigorously implemented and evaluated (National Institute for Clinical Excellence, 2001) (see chapter 4). Although many other referral guidelines for non-urgent conditions have been produced, both in the UK and abroad, none are widespread throughout the NHS.

3.1.1 Related reviews

Two recently published systematic reviews have addressed a related subject area (Faulkner *et al.*, 2003; Grimshaw *et al.*, 2005). In 2003, Faulkner *et al.* carried out a review of primary care based service innovations that affect referral to secondary care. A range of intervention types were included. These were classified as "professional", "organisational", "financial and regulatory", and "public/patient oriented". In 2005, Grimshaw *et al.* reviewed interventions designed to improve outpatient referrals from primary to secondary care, including "professional educational", "organisational", and "financial" interventions.

In these reviews, referral guidelines were classified as "professional" or "professional educational" interventions. Faulkner reported that while referral guidelines had little impact on rates of referral, they often improved the quality of the process, for example by increasing the appropriateness of investigations carried out by general practitioners prior to referral. Grimshaw found that while passively disseminated guidelines had little impact on the quality or quantity of referrals, guidelines accompanied by a

structured referral sheet had a greater effect. Grimshaw's review found that organisational interventions seemed to have a more pronounced effect on referral rates than educational interventions such as referral guidelines. However, both reviews could only make tentative conclusions, due to the small number of relevant studies of adequate quality that were identified. Faulkner *et al* highlighted the problem of identifying studies on the topic of referral, which he concluded was due to poor indexing of the concept in electronic databases.

3.1.2 Aim

To identify evaluations of guidelines for the referral of adults with non-urgent common conditions to surgical specialties in secondary care in order to inform development of guidelines in Phase 2 of the REFER project.

3.1.3 Review questions

The review questions were for referral from primary care to surgical specialties in secondary care, for the care of adult patients with non-urgent conditions were as follows:

1. Do referral guidelines increase general practitioners' knowledge and awareness of appropriateness of referral?
2. Do referral guidelines increase the appropriateness of referral?
3. What is the impact of referral guidelines on costs of and outcomes of treatment?
4. Are specific aspects of the guideline development process associated with the outcomes of interest?

3.1.4 Purpose of referral

For this systematic review, we considered that referral can have a number of purposes: to meet identified clinical needs through effective diagnosis and treatment; to reduce practitioner uncertainty in primary care; to transfer responsibility to, or share responsibility with secondary care practitioners; to comply with patients' expressed preferences for treatment location; and to comply with compulsory directives or guidelines

3.2 Methods

We searched for published evaluations of guidelines for the referral from primary care of adults with non-urgent conditions to surgical specialties in secondary care. We used guidance on systematic review methods produced by the NHS Centre for Reviews and Dissemination (CRD) to develop our search strategy and assessment criteria (NHS Centre for Reviews and Dissemination, 2001).

3.2.1 Search strategy

We worked closely with information experts to develop a suitable search strategy. The final search strategy consisted of three key component topic areas. These were primary care, guidelines, and referral. Subject headings and text words were combined to ensure a high level of sensitivity. We conducted searches of Medline, EMBASE and CINAHL (See Appendix 1 for complete search strategy).

3.2.2 Study selection criteria

Populations of interest included general practitioners / primary care practitioners, and adult patients seen by a general practitioner in primary care for a non-urgent condition where referral to a surgical speciality was a management option. The interventions of interest were referral guidelines. Referral guidelines were defined as a set of rules, an algorithm or a protocol which gives guidance on the circumstances in which a formal request is made from primary care on behalf of a patient, for treatment or consultation by a specialist. A specialist was defined as a surgeon, i.e. a medical practitioner who has undertaken a recognised specific training in order to be able to undertake elective, non-urgent surgery in the included specialties.

Outcomes under investigation were both intermediate and definitive. Intermediate outcomes related to the appropriateness of referral and primary care practitioners' knowledge of the appropriateness of referral. Both of these outcomes ideally required that there should be a "gold standard" against which appropriateness could be judged. Definitive outcomes included change in health status or quality of life.

We searched for studies published since 1980. No language restrictions were imposed, and no study design was excluded from the review.

The complete table of inclusion and exclusion criteria is included in Appendix 2.

3.2.3 Study selection

One researcher (NL) screened search results to identify studies where one or more exclusion criteria were fulfilled. Abstracts of all other studies were obtained, and each was examined for eligibility by two of the three reviewers (NL, IF and AC).

Full texts of potentially relevant studies were obtained and independently assessed against the inclusion criteria of the review by two of the three reviewers (NL, IF and AC), who independently selected studies for inclusion or exclusion. Disagreements were first resolved by discussion between two reviewers, and if no consensus could be reached following this, the third reviewer adjudicated.

3.2.4 Data extraction

The data extraction form was an adapted version of a standardised pro forma suggested by the Centre for Reviews and Dissemination. The form was pilot tested by two reviewers and was found to be suitable. Data were extracted by two reviewers of the three reviewers (NL, IF and AC) and discrepancies resolved through discussion with a third reviewer (further information is available from the Project Team).

3.2.5 Assessment of study quality

Studies were appraised using the CRD hierarchy of study designs for studies of effectiveness, and a score was allocated based on this. Scores are presented in the summary table of study findings (further information is available from the Project Team).

3.2.6 Data synthesis and presentation

Due to the nature of the topic and the heterogeneity of the studies included in the review in terms of design, methods of evaluation and outcome measures, quantitative summary estimates of effect could not be calculated. The data synthesis is therefore presented in a narrative format.

3.3 Findings

3.3.1 Study selection

Initial searches of three electronic databases (Medline, EMBASE, and CINAHL) yielded 6750 papers. 6082 were excluded following a basic screening of titles by one reviewer as they met one or more of the exclusion criteria.

Titles and abstracts, where available, of 668 remaining studies were examined by two reviewers. 563 further studies were excluded with reasons. The full text of 105 papers was retrieved for further study and examined by two reviewers. Discrepancies were resolved by discussion with a third reviewer. 20 papers were identified for inclusion in the study.

3.3.2 Study characteristics

Table 1 summarises the characteristics of the twenty included studies, which are described below.

Year of publication and country of origin

Publication dates of the 20 included studies ranged from 1993 to 2005. The majority of studies were conducted in the UK, with four based in England (Fertig *et al.*, 1993; Bradshaw *et al.*, 1997; Kumar *et al.*, 1998 (a), Kumar *et al.*, 1998 (b)), three in Scotland (Thomas *et al.*, 2003; Emslie *et al.*, 1993; Morrison *et al.*, 2001) and one in Wales (Maddison *et al.*, 2004). Six studies were carried out in the US (Gatter *et al.*, 1996; Benninger *et al.*,

Table 1. Study characteristics

<i>Main Author</i>	<i>Year</i>	<i>Country of origin</i>	<i>Area</i>	<i>Ref</i>	<i>Condition/specialty</i>	<i>Study design</i>	<i>Outcomes measured</i>
Guideline plus "one-stop service"							
Thomas	2003	UK (Scotland)	Local	12	LUTS and MH	Cluster RCT	<ul style="list-style-type: none"> • Guideline compliance • Referral rates • Patient outcomes • Waiting times
Cerdan Carbonero	2005	Spain	Local	24	General surgery	Descriptive case series	<ul style="list-style-type: none"> • Guideline compliance • Waiting times • Concordance between PCP and specialist
Arroyo	2001	Spain	Local	25	General surgery	Descriptive case series	<ul style="list-style-type: none"> • Guideline compliance • Waiting time
Padilla	1998	Spain	Local	26	BPH	Descriptive case series	<ul style="list-style-type: none"> • Guideline compliance • Cost • Waiting times
Guideline plus referral triage							
Maddison	2004	UK (Wales)	Local	15	Orthopaedics	Before and after study	<ul style="list-style-type: none"> • Referral rates • Surgery conversion rate • Waiting time
Guideline plus structured management sheet							
Emslie	1993	UK (Scotland)	Local	13	Infertility	RCT	<ul style="list-style-type: none"> • Guideline compliance
Morrison	2001	UK (Scotland)	Local	14	Infertility	Cluster RCT	<ul style="list-style-type: none"> • Guideline compliance • Cost
Gatter	1996	US	Local	16	Low Back Pain	Before and after study	<ul style="list-style-type: none"> • Guideline compliance • Referral rates • Cost
Management guideline							
Benninger	1995	US	Local	17	ENT	Before and after study	<ul style="list-style-type: none"> • Guideline compliance • Referral rates • Waiting times
Spatafora	2005	Italy	National	27	LUTS	Before and after study	<ul style="list-style-type: none"> • Guideline compliance • Referral rates • Cost • Waiting times
Rao	2002	US	National	18	Low Back Pain	Before and after study	<ul style="list-style-type: none"> • Guideline compliance • Referral rates

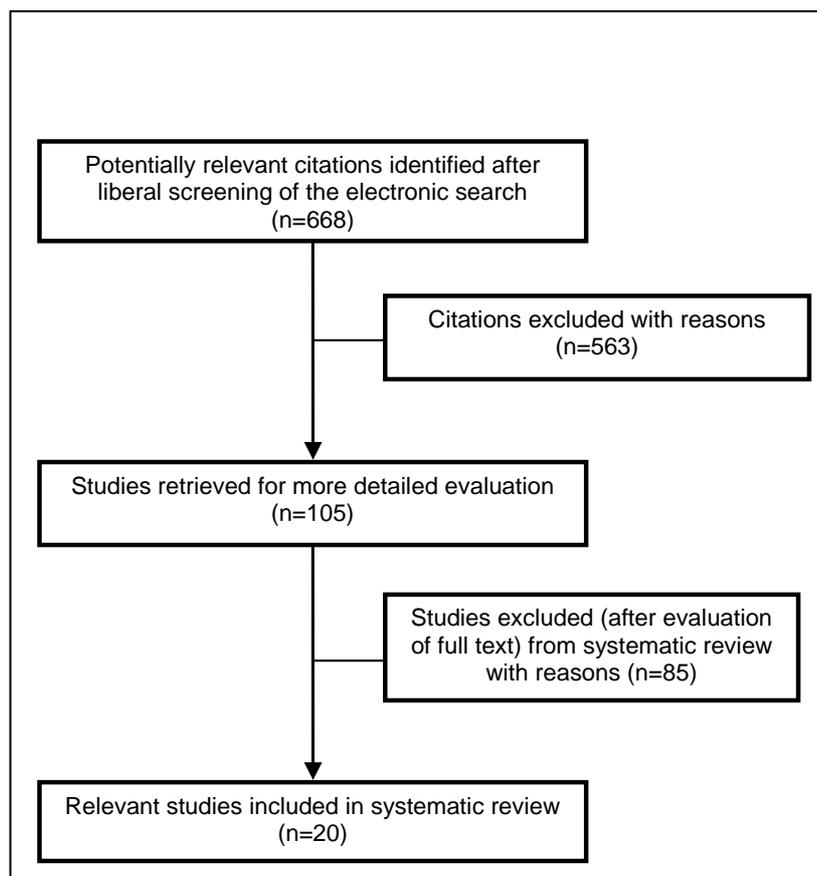
<i>Main Author</i>	<i>Year</i>	<i>Country of origin</i>	<i>Area</i>	<i>Ref</i>	<i>Condition/specialty</i>	<i>Study design</i>	<i>Outcomes measured</i>
Rossignol	1996	Canada	International	22	Low Back Pain	Descriptive case series	<ul style="list-style-type: none"> • Guideline compliance • Referral rates • Waiting times
Bishop	2003	Canada	Local	23	Low Back Pain	Descriptive case series	<ul style="list-style-type: none"> • Guideline compliance
Collins	1997	US	National	19	BPH	Cross-sectional study	<ul style="list-style-type: none"> • Guideline compliance
Management guideline plus education							
Goldberg	2001	US	National	20	Low Back Pain	RCT	<ul style="list-style-type: none"> • Surgery rates
Management guideline plus telephone based referral prior authorisation scheme							
Friedlieb	1994	US	Local	21	Low Back Pain	Descriptive case series	<ul style="list-style-type: none"> • Rate of reversal of referral decisions • Cost
Referral guideline							
Fertig	1993	UK (England)	Local	8	Orthopaedics, ENT, Gynae, Ophthalmology	Descriptive case series	<ul style="list-style-type: none"> • Referral rates
Referral guideline for direct listing for surgery							
Bradshaw	1997	UK (England)	Local	9	General surgery.	Mixed design	<ul style="list-style-type: none"> • Guideline compliance • Waiting times
Kumar	1998	UK (England)	Local	11	Tonsillectomy	Before and after study	<ul style="list-style-type: none"> • Guideline compliance
Kumar	1998	UK (England)	Local	10	Tonsillectomy	Descriptive case series	<ul style="list-style-type: none"> • Guideline compliance

1995; Rao *et al.*, 2002; Collins *et al.*, 1997; Goldberg *et al.*, 2001; Friedlieb, 1994) and two in Canada (Rossignol *et al.*, 1996; Bishop and Wing, 2003). Three were undertaken in Spain (Cerdan Carbonero *et al.*, 2005; Arroyo *et al.*, 2001; Padilla *et al.*, 1998) and the final study was carried out in Italy (Spatafora *et al.*, 2005).

Study design

The majority of studies were observational studies (Fertig *et al.*, 1993; Kumar *et al.*, 1998 (a); Collins *et al.*, 1997; Friedlieb, 1994; Rossignol *et al.*, 1996; Bishop *et al.*, 2003; Arroyo *et al.*, 2001; Padilla *et al.*, 1998). Two studies were RCTs (Emslie *et al.*, 1993; Goldberg *et al.*, 2001, and two were cluster RCTs (Thomas *et al.*, 2003; Morrison *et al.*, 2001). Seven were before and after studies (Kumar *et al.*, 1998 (b); Maddison *et al.*, 2004; Gatter and Klein, 1996; Benninger *et al.*, 1995; Rao *et al.*, 2002; Cerdan Carbonero *et al.*, 2005; Spatafora *et al.*, 2005). One study was of mixed design, using a combination of historic control data and concurrent control data depending on which outcome was being measured (Bradshaw *et al.*, 1997).

Box 1: Flow diagram of study selection process



Interventions

The twenty included studies evaluated a range of interventions. Only one study assessed specific referral guidelines which were not embedded in another intervention (Fertig *et al.*, 1993), and six evaluated management guidelines which included explicit referral criteria (Benninger *et al.*, 1995; Rao *et al.*, 2002; Collins *et al.*, 1997; Rossignol *et al.*, 1996; Bishop and Wing, 2003; Spatafora *et al.*, 2005).

Thirteen studies evaluated a guideline that was an integral part of a broader, often complex, intervention. The most common type of intervention was a "one-stop service", which was a guideline-based system enabling general practitioners to select suitable patients for surgical intervention; carry out investigations prior to referral, and refer patients. The aim was that patients would need only one outpatient appointment before having their operation. Four studies evaluated this type of intervention, including the three Spanish studies (Thomas *et al.*, 2003; Cerdan Cabonero *et al.*, 2005; Arroyo *et al.*, 2001; Padilla *et al.*, 1998). A similar type of intervention to this was guideline-based direct access to surgical waiting lists. Direct access schemes provided general practitioners with explicit criteria for the selection of patients who were definitely suitable to undergo an operation. This tended to be for relatively simple general surgical or ENT procedures, such as hernia repair or tonsillectomy. Three studies evaluated this type of intervention, all of which were UK based (Bradshaw *et al.*; 1997; Kumar *et al.*; 1998 (a); Kumar *et al.*, 1998 (b)). Two studies evaluated the same direct access scheme but at different points in time, following apparent improvements to the system. Three assessed referral guidelines accompanied by a structured management sheet (Emslie *et al.*, 1993; Morrison *et al.*, 2001; Gatter and Klein, 1996) and one evaluated a guideline with an educational package (Goldberg *et al.*, 2001). One study was of a management guideline plus a telephone-based prior authorisation scheme for referral (Friedlieb, 1994). The final type of intervention was a guideline-based referral triage scheme, whereby the guideline provided criteria for primary care practitioners to refer to a central point which re-distributed referrals in order to ensure that patients were seen by the most appropriate provider (Maddison *et al.*, 2004).

Clinical area of interest

Guidelines were most frequently developed for the referral of patients with low back pain (LBP) and other orthopaedic conditions, with eight studies concentrating on this area (Fertig *et al.*, 1993; Maddison *et al.*, 2004; Gatter and Klein, 1996; Rao *et al.*, 2002; Goldberg *et al.*, 2001; Friedlieb, 1994; Rossignol *et al.*, 1996; Bishop and Wing, 2003). The six studies which focused purely on low back pain originated in the US and Canada, while the two which looked at a broader range of orthopaedic conditions originated in the UK. Five studies were of guidelines for urological conditions; three for benign prostatic hyperplasia (BPH) (Thomas *et al.*, 2003; Collins *et al.*, 1997; Padilla *et al.*, 1998) and two for lower urinary tract symptoms (LUTS) (Fertig *et al.*, 1993; Spatafora *et al.*, 2005), one of which also looked at microscopic haematuria (MH). Three studies reported

on guidelines for the referral of a range of general surgical procedures (Bradshaw *et al.*, 1997; Cerdan Carbonero *et al.*, 2005; Arroyo *et al.*, 2001), four for referral to ENT (Fertig *et al.*, 1993; Kumar *et al.*, 1998 (a); Kumar *et al.*, 1998 (b); Benninger *et al.*, 1995), three for infertility or gynaecology referrals (Fertig *et al.*, 1993; Emslie *et al.*, 1993; Morrison *et al.*, 2001), and one for ophthalmology referrals (Fertig *et al.*, 1993).

Organisational Context

Identified studies emanated from different health systems and organisational contexts, including the NHS (e.g. Morrison 2001; Fertig *et al.*, 1993 and Bradshaw *et al.*, 1997), social insurance systems (e.g. Cerdan Carbonero *et al.*, 2005, Arroyo *et al.*, 2001, Padilla *et al.*, 1998), and US managed care, Rao *et al.*, 2002). Nevertheless all fitted the inclusion criteria (adults with a non-urgent condition amenable to surgical intervention, seen in primary care by a primary care practitioner/general practitioner and referred to a surgeon/ practitioner in a surgical specialty in secondary care for assessment).

3.3.3 Study questions

Do referral guidelines increase general practitioners' knowledge and awareness of appropriateness of referral?

Three studies reported directly on the change in provider knowledge as a result of guideline implementation (Bradshaw *et al.*, 1997; Benninger *et al.*, 1995; Padilla *et al.*, 1998). Unfortunately none of these provided control data for this outcome measure.

One study of a management guideline for ENT conditions reported on providers' awareness of guidelines, and particularly their self-reported improvement in knowledge as a result of the guideline (Benninger *et al.*, 1995). 86% of respondents reported using the guidelines, and 72% believed that the guidelines improved their ability to treat patients with these specific ENT disorders. Again, however, this study only had historic controls. A study of a one-stop service for BPH reported that the guideline improved providers' knowledge of conditions, but provided no explicit data to back this up (Padilla *et al.*, 1998). Finally, a study of direct referral onto a waiting list for general surgical procedures reported that staff were satisfied with the guideline, with over 40% of general practitioners believing that the provision of clear and concise information for use with patients was a positive feature, although again these data are not reported in relation to any controls (Bradshaw *et al.*, 1997).

Studies reached contradicting conclusions regarding the effect of guidelines on general practitioners' knowledge and awareness about the appropriateness of referral. One study reported that nearly three quarters of study general practitioners had benefited from guideline implementation; one reported that just under half of the study general practitioners had done so, and one gave no

reliable data. The methodological quality of the studies in this area was poor and it is not possible to draw conclusions on this issue.

Do referral guidelines increase the appropriateness of referral?

Appropriateness of referral was measured in a range of different ways although no study used our definition “the extent to which it is likely that the referral will have a beneficial effect on a patient’s health” explicitly. The majority of studies looked at referral appropriateness based on guideline compliance, either in terms of concordance with referral criteria or in terms of appropriateness of diagnostic investigations carried out by general practitioners prior to referral. A number looked at diagnostic concordance between primary care practitioners and specialists, and others measured numbers or rates of referral as a proxy measure for referral appropriateness.

Guideline compliance: referral criteria

Fifteen studies reported explicitly on appropriateness of referral in relation to guideline compliance (Fertig *et al.*, 1993; Bradshaw *et al.*, 1997; Kumar *et al.*, 1998 (a); Kumar *et al.*, 1998 (b); Maddison *et al.*, 2004; Gatter and Klein, 1996; Benninger *et al.*, 1995; Rao *et al.*, 2002; Collins *et al.*, 1997; Friedlieb, 1994; Rossignol *et al.*, 1996; Bishop and Wing, 2003; Cerdan Carbonero *et al.*, 2005; Arroyo *et al.*, 2001; Padilla *et al.*, 1998; Spatafora *et al.*, 2005). Only three of these provided control data.

Of the three studies which reported on the impact of guidelines on referral appropriateness in comparison to a control group, one was a cluster RCT (Morrison *et al.*, 2001) and two were before and after studies (Benninger *et al.*, 1995; Rao *et al.*, 2002). All three studies reported improvements in referral appropriateness as a result of guideline implementation. The RCT, an evaluation of a guideline plus a structured management sheet for infertility (Morrison *et al.*, 2001), reported on the proportion of patients referred before twelve months had elapsed, a practice that was recommended by the guideline only in specific and unusual circumstances. 3.3% of patients referred before 12 months in the control group were referred for guideline-concordant reasons, compared to 12.2% of the intervention group. Unfortunately the authors did not report whether this finding reached statistical significance. Both before and after studies were evaluations of management guidelines; one for low back pain (Rao *et al.*, 2002) and one for ENT (Benninger *et al.*, 1995). The ENT study reported a statistically significant improvement in the proportion of appropriate referrals after the intervention, from 45.1% to 88.1% ($p=0.019$). In a slightly different approach, the low back pain study reported that after the intervention, patients were less likely to be referred for surgical consultation at the same time as MRI scanning, and more likely to be referred purely for MRI, a finding which suggests a more appropriate use of surgical referral.

Nine studies simply measured general practitioners’ compliance with referral guidelines after the intervention was implemented, without control data (Bradshaw *et al.*, 1997; Kumar *et al.*, 1998 (a); Kumar *et al.*, 1998 (b); Gatter and Klein, 1996; Collins *et al.*, 1997; Rossignol *et al.*, 1996; Bishop

and Wing, 2003; Cerdan Carbonero *et al.*, 2005; Spatafora *et al.*, 2005). Three of the studies did not provide clear data to demonstrate either high or low concordance with guidelines (Gatter and Klein, 1996; Rossignol *et al.*, 1996; Spatafora *et al.*, 2005). Of the six that did, two indicated a good level of concordance (>95%) (Bradshaw *et al.*, 1997; Kumar *et al.*, 1998 (b)), two indicated a reasonable level of concordance (90% - 95%) (Bishop and Wing, 2003; Cerdan Carbonero *et al.*, 2005) and two reported low concordance (Kumar *et al.*, 1998 (a); Collins *et al.*, 1997).

Controlled studies measuring compliance with referral criteria in guidelines reported that appropriateness was improved. The quality of the studies and the subsequent analysis however mean that this conclusion cannot be regarded as definitive. Uncontrolled studies reported that concordance was medium to good in the majority of cases.

Guideline compliance: pre-referral evaluation

Seven studies reported on the impact of referral guidelines on the appropriateness of diagnostic evaluations carried out by general practitioners prior to making a referral (Thomas *et al.*, 2003; Emslie *et al.*, 1993; Morrison *et al.*, 2001; Cerdan Carbonero *et al.*, 2005; Arroyo *et al.*, 2001; Padilla *et al.*, 1998; Spatafora *et al.*, 2005). One of these studies was an RCT (Emslie *et al.*, 1993), two were cluster RCTs (Thomas *et al.*, 2003; Morrison *et al.*, 2001), one was a before and after study (Spatafora *et al.*, 2005) and three were observational studies (Cerdan Carbonero *et al.*, 2005; Arroyo *et al.*, 2001; Padilla *et al.*, 1998). All of these implied at least some improvement as a result of the implementation of guidelines.

Five studies, including the RCT, the two cluster RCTs and the before and after study, reported a significant improvement in the use of investigations prior to referral. One cluster RCT, evaluating a "one-stop service" for urological conditions, reported a significant improvement in compliance with appropriate use of diagnostic tests prior to referral (Thomas *et al.*, 2003). Practitioners were given a compliance "score", ranging from 0 to 5, based on the number of guideline-recommended investigations carried out before referral. Following the intervention, the mean compliance score was significantly improved in the intervention group by 0.5. The RCT, which evaluated a guideline plus structured management sheet for patients with infertility, reported a small significant difference in the percentage of referrals made with the appropriate diagnostic investigations and history-taking having been carried out by the general practitioner prior to referral (Emslie *et al.*, 1993). For example, 72% of referred couples in the study group, compared to 41% in the control group had an assessment of day 21 progesterone levels ($p < 0.001$). A second study (cluster RCT) evaluating the same type of intervention reported that referrals from intervention practices were significantly more likely to have relevant investigations carried out (Mean number of relevant tests: 2.81 v 2.50: odds ratio 1.32 95% CI 1.00 to 1.75, $p = 0.025$) (Morrison *et al.*, 2001).

The before and after study of a management guideline for patients with lower urinary tract symptoms reported an increase in the use of guideline-

recommended tests (Spatafora *et al.*, 2005). For example, the use of the digital rectal examination (DRE) in all patients presenting with the condition increased from 32% to 41.1% ($p < 0.001$). Conversely, the use of tests not recommended by the guideline decreased. For example the use of transrectal and suprapubic ultrasonography decreased from 33% to 23%, and 53% to 44%, respectively ($p < 0.001$). An uncontrolled cohort study of a one-stop service for BPH reported an improvement in general practitioners' use of investigations, but no clear data were provided to demonstrate this (Padilla *et al.*, 1998).

Two observational studies of one-stop services for general surgical referrals gave unclear conclusions (Cerdan Carbonero *et al.*, 2005; Arroyo *et al.*, 2001). Neither provided control data. One study reported that 9% of referred patients did not bring pre-operative test results with them (Cerdan Carbonero *et al.*, 2005). The second study reported simply that the appropriate tests had been carried out in 89.5% of cases (Arroyo *et al.*, 2001). The lack of control data makes it impossible to ascertain whether this was an improvement or not and if a change had occurred whether it could be attributed to the guideline.

One of the studies which reported improvements in the appropriateness of pre-referral investigations also reported that there continued to be a certain proportion of referrals made with no pre-referral diagnostic evaluation having been carried out (Spatafora *et al.*, 2005). This was a study of a management guideline for patients with lower urinary tract symptoms. The proportion of patients referred with no pre-referral diagnostic evaluation in the post-intervention cohort was similar to that before the intervention, changing only from 4.5% to 4.6%.

All studies which provided evidence reported that referral guidelines improved the appropriateness of diagnostic evaluations carried out by general practitioners prior to referral. This reported range of benefit was wide, varying from a 0.1% to a 31% increase in appropriateness of diagnostic investigations. All the randomised controlled trials however reported a significant improvement in the number of appropriate pre-referral investigations in intervention groups.

Other measures of appropriateness

There were four further measures of appropriateness adopted for studies. One was the level of diagnostic concordance between the primary care practitioner and the specialist. Two observational studies measured this. One reported 96% concordance between primary and secondary care (Cerdan Carbonero *et al.*, 2005), and the other reported 90.7% concordance (Arroyo *et al.*, 2001).

It is of interest that one of the observational studies of a management guideline plus telephone-based referral prior-authorisation scheme reported on the proportion of patients who were not referred, based on the guideline's recommendations, but whose referral decision was overturned at a later stage (in screening terminology - false negatives). General

practitioners wanted to refer 1796 patients, of whom 9% (168 cases) were refused referral by the scheme based on guideline recommendations. Of these cases, the review decision was eventually overturned in 26 (15.5%) patients whose referrals had originally been rejected, because their symptoms persisted (Friedlieb, 1994).

Finally, a single before and after study of a guideline-based referral triage programme reported that the number of referrals to two specialists simultaneously was almost eliminated as a result of the guideline, indicating an improvement in appropriateness, but that the conversion rate for surgery was unchanged, indicating that patients suitable for surgery were equally likely to be identified by general practitioners both with and without the guideline (Maddison *et al.*, 2004).

No additional conclusions about the impact of referral guidelines on appropriateness of referral can be drawn from these four studies. Although all reported a good level of referral appropriateness, only one was able to attribute improvements in some elements of appropriateness to the intervention.

Numbers and rates of referral

Eight studies reported the impact of referral guidelines on numbers or rates of referrals (Fertig *et al.*, 1993; Thomas *et al.*, 2003; Maddison *et al.*, 2004; Gatter and Klein, 1996; Benninger *et al.*, 1995; Rao *et al.*, 2002; Rossignol *et al.*, 1996; Spatafora *et al.*, 2005). A range of measures of referral were employed. These included the total number of patients referred before and after the intervention (Maddison *et al.*, 2004; Thomas *et al.*, 2003), the percentage of a given group of patients referred (Fertig *et al.*, 1993; Rao *et al.*, 2002; Rossignol *et al.*, 1996; Spatafora *et al.*, 2005), and the number of visits to surgeons per patient per year before and after the intervention was implemented (Gatter and Klein, 1996). One study reported on the number of general practitioners referring once a month or less before and after the intervention (Benninger *et al.*, 1995).

Four studies, all with a before and after design, reported that the implementation of guidelines reduced referrals (Maddison *et al.*, 2004; Gatter and Klein, 1996; Benninger *et al.*, 1995; Rao *et al.*, 2002). One evaluated a management guideline for LBP (Rao *et al.*, 2002), one evaluated a management guideline for ENT conditions (Benninger *et al.*, 1995), one evaluated a management guideline with structured management sheet for LBP (Gatter and Klein, 1996), and the final study was about a referral triage intervention for orthopaedic referrals (Maddison *et al.*, 2004). The impact of the LBP management guideline on referral was measured by assessing numbers referred either for MRI or for surgical consultation before and after the intervention was implemented. The authors also looked at the proportion of patients referred simultaneously for a surgical consultation and MRI. The percentage of the post intervention cohort who were referred solely for a surgical consultation was significantly lower, at 84% reduced from 94%, $p=0.0002$. The LBP guideline with structured management sheet was evaluated by looking at the number of specialist visits per patient, per year, before and after the intervention. The figure decreased

from 0.205 to 0.198, a reduction of 3% in specialist visits. A study of management guidelines for ENT reported that before the intervention, 24% of primary care practitioners referred patients once a month or less, and after the intervention this was increased to 42%, indicating an overall reduction in general practitioners' personal referral rates. The referral triage scheme was reported to have increased the total number of monthly referrals for musculoskeletal problems by 116%, a figure which included referrals to pain management, therapy service and rheumatology as well as orthopaedics, but to have actually resulted in a slight decrease in the number of orthopaedic referrals.

Two studies reported no difference in referral rates in intervention compared to control groups. Both were urology guideline studies. One was a cluster RCT, evaluating a "one-stop service" for LUTS and MH (Thomas *et al.*, 2003), and the other was before and after study evaluating a management guideline for LUTS (Spatafora *et al.*, 2005). The management guideline study reported that there was no change in the percentage of patients presenting with the condition who were referred to surgery before and after the intervention, and that this remained at 51.2%. Taking a different approach, the "one-stop service" study reported practice level data on the mean difference in number of referrals before and after the intervention. There was no significant difference in the number of referrals between intervention and control practices. One study reported that guidelines would have the effect of increasing numbers of referrals. However, the data were hypothetical and the reported potential increase in referral was not statistically significant. This was an observational study reporting on referral guidelines for a range of conditions (Fertig *et al.*, 1993). (General practitioners recorded data on 194 consultations including 22 referrals. Decisions were assessed and compared to referral guidelines, and general practitioners reported that if the guidelines had been followed, 2 referred patients would not have been referred and an additional six would have been referred, thus increasing the referral rate by 2.1%).

One observational study of a management guideline for LBP was unable to provide control data, and so reported only that following the intervention, 21.3% of the sample were referred to a specialist (Rossignol *et al.*, 1996). The patients included in the study had all received compensation for at least 1 day of absence from work caused by disability due to LBP. It is not possible to know whether the guidelines in this study had the effect of increasing or reducing referral rates.

We can draw no overall conclusions about the impact of referral guidelines on rates of referral based on these studies. Many studies did not report rates at all; four studies reported a reduction in referrals, three reported no change, one was unable to report the impact of the intervention on referrals and one suggested that guidelines would increase the referral rate by 2.2%. Two well-designed randomised trials reported no change in referral rates in intervention as compared to control groups with use of referral guidelines as part of broader management guidelines for lower urinary tract symptoms.

What is the impact of referral guidelines on cost and outcomes of treatment?

Cost

No studies reported formal cost-effectiveness, cost-benefit or cost-utility studies. Four reported reductions in costs and use of resources after use of a referral guideline (Gatter and Klein, 1996; Friedlieb, 1994; Padilla *et al.*, 1998; Spatafora *et al.*, 2005). One reported lower costs in control groups (Morrison *et al.*, 2001).

Two studies reported net savings as a result of the intervention. One observational study of a management guideline plus telephone-based referral prior-authorisation scheme for LBP, reported (estimated) net savings of \$400,000 and savings of \$535,000 as a result of reducing the number of inappropriate procedures carried out (Friedlieb, 1994). Another observational study of a one-stop service for BPH reported estimated annual savings of 30 million pesetas as a result of the intervention (Padilla *et al.*, 1998).

One study did not report explicitly on monetary amounts, but commented on reductions in the use of health care resources. This was a before and after study of a guideline plus structured management sheet for low back pain, and it demonstrated a significant reduction of 3% in physician visits following implementation of the intervention (Gatter and Klein, 1996).

Two studies reported on cost per referral, or per patient. A before and after study of a management guideline for patients with LUTS reported a reduction in cost from €71.82 to €61.93 per patient (Spatafora *et al.*, 2005). In contrast, a cluster RCT of a guideline plus structured management sheet for infertility reported a higher median cost per referral in intervention practices, of £251 compared to £215, but the difference was not significant (Morrison *et al.*, 2001).

No formal evaluations of the costs and benefits of referral guidelines were found. Four studies suggested that cost savings would occur after the implementation of referral guidelines. One randomised trial reported a non-significant 18% increase in costs.

Patient outcomes

Only one study reported explicitly on the impact of guidelines on patient health outcomes. This was an RCT of a "one stop service" intervention (Thomas *et al.*, 2003). Patients were sent a postal questionnaire when they were first identified and a further questionnaire twelve months after their referral. Four validated measures of health status were used: the SF36 Mental (MCS) and Physical Component Summary Scales (PCS), the anxiety component of the Hospital Anxiety and Depression (HADS) Scale, and the American Urological Association symptom score (AUA). No change in patient outcome between intervention and control groups was identified. This could be seen as a positive outcome of the intervention, although this

study also showed no effect of the intervention on referral rates and only a small (although significant) effect on the number of appropriate investigations.

Although not strictly measuring patients' definitive health outcome, a further study contains data related to the patient experience. A cluster RCT of a guideline plus structured management sheet for infertility measured the proportion of intervention compared to control couples who had a management plan agreed within 12 months of referral (Morrison *et al.*, 2001). No improvement was seen; the percentage for both being 47%.

One study assessed effect on patient health outcome and in this well-designed RCT, referral guidelines had no effects on patient outcome.

Waiting times

In addition to the outcome measures of interest, it was noticed that many studies reported the impact of referral guidelines on waiting times and delays experienced by patients. Nine studies reported the impact that interventions had on waiting times (Bradshaw *et al.*, 1997; Thomas *et al.*, 2003; Maddison *et al.*, 2004; Benninger *et al.*, 1995; Rossignol *et al.*, 1996; Cerdan Carbonero *et al.*, 2005; Arroyo *et al.*, 2001; Padilla *et al.*, 1998; Spatafora *et al.*, 2005). Unfortunately, synthesis is difficult because a variety of start and end points were used. Periods of time that were measured were: time from referral to first specialist consultation (Thomas *et al.*, 2003; Maddison *et al.*, 2004; Arroyo *et al.*, 2001; Padilla *et al.*, 1998); time from referral to surgery (Bradshaw *et al.*, 1997; Cerdan Carbonero *et al.*, 2005); and time from first general practitioner visit to final diagnosis (Spatafora *et al.*, 2005). Complicating matters further, two explicit ways of measuring the outcome were employed. An alternative to looking at patients' average waiting time was to examine the percentage of eligible patients seen by a specialist within a given time frame from the date of referral (Maddison *et al.*, 2004; Benninger *et al.*, 1995; Rossignol *et al.*, 1996).

Overall, six studies reported reductions in waiting times (Bradshaw *et al.*, 1997; Maddison *et al.*, 2004; Benninger *et al.*, 1995; Cerdan Carbonero *et al.*, 2005; Arroyo *et al.*, 2001; Padilla *et al.*, 1998), one study reported improvements for one condition but no change for another (Thomas *et al.*, 2003), one study reported no change (Spatafora *et al.*, 2005), and the final study reported that concordance with guideline waiting time recommendations was low (Rossignol *et al.*, 1996).

Four studies measured time from referral to first specialist consultation (Thomas *et al.*, 2003; Maddison *et al.*, 2004; Arroyo *et al.*, 2001; Padilla *et al.*, 1998). A cluster RCT of referral to a "one-stop service" for referrals for LUTS and MH reported an overall reduction of 11 weeks in waiting times for all urological referrals, and a reduction of 30% in waiting times for patients with LUTS, but no change in waiting times for patients with MH (Thomas *et al.*, 2003). A before and after study of referral triage for orthopaedic referrals reported a reduction from just over 50 weeks before the

intervention, to just over 20 weeks after the intervention (Maddison *et al.*, 2004). Two observational studies stated that waiting times were reduced. One was a study of a one-stop service for general surgical conditions which achieved a wait of 38 days for hernia patients, compared to the 2 years figure that routine data apparently suggested (Arroyo *et al.*, 2001). The second was a one-stop service for BPH which had no control data but gave waiting times from two points in the study after the intervention was implemented (Padilla *et al.*, 1998). The waiting time was 14 days in 1996 and 3 days in 1997, implying a continued reduction in waiting times although this cannot necessarily be attributed to the effects of the one-stop service.

Two studies measured time from general practitioner referral to surgery, and both reported reductions in the waiting time. One was a mixed design study, citing cohort data with both concurrent and historic controls (Bradshaw *et al.*, 1997) and one was a before and after study (Cerdan Carbonero *et al.*, 2005). The controlled cohort study examined the impact of a direct access to surgical waiting list intervention, and reported that for hernia patients, the median wait for intervention patients was 91 days less than that for control patients ($p < 0.0001$). The before and after study looked at a one-stop service for general surgical referrals and reported that after the intervention, time from referral to surgery was 1.9 (+/- 1.2 months), reduced from 4.8 months.

One study measured time from first general practitioner visit to final diagnosis (Spatafora *et al.*, 2005). This was a before and after study of a management guideline for LUTS, and it reported no significant change. The waiting time changed only from 29 to 28 days.

Three studies measured either a number or percentage of patients seen by a specialist in a specified time frame from the date of referral (Maddison *et al.*, 2004; Benninger *et al.*, 1995; Rossignol *et al.*, 1996). Two of these studies were before and after studies, and both reported an improvement. The first, an evaluation of a management guideline for ENT conditions, reported an increase from 39% to 59% of patients seen within a month of referral ($p = 0.019$) (Benninger *et al.*, 1995). The second, an evaluation of a referral triage intervention for orthopaedic referrals, reported an overall decrease in the number of patients waiting more than four months for their initial outpatient appointment, from 823 patients in August 2002 to 607 patients in September 2003¹⁵. The final study was an observational study examining the impact of national LBP management guidelines (Rossignol *et al.*, 1996). It reported that only 61.5% of referred patients were seen within the timeframe recommended by the guideline, implying that concordance was low.

The majority of studies reported that referral guidelines appeared to be associated with reductions in waiting times and delays experienced by patients. However, attribution of any effect to the interventions is problematic since waiting times and delays are multifactorial and local, thus even findings where the study design is good and attribution is clear are not necessarily generalisable.

Are specific aspects of the guideline development process associated with the outcomes of interest?

Twelve of the twenty included studies included information about the guideline development process. In summary, the most important features of the guideline development process, used in various combinations, were consensus development panels (Morrison *et al.*, 2001; Gatter and Klein, 1996; Rao *et al.*, 2002; Friedlieb, 1994; Arroyo *et al.*, 2001; Spatafora *et al.*, 2005), multidisciplinary panels (Morrison *et al.*, 2001; Benninger *et al.*, 1995; Cerdan Carbonero *et al.*, 2005), specialist experience (Emslie *et al.*, 1993; Gatter and Klein, 1996; Benninger *et al.*, 1995; Rao *et al.*, 2002; Friedlieb, 1994; Bishop and Wing, 2003; Spatafora *et al.*, 2005), general practitioner consultation (Emslie *et al.*, 1993; Maddison *et al.*, 2004; Benninger *et al.*, 1995; Spatafora *et al.*, 2005), and literature review (Emslie *et al.*, 1993; Morrison *et al.*, 2001; Gatter and Klein, 1996; Benninger *et al.*, 1995; Friedlieb, 1994; Bishop and Wing, 2003; Padilla *et al.*, 1998; Spatafora *et al.*, 2005). Of the four which involved general practitioners in the development process, three were before and after studies and one was an RCT. All reported improvements for at least one outcome measure as a result of implementation of the guideline.

None of the studies included an explicit comparative evaluation of different development methods. Most studies reported benefits which they attributed to the interventions under investigation - however because of the heterogeneity and variable quality of the studies, it is impossible to assess whether any particular methods of development might be more or less likely to result in beneficial outcomes.

3.4 Discussion

Unlike the two reviews discussed earlier, this review focuses solely on referral guidelines as the intervention of interest. We placed a further restriction, in that the guidelines needed to be for the referral of adults with non-urgent conditions to surgical specialties. This ensured that the review met the needs of the REFER project. Extensive work went into developing a search strategy which accurately covered the full range of terms that may be used to describe the concept of "referral", and as a result we have identified a number of additional relevant studies to these existing reviews.

Although we considered evidence from other health systems, we were primarily interested in findings that are applicable to the NHS in the UK. It should be noted that the evidence derived from the systematic review does not directly relate to current developments within the NHS such as integrating and sharing care and specialist skills across organisational boundaries through e-health and polyclinics. Also, the role of private referrals or referrals for complementary or alternative treatments did not arise within the context of our thorough search strategies.

An important concomitant observation is that only eight of the guidelines explicitly mentioned literature review as part of their development process, which suggests that some of the referral guidelines included in this review are clearly not themselves based on strong evidence.

3.4.1 Summary of findings

Our search strategy identified 20 studies of which only four used randomised designs; nine studies were uncontrolled observational studies and the remaining seven used historic controls, also known as before and after designs. Studies were from a number of different countries - eight studies were from the UK and eight from North America, with the remainder from Spain and Italy. Guidelines covered a number of different conditions including low back pain (LBP) and other orthopaedic conditions (8), urological conditions (4), ENT (4), general surgical procedures, infertility or gynaecology and ophthalmology.

It is of note that only one simple referral guideline study was identified. It is possible that this does not reflect the actual prevalence of standalone referral guidelines. In the studies we found there were three types of complex intervention. A referral guideline plus structured management sheet intervention, and a referral guideline plus education package intervention, appear to have a common concern in including mandatory referral forms to complete, presumably to heighten physician awareness of recommendations. One-stop services and direct access to waiting list schemes share a common feature of streamlining access to secondary care. The management guideline plus telephone-based referral prior-authorisation scheme appeared to be concerned purely with acting as a deterrent to referral.

1. Studies reached contradictory conclusions regarding the effect of guidelines on general practitioners' knowledge and awareness of appropriateness of referral for the condition under investigation.
2. Controlled studies measuring compliance with guideline referral criteria reported improvements. Uncontrolled studies also reported that guideline compliance was medium to good in the majority of cases.
3. All studies which provided evidence, reported that referral guidelines improved the appropriateness of diagnostic evaluations carried out by general practitioners prior to referral. We could draw no overall conclusions about the impact of referral guidelines on rates of referral based on the studies identified. However, two well-designed randomised trials reported no change in referral rates in intervention as compared to control groups.
4. No formal evaluations of costs and benefits of referral guidelines were found. Four non randomised studies estimated that guidelines would engender cost savings whilst one randomised trial reported a non-significant 18% increase in costs.
5. Only one study assessed patient outcomes. No effects were found by this well-designed RCT on patient health outcome.

6. The majority of studies reported reductions in waiting times. However attribution of any effect to referral guidelines is problematic.
7. Studies provided no information on whether specific aspects of the guideline development process were associated with the outcomes of interest

The evidence base for referral guidelines is poor. Whilst they may improve appropriateness of referral, it is difficult to assess any independent effect due to the lack of comparison groups in many studies. Well designed studies reported improvements to process measures, e.g. compliance with referral criteria and recommended diagnostic tests. No evidence was found for effects of referral guidelines on practitioners' knowledge of appropriateness of referral, on rates of referral, or on health outcomes or costs. No conclusions could be drawn on specific development aspects of guidelines associated with better outcomes. More research on referral and on guidelines to improve referral would be valuable.

3.4.2 Conclusions

If referral guidelines have an effect it may only be as a result of use as part of a broader referral management programme or complex intervention, but the evidence base is on the whole poor and no strong conclusions can be drawn. The heterogeneous studies we found of guidelines for referral from primary care to surgical specialties in secondary care, for the care of adult patients with non-urgent conditions, almost uniformly reported benefits of referral guidelines. However the attribution of the benefits to the use of the guidelines is not straightforward. Well designed studies reported improvements to process measures such as compliance, for example, with regard to referral criteria and recommended diagnostic tests; but we found no evidence of effects of referral guidelines on practitioners' knowledge of appropriateness of referral, on rates of referral, or on health outcomes or costs.

3.5 Implications for development of referral guidelines

1. Referral guidelines appear on the whole to be of benefit, but this conclusion should be made with caution due to insufficient evidence.
2. It will be valuable to develop guidelines for conditions which have not yet been addressed in existing good quality studies. For example, good quality RCT studies already exist of infertility referral management programmes. Therefore it may be valuable to extend knowledge by selecting alternative topic areas for guideline development.
3. It is important to consider whether guidelines should be developed in isolation or as part of a more general referral organisation and management package.
4. It is be important to undertake a formal evaluation of any guidelines produced.

4 Policy analysis: context for referral tools

4.1 Introduction

The current policy context for referral and development of referral guidelines is changing rapidly. This policy analysis was undertaken to inform the development of referral guidelines in the second phase of the REFER project.

Aims were:

1. to develop an overview of the current national policy context for the use of tools for referral from primary to secondary care
2. to develop an understanding of the policy context at local level for the use of tools for referral from primary to secondary care
3. to identify conditions where new referral tools are needed.

The policy analysis was carried out in three parts:

1. an analysis of relevant websites and policy documents
2. semi-structured interviews with key informants: experts in the field and representatives of stakeholding organisations
3. a qualitative survey of five primary care trusts and their associated acute hospital trusts.

4.2 Website and documentary analysis

4.2.1 Aims

We aimed to identify and analyse relevant websites and policy documents to contribute to an overview of the policy context for the use of tools for referral from primary to secondary care. The website and documentary analysis was intended to complement the findings of the two sets of qualitative interviews.

4.2.2 Methods

We looked both specifically at guidelines for the referral of adults with non-urgent conditions to surgical specialties in secondary care, and more generally at policies affecting general practitioner referral behaviour and related issues.

To identify existing guidelines for referral currently in use in the UK and internationally we consulted known resources for clinical practice guidelines, in particular websites for relevant organisations such as the National Institute for Health and Clinical Excellence (NICE), the Scottish

Intercollegiate Guidelines Network (SIGN), the National Guideline Clearinghouse (a US source), the New Zealand Guidelines Group, the Cochrane Collaboration Effective Practice and Organisation of Care (EPOC) group and the National Electronic Library for Health. We also consulted the websites of the UK Royal Colleges and relevant specialty associations.

To identify relevant information relating to broader issues that may have an impact on the referral practice of general practitioners we searched for grey literature on topics such as referral from primary to secondary care, demand management, and clinical practice guidelines. Sources included websites for the Department of Health, NICE, the Royal Colleges, and the British Medical Association

Websites of relevant organisations were examined. All relevant policy documents and referral guidelines were retrieved for closer study. Website and document content relevant to the REFER project's aims were analysed by two researchers, and their impact on referral to surgical specialties was agreed. Findings of the website and grey literature analysis are presented in the form of a narrative descriptive summary.

4.3 Key informant interviews

4.3.1 Aims

Our aim in carrying out semi-structured interviews with representatives of stakeholding organisations and other experts was to develop an overview of the current national policy context for the use of tools for referral from primary to secondary care.

4.3.2 Methods

Development of interview topic guide

We developed an initial draft of the interview topic guide which consisted of five core sections:

1. the interviewee's role and background in the topic area;
2. variation in referral rates and referral appropriateness, including the participant's views on whether these are important and why;
3. the role of referral guidelines and their usefulness in addressing the issue of referral variation;
4. the participant's experience of developing referral guidelines and any lessons learnt;
5. other comments and suggestions for further contacts.

The initial draft of the topic guide was tested in a small number of interviews and revised so that the structure was logical and no important sub-topics were excluded.

Sampling strategy

We purposively sampled representatives of organisations who we considered to have an interest in the issue of referral from primary to secondary care, and other experts in this policy area. We identified potential study participants using existing contacts held by the Project Team and study Steering Group, as well as information available on organisations' websites.

The organisations approached were the Department of Health (DH), the National Institute for Health and Clinical Excellence (NICE), the (now disbanded) NHS Modernisation Agency, the Royal College of General Practitioners (RCGP), and the Royal College of Surgeons of England (RCS). We also invited academics with experience of guideline development and related areas of research (priority scoring, variation in referral rates, and guideline effectiveness) to participate.

We initially contacted potential interviewees by letter, enclosing a copy of the study protocol. We informed invitees that we would contact them by telephone within two weeks to invite them to take part in an interview.

Interviewing and analysis

Interviews were face-to-face and lasted approximately one hour. All interviews were tape-recorded and transcribed for the purposes of analysis. Interviews were analysed using N6, with analysis being guided by the Framework method (Ritchie and Spencer, 1993). This has been developed for qualitative research which is focused on policy analysis. It uses five stages of familiarisation; identifying a thematic framework; indexing themes from interviews systematically on the basis of the framework; and charting, mapping and interpretation.

4.4 Qualitative PCT survey

4.4.1 Aims

We carried out a qualitative survey of five primary care trusts using semi-structured interviews to develop a detailed representation of the policy context at local level for the use of tools for referral from primary to secondary care.

4.4.2 Methods

Development of interview topic guide

We developed an initial draft of the interview topic guide which consisted of five broad sections:

1. the background of the primary care trust or acute trust and the interviewee's role;

2. local referral patterns, including areas for concern or interest and interventions relating to these;
3. local use of referral guidelines;
4. impact of national policy on local referral patterns;
5. other comments including any general advice for guideline development.

The initial draft of the topic guide was tested in a small number of interviews and revised so that the structure was logical and no important sub-topics were excluded.

Sampling strategy

We purposively sampled five primary care trusts with contrasting locations and population types. Some primary care trusts were known to be implementing various measures to manage demand, for example as “early adopters” of Practice Based Commissioning, while others were known to be less active in this area. To develop a balanced representation of the policy context for referral in each locality we interviewed staff both in the primary care trusts and in their corresponding acute trusts. Suitable participants included senior staff with an interest in referral practice such as Chief Executives, PEC Chairs, Directors of Public Health in primary care trusts and Medical Directors, and frontline staff including general practitioners, consultants and physiotherapists.

Within each primary care trust we identified initial interview participants using a combination of existing contacts and direct communication with Chief Executives and PEC Chairs. We went on to use a snowballing approach to identify further contacts, asking interviewees in the interview setting to suggest other potential participants.

A letter was sent to potential participants, enclosing a copy of the study protocol. The letter contained information about the study and told the recipient that they would be contacted by a member of the Project Team within two weeks and invited to take part in a semi-structured interview. On contacting the individuals, it was not possible for them to participate in some cases, but where this happened they were asked to suggest a suitable alternative interviewee to participate in the study.

Interviewing and analysis

Interviews were face-to-face and lasted approximately one hour. All interviews were tape-recorded and transcribed. Interviews were analysed using N6, with analysis guided by the Framework method.

4.5 Results

Key informant interviews were carried out with four academics who were experts in the field and seven representatives of stakeholding organisations. Stakeholding organisations were the NHS Modernisation Agency (2), NICE

(2), the Department of Health (1), the Royal College of Surgeons (1) and the Royal College of General Practitioners (1).

Table 2. PCT characteristics

<i>PCT</i>	<i>ONS Supergroup</i>	<i>Star rating 2004</i>	<i>Population (approx)</i>	<i>Interview participants</i>	<i>Characteristics</i>
1	Cities and Services	-	165,000	-Joint medical director/general practitioner -Joint medical director/audiology consultant (acute trust) -Director of Public Health	-Predominantly working class, poor, low average income, high deprivation, high mortality from chronic diseases -18% ethnic minority -"An outer London borough with inner London characteristics"
2	Prospering UK	**	260,000	-Head of Primary Care -Service Development Manager -general practitioner/PCT medicines management team -General surgeon (acute trust)	-Over 7 town areas -Variation – some areas of high deprivation; some very affluent areas -High variation – elderly population high in 2 towns -Lots of rural areas -"Discrete populations with quite discrete health needs" -Very low ethnic minorities except for quite high Polish population in one area
3	Coastal and Countryside	***	110,000	-Lead Commissioning general practitioner -Specialist Orthopaedic Physiotherapist -general practitioner -Joint medical director (acute trust) -Director of Operations (acute trust)	-Over 7 market towns -High number of retired elderly along coast -7 Community Hospitals, quite strong communities
4	Prospering UK	**	150,000	-Director of Commissioning -Development Nurse -Chief Executive -Director of Planned Care and Acting Director of Tertiary Services (acute trust) -Consultant general and colorectal surgeon (acute trust)	-Over one town, one semi-rural town and one very rural locality -Quite prosperous, a few small pockets of deprivation. -Average, with some small areas with a high elderly population -Mix of rural, semi-rural and towns
5	London Centre	*	222,000	-Consultant in Public Health -Information Manager -Head of Public Health Intelligence -Public Health Information Analyst Medical Director (Joint role)	-Quite affluent but including some of the most deprived areas in the country Specialist services e.g. for high numbers of homeless

For the qualitative primary care trust survey we carried out interviews with between three and five staff in each primary care trust and their corresponding acute NHS Trust, interviewing 22 people in total. Table 2 shows the characteristics of the five participating primary care trusts.

Summary results are presented under the following headings:

1. Overview and broad description of policy context in relation to referral
2. Interest in referral: concern about numbers, appropriateness
3. Role of guidelines: especially in contrast to organisational interventions
4. General practitioner role: perceptions of general practitioners and their own views of their workload
5. Patient involvement & experience of referral process

4.5.1 Overview and broad description of policy context, in relation to referral

Major organisational change is a key characteristic of current UK health policy. Policy relating to referral from primary to secondary care is particularly complex and in a seemingly constant state of transformation. Important national policies with a perceived impact on referral practice include Choose and Book (Department of Health, 2004 (a)) Practice Based Commissioning (Department of Health, 2004 (b)) Payment by Results (Department of Health, 2006 (a)) and the national tariff; the GMS contract (Department of Health, 2003) and the Quality and Outcomes Framework (Department of Health, 2004 (c)) and Commissioning a Patient Led NHS (Department of Health, 2005).

The individual effects of some of these innovations are hard to predict as they are rolled out over the next 12 months, but as one of our senior stakeholder interviewees commented, their combined effect can only be guessed, even by those designing such policies.

At a local level and partly in response to NHS policy, a number of primary care trusts have introduced a range of measures to monitor and control specialist referrals. These are Clinical Assessment Services, which are also known as referral triage or Tier 2 schemes.

Explicit national referral guidelines for non-urgent conditions are not widely used; NICE referral advice published in 2001 was not rigorously implemented. A small number of local referral guidelines have been developed and implemented, but these had not been evaluated in the study primary care trusts. In addition to variation in the availability and uptake of guidelines, there is wide variation in local availability of services. Some general practitioners, for example, do not have access to certain diagnostic services (Barking and Dagenham: general practitioners do not have access to MRI scanning), while others are affected by short-staffing in certain specialties in their local acute trust (Central Cheshire: lack of rheumatologists).

It is important to remain aware of changes and complex organisational structures into which new guidelines will need to fit. The current changes in the NHS mean that current organisational structures at primary care trust level may soon be disbanded. Guidelines will need to be sensitive enough to adapt to local variations in structure and availability of services.

4.5.2 Interest in referral: concern about numbers, appropriateness

While primary care trust staff reported that high numbers of unnecessary¹ referrals were a problem, consultants and general practitioners themselves usually found it difficult to identify what might constitute an inappropriate referral².

There is clearly a significant amount of interest at primary care trust level in numbers and appropriateness of referrals to secondary care. From a demand management perspective, and also in an attempt to make best use of primary care trust resources, a reduction in unnecessary referrals to specialists was seen by interviewees as obviously desirable. A range of methods was adopted to measure referral rates and reasons for referral, as well as to control numbers of referrals. All five primary care trusts had either implemented or were considering implementing special Clinical Assessment Services or schemes or "Tier 2" schemes. These usually focused on specific conditions or specialties where a need was identified. The need for intervention was based on a number of factors, which included numbers of procedures carried out, waiting times for outpatient appointments, and referred patients' conversion rates to surgery. The most frequently mentioned specialty was orthopaedics. Other important areas were ENT, gynaecology and vascular surgery.

In contrast, general practitioners and consultants tended not to agree that patients were being referred inappropriately. General practitioners were confident that their decision making was appropriate and consultants tended to trust general practitioners' judgement. Patient-initiated referrals, whereby a patient requested a referral that was deemed clinically inappropriate by both the general practitioner and the specialist, were recognised as something which happened relatively infrequently, but in these cases it was generally accepted that there was no option but to refer the patient.

There is a discrepancy between the medical view and the view of primary care trust managers as to the extent of and nature of inappropriate referral to specialists. There is a perceived need within primary care trusts from a demand management perspective for measures to address unnecessary referrals. Primary care trusts may support the development and implementation of referral guidelines for conditions and specialties that they have identified as priority areas.

¹ Unnecessary referral was usually defined by respondents as one where the patient would normally be expected to be cared for in a primary care setting.

² Most respondents, general practitioners as well as consultants, defined the appropriateness of referral as the extent to which it is likely that the referral will have a beneficial effect on a patient's health (see also 2.5.1).

4.5.3 Role of guidelines: especially in contrast to organisational interventions

Both primary care trust staff and general practitioners found it difficult to identify any referral guidelines for non-urgent conditions, national or local, that were currently being used. There was a general sense of awareness of the NICE *Referral Advice* booklet, but this had not been rigorously implemented and its content was considered to be simplistic. Interview participants who were aware of the guidance reported that it had not had any impact on local referral practice.

At a national level the two week rule system for urgent referral of patients with suspected cancer was seen by both general practitioners and primary care trust staff to work well and to have become well embedded.

Some local referral guidance had been developed, for example as part of the local implementation of Choose and Book (Central Cheshire, referral guidelines for range of conditions). Other guidelines had initially been developed as local guidance in other primary care trusts and subsequently adopted by primary care trusts in our study (Witham Braintree and Halstead, varicose veins referral guideline). Primary care trusts did not have information about the uptake and effectiveness of these guidelines. However there was a general feeling among participants that general practitioners did not like guidelines and that they were therefore difficult to implement effectively.

General practitioners reported that guidelines in general were difficult to use simply because they received so many. It seemed to be difficult to sift through them, assess them and make a decision regarding which were useful and which were not. An important issue for general practitioners is the short amount of time they have to assess patients in the consultation setting.

Many interviewees described a seemingly well-known process of passive dissemination of guidelines which are then not used and which therefore have little or no impact on practice. This perception in combination with the perceived reluctance of general practitioners to use guidelines has contributed to decisions to develop and implement organisational interventions to address referral appropriateness instead. In the last twelve months, guidelines have increasingly been disregarded in favour of organisational interventions such as Clinical Assessment Services in their various forms. Primary care trusts have shared learning and adopted interventions that have been successful in other parts of the country. Organisational interventions are seen as an easier and more effective way of quickly reducing numbers of referrals and increasing referral appropriateness because they do not require the education or even co-operation of general practitioners.

Widespread passive dissemination of guidelines is perceived as commonplace and ineffective and has caused a reduction in confidence in the ability of guidelines to influence practice. It is thought that guidelines will work if they are disseminated and

implemented using methods that are proven to be effective or embedded in the referral process as with the two week rule. Good quality referral guidelines may be welcomed by general practitioners as an educational alternative to organisational measures which question their skill and damage their relationships with primary care trusts.

4.5.4 General practitioner role: perceptions of general practitioners and their own views of their workload

A strong sense of general practitioner overburdening and fatigue came across in interviews both with primary care trust senior staff and with general practitioners themselves. General practitioners have recently been inundated with a proliferation of policies and interventions that they are required to acknowledge and adhere to in everyday practice; including Choose and Book, the Quality and Outcomes Framework, and Practice Based Commissioning. Those that were using Choose and Book or who knew about it were concerned that Choose and Book was already taking extra time in the consultation.

A new referral guideline should not be seen as an additional piece of work that will take up valuable time in the general practitioner consultation, but should be integral to and streamline the referral process. The two week rule system for urgent referral for suspected cancer may be a good model to emulate.

4.5.5 Patient involvement & experience of referral process

While primary care trusts' main source of pressure was clearly a need to make best use of resources, there was a strong sense of commitment to ensuring patients had a good experience of the referral process. Referral management interventions were believed to have a number of benefits for patients, including extended consultations with non-consultant specialists (e.g. physiotherapists) and reduced waiting times for those patients who were referred to a consultant. General practitioners clearly described the involvement of patients in referral decisions as essential and listed a number of reasons for referral including diagnosis, development of a primary care clinical management plan, investigation and reassurance (of doctor or patient) as well as listing for surgical intervention.

Referral guidelines could potentially have the same benefits to patients as referral management schemes. They should take advantage of the wide variety of services available (general practitioners with special interests, physiotherapists etc) and enable general practitioners to enter a dialogue with patients to decide which is the most appropriate.

4.5.6 Conclusions

Unprecedented change is occurring in the NHS. Unevaluated and previously untried methods for demand management of referrals are being introduced

at primary care trust level in “Tier 2” systems which have become widespread, but which may not remain in the new NHS structures. These changes exemplify what appears to be a different approach to appropriateness of referral between doctors and managers. However, they also mean that guidelines will need to be adaptable to different situations. Interviews were not on the whole helpful in identifying conditions where new referral tools are needed. Successful guidelines are likely to be those which are integral to and can become embedded in the referral process and which acknowledge the input of the patient into the referral decision.

4.6 Implications for development of referral guidelines

1. When developing new referral guidelines, it will be important to pay close attention to developments in health policy relating to referral in order to ensure that the guidelines will fit into existing structures. Current policy changes suggest that primary care trusts may change dramatically, whilst general practitioners entering the process of Practice Based Commissioning may welcome referral guidelines.
2. It will be essential to be aware of the wide variations in local availability of services, and to ensure that any new guidelines are sensitive and adaptable to these variations.
3. It will be useful to seek support from primary care trusts or their new replacements in implementing referral guidelines: to do this it may be helpful to address conditions that have already been identified by primary care trusts as priority areas (e.g. orthopaedics). However, interviews were on the whole not helpful in identifying conditions where new referral tools are needed.
4. In addition to developing good quality referral guidelines it will be essential to ensure that methods of implementation are considered at the time of design, for example, by ensuring that the guideline is integral to the referral process.
5. Guidelines should be advocated as an alternative to Clinical Assessment Services or other similar organisational interventions, by emphasising that in contrast to these, they acknowledge general practitioners’ decision making skills and training, and return them to their role of gate-keeper.
6. Efforts should be made to ensure that new referral guidelines aid general practitioners by streamlining the referral process and that they do not simply increase their workload. It may, for example, be appropriate to bring referral decision making and the Choose and Book process together in a single tool.
7. Guidelines should enable general practitioners to enter a dialogue with patients to decide whether referral is appropriate, and should provide clear information for patients to help general practitioners explain when referral is not clinically appropriate.

5 Survey of general practitioners' views and use of referral guidelines

5.1 Introduction and aims

Several studies in recent years have been carried out to examine general practitioners' attitudes to clinical practice guidelines and to identify characteristics which affect the use of guidelines by practitioners. For example, evidence has shown that general practitioners are more likely to use guidelines which are clear, concise and accessible (Langley *et al.*, 1998; Young and Ward, 2001; Coleman and Nicholl 2001), evidence-based and from a credible source (Sturmburg, 1999; Grilli *et al.*; 1999; Gupta *et al.*, 1997). In a series of twenty qualitative interviews with general practitioners in the Avon region, Langley *et al* found that general practitioners were more likely to accept guidelines if they had a sense of ownership of them, and if the guidelines were believed to be relevant to everyday practice (Langley *et al.*, 1998). This research also suggested that guidelines need to address issues which are perceived as relevant by general practitioners, for example, conditions which are seen rarely or where practice is changing (Langley *et al.*, 1998). However, few studies have looked in detail at the ways in which guidelines are used by general practitioners, and their motivation for using them.

Our principal aim in carrying out a nationally representative survey of general practitioners in England was to gather data to inform the development of new referral tools in Phase 2 of the REFER project.

In particular, we aimed to:

1. Explore general practitioners' attitudes to, and current use of, referral guidelines and tools
2. Identify conditions for development of new referral guidelines
3. Explore general practitioners' attitudes to patient involvement in the referral decision

5.2 Methods

5.2.1 Questionnaire development

An 8-page self-completion questionnaire was developed based on previous research and the knowledge of the research team. An initial draft was tested with ten general practitioners, who were given a choice of how to provide feedback (either by commenting in writing or by taking part in cognitive pilot interviews, in which they were asked to explain their thoughts as they worked through the questionnaire). Feedback from the

pilot was used to revise questions and response options. The final draft of the questionnaire was pilot-tested with a further ten general practitioners to ensure clarity of language and question-wording, and to ensure that response options were exhaustive and mutually exclusive, where applicable.

The development of questions for each topic area is discussed in detail below (see Appendix 3).

Definition of “referral guidelines”

In the introductory text, referral guidelines were defined as “any structured paper-based or computer based guide designed to assist those in primary care in making the decision whether or not to refer a patient to another professional”.

Questions 1.2, 1.3, and 1.5: Identifying how and why general practitioners use guidelines and support required for guideline use

These questions were included as a result of cognitive interviews with general practitioners at the pilot stage, in order to gain a clear idea of the role guidelines play in general practitioners’ everyday practice. Questions 1.2 and 1.3 asked general practitioners “how” and “why” they used guidelines, and Question 1.5 was designed to find out about which types of support would contribute to more widespread use of guidelines by practitioners.

Questions 1.1 and 1.4: Identifying common conditions for guideline development

A key purpose of the survey was to help identify conditions for development of new referral guidelines. We were interested in identifying conditions for which general practitioners have used, or currently use, referral guidelines, and conditions where they believed new guidelines are needed. The two questions covering this issue are Q1.1 and Q1.4.

Response options for both questions consisted of a list of common, non-urgent conditions amenable to elective surgical intervention. The Department of Health Hospital Episode Statistics (HES) data for England for 2003/4³ were used to identify all conditions where a minimum of 10,000 elective procedures per annum were carried out, and where direct referral to a surgeon could be expected. We included only conditions that could be considered non-urgent at the time of surgery.

The final list of conditions was as follows:

1. Back pain
2. Osteoarthritis of knee
3. Varicose veins

³ Department of Health’s Hospital Episode Statistics (HES) for the years 2003 – 2004 located at <http://www.dh.gov.uk/assetRoot/04/09/71/18/04097118.xls> (accessed 30.03.2006)

4. Menorrhagia
5. Sterilisation
6. Osteoarthritis of hip
7. Prostate problems
8. Stress incontinence
9. Inguinal hernia
10. Cataract
11. Haemorrhoids
12. Infertility

Question 2: Measuring attitudes to patient involvement in the referral decision

Three existing alternative measures of general practitioner attitudes to patient involvement in decision making were tested with ten general practitioners in the early stages of the questionnaire development process. Tools tested were the "Sharing" subscale of Krupat's two-part Patient-Practitioner Orientation Scale (Krupat *et al.*, 2000); the patient involvement section of Ogden *et al.*'s four-part measure of general practitioners' and patients' beliefs about "patient-centredness" (Ogden *et al.*, 2002) and a tool developed by Edwards and Elwyn to measure the effect of an educational intervention on general practitioner attitudes to shared decision making (Edwards and Elwyn, 2004). At the pilot stage, general practitioners were asked to comment on the acceptability of the content and language of each measure. Based on these comments, the Edwards and Elwyn tool was selected as most suitable for inclusion in the final version of the REFER questionnaire.

In the version of this tool used for the survey, general practitioners were presented with a set of nine statements relating to their attitudes towards, and practice of, involving patients in decision making and sharing risk information. They were asked to indicate their level of agreement with each statement on a five point Likert scale, considering their approach to patient involvement in decision regarding elective surgical referral.

Question 3

Question 3 was a "free text" question asking respondents for further comments they had about referral guidelines for elective surgery.

Questions 4.1 – 4.6

Questions 4.1 to 4.6 were designed to gather background data about participants; including demographic data; years since qualification; characteristics of practice; and membership of professional organisations.

5.2.2 Sampling

The sampling frame was all general practitioners in England. A stratified random sample of general practitioners equivalent to a 1% sample was selected.

Sampling of primary care trusts

After obtaining multi centre research ethics committee approval, a sample of ten English primary care trusts was selected broadly reflecting variation described in the Office of National Statistics' (ONS) data on classification of health areas (Table 3). The ONS categorises primary care trusts under eight headings or Supergroups which group together geographic areas according to key characteristics common to the population in that grouping using data on a range of factors including age group distribution, ethnic group distribution, household composition, housing, socio-economic information, employment and dominant industry sector.

Sampling of general practitioners

Research governance approval was obtained from each of the ten primary care trusts, and lists of practising general practitioners were requested and received from each. The general practitioner lists of the primary care trusts were cleaned and validated using the NHS website (<http://www.nhs.uk/England/AuthoritiesTrusts/Pct/Default.aspx>; accessed 30.03.2006) and by contacting practices by telephone where discrepancies were identified. Lists were stratified into single handed and group general practitioner practices. A 30% random sample of general practitioners, stratified by practice size, was drawn from each primary care trust.

Table 3. PCT classification

<i>ONS Health Area Classification (Supergroup)</i>	<i>% of UK population</i>	<i>Number of PCTs selected from group</i>
Cities and services	21.2	2
Coastal and Countryside	10.3	2
London centre	2.5	1
London cosmopolitan	3.6	1
London suburbs	4.3	1
Mining and Manufacturing	20.6	1
Northern Ireland Countryside	1.0	0 (Not applicable)
Prospering UK	36.6	2

Implementing the survey

The survey was implemented in 5 stages, with measures taken to enhance response rate at each stage. An eye-catching postcard was mailed to the sample of general practitioners two weeks prior to the initial mailing of the questionnaire. The postcard informed general practitioners about the study aims and methods, emphasised the importance of their involvement in the guideline development process, and notified them that they would soon receive a questionnaire about referral guidelines. The postcard also informed general practitioners of alternative methods for participation in the survey, including the option of completing the questionnaire online, over the telephone, or via fax as well as by post. An incentive was offered, in the form of a prize draw (for an iPod or a case of champagne).

Two weeks after mailing the postcard, the questionnaire was mailed to general practitioners, accompanied by an information letter about the study. The letter reminded general practitioners about the alternative methods for participating in the survey and a Freepost envelope was provided for participants to return the questionnaire.

Two weeks after the initial mailing, non-responders were sent a new copy of the questionnaire, accompanied by a letter reminding them about the study, a Freepost envelope and an adapted version of the initial postcard.

Four weeks after the initial mailing, non-responders were sent a personalised letter, notifying them that a member of the Project Team might contact them by telephone over the subsequent six weeks and inviting them to take part in the survey by telephone interview. The letter also reminded general practitioners again of the various methods for participation.

Finally, six to ten weeks after the initial mailing of the questionnaire, a selection of non-respondents was contacted by telephone⁴ and invited to take part in the survey over the telephone, online, or by fax.

Data handling

A data entry form in exactly the same format as the paper questionnaire was designed and put onto the study website. This electronic completion form was set up so as to link directly to a database, general practitioners choosing to respond using the web were given a unique entry number to complete their questionnaire electronically. Responses to the questionnaire on paper and telephone responses were entered by study staff directly into the database. Data were cleaned. Analysis was undertaken using SPSS 12.0 to provide simple descriptive statistics. Chi-squared tests were used to assess the significance of the difference in responses between groups.

⁴ A minimum of one phone call was made to all non-responding general practitioners in 5 of the 10 sampled PCTs.

Table 4. Response rates by PCT

<i>PCT</i>	<i>ONS Supergroup</i>	<i>Geographical setting</i>	<i>Sample n</i>	<i>Response n</i>	<i>Response rate (%)</i>
A	Cities and Services	Outer London	23	9	39.1
B	Cities and Services	North West	16	4	25.0
C	Coastal & Countryside	South West	23	12	52.2
D	Coastal & Countryside	North East	34	20	58.8
E	London Centre	Inner London	32	9	28.1
F	London Cosmopolitan	Outer London	42	17	40.5
G	London Suburbs	Outer London	42	17	40.5
H	Mining and Manufacturing	North	28	12	31.6
I	Prospering UK	North West	47	14	29.8
J	Prospering UK	South East	23	14	60.9

5.3 Results

5.3.1 Response rates

Questionnaires were sent to 324 general practitioners in 10 primary care trusts in England. 4 general practitioners were excluded (1 retired, 1 moved to another practice, 2 locum general practitioners). Of the 320 eligible practitioners, 129 completed the questionnaire, giving a final response rate of 40.3%. Response rates varied by primary care trust from 25.0% to 60.9% (Table 4). Overall, response rates were lower in urban than in rural areas and for single-handed general practitioners rather than those working in a group practice (single-handed practitioners made up 4% of respondents and 11.9% of the sample).

Table 5. Respondent characteristics

	<i>Respondents %</i>	<i>Sample %</i>	<i>England general practitioners %⁵</i>
Age group (n=128)			
25 – 34 years	10.9	-	12.0
35 – 44 years	28.9	-	34.1
45 – 54 years	38.3	-	33.5
55 – 64 years	18.8	-	18.0
65 years or over	3.1	-	2.4
Sex (n=129)			
Male	61.2	62.4 ⁶	59.6
Female	38.8	37.6	40.4
Practice size (n=126)			
1	4.0	11.9	-
2 – 3	34.1	36.6	-
4 – 5	32.5	25.0	-
6 – 7	7.1	8.4	-
More than 7	22.2	18.1	-

5.3.2 Respondent characteristics

The majority of respondents were male (Table 5). Most were over the age of 45 years. A quarter of respondents reported that they had been fully qualified for less than ten years (25.6%), while just over one in ten had qualified 30 or more years ago (11.6%). A third of respondents were based in small practices of 2 or 3 general practitioners and 4% worked in single-handed practices. Nearly 40% of respondents were based in medium sized practices of between 4 and 7 general practitioners, however many worked in even larger practices, of 8 or more general practitioners. Women were significantly more likely to work in smaller practices of 1 to 3 general practitioners, with nearly half of them doing so compared to only a third of male general practitioners ($p=0.045$). 17.3% of respondents reported that

⁵ DH General and Personal Medical Services Statistics, England and Wales, 30 September 2004
http://www.dh.gov.uk/PublicationsAndStatistics/Statistics/StatisticalWorkAreas/StatisticalWorkforce/StatisticalWorkforceArticle/fs/en?CONTENT_ID=4107332&chk=3U51Gj (accessed 30.03.2006)

⁶ Data on sex available for 7 of 10 participating PCTs only.

they did not have a personal patient list. Of those general practitioners who did have a personal list, three quarters of general practitioners had a list of between 1000 and 3000 patients, whilst just over one in five had a personal list of 3000 or more. More than three quarters of respondents were members of the British Medical Association (77.5%) and about half were members of the Royal College of General Practitioners (43.4%).

Respondents were fairly representative of the sample as well as general practitioners in England in terms of age distribution, sex and practice size.

Table 6. Why general practitioner use referral guidelines (excludes respondents who do not use referral guidelines)

<i>Which of the following options best describes <u>why</u> you use referral guidelines? (You may tick more than one option)</i>	<i>% (n=105)</i>
I believe they help me to make good decisions / improve quality of care	63.8
They help me to explain or share information about treatment decisions with patients	37.1
I am required to by my local hospital trust / local surgeons	29.5
I am required to by my local primary care trust (e.g. as part of a "Choose & Book" scheme)	21.0
I believe they will reduce the possibility of litigation	18.1
I am required to by someone else (e.g. Department of Health, NICE, RCGP, etc)	15.2
I use guidelines for another reason	6.7
The primary care trust offers incentives to encourage me to use them	1.9

5.3.3 Why general practitioners use referral guidelines

In response to question 1.3, nearly one in five respondents stated that they had never used referral guidelines (18.0%). For the remaining 82%, responses indicated that guidelines are seen in a positive light, and are believed to provide useful information for practitioner and the patient (Table 6). Nearly two thirds of respondents indicated, *"I believe they help me to make good decisions/improve quality of care"* (63.8%) and more than a third said, *"they help me to explain or share information about treatment decisions with patients"* (37.1%).

More than a quarter of general practitioners reported that they use guidelines because they are required to by their local hospital trust or surgeons (29.5%), and a further fifth use them because they have been asked to by their primary care trust (21.0%).

Table 7. How general practitioners use referral guidelines

<i>Which of the following options best describes <u>how</u> you use</i>	<i>%</i>
I look at guidelines when I encounter difficult/unfamiliar circumstances	51.06
I read guidelines once or twice for background education and/or to improve my knowledge of conditions	44.3
I read guidelines once or twice and rely on memory in order to apply recommendations to individual patients	36.1
I <u>never</u> look at guidelines in individual patient consultations	16.4
I use guidelines in teaching	16.4
I use guidelines to help me audit my practice	9.8
I have never used referral guidelines	7.4
I look at guidelines in most or all individual patient consultations where a referral might be necessary	2.5
Don't know	1.6
Use guidelines in another way	1.6

5.3.4 How general practitioners use referral guidelines

When general practitioners were asked to report on how they use referral guidelines (Table 7), their responses confirmed that it is rare to look at a guideline on every occasion that a referral decision is made, with only 2.5% of respondents indicating that they used referral guidelines in this way, and 16.4% of respondents further emphasising the point by indicating that they *never* look at guidelines in the consultation setting⁷.

⁷ During pilot cognitive interviews with general practitioners, assumptions about how guidelines are, or should be, used, were challenged. Even general practitioners who perceived guidelines to be beneficial reported that they were unlikely to consult a guideline every time a treatment or referral decision needs to be made, with the exception of guidelines for conditions that are seen particularly rarely in general practice. It seemed to be far more typical for a guideline to be read through once or twice when it is first received, and its key points internalised by the practitioner. While guidelines are used on occasion within the consultation setting, this tends to be only in situations where a particularly difficult or unfamiliar problem is presented.

Table 8. Conditions for guideline development

Condition	Has used referral guidelines (%)	Has not used referral guidelines: Indicated guidelines <u>would</u> be useful (%)	Has not used referral guidelines: Did not indicate guidelines would be useful (%)
Osteoarthritis of knee (n=114)	11.4	33.3	55.3
Prostate problems (n=114)	30.7	30.7	38.6
Stress incontinence (n=114)	12.3	29.8	57.9
Osteoarthritis of hip (n=114)	6.1	28.9	64.9
Infertility (n=115)	39.1	25.2	35.7
Back pain (n=115)	45.2	22.6	32.2
Menorrhagia (n=116)	24.1	21.6	54.3
Haemorrhoids (n=114)	6.1	21.1	72.8
Varicose veins (n=114)	20.2	19.3	60.5
Cataract (n=114)	12.3	16.7	71.1
Inguinal hernia (n=114)	4.4	13.2	82.5
Sterilisation (n=114)	15.8	9.6	74.6

The most important way in which referral guidelines are used is in providing help or information when the general practitioner's existing knowledge and experience do not provide the solution to a problem. 51.6% of general practitioners indicated, "*I look at guidelines when I encounter difficult/unfamiliar circumstances*". This response was more frequently made by less experienced general practitioners, with 58.7% of those who qualified less than twenty years ago selecting this option, compared to only 40.4% of those with 20 or more years of experience (p=0.05).

The second most frequently cited way of using a referral guideline was reading the tool once or twice to improve the general practitioner's knowledge about conditions (44.3%). Similarly 36.1% indicated that they read guidelines once or twice and rely on memory alone to apply recommendations to individual patients.

Table 9. Support for use of referral guidelines

<i>Which of the following types of support would help you make best use of referral guidelines?</i>	<i>% (n=126)</i>
Good access to electronic or internet based guidelines	52.4
Information telling me what guidelines are available	46.0
Expert advice on which are the best available guidelines	43.7
Regular updates telling me when new guidelines are produced	35.7
Good access to paper based guidelines	28.6
Technical support to help me find/access the best online/electronic guidelines	21.4
An internet source giving links to electronic guidelines	14.3
Technical support to help me USE online/electronic guidelines	12.7
General training on how to use guidelines	8.7
No support required - I choose not to use referral guidelines	7.1
No support required	4.0
Other type of support required	2.4

5.3.5 Conditions for which referral guidelines are needed

Table 8 shows general practitioners' combined responses to question 1.1 (the conditions for which guidelines had already been used), and question 1.4 (the conditions for which guidelines were perceived as useful). Conditions are ranked in descending order of percentage of respondents who have *not* already used guidelines for each condition but who feel guidelines are needed. Conditions where this percentage is high are considered to be areas where there is a greater need for new guidelines to be developed.

Table 10. Involving patients in the referral decision*

<i>Statement</i>	<i>Strongly agree</i>	<i>Slightly agree</i>	<i>Neither agree nor disagree</i>	<i>Slightly disagree</i>	<i>Strongly disagree</i>
A. I feel that sharing decision making with patients is an important principle (n=127)	56.7	33.1	6.3	2.4	1.6
B. I frequently involve patients in decision making (n=127)	55.1	31.5	7.1	5.5	0.8
C. Lack of time is a major problem in discussing treatment decisions with patients (n=126)	32.5	27.8	24.6	11.1	4.0
D. I feel "competent" in involving patients in decision making (n=125)	28.8	52.8	12.8	4.8	0.8
E. I have found that patients respond positively to involvement in decision making (n=127)	28.3	47.2	15.7	7.9	0.8
F. Lack of available data is a major problem in trying to share decisions (n=126)	12.7	35.7	35.7	15.1	0.8
G. I feel confident in discussing risk information about treatments with patients (n=122)	9.0	50.0	24.6	13.9	2.5
H. Many of my patients expect specific information to be provided in discussions about treatments (n=126)	8.7	35.7	34.1	19.0	2.4
I. I feel my role is to direct patients rather than discuss risk information about treatments (n=123)	1.6	16.3	23.6	36.6	22.0

*Most frequent response to each statement is in bold type.

5.3.6 Support general practitioners need to use guidelines

Question 1.5 asked general practitioners for the support they believed would help them to use guidelines (Table 9). More than half reported that they would like to have good access to electronic guidelines, while information about guidelines available and their quality were also thought particularly important (46%, and 43.7%, respectively). In contrast, a relatively low proportion of general practitioners felt they would benefit from more general training in how to use guidelines (8.7%).

More than a quarter of respondents said that they require good access to paper-based guidelines (28.6%). This response was more common among general practitioners from smaller practices (1-3 general practitioners), with 46.7% of these general practitioners selecting this option, compared to only 17.9% of general practitioners in larger practices ($p < 0.001$).

One in five respondents said that they need technical support to help them *access* electronic guidelines (21.4%), and a further 12.7% would like technical support to help them *use* electronic guidelines.

5.3.7 Involving patients in the referral decision

Grouping together the “strongly agree” and “slightly agree” responses, the data suggest that on the whole general practitioners feel that sharing decision making with patients is an important principle (statement A, 89.8%) and that they do involve patients in decision making (statement B, 86.6%; Table 10). Lack of time was considered to be a problem by just over 60% of general practitioners (statement C, 60.3%), while lack of data was not so commonly regarded as a problem (statement F, 48.4%).

In contrast to their overall support for the *concept* of shared decision making, general practitioners were less inclined to indicate that they strongly agreed regarding their confidence in their own skills in sharing decisions with patients (statement D, 28.8% strong agreement, and statement G, 9.0% strong agreement). Large proportions only slightly agreed that they felt competent or confident (statement D, 52.8% slight agreement, and statement G, 50.0% slight agreement).

We grouped responses into 2 categories: “Agree”, and “Disagree/Undecided”. There was no difference by age group or years since qualification in attitudes towards sharing decision making. However there was a marked difference relating to the sex of the general practitioner, with male doctors being significantly more likely than female doctors to feel that their role was to *direct* patients rather than to discuss risk information (statement I, $p = 0.04$). Female doctors seemed slightly more inclined to agree with statements A and B, showing slightly more enthusiasm for the concept of shared decision making, but the difference was not statistically significant.

General practitioners working in smaller practices of between one and three general practitioners were significantly less likely than those in large

practices to report that they frequently involve patients in decisions (statement B, $p=0.006$). They were also less likely to agree that sharing decision making is an important principle (statement A, $p=0.026$) and less likely to report that they feel competent in involving patients in decision making (statement D, $p=0.017$). Similarly, among general practitioners with their own personal patient list, those with large list sizes (more than 2000 patients) were significantly less likely to agree with both statement A and statement B ($p=0.016$, and $p=0.025$ respectively).

Membership of organisations only had a statistically significant effect when we looked at the responses in three categories: "Agree", "Undecided", and "Disagree". Members of the RCGP were significantly more likely than non-members to indicate that they frequently involve patients in decisions, while non-members were more likely to be undecided than members (statement B, $p=0.034$).

5.4 Discussion

A postal survey was considered to be a useful method of consulting a large and nationally representative sample of general practitioners and eliciting their views on the most appropriate format, focus and content of referral guidelines. Unfortunately although strenuous attempts were made to encourage a good response, the response rate at just over 40% is lower than desirable for drawing conclusions about the attitudes and behaviour of general practitioners overall with regard to referral guidelines. Nevertheless we have some valuable pointers towards how to take forward the development of referral guidelines.

1. A majority of respondents were positive about the reasons for use of referral guidelines, indicating that they helped them to make good decisions and/or improve the quality of care. They also indicated that they tended to use guidelines when they had a problem with which they were unfamiliar or as background education. Very few indicated that they would use guidelines as a routine part of a consultation.
2. There were a number of conditions for which general practitioners felt new referral guidelines would be particularly useful. Osteoarthritis of the knee, prostate problems, stress incontinence, osteoarthritis of the hip, infertility, back pain and menorrhagia were highlighted.
3. On the whole, general practitioners were supportive of the concept of sharing referral decisions with patients, although less confident about their ability to do so. General practitioners from smaller practices were less enthusiastic.

5.5 Implications for development of referral guidelines

1. New referral guideline will need to have three core components:
 - 1.1. An educational component for background reading

- 1.2. Key messages for general practitioners to internalise and apply in the consultation
- 1.3. A format which enables general practitioners to locate information easily when a difficult or unfamiliar situation occurs at the time of the consultation
2. Guidelines will need to be available in both paper and electronic formats to enable widespread usage
3. General practitioners with demanding workloads should not be deterred from using the guidelines. Guidelines will need to be concise and accessible.
4. Based on responses to the survey, good conditions to concentrate on in guideline development are likely to be:
 - 4.1. Osteoarthritis of the hip or knee
 - 4.2. Symptoms of benign prostatic hypertrophy
5. Content and language will need to be transparent to enable general practitioners to share information with patients.

6 Referral guideline for osteoarthritis of the knee incorporating patients' preferences

6.1 Introduction

As indicated in chapter 2, the REFER project was divided into two phases. In the first phase of the project, we aimed to describe the context for the development of referral guidelines. In the second phase, we developed referral guidelines for patients with non-urgent conditions that may need surgical treatment. It was our aim that these guidelines explicitly incorporate patients' preference for referral and to receive a specialist opinion on their condition.

In this chapter, we describe the development of a referral guideline for patients with osteoarthritis of the knee. In the next chapter, we describe the development of a referral guideline for men with lower urinary tract symptoms. These conditions were chosen as they are frequent and general practitioners are uncertain about the referral appropriateness (see chapter 5).

About 10% of adults over 60 years of age experience chronic pain and disability that is caused by wear and tear of the cartilage in the knee. Initial treatment options for this condition, often referred to as osteoarthritis, are analgesics, physiotherapy and patient education, and weight loss in overweight patients (Chard J *et al.*, 2006).

A further option is referral to a specialist service. In 2001, the National Institute for Health and Clinical Excellence (NICE) recommended that patients with rapidly increasing symptoms of osteoarthritis of the knee and those whose quality of life was impaired should be referred (National Institute for Clinical Excellence, 2001). This advice was reiterated in the clinical guideline that was issued by NICE in 2008 with the addition that referral should be made "before there is prolonged and established function limitation and severe pain" (National Institute of Clinical Excellence, 2008).

There is increasing pressure on primary care staff to manage demand for health care services. One of the most visible initiatives in this context is the establishment of referral management schemes by primary care trusts that aim to avoid referrals that are not deemed to be cost-effective (Davies and Elywn, 2006). On the other hand, there is also a commitment to strengthen patients' involvement in the decision making process (Department of Health, 2001).

There is a potential conflict between these initiatives. For example, what are general practitioners supposed to do when they see a patient with osteoarthritis of the knee who has only mild symptoms but a strong preference to be referred? Currently, there are no clinical guidelines as regards to whether a referral is appropriate or not, nor how to incorporate

patients' preferences. A similar dilemma also exists for health care professionals working within the referral management schemes that have been set up by many primary care trusts in England to reduce the numbers of inappropriate referrals (British Medical Association, 2007).

We used a "streamlined" approach to develop this guideline, largely based on a recently published method that aims to make guideline development process more succinct and transparent (Raine *et al.*, 2004).

6.2 Methods for guideline development

The guideline development process

The guideline was developed by a group who used an iterative consensus development method (Murphy *et al.*, 1998). This group included 12 representatives of relevant stakeholders in the management of osteoarthritis (three patients, three general practitioners, three orthopaedic surgeons, one nurse specialist, one physiotherapist and one public health consultant).

In the preparatory phase, the Project Team supported by a general practitioner and an orthopaedic surgeon from the guideline development group identified areas of uncertainty that required reviews of the literature. The team also carried out a review of existing clinical guidelines for the management of osteoarthritis of the knee.

First meeting of the guideline development group

At the first meeting the guideline development group defined three key concepts: the patient population of interest; referrals from general practice straight to secondary care; and appropriate referral (Table 11).

Table 11. Definition of key concepts of referral process for patients with osteoarthritis of the knee.

<i>Osteoarthritis of the knee</i>	Patients are considered to have osteoarthritis of the knee if they are 50 years or older and have chronic knee pain that worsens with use and is not caused by rheumatoid arthritis.
<i>Referral decision</i>	Referrals from a GP to a healthcare professional who is in a position to put patients on the waiting list for knee replacement. This professional can be an orthopaedic surgeon, an orthopaedic nurse specialist, or a physiotherapist.
<i>Appropriate referral</i>	A referral is appropriate if it is likely to be beneficial to a patient, given the best available research evidence as well as the patient's preferences.

The Project Team presented the results of the following evidence reviews: a systematic review of predictors of outcome after knee replacement that can readily be evaluated in primary care; existing guidelines on non-surgical and non-pharmacological interventions for patients with osteoarthritis of the knee (the NICE osteoarthritis guideline 2008 was not yet available at that time); and mortality and its risk factors after knee replacement surgery. Four additional topics were identified by the group during its first meeting: role of an x-ray of the knee; patient satisfaction after knee replacement; revision rates; mortality after knee replacement according to age and gender. Subsequently, rapid reviews were carried out. Also, post-operative mortality according to the National Joint Registry was compared to age and sex standardised mortality that in the general population (National Joint Registry, 2007).

In the systematic review of predictors of outcome after knee replacement, studies were included if they considered characteristics that can be assessed by a general practitioner during a consultation (i.e. age, gender, body mass, physical function and pain), if the studies described short-term outcomes that are immediately relevant to patients (i.e. pain, physical functioning, and health-related quality of life, revision of prosthesis, and mortality), and if the studies were large enough to have sufficient power to detect the influence of patient characteristics on the outcomes (i.e. $n > 1000$). Only two studies were included (Parvizi *et al.*, 2001; Harrysson *et al.*, 2004).

Period between the first and second meetings

After the first meeting, we drafted 12 recommendations for good primary care practice based on the group's informal views. We also designed some case scenarios (see Box 2 for an example) based on five patient characteristics (Table 12): age; symptom severity expressed in terms activities of daily living; body mass; comorbidity according to the American Society of Anesthesiologists (ASA) scale; and patient preference for referral. The number of possible combinations amounted to 108.

Table 12. Characteristics of paper patients

Patient characteristic	Levels of each characteristic		
<i>Severity of knee symptoms</i>	Mild	Moderate	Severe
<i>Age</i>	60 years	70 years	80 years
<i>Comorbidities</i>	ASA Grade 2	ASA Grade 3	
<i>Body mass index (BMI)</i>	25 kg/m ²	35 kg/m ²	
<i>Patient preference</i>	Strong preference of referral	No referral preference either way	Strong preference against referral

ASA = American Society of Anesthesiologists.

Box 2. Example of a case scenario

Referral is appropriate for a patient with osteoarthritis of the knee								
<ul style="list-style-type: none">• with severe symptoms• aged 60• with mild systemic disease• with a strong preference against referral								
strongly disagree						strongly agree		
1	2	3	4	5	6	7	8	9

A questionnaire was mailed to the members of the guideline development group asking them to rate their agreement with the 12 recommendations for primary care as well as with the appropriateness of referral of patients described in the randomised 108 case scenarios. Agreement was scored on a scale of 1 ("strongly disagree") to 9 ("strongly agree"). The members were asked to assume that the patients were fully informed by their general practitioner about all treatment options, that they had not had a previous surgical procedure on any of their knees, and that they were already receiving physiotherapy and drug treatment. It was also indicated that the referral decision has to be made in the context of the resources currently available in the NHS.

Second meeting of the guideline development group

At the second meeting, graphical representations of the distribution of the group's ratings were presented. Following discussions of each rating, the group members had the opportunity to rescore. A number of practice recommendations were modified to clarify any perceived ambiguity and subsequently rescored.

Definition of consensus

We based our definition of consensus largely on the "strict" definition in the RAND approach (Fitch *et al.*, 2001). Ratings of 1 - 3 were considered as indicating "disagreement", rating of 4 - 6 as "equivocal", and ratings of 7 - 9 as indicating "agreement". Four levels of consensus were established: "unanimous" consensus (12 out of 12 group members have ratings either in any of the three ranges), "strong" consensus (11 out of 12), "moderate" consensus (10 out of 12) and "weak" consensus (9 out of 12). When ratings were considered for a series of case scenarios, we used the corresponding percentages to determine the level of consensus. In other words, we considered that consensus was unanimous if 100% (= 12/12) of the ratings were either in the ranges 1 to 3 or 7 to 9, strong if more than 92% (= 11/12) but less than 100% were in these ranges, and so on.

Statistical analysis

To study the effect of the patient characteristics on the appropriateness of referral, we compared the means of the ratings for each level. The differences were tested with a regression model in which "group member" was defined as a random effect. Random-effect regression modelling was used because the ratings of a single group member were expected to be less variable than the ratings from all guideline development group members together. We tested for interaction between patient characteristics to investigate whether the effect of one of these characteristics depended on the level of another.

6.3 Results

Overview of the evidence reviews provided to the guideline development group

In general practice, the value of a knee X-ray to judge the need for surgery is uncertain, mainly because there is only a weak link between radiological abnormalities and severity of the knee pain (Peat *et al.*, 2001; McAlindon *et al.*, 1993; Dieppe *et al.*, 1997; Hannan *et al.*, 2000).

About 80% of the patients who had a knee replacement say that they are satisfied with the results one year after surgery (Anderson *et al.*, 1996; Hawker *et al.*, 1998; Heck *et al.*, 1998; Robertsson *et al.*, 2000). Patients with severe osteoarthritis undergoing surgery are likely to have greater *improvement* of their symptoms than patients with mild osteoarthritis, patients who have surgery before the osteoarthritis becomes too severe have the best overall outcome (Australian Orthopaedic Association, 2006).

In the first three months after the surgery, about 1 in 200 patients (0.5%) die, which is about twice as low as the death rate observed in the general population when age and sex are taken into account (National Joint Registry, 2007). About 1 in 30 patients (3%) needs a revision of their prosthesis (second knee replacement) within the first five years after surgery (Australian Orthopaedic Association, 2006).

Recommendations on good primary care practice

Consensus was reached in support of all but one of these recommendations (Table 13). The guideline development group recommended the following: General practitioners should verify the origin of the knee pain by taking a detailed medical history and carrying out a physical examination, but general practitioners do not need to consider the results of a knee X-ray. Where possible, comorbidities should be controlled and other surgical risk factors such as smoking and obesity should be addressed. Patients should be informed about the outcomes that can be expected of the knee replacement surgery.

Table 13. Recommendations for good primary care practice

Recommendations for good primary care practice	Level of consensus	Distribution of ratings (%)*		
		<=3	4-6	>=7
In patients with suspected osteoarthritis of the knee, a clinical assessment that includes both medical history and a physical examination should be used by General Practitioners to ascertain that the experienced knee pain is not originating from elsewhere in the body (such as the back or hip).	Unanimous in favour	0	0	100
Non-specialist General Practitioners should have the results of an X-ray (weight-bearing, AP view) of the knee for patients with osteoarthritis of the knee when making the referral decision	Weak against	75	8	17
A patient with osteoarthritis of the knee should only be referred if non-surgical and non-pharmacological interventions, in addition to conservative management, have not sufficiently improved the limited daily activities.	No consensus	8	33	58
Comorbidities that increase the risk of peri- and post-operative complications should be reversed or stabilised as soon as the decision is made to refer a patient with osteoarthritis of the knee.	Strong in favour	0	8	92
Patients with osteoarthritis of the knee who are smokers and are considered for referral should be advised to stop smoking.	Strong in favour	0	8	92
Patients with osteoarthritis of the knee who are smokers and are considered for referral should be advised to participate in a smoking cessation programme.	Weak in favour	0	25	75
Patients with osteoarthritis of the knee who are obese and are considered for referral should be advised to loose weight.	Strong in favour	0	8	92

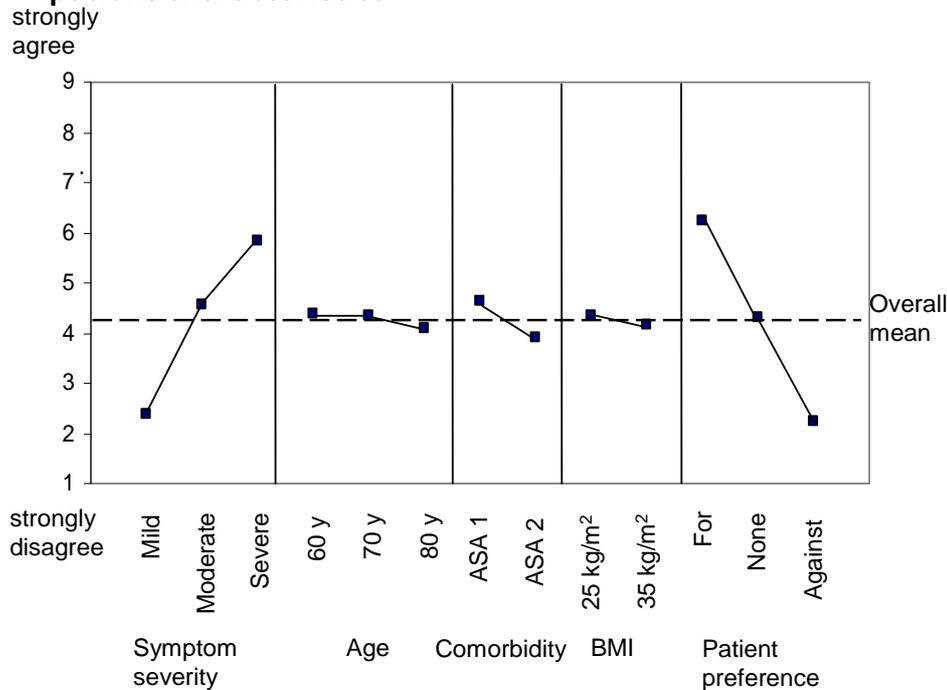
Recommendations for good primary care practice	Level of consensus	Distribution of ratings (%)*		
		<=3	4-6	>=7
Patients with osteoarthritis of the knee who are obese and are considered for referral should be advised to participate in a weight loss programme.	Moderate in favour	0	17	83
Patients with osteoarthritis of the knee considering referral should be informed about the likely outcomes after the surgical procedure as much as possible, whilst taking their individual condition and circumstances into account.	Moderate in favour	0	17	83
Patients with osteoarthritis of the knee considering referral should be informed about the risk of mortality following the surgical procedure.	Moderate in favour	8	8	83
Patients with osteoarthritis of the knee considering referral should be informed about health-related quality of life following the surgical procedure.	Weak in favour	0	25	75
Patients with osteoarthritis of the knee considering referral should be informed about satisfaction of patients who have undergone the surgical procedure.	Moderate in favour	8	8	83

The only recommendation for which consensus was not reached was that patients should be referred only if non-drug and non-surgical interventions had not provided sufficient improvement. Some guideline development group members felt that such a recommendation would too strongly ignore a potential patient's preference for referral.

Recommendations about the appropriateness of referral

Members' ratings of referral appropriateness for the 108 case scenarios were strongly influenced by the severity of the symptoms and the patient preferences ($p < 0.001$ for both) (Figure 1). Also, comorbidity influenced the group's rating ($p < 0.001$), but its impact was relatively small. Age and body mass index did not seem to have a significant impact ($p = 0.2$ for both).

Figure 1. Mean rating of referral appropriateness for each level of the patient characteristics



The influence of patient preferences depended on the severity of symptoms (p for interaction < 0.001) (Figure 2). Patient preferences had a greater impact when symptoms were moderate or severe than when they were mild.

As a consequence of these findings, the group's recommendations were based only on patient preferences and symptom severity (Table 14). This implies that we distinguished nine distinct profiles (3 preference levels x 3 severity levels) each of which included 12 case scenarios (3 age levels x 2 comorbidity levels x 2 BMI levels).

The patient profiles that the group agreed should not be referred were those with mild symptoms and either no or strong preference against referral and

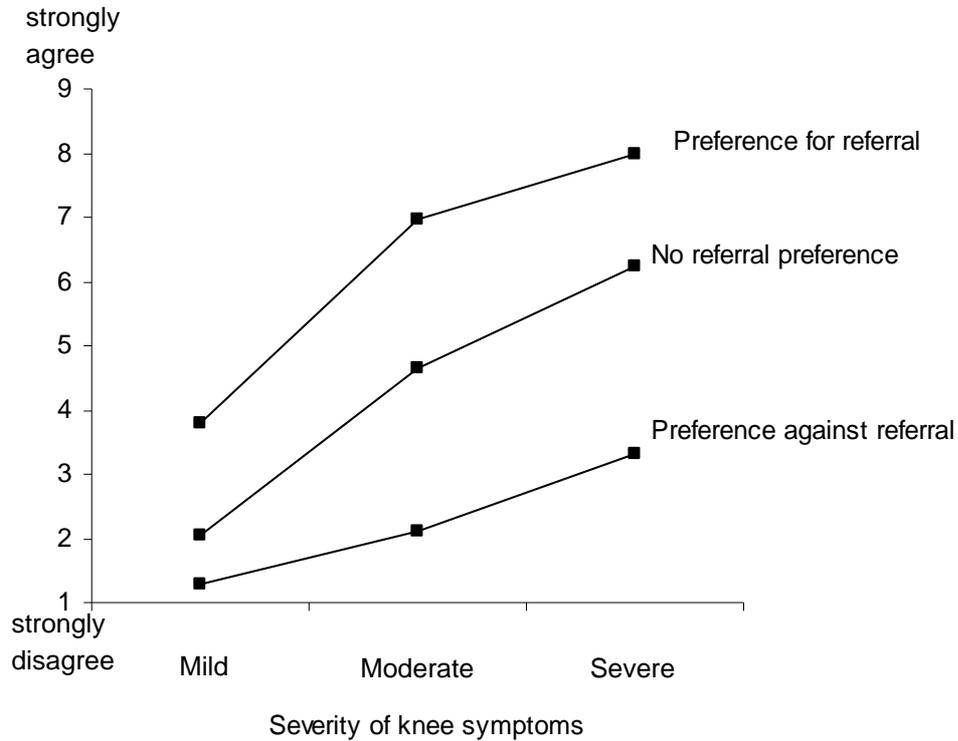
those with moderate symptoms and a strong preference against referral. In contrast, there was a consensus in favour of referral for those patients with severe symptoms and a strong preference for referral. For all other profiles, there was no consensus view.

Table 14. Recommendations for appropriateness of referral

Severity of symptoms	Patient preference	Level of consensus on appropriateness of referral	Distribution of appropriateness ratings (%) *		
			<=3	4-6	>=7
Mild	For referral	No consensus	51	36	13
	No preference	Moderate against	88	8	4
	Against referral	Strong against	99	1	0
Moderate	For referral	No consensus	2	33	65
	No preference	No consensus	32	49	19
	Against referral	Moderate against	90	7	3
Severe	For referral	Moderate in favour	1	9	90
	No preference	No consensus	11	43	46
	Against referral	No consensus	61	26	13

During the group's discussions it became clear that an important factor underlying the lack of consensus on the appropriateness of referral for patients with mild symptoms and a strong preference for referral was that some group members felt that these patients may benefit from receiving information about the benefits of knee replacement surgery from a specialist, whereas others took the view that general practitioners should be equally competent to provide this information. Moreover, a lack of consensus for patients with severe symptoms and a strong preference against referral was due to some group members proposing that these patients might benefit from referral as they believed a surgeon could persuade them of the benefits of surgery.

Figure 2. Mean rating of referral appropriateness according to symptom severity and referral preference



Comparison of views of group members

Overall, the ratings of the appropriateness of referral were the same in the patient representatives (4.8) and surgeons (4.8) whereas they were lower in the general practitioners (3.9) and the other healthcare professionals (3.6) (p for group differences = 0.02).

Patient representatives and general practitioners seemed to be more strongly influenced by patient preferences than by symptom severity. Among the patient representatives, the difference between the ratings for scenarios describing patients with a strong preference against referral and those with a strong preference in favour of referral was 3.4 and between those describing patients with mild symptoms and those with severe symptoms was 1.8. In contrast, the differences among the general practitioners were considerably greater, 4.3 and 3.5, respectively.

The impact of patient preferences and symptom severity was similar both for the surgeons (differences of 4.6 for patient preferences and 4.8 for symptom severity) and for the other health care professionals (differences of 3.7 and 3.9, respectively).

6.4 Discussion

Findings

The guideline development group reached consensus on the appropriateness of referral for patients with severe knee symptoms who want to be referred and the inappropriateness of referral for patients with mild symptoms and either no or a strong preference against referral. For all other groups of patients defined according to symptom severity and referral preference, there was a lack of consensus. Patient characteristics that influence the outcome of replacement surgery (age, comorbidity, body mass) had little or no impact on the group's judgement (see Appendix 4).

These consensus results on the appropriateness of referral should be interpreted in the light of the group's recommendations for good primary care practice. General practitioners should take a detailed medical history and carry out a physical examination to verify the origin of the knee pain, however, the results of a knee X-ray need not to be considered. Furthermore, it was recommended to attempt to reverse surgical risk factors and to provide information about the expected outcome of knee replacement surgery.

Our results demonstrate for the first time the relative weight given to the referral preference of patients in conjunction to the severity of their symptoms. In this way, they reflect how the guideline development group "juggled" with a number of key principles of "evidence-based patient choice" (Edwards and Elwyn, 2001). First, the guideline development group demonstrated a strong commitment to the principle of patient autonomy. This commitment became especially apparent during discussions of case scenarios describing patients with mild symptoms but with strong preference for referral or patients with severe symptoms with strong preference against referral. Second, arguments related to patient benefit were often mentioned. For example, a number of guideline group members felt that the risk of surgery outweighs the benefit of knee replacement in patients with mild symptoms. Third, referrals of patients with mild symptoms were by some members considered to be an inefficient use of limited resources given that it is unlikely that the referral will lead to a surgical intervention or other forms of specialist treatment. Others, however, argued when discussing this issue that a referral to an orthopaedic surgeon might help patients with mild symptoms but with strong preference for referral because these patients might need a consultation with a specialist before they accept that surgical treatment might not be beneficial.

This juggling act produced a number of remarkable results. First, patients and surgeons produced on average higher ratings for referral appropriateness than general practitioners and other healthcare professionals, which corresponds to the more active involvement of the latter groups in demand management. Second, general practitioners were more responsive to the preference for referral than to the symptoms severity which fits with their different position and roles in the referral pathway. Third, the impact of patient preferences on the ratings of referral

appropriateness was on average smaller in patients with mild symptoms than in those with severe symptoms. In other words, the guideline development group assigned a greater value to avoiding inefficient resource use in patients who were least likely to benefit from referral and a greater value to respecting patient autonomy in patients who are most likely to benefit from surgery.

Methodological considerations

There is little if any high-quality research evidence on predictors of outcomes of non-surgical and surgical treatments of patients with chronic knee pain. As a result, the discussions within the guideline development group were predominantly determined by the knowledge and experience of the group members with a clinical background.

The group consisted of 12 members, a group size which is often recommended (Murphy *et al.*, 1998; Shekelle *et al.*, 1999). Inevitably, the number representing each type of stakeholder was small, limiting our ability to compare stakeholders' views.

The results may have been unduly influenced by the opinions and judgements of individual members. To investigate the extent to which judgements are representative, we mailed a questionnaire containing nine simplified case scenarios that only varied according to symptom severity and referral preference to wider groups of patients (who responded to a magazine advert), general practitioners (who were randomly selected within 10 primary care trusts) and orthopaedic surgeons (who were randomly selected from the membership list of the British Orthopaedic Association). The results were similar to the results observed within the guideline development group, which confirms the referral guideline's validity (see chapter 8).

The members of the group were aware that the referral guideline was developed in the context of a study on the impact of patient preferences. This may have influenced their rating patterns as they may have responded as they think they should respond. However, the preliminary results of the validation exercise describe above that considered wider groups of patients, general practitioners and surgeons suggest that the impact of this social desirability phenomenon is negligible.

The group was asked to take the resources currently available in the National Health Service into account. However, they were not presented with explicit evidence on the cost-effectiveness of different management options for two reasons. First, the group felt that explicit economic evidence was only relevant if it contained an analysis of the cost-effectiveness of referral from a societal perspective, in other words, including indirect costs as a result of time off work as well as the costs of extra care needed for patients with severe symptoms. Such an analysis, which would need to include all treatment options available with and without referral as well as all their expected outcomes, was considered to be outside the scope of the current project. Second, a recent experimental study suggested that context factors related to the availability of resources have

only a limited effect on the outcomes of a consensus development process (Raine *et al.*, 2004).

A final consideration is that the case scenarios that were used contained only a limited number of patient characteristics. However, a recent study demonstrated that there is a strong agreement in responses to the case scenarios and actual patients (Bouma *et al.*, 2004).

Comparison with other studies

Our referral guideline for patients with osteoarthritis differs fundamentally from the referral advice published by NICE in that it explicitly considers the referral preference of patients alongside a number of clinical characteristics (National Institute for Clinical Excellence, 2001). Another difference is that we produced consensus statements about the appropriateness of referral for a number of individual patient profiles whereas the NICE guideline is restricted to general recommendations. Despite these differences in approach, the recommendations are similar. Both highlight the severity of the patient's symptoms and warn against the use of age, comorbidity and body mass.

A study carried out in the UK that sought to explore the views of patients on a waiting list for joint replacement found that pain and disability should determine priority for knee replacement, which is in agreement with the results of our consensus exercise (Woolhead *et al.*, 2004). However, the patients also felt that other patient-specific factors, such as how long patients have had their symptoms, and whether there is a chance that they will get back to work should be taken into account. Such factors were briefly discussed during the first meeting of the guideline development group but none was included in the case scenarios. Duration of symptoms was not included given that for referral decisions, in contrast to decisions involving waiting list priority, symptom severity rather than their duration was considered to be the dominant factor. Other factors were dismissed as their inclusion would potentially give younger and healthier patients an undue advantage.

Previous consensus development concluded that the appropriateness of referral and knee replacement strongly depend on the severity of symptoms (Naylor and Williams, 1996; Dieppe *et al.*, 1999). Similarly, a Spanish study found that severity of symptoms was a dominant factor, but in this case the appropriateness ratings were also influenced by the age of the patient and the presence of severe radiological abnormalities (Escobar *et al.*, 2003). However, none of these previous studies explicitly considered patient preferences.

Implications

These results confirm that within primary care there is a "gap between abstract ethical principles and practice" (Jones *et al.*, 2004). There are clear tensions between general practitioners' role of "patient advocate", which makes them responsive to patient preferences and that of "gate keeper", which makes them accountable to the wider population for the efficient use

of resources. Although there are no simple solutions, if explicit referral procedures are to be implemented, they can only be sensibly developed if the potentially contradictory interest of individual patients and that of society in general are addressed. The musculoskeletal services framework published by the Department of Health in 2006 seeks to improve the quality of the referral process and to control the number of patients referred to hospital by developing integrated care pathways and setting up intermediary multidisciplinary clinical assessment and treatment services (CATS) (Department of Health, 2003). The detailed advice in this framework about how to set up a clinical assessment however does not acknowledge that patients may have different preferences about where and by whom they will be treated.

Furthermore, there is a dearth of prognostic information about the outcomes of joint replacements. As a consequence, patients cannot make informed decisions. However, it has been shown that patients' decisions are an important determinant of required capacity for knee replacement surgery. In two studies about 40% of people who might benefit from surgery, declined this option (Hawker *et al.*, 2001; Jüni *et al.*, 2003). Large studies describing the outcome immediately relevant to patients are urgently needed. The English Department of Health recently announced that all NHS providers are expected to start collecting patient-reported outcome measures in patients undergoing elective surgical procedures in 2009. It is expected that these measures are going to be introduced for a wider range of interventions in the following years. These patient-reported outcome measures have the potential to provide patients with an information source about the outcomes that they can expect of treatments in secondary care given their specific individual characteristics and circumstances (Department of Health, 2007).

Lastly, it should be recognised that a recent study has shown that the willingness of patients with osteoarthritis to undergo surgery is constantly changing as a result of their accommodation to pain and disability, a phenomenon sometimes called "the moving target" (Clark *et al.*, 2004). A further conclusion of this study was that a quantitative approach is unlikely to be able to capture the range of factors that many patients take into account. As a result, general practitioners and others who are responsible for referral decisions in primary care need to be prepared to respond to the specific circumstance of individual patients.

7 Referral guideline for lower urinary tract symptoms in men incorporating patients' preferences

7.1 Introduction

As indicated in chapter 2, we developed two referral guidelines that explicitly incorporate patients' preference for referral in the second phase of the REFER project. In this chapter, we describe the development of referral guidelines for guidelines for men with lower urinary tract symptoms. In the previous chapter, the development of a referral guideline for patients with osteoarthritis of the knee is presented.

Lower urinary tract symptoms (LUTS) are common in ageing men. Their prevalence increases with age (Boyle *et al.*, 2003, Treagust 2001) and it is estimated that at least 50% of men aged 65 and over experience some form of these symptoms (Garraway *et al.*, 1991). LUTS are the result of anatomical and functional changes in prostate, bladder and urethra. The symptoms are typically divided into obstructive symptoms (straining, hesitancy, weak stream, and incomplete bladder emptying) and irritative symptoms (urgency, frequency and nocturia) (Beckman & Mynderse, 2005).

LUTS can have a significant effect on a man's quality of life but they do not pose a significant health threat if they are not associated with other urological symptoms (Beckman & Mynderse, 2005; Emberton *et al.*, 2007). Without treatment, the symptoms slowly worsen in most men and the risk of acute urinary retention increases (Emberton *et al.*, 2003). The standard therapy involves a cascade of treatments that escalates from watchful waiting and lifestyle advice through a variety of drugs to minimally invasive interventions or more traditional forms of surgery (De la Rosette *et al.*, 2006; AUA, 2003).

Patients tend to seek treatment if their symptoms interfere with their daily activities and if they are worried that they may have cancer (Emberton & Martorana, 2006). The National Institute for Health and Clinical Excellence (NICE) recommended in 2001 that many patients with LUTS can be managed in primary care but that they should be referred to a specialist service if they have additional urological symptoms including renal failure, haematuria, dysuria and recurrent urinary tract infections.

There is increasing pressure on general practitioners and other primary care staff within the NHS to reduce the number of referrals and to manage the risk of "supply induced demand" in the acute sector (Department of Health, 2005). Referral management is especially challenging for men with LUTS as there is no obvious point within the cascade of treatments where a referral to a specialist is definitely indicated. Another key policy direction is the growing emphasis on public involvement and patient empowerment in the

primary and community setting (Department of Health, 2008). General practitioners are encouraged to give patients greater control over the management of their health problems.

In this chapter, we present a referral guideline for patients with uncomplicated LUTS that explicitly aimed to address these potentially conflicting policy initiatives. For example, a general practitioner may feel that they are perfectly placed to prescribe drug treatment for a patient with uncomplicated LUTS, whereas this patient may prefer referral to a urologist to receive the opinion of a specialist. Currently, there are no clinical guidelines indicating whether a referral of a patient with LUTS is appropriate or not, nor how to respond to patient preferences.

We used the same approach for the development of this referral guideline as we did when developing the referral guideline for osteoarthritis of the knee (chapter 6), largely based on a recently published method that aims to make guideline development more succinct and transparent (Raine *et al.*, 2004).

7.2 Methods for guideline development

The guideline was developed by a group who used a formal consensus development method (Murphy *et al.*, 1998). This group included 11 stakeholders in the management of lower urinary tract symptoms (two patients, three general practitioners, three urologists, two nurse consultants and one primary care trust commissioner).

In the preparatory phase, the Project Team supported by one general practitioner and one urologist from the guideline development group identified areas of uncertainty that required reviews of the literature. Subsequently, the team addressed these areas by carrying out a review of existing clinical guidelines for the management of LUTS. It was felt that systematic reviews of the primary evidence were not necessary given the availability of a number of high-quality clinical guidelines.

First meeting of the guideline development group

At the first meeting, the guideline development group defined five key concepts (Table 15): 1) uncomplicated LUTS, 2) the referral decision, 3) the definition of appropriate, 4) specialist services, and 5) self-management and lifestyle advice.

The Project Team presented the results of a review of existing guidelines (De la Rosetta *et al.*, 2006; AUA, 2003): 1) tools for the assessment of severity of lower urinary tract symptoms, 2) treatment of LUTS, and 3) indications for surgery. Three additional topics were identified during the meeting: 1) accuracy of digital rectal examination to estimate prostate size, 2) effectiveness of non-surgical treatments (self-management, alpha-blockers and 5-alpha reductase inhibitors), and 3) effectiveness of 5-alpha reductase inhibitors according to prostate size.

A brief summary of the findings of the evidence reviews are presented in the Results section. A full description of the findings is available from the Project Team on request.

Table 15. Definition of key concepts of referral process for patients with lower urinary tract symptoms.

<i>Uncomplicated lower urinary tract symptoms (LUTS)</i>	Urinary symptoms including the need to urinate frequently, a sudden uncontrollable urge to urinate, difficulty or delay when wanting to urinate, poor urine flow, incomplete emptying of the bladder, dribbling and loss of bladder control in a man who does not show any of the characteristics described below:
Age	<ul style="list-style-type: none"> • < 40 years old
Medical history	<ul style="list-style-type: none"> • History of acute urinary retention (AUR) • History of previous prostate surgery or minimally invasive procedure
Symptoms	<ul style="list-style-type: none"> • Severe or continuous urinary incontinence • Urinary retention • Voiding pain (including infections, stones, possibly cancer)
Signs	<ul style="list-style-type: none"> • Prostate size and texture suggestive of tumour determined with digital rectal examination
Alarm signs and symptoms	<ul style="list-style-type: none"> • Signs and symptoms that identify the patient to be at risk of having malignant disease (e.g. weight loss, malaise, bone pain, neurological symptoms, frank haematuria)
Diagnostic test results	<ul style="list-style-type: none"> • Proteinuria and haematuria according to dipstick test • Prostate-specific antigen (PAS) serum level > 4 ng/ml • Creatinine serum level > 100 µmol/l
Neurological comorbidity	<ul style="list-style-type: none"> • Stroke • Parkinson's disease
<i>Referral decision</i>	The decision that has to be considered is whether it is <i>appropriate</i> for a General Practitioner to refer a patient with <i>uncomplicated LUTS</i> to a <i>specialist service</i>
<i>Appropriate referral</i>	A <i>referral</i> is appropriate if it is likely to be beneficial to a patient, given the best available research evidence
<i>Specialist service</i>	A specialist service for men with LUTS can perform specific diagnostic procedures (e.g. uroflowmetry to assess abnormal voiding, urodynamics to define obstruction, ultrasound scan to assess post-void residual volume and prostate size) and/or can deliver specialist expertise in the pharmacological and surgical management of LUTS
<i>Self-management and lifestyle advice</i>	Self-management is a form of treatment that aims to involve patients in the day to day control of their symptoms by enhancing their problem-solving and goal-setting skills. Patients are encouraged to take control of the treatment of their symptoms. This is achieved through education, reassurance and discussions on changes in a patient's day-to-day lifestyle and behaviour. For patients with LUTS these changes involve, but are not limited to, fluid management, bladder training and toileting.

Period between the first and second meetings of the guideline development group

After the first meeting, the Project Team and the clinical project leads drafted 12 recommendations for good primary care practice based on the group's informal views (Table 16). The team also designed the case scenarios (see Box 3 for an example) based on five patient characteristics: 1) age, 2) symptom severity, 3) prostate size, and 4) patient preference for referral (see Appendix 5 for definitions). The number of possible combinations amounted to 54 (= 3 x 3 x 2 x 3). Comorbidity was not included in the case scenarios as according to the guideline development group the presence of other disease has little prognostic effect on the natural history of LUTS or on the outcome of any treatment.

A questionnaire was mailed to the members of the guideline development group asking them to rate their agreement with the 12 draft recommendations for primary care practice as well as with the appropriateness of referral of patients described in the 54 randomised case scenarios. Agreement was scored on a scale of 1 (strongly disagree) to 9 (strongly agree). The group members were asked to assume that patients described in the case scenarios were fully informed by their GP and that their symptoms had failed to improve after self-management and changes in lifestyle. It was furthermore highlighted that decisions on the appropriateness of referral had to be made in the context of the resources currently available in the NHS.

Second meeting of the guideline development group

At the second meeting, graphical representations of the group's ratings were presented to the guideline development group. Following discussions of each rating, the group members had the opportunity to rescore. A number of practice recommendations were modified to clarify any perceived ambiguity.

Definition of consensus

There is no generally accepted definition of consensus (Murphy *et al.*, 1998). We based our definition of consensus largely on the "strict" definition in the RAND approach (Fitch *et al.*, 2001). Ratings of 1, 2 and 3 were considered as indicating "disagreement", rating of 4, 5 and 6 as "equivocal", and ratings of 7, 8 and 9 as indicating "agreement". Four levels of consensus were established: unanimous consensus (11 out of 11 group members had ratings in any of the three ranges), strong consensus (10 out of 11), moderate consensus (9 out of 11) and weak consensus (8 out of 11). When ratings were considered for a series of case scenarios, we used the corresponding percentages to determine the level of consensus. In other words, there was unanimous consensus if 100% (= 11/11) of the ratings were in any of the ranges, strong consensus if more than 91% (= 10/11) but less than 100% of the ratings were in these ranges, and so on.

Table 16. Recommendations for good primary care practice

Recommendations for good clinical practice	Level of consensus	Distribution of ratings (%)*		
		<=3	4-6	>=7
As a first step in the clinical assessment of men with LUTS, General Practitioners should distinguish between uncomplicated and complicated LUTS.	Unanimous in favour	0	0	100
In order to make the distinction between complicated and uncomplicated LUTS, General Practitioners should find out whether there is a history of acute urinary retention and previous prostate surgery.	Unanimous in favour	0	0	100
In order to make the distinction between complicated and uncomplicated LUTS, General Practitioners should carry out a digital rectal examination for nodularity / signs of malignancy.	Unanimous in favour	0	0	100
In order to make the distinction between complicated and uncomplicated LUTS, General Practitioners should perform a dipstick test for proteinuria and haematuria.	Strong in favour	0	9	91
In order to make the distinction between complicated and uncomplicated LUTS, General Practitioners should request blood tests for prostate-specific antigen (PSA) levels.	No consensus	46	18	36
In order to make the distinction between complicated and uncomplicated LUTS, General Practitioners should request blood tests for serum creatinine levels.	No consensus	9	36	55
General Practitioners should refer men with complicated LUTS to a specialist service.	Unanimous in favour	0	0	100
General Practitioners should consider lifestyle advice as a possible first-line intervention in men with uncomplicated LUTS.	Strong in favour	9	9	82
General Practitioners should consider a therapeutic trial in men with uncomplicated LUTS whose symptoms failed to respond to lifestyle advice.	Strong in favour	0	18	82
Recommendations for good clinical practice	Level of	Distribution of ratings (%)*		

	consensus	<=3	4-6	
General Practitioners should consider alpha-blockers as a therapeutic trial for 1 month [†] for men with uncomplicated LUTS.	Strong in favour	0	9	91
General Practitioners should consider 5-alpha reductase inhibitors as a therapeutic trial for at least 6months for men with uncomplicated LUTS.	Strong against	82	0	18
General Practitioners should discuss with men with LUTS if they want to be screened for prostate cancer.	Strong in favour	0	9	91

[†] Due to the fast-acting nature of alpha-blockers, a footnote should be included that the patient should stop the medication after 1 week if there is no improvement in symptoms

Statistical analysis

To study the effect of the patient characteristics on the appropriateness of referral, we compared the means of the ratings for each level of the patient characteristics. The differences were tested with a multiple regression model in which “group member” was defined as a random effect. Random-effect regression modelling was used because the ratings of a single group member were expected to be less variable than the ratings from all guideline development group members together. We tested for interaction between patient characteristics to investigate whether the effect of one of these characteristics depended on the level of the other.

Box 3. Example of a case scenario

Referral is appropriate for a man with lower urinary tract symptoms									
<ul style="list-style-type: none">• with severe symptoms• aged 70• with an enlarged prostate• with no strong referral preference either way									
strongly disagree							strongly agree		
1	2	3	4	5	6	7	8	9	

7.3 Results

Overview of existing guidelines and additional evidence reviews

None of the American and European clinical guidelines that were available in 2007 contained guidance on referral from primary care to a specialist (AUA, 2003; Speakman *et al.*, 2004; De la Rosette *et al.* 2006). For the assessment of a patient with LUTS, both guidelines recommended a careful medical history including the use of the International Prostate Symptoms Score (IPSS), a physical examination including digital rectal examination, and urine analysis with a dipstick test. The European guideline also recommended uroflowmetry, post-void volume measurements, serum creatinine measurements as well as upper urinary tract imaging.

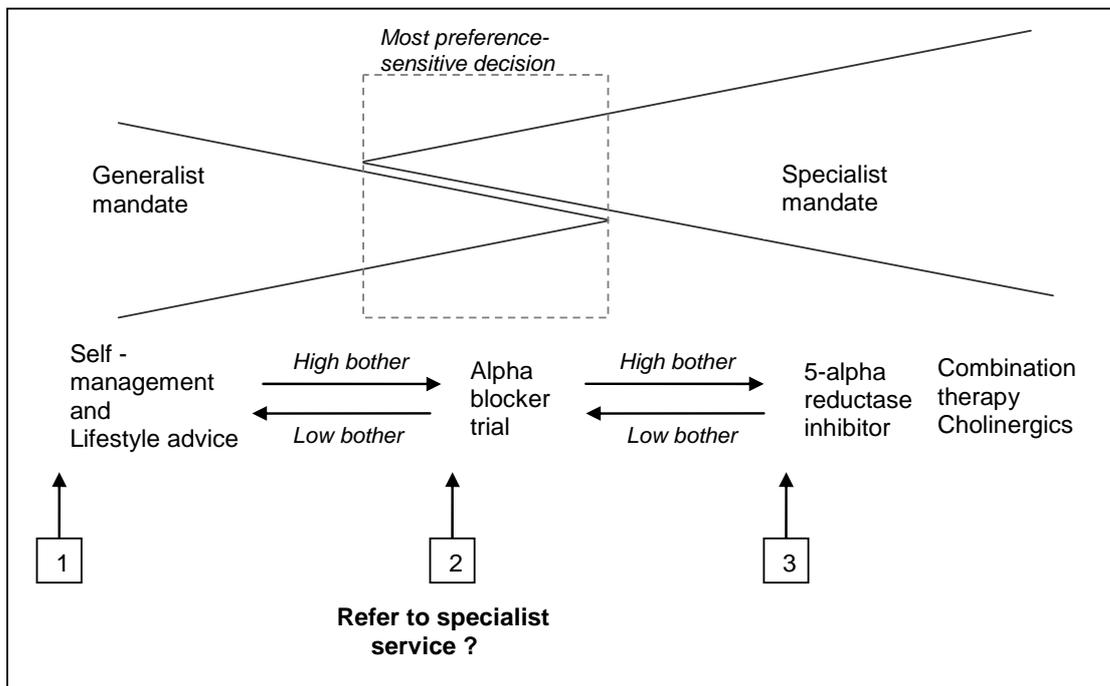
Based on the discussions within the guideline development group, the Project Team produced a diagram that represents the treatment sequence of men with LUTS (see Box 4). This treatment sequence is thought to start with lifestyle advice, using alpha-blockers if symptoms fail to improve with lifestyle advice, and finally using 5- alpha reductase inhibitors or other treatment modalities including surgery if symptoms fail to improve.

There are four arguments for this treatment sequence. First, lifestyle advice and self-management have been found to be successful in 90% of

men with uncomplicated LUTS and the reduction in symptom severity is at least as large – if not larger – than that seen when medical treatment is compared with placebo (Brown *et al.*, 2007). Second, the effect of alpha-blockers becomes apparent very quickly (within days) and about two third of men experience an improvement of symptoms (EAU, 2006). Third, treatment with 5-alpha reductase inhibitors is only effective in men with an enlarged prostate and it will take longer (several months) for the symptoms to improve (Boyle *et al.*, 1996; Kaplan, 2006; EAU 2006). Fourth, estimate of prostate size using digital rectal examination is inaccurate when compared with rectal ultrasound. Prostate size is underestimated especially when prostates are large (> 40 ml) (Roehrborn *et al*, 1997).

The guideline development group accepted that the decision to initiate treatment based on lifestyle advice (decision point 1 in Box 4) is predominantly the “mandate” of the general practitioner and the decision to use 5-alpha reductase inhibitors (decision point 3) is that of the experts working within a specialist service. The point at which uncertainty exists about whether the patient should be referred or not is when lifestyle advice is found to be unsuccessful (decision point 2). At this point, the decision whether referral is appropriate or not is preference-sensitive.

Box 4. Treatment sequence of men with uncomplicated lower urinary tract symptoms



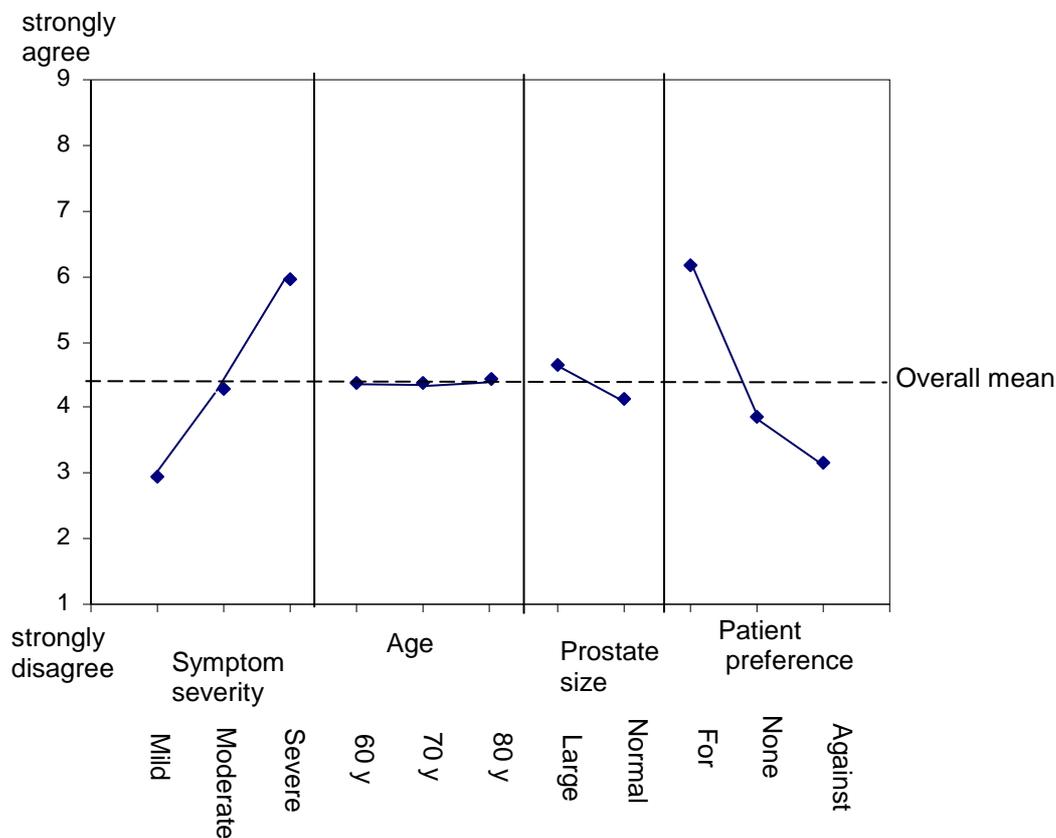
Recommendations on good primary care practice

Twelve draft recommendations for good primary care were formulated based on the guideline development group’s discussions of the evidence

(see Table 16). Consensus was reached in favour of nine of these recommendations and against one. In summary, general practitioners should first confirm that the patient has uncomplicated LUTS by taking a detailed medical history that rules out previous acute urinary retention and previous surgery of the prostate, carrying out a digital rectal examination to assess the prostate for nodules which may be suggestive of a tumour, and performing a dipstick test for protein and blood in the urine. Patients with uncomplicated LUTS should be first offered lifestyle advice, after which a therapeutic trial with alpha-blockers should be commenced for at least one week. General practitioners should not consider a trial of 5-alpha reductase.

The group failed to reach consensus about the prostate-specific antigen test. Some members argued that this test should be requested to rule out prostate cancer as much as possible, whereas others pointed out that the risk of prostate cancer is not increased in men with LUTS who have an enlarged prostate but a digital rectal examination not indicative of cancer (Young, 2000) and that as a consequence prostate cancer screening with the prostate-specific antigen test is unwarranted (National Screening Committee, 2006). As a consequence, a new recommendation was considered, now saying that screening for prostate cancer should be discussed with the patients, which received unanimous support.

Figure 3. Mean rating of referral appropriateness for each level of the patient characteristics



The guideline development group also failed to reach consensus about whether serum creatinine levels should be tested and the glomerular filtration rate be estimated to rule out kidney failure. Some argued that kidney failure is a serious condition that needs urgent management. Others indicated that they felt that kidney failure occurs too infrequently in men with LUTS to justify this test.

Recommendations on appropriateness of referral

Severity of symptoms and patient preference had a strong impact on the group’s ratings of referral appropriateness for the 54 case scenarios ($p < 0.001$ for both; see Figure 3). Prostate size influenced the groups rating as well ($p = 0.005$) but its impact was relatively small. Age did not have significant impact ($p = 1.0$).

The influence of symptom severity depended on patient preferences (p for interaction = 0.001; see Figure 4). Symptom severity appeared to have a greater impact when patients had no referral preference.

As a consequence, the group based its recommendations only on patient preferences and symptom severity (Table 17). We therefore, distinguished nine scenario profiles (3 severity levels x 3 preference levels) each of which included six scenarios (3 age levels x 2 prostate size levels). In summary, the patient profiles that the group agreed should not be referred were those with mild symptoms who have no preference or a preference against referral. In contrast, there was consensus in favour of referral for patients with severe symptoms and a strong preference for referral.

Figure 4. Mean rating of referral appropriateness according to symptom severity and referral preference

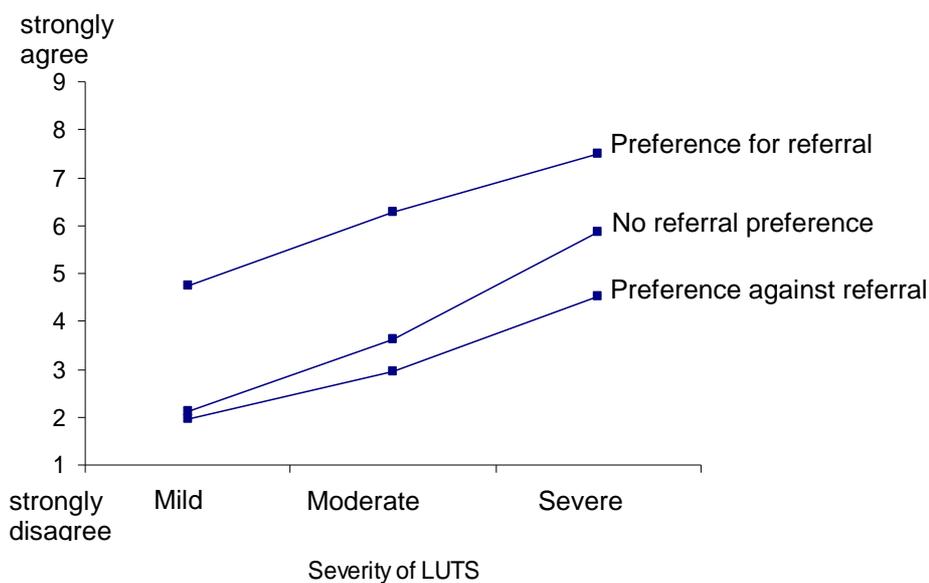


Table 17. Recommendations for appropriateness of referral

Severity of symptoms	Patient preference	Level of consensus on appropriateness of referral	Distribution of appropriateness ratings (%)		
			<=3	4-6	>=7
Mild	For referral	No consensus	39.4	33.3	27.3
	No preference	Moderate against	87.9	12.1	0
	Against referral	Moderate against	89.4	10.6	0
Moderate	For referral	No consensus	9.1	30.3	60.6
	No preference	No consensus	48.5	43.9	7.6
	Against referral	No consensus	71.2	22.7	6.1
Severe	For referral	Moderate in favour	6.1	9.1	84.9
	No preference	No consensus	24.2	19.7	56.1
	Against referral	No consensus	39.4	34.9	25.8

An important factor underlying the lack of consensus for some profiles was that a number of group members felt that referral should be considered only if patients have failed to respond to a therapeutic trial with an alpha-blocker whereas the case scenarios described patients who only had failed to respond to lifestyle advice and self-management (decision point 2). This view, which underlines the above-mentioned uncertainty about whether therapeutic decisions at this point in the treatment sequence are the mandate of general practitioner or urological specialist, was expressed especially with regards to patients with severe symptoms who did not have a referral preference or who preferred not to be referred.

Group differences in ratings of referral appropriateness

Overall, the ratings of the appropriateness of referral were similar for all the stakeholder groups. The mean appropriateness ratings were 4.5 in patient representatives, 4.2 in general practitioners, 3.9 in urologists, and 5.0 in the other healthcare professionals (p for group differences = 0.8).

However, patient representatives, general practitioners and urologists and patient representatives were more strongly influenced by patient preferences than by symptom severity. For the patient representatives, the

difference between the ratings for scenarios describing patients with a strong preference in favour of referral and those with a strong preference against of referral was 3.6 and between those describing patients with severe symptoms and those with mild symptoms was 1.8. For the GPs, corresponding differences were 3.7 and 2.9, respectively, whilst for urologists these corresponding differences were 3.0 and 2.1 respectively. In contrast, the other healthcare professionals seemed to be more strongly influenced by symptom severity than by patient preferences (differences of 2.0 for patient preferences and 4.8 for symptom severity).

7.4 Discussion

Findings

The guideline development group reached consensus on the appropriateness of referral for patients with severe uncomplicated LUTS who want to be referred and the inappropriateness of referral for patients with only mild symptoms who do not want to be referred or who do not have a referral preference. For all other patient groups, defined according to symptom severity and referral preference, there was no consensus. Age and prostate size assessed through digital rectal examination had little or no impact on the group's judgement (see Appendix 5).

These referral recommendations apply to patients whose symptoms had not responded successfully to lifestyle advice (decision point 2 in Box 4). They should be interpreted in the light of the group's recommendations for good primary care practice. First, the group unanimously supported that general practitioners should have verified that the LUTS are uncomplicated. Patients with complicated LUTS should always be referred. Second, there was strong consensus that general practitioners should consider a therapeutic trial with alpha-blockers before referral. It is therefore not surprising that the group only supported referral of patients with severe symptoms who want to be referred.

An important implication of these results is that digital rectal examination should be carried out in all patients with LUTS not so much to determine prostate size as to examine the prostate for nodularity which may be suggestive of cancer. It is important to note in this context that there was no consensus about the use of prostate-specific antigen screening for prostate cancer. However, the group strongly supported that general practitioners should discuss the need for prostate cancer screening with men with LUTS.

Patient preferences

Only a minority of currently available guidelines have explicitly considered evidence on patient preferences (Chong *et al.*, 2007; McCormack & Loewen, 2007). One of the reasons why preferences have not been given a more central role is that there is a lack of "preference-related evidence" (McCormack & Loewen, 2007). There is furthermore no agreement on how

patient preferences can be identified and integrated in the guidelines' recommendations (Schuneman *et al.*, 2006). The term preference is often poorly defined and interchangeably used in a number of ways. In the context of our referral guideline, it may represent the desirability ("utility") of a particular *health-related outcome* (for example, living with severe LUTS) or the feelings about undergoing a particular *health care process* (for example, digital rectal examination or transurethral prostatectomy) or *treatment strategy* (for example, referral to a urological specialist) (Krahn & Naglie, 2008).

In an ideal world of shared decision making, a patient would determine his or her preference for a treatment strategy by first seeking evidence about all possible health-related outcomes - including their probabilities and expected duration - following all possible options. In a second step, this evidentiary information would be combined with the process and outcome preferences to identify the treatment option with the highest "expected value". This process is in essence equivalent to formal clinical decision analysis.

When designing the development process of the referral guideline, the Project Team decided for a number of reasons that the only feasible way to include patient preferences was to consider preferences for referral as one of the determinants of referral appropriateness. First, there is no research evidence on the differences in outcomes of patients with LUTS treated by general practitioners and urological specialists. Second, considering preferences for health outcomes – although possible in theory – would be impractical given the time and resources required to develop guideline recommendation based on a decision-analytical approach. Third and most importantly, it is unlikely that general practitioners would implement a referral guideline that requires a detailed and explicit consideration of the relative value that patients assign to a number of specific outcomes.

Demand management and patient involvement

Our results highlight the difficulties that general practitioners face combining their role as "gate keeper" and "patient advocate". The fundamental issue is how general practitioners are supposed to respond to demands to protect patient autonomy in contrast to meeting other objectives such as providing care that is of direct benefit to their patients and considering the wider issue of a fair and equitable distribution of resources.

A recent study carried out in 18 European countries found that patients rate the care provided by their general practitioners more positively if they have more freedom of choice of whether they are treated by a primary care practitioner or secondary care specialist (Kroneman *et al.*, 2006). Similarly, an earlier study carried out in the United States suggested that policies that emphasise the role of primary care physicians as gate keepers have a negative impact on how patients value the role of these practitioners (Grumbach *et al.*, 1999).

To the best of our knowledge, our referral guideline is the first that explicitly addresses the tension in this dual role of general practice. The results suggested that symptom severity has the strongest impact if patients do not have a strong referral preference.

Comparison with other studies

A group of experts of the British Association of Urological Surgeons who produced a guideline for the management of patients with LUTS in primary care also recommended that general practitioners should consider lifestyle advice and a therapeutic trial with alpha blockers for men with uncomplicated LUTS (Speakman *et al.*, 2004). However, they also advocated that general practitioners prescribe 5-alpha reductase inhibitors in men with large prostates. This was not adopted by our group because estimates of prostate size with digital rectal examination are known to be inaccurate and it takes at least three months treatment with this drug before symptoms improves.

Few studies have addressed the appropriateness of referrals of patients with LUTS from primary care to urological specialists. One British study analysed referral letters in the late nineties as a first step in developing a "performance indicator" for the referral for "prostatism". Over a third of referral letters did not provide information about digital rectal examination and over two thirds did not contain results of simple tests (Elwyn *et al.*, 1999a). In an accompanying paper, the authors suggested two reasons why it was difficult to define referral appropriateness (Elwyn *et al.*, 1999b). First, there was a lack of agreement between primary and secondary care about the optimal management plan for patients with LUTS. Second, they were uncertain about where components of this management plan, including medical history taking and examining the prostate by digital examination and ultrasound, should be carried out. In turn, our referral guideline explicitly addresses these issues for men with *uncomplicated* LUTS by defining the "mandates" of the general practitioner and the urological specialist (Box 4).

A more recent Dutch survey of general practitioners and urologists found that general practitioners involved in shared-care initiatives for men with LUTS had shifted their working style towards that of hospital specialists and that urologists more often chose surgical interventions (Wolters *et al.*, 2004). General practitioners ordered more tests and less often choose watchful waiting for men with mild symptoms. These results suggest that a reduction of referral rates may lead to an increased rather than a decreased use of diagnostic investigations and medical and surgical interventions. This highlights the importance of our approach in which we developed referral guidelines as well as recommendations for good primary care practice.

As described in chapter 6, we developed referral recommendations for patients with osteoarthritis of the knee using similar methods. Also for these patients, the appropriateness of referral was found to be determined only by symptom severity and the patients' referral preferences. The impact of patient preference on the ratings of referral appropriateness was

largest if symptoms were severe. This demonstrates that for patients with osteoarthritis the gate keeping role of general practitioners was found to be prevailing for patients with mild symptoms who are less likely to benefit from referral.

Methodological considerations

The evidence reviews were collated from secondary sources (the most recent American and European guidelines available in 2007) supplemented with a number of rapid reviews. It is unlikely however that full systematic reviews of the literature and an evaluation of the primary studies would have provided the guideline development group members with different views on the appropriateness of referral.

The group consisted of only 11 members and the results may have been unduly influenced by the opinions of individuals. Furthermore, the members of the guideline development group were aware that the referral guideline was developed in the context of a study on the impact of patient preference. To investigate the extent to which the judgements of the group were representative, we mailed a questionnaire containing nine simplified case scenarios that only varied according to symptoms severity and referral preferences to wider groups of patients, general practitioners and orthopaedic surgeons. The results were very similar to those observed within the guideline development group, including the observed interaction between symptom severity and referral preference (see chapter 8).

Other limitations were that case scenarios can only contain a limited number of patient characteristics and that no evidence on cost effectiveness was made available to the group members. However, a recent study has demonstrated that there is a strong agreement in responses to case scenarios and to actual patients (Bouma *et al.*, 2004) and another recent study has shown that the availability of resources has only a limited effect on the judgements of guideline development groups (Raine *et al.*, 2004).

Implications

It is increasingly being emphasised in the urological literature that clinicians should consider how patients themselves perceive the symptoms associated with benign prostatic hyperplasia when planning their management (Hong *et al.*, 2005). Referral guidelines that explicitly include patient preferences may help to achieve just that at a time that intermediary referral management services are being set up in order to tackle the volume and improve the quality of referrals (Davies & Elwyn, BMJ 2006).

The development of referral guidelines requires an explicit consideration of the tension between the role of general practitioners as patient advocate and gate keeper. Our study demonstrates how formal consensus development methods can be used to produce referral recommendations that take into account this potential conflict between the interest of individual patients and that of society in general.

8 Representativeness of the guideline development groups' views on the appropriateness of referral of patients with osteoarthritis of the knee or lower urinary tract symptoms

8.1 Introduction

General practitioners have to combine two conflicting roles. On one hand, they have to manage demand in their role as "gate keepers" to specialist services, and on the other they need to act as "patient advocates" and take the referral preference of individual patients into account. To explore the importance of patients' preferences, referral guidelines for patients with osteoarthritis of the knee and patients with lower urinary tract symptoms were developed (see chapters 6 and 7). The guideline development groups rated the appropriateness of referral for a number of case scenarios that varied according to symptoms severity, age, the patients' preference, comorbidity (for osteoarthritis only), body mass (for osteoarthritis only) and prostate size (for LUTS only).

For both conditions, the guideline development groups were strongly influenced by both the severity of the patients' symptoms and their preferences for referral but not by the other factors. There was a consensus that it is appropriate to refer patients with severe symptoms who want to be referred and not to refer patients with mild symptoms who do not want to be referred.

The discussions within the groups centred around two arguments. Group members wanted to protect "patient autonomy", but they also argued that referral should only be recommended if there was evidence of "patient benefit" and "efficient use of limited resources". As a result, the osteoarthritis group seemed to be more responsive to the referral preferences represented in the case scenarios if symptoms were severe than if they were mild (see Figure 2 in chapter 6), suggesting a shift from the gate keeper towards the patient advocate role with increasing symptom severity. The group that developed the referral guideline for lower urinary tract symptoms seemed to be more responsive to symptom severity when patients did not have a referral preference than when patients have a strong preference for or against referral (see Figure 4 in chapter 7).

The guideline development groups consisted of 12 members for the osteoarthritis guideline and 11 for the lower urinary tract symptoms guideline and included patient representatives, general practitioners, surgeons and other healthcare professionals. The judgement of individual members may therefore have influenced the results. Furthermore, the

group members were aware that the referral guidelines were being developed in the context of a study on the impact of patient preference.

In this chapter, we determined the representativeness of the groups' ratings of referral appropriateness and examined differences in the ratings of referral appropriateness between three stakeholder groups: general practitioners, specialists and the public.

8.2 Methods

Questionnaires were developed for osteoarthritis of the knee and for lower urinary tract symptoms (see Appendix 6). Each questionnaire provided some background on the conditions, a short summary of the research evidence, definitions of terms used in the questionnaire (such as referral, specialist service, symptoms severity and patient preference), and assumptions about available health care resources. In addition, assumptions about patients' previous treatment in primary care under their general practitioner were provided. The questionnaires are available on request from the Project Team.

Respondents were asked to rate their agreement with the appropriateness of referral of patients described in nine case scenarios. These case scenarios were similar to those used in the guideline development groups, but they only described three levels of symptoms severity and three levels of referral preference). Agreement was scored on a scale of 1 ("strongly disagree") to 9 ("strongly agree").

Questionnaires were mailed to a random sample of general practitioners (n = 151 for osteoarthritis and n = 151 for lower urinary tract symptoms) from ten selected representative primary care trusts in England stratified by practice size (see also chapter 5) and to a random sample of general practitioners from Warwickshire, Coventry and Worcestershire primary care trusts (n = 150 for osteoarthritis and n = 150 for lower urinary tract symptoms). A random sample of urologists who were members of the British Association of Urological Surgeons register (n = 200) were sent the lower urinary tract symptoms questionnaire and a random sample of orthopaedic surgeons who were members of the British Orthopaedic Association register (n = 200) were sent the osteoarthritis questionnaire. All members of The Royal College of Surgeons of England Patient Liaison Group (n = 12) were sent the osteoarthritis questionnaire, and members of the public who had responded to an advertisement in SAGA magazine, a magazine that targets people over 50, were sent the osteoarthritis questionnaire (n = 80) or the lower urinary tract symptoms questionnaire (n = 42 men).

The definition of consensus was based on a "strict" definition in the RAND approach (Fitch *et al*, 2001). Ratings of 1-3 were considered as indicating "disagreement", ratings of 4-6 as "equivocal", and ratings of 7-9 as "agreement". Four levels of consensus were established: "unanimous" (100% of the respondents have ratings in any of the three ranges), "strong" (more than 92% in any of the ranges but less than 100%), "moderate"

(between 83% and 92% in any of the ranges), and “weak” (between 75% and 83% in any of the ranges). The cut-off percentages for the different levels of consensus were based on the idea that 12 is a commonly recommended number of members of a formal consensus group and that consensus is strong if all but one, moderate if all but two, and weak if all but three of 12 participants have ratings within any of these three ranges.

Statistical analysis

To study the effect of symptom severity and patient preference on the ratings of the appropriateness of referral, the means of the ratings we compared for each level of severity and preference. The differences were tested with a multiple regression model in which “stakeholder” was defined as a random effect. Random-effect regression modelling was used because the ratings of a single respondent were expected to be less variable than the ratings from all respondents together. We tested for interaction between symptom severity and patient preference to investigate whether the effect of one depended on the level of the other.

Table 18. Response rates of postal questionnaires sent to general practitioners, consultant specialists and members of the public

<i>Osteoarthritis of the knee</i>	Number of sent questionnaires	Respondents (%)
General practitioners	301	39 (13.0%)
Orthopaedic surgeons	200	57 (28.5%)
Members of the public	92	69* (75%)
<i>LUTS</i>		
General practitioners	301	32 (10.6%)
Urologists	200	54 (27.0%)
Members of the public	42	37** (88.1%)

* 32 (47%) had osteoarthritis of the knee and 11 of these (34%) had surgical intervention

** 21 (60%) had lower urinary tract symptoms and 4 of these (19%) had surgical intervention

8.3 Results

Osteoarthritis of the knee

In total, 593 questionnaires containing case scenarios describing patients with osteoarthritis of the knee were sent out and 165 of these (27.8%) were completed and returned (Table 18). The response rate was highest for

members of the public (75.0%) and lowest for general practitioners (13.0%).

The ratings of referral appropriateness were strongly influenced by the severity of the symptoms and the patient preferences (both $p < 0.001$; Figure 5). The influence of patient preferences depended on symptom severity (p for interaction < 0.001). Patient preferences seemed to have a greater impact when knee symptoms were moderate or severe than when they were mild.

The mean ratings on the appropriateness of referral differed in the three stakeholder groups ($p < 0.001$), with the highest ratings given by members of the public (5.4) followed by the surgeons (4.9) and then the general practitioners (4.3). The pattern of the ratings was similar between the groups (Figure 6).

The appropriateness of ratings of general practitioners and specialists corresponded closely to those of their representatives on the guideline development group (Figure 6). However, the ratings of the members of the public differed from those of the patient representatives. The latter gave the same weight to preferences in patients with mild symptoms as those with moderate or severe symptoms, whereas the members of the public gave a greater weight to preferences when symptoms were severe.

The 165 respondents reached consensus that referral was appropriate for patients with severe symptoms if they either had a strong preference for referral or no referral preference (Table 19). In addition, there was consensus that it was not appropriate to refer patients with mild symptoms who did not want to be referred or who had no referral preference. These results resemble those of the guideline development groups (see chapters 6 and 7).

Figure 5. Mean referral appropriateness rating for each level of the patient characteristics for 185 respondents for osteoarthritis and 123 for lower urinary tract symptoms (black) and the guideline development groups (grey). Circles indicate strong preference against referral, triangles no referral preference, and squares strong preference in favour of referral

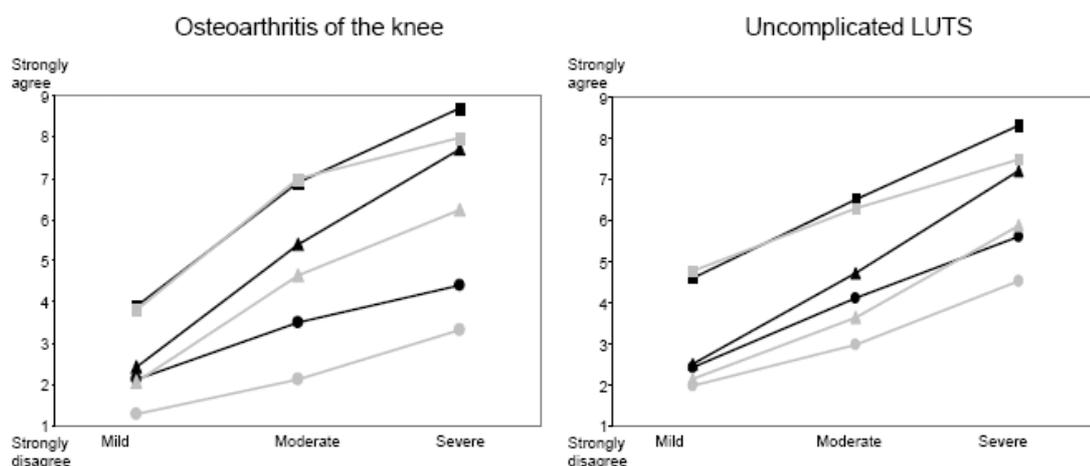


Figure 6. Mean group ratings of appropriateness of referral of patients with osteoarthritis of the knee according to symptom severity and preference for referral. (See Figure 5 for further explanation.)

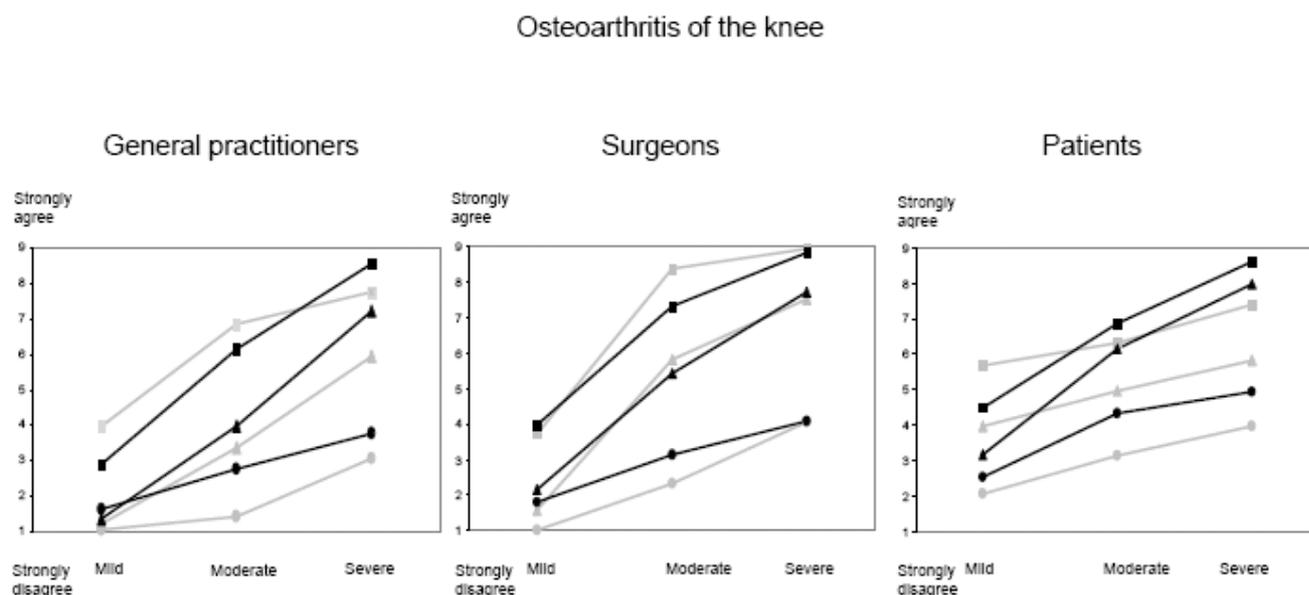


Table 19. Recommendations for appropriateness of referral of patients with osteoarthritis of the knee

Severity of symptoms	Patient preference	Level of consensus on appropriateness of referral	Distribution of appropriateness ratings (%) [†]		
			<=3	4-6	>=7
Mild	For referral	No consensus	47	36	16
	No preference	Weak against	80	15	5
	Against referral	Moderate against	86	8	6
Moderate	For referral	No consensus	8	22	70
	No preference	No consensus	25	38	37
	Against referral	No consensus	53	36	11
Severe	For referral	Strong in favour	0	1	99
	No preference	Moderate in favour	6	10	84
	Against referral	No consensus	41	37	22

[†] Consensus was defined as a frequency of 75% agreement or more

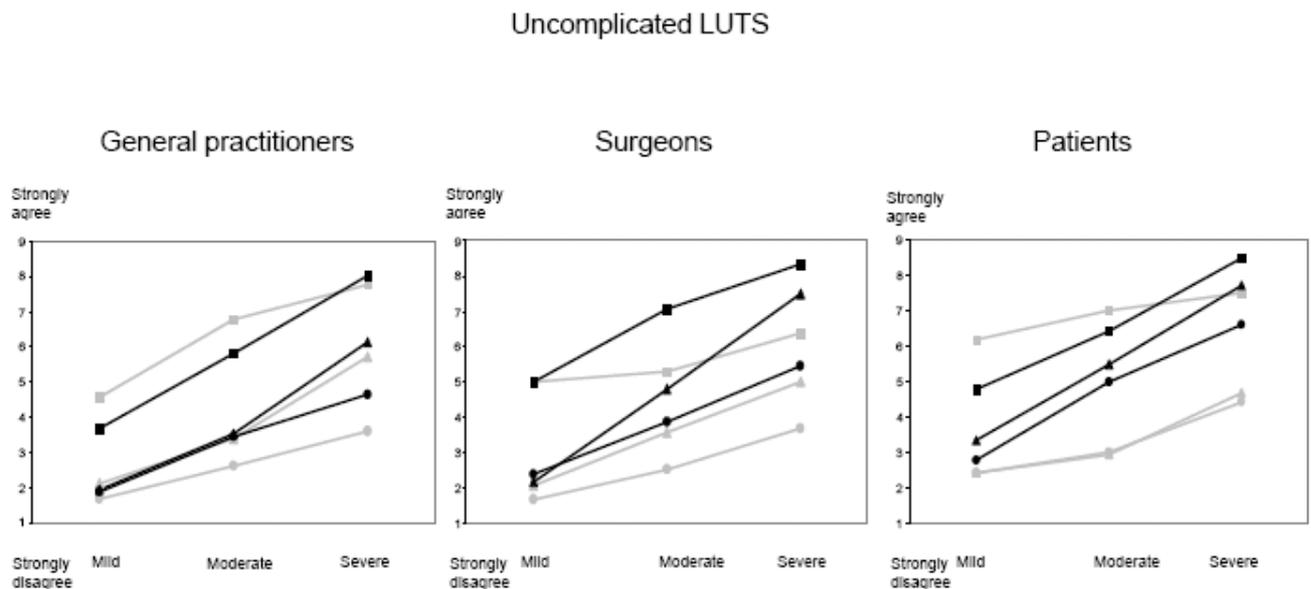
Uncomplicated LUTS in men

Of the 543 questionnaires sent out 123 (20.7%) were completed and returned (Table 18). The response rate was highest for members of the public (88.1%) and lowest for general practitioners (10.6%).

Ratings were strongly influenced by the severity of the symptoms and patient preferences (both $p < 0.001$; Figure 5) and the influence of symptom severity depended on the patient preferences (p for interaction < 0.001). Symptoms severity seemed to have a greater impact when patients did not have a strong preference for referral.

As with osteoarthritis of the knee, the highest mean appropriateness ratings were given by members of the public (5.6) followed by specialists (5.2) and then general practitioners (4.3). The pattern of general practitioners' and surgeons' rating was similar (Figure 7). The ratings of the members of the public however did not show an interaction (i.e. impact of symptoms severity on the appropriateness ratings did not depend on referral preference).

Figure 7. Mean group ratings of appropriateness of referral of patients with lower urinary tract symptoms according to symptom severity and preference for referral. (See Figure 5 for further explanation.)



The appropriateness ratings of general practitioners was similar to those of their representatives on the guideline development group (Figure 7), although this was not true for ratings of the specialists and the members of the public. Specialists gave a greater weight to symptom severity, especially in those with no strong referral preferences and those with a preference in favour of referral. The members of the public responded more strongly to symptom severity than had the patient representative in the guideline development group.

There was consensus among the 123 respondents that referral was appropriate for patients with severe symptoms if they had a strong preference for referral or no referral preference (Table 20). Consensus was also reached that referral was inappropriate for patients with mild symptoms who did not want to be referred or did not have referral preferences. Again, these consensus results resemble the results of the

formal consensus development methods in the guideline development groups (see chapters 6 and 7).

Table 20. Recommendations for appropriateness of referral of patients with osteoarthritis of the knee

Severity of symptoms	Patient preference	Level of consensus on appropriateness of referral	Distribution of appropriateness ratings (%) [#]		
			<=3	4-6	>=7
Mild	For referral	No consensus	35	46	19
	No preference	Moderate against	83	12	5
	Against referral	Moderate against	82	11	7
Moderate	For referral	No consensus	10	33	58
	No preference	No consensus	37	42	22
	Against referral	No consensus	42	46	12
Severe	For referral	Strong in favour	1	6	94
	No preference	Weak in favour	7	17	76
	Against referral	No consensus	23	35	42

[#] Consensus was defined as a frequency of 75% agreement or more

8.4 Discussion

Findings

The survey demonstrates that the view of the general practitioners, specialists and members of the public on the appropriateness of referral of patients with non-urgent conditions is remarkably similar. In all three groups, preference of patients had a strong impact on the ratings of referral appropriateness and its impact depended on the condition and the severity of the symptoms. For both conditions, there was consensus that patients with severe symptoms who have a strong preference in favour of referral or no referral preference should be referred and that patients with mild symptoms who have strong preference against referral or no referral preference should not. These views correspond closely with those of two guideline development groups who used a formal consensus development method.

Methodological considerations

The response rates of the general practitioners and the surgeons were very low, thus challenging the representativeness of the results. The crucial question is to what extent those who did not respond might have given different answers than those who did. A recent study comparing general practitioners who had and had not responded to a survey on prescribing of

statins and asthma medication did not find evidence that non-responders would have provided different answers (Rashidian *et al.*, 2008).

The response rates of the members of public were considerably higher, but these respondents were a self-selected group as they had responded to an advertisement. However, the advertisement that invited patients to participate did not explain that an important aspect of the study was how patients' views on referral should be taken into account, which makes it less likely that only those people with a particular view on the impact of patient preferences participated. It is interesting to note in this context that about half the respondents in each group had the condition and that about one in seven to eight patients had undergone surgery.

Comparison with other studies

A study exploring patient preferences for specific angina treatments found that patients were more strongly influenced by their perceptions of effectiveness than by emotional and lifestyle factors (Lamberts *et al.*, 2004). This may partly explain the similarity that we observed between the ratings of the members of the public on the one hand and the general practitioners and the surgeons on the other given that the questionnaire provided a short evidence summary which provided the patients with essential information about the effectiveness of the available treatment options.

It has been shown that clinicians who are members of consensus development groups are more likely to rate as appropriate treatments that they themselves are familiar with (Coulter *et al.*, 1995; Carpenter *et al.*, 2007). We found that surgeons had on average higher ratings of referral appropriateness than general practitioners which may reflect their greater familiarity with the treatments that specialist services can offer.

Implications

This survey indicates that the guideline development groups' views on the appropriateness of referral of patients with osteoarthritis of the knee and lower urinary tract symptoms are shared by wider groups of general practitioners, surgeons and members of the public. The pattern of the ratings of referral appropriateness according to the severity of a patient's symptoms and his or her referral preference demonstrates that developers of referral guidelines should explicitly consider how the guidelines can represent individual patients' preferences for referral.

The recommendations in referral guidelines underpin the conflicting roles of general practitioners as patient advocate and gate keepers. Guideline development groups have to make complex value judgements that involve arguments related to fundamental ethical principles such as patient autonomy, beneficence and fairness. Our work demonstrates that a survey with simple descriptions of hypothetical patients can be used to establish whether there is wider support for these judgements within the wider population.

9 Conclusions and implications

The REFER project was carried out to improve the process of referral from primary to secondary care for patients with non-urgent conditions who may benefit from surgical treatment. General practitioners are supposed to respond to two potentially conflicting policy developments: the emphasis on managing demand for specialist services on the hand and the overall political pressure to allow patients choice on the other (Department of Health, 2005; Department of Health, 2008).

The “priority scoring tools” that had been developed during the nineties to prioritise patients for surgical treatment did not meet essential criteria for validity (assessed by comparing with implicit clinical judgement or with actual health outcomes) and reliability (assessed by comparing different examiners or by comparing results of same tool within a time interval) (Kipping *et al.*, 2002). A further criticism of these tools was that they did pay little attention to the views and preferences held by the patients themselves.

9.1 REFER project phase 1

The first phase of the REFER project aimed to provide a better understanding of the context of the use of referral guidelines in the NHS. This was achieved by carrying out a systematic review and evaluation of available referral tools (chapter 3), a policy analysis (chapter 4), and a survey of general practitioners (chapter 5).

9.1.1 Summary of results of phase 1,

Systematic review of effectiveness of referral guidelines

This literature review demonstrated that there is very little evidence to answer the question of whether referral guidelines improve the appropriateness of referrals. It is difficult to assess any independent effect due to the lack of comparison groups of many studies. Well-designed studies reported improvements in process measure, such as compliance with referral criteria or use of diagnostic investigations. No evidence was found for effects of referral guidelines on general practitioners' knowledge of appropriateness of referral, on rates of referral, or on health outcomes or costs.

Policy analysis: context for the use of referral guidelines

Based on an analysis of policy documents, interviews with experts and stakeholders and qualitative survey of five primary care trusts, it was concluded that unprecedented change is occurring in the NHS. Unevaluated

methods for demand management are being introduced in many primary care trusts.

These changes demonstrate a diverging view on the appropriateness of referral between doctors and managers. However, they also mean that guidelines will need to be adaptable to different situations. Successful guidelines are likely to be those which can become embedded in the referral process and which acknowledge the input of the patient into the referral decision.

Survey of general practitioners' views and use of referral guidelines

For referral guidelines to be successful they should have a number of key recommendations that can easily be remembered and applied. The educational contribution that referral guidelines could make if general practitioners were confronted with a difficult or unfamiliar situation was also found to be important. The general practitioners also indicated that they were supportive of sharing referral decisions with patients.

9.1.2 Comparison with other studies

The evidence that guidelines alone are effective at changing clinician behaviour is limited (Gabbay and le May, 2004; Worrall *et al.*, 1997; Grimshaw *et al.*, 2001; Fertig *et al.*, 1993). Our findings are therefore in accordance with other research and publications on both guidelines and referral. Evidence would suggest that there is a definite role for guidelines in encouraging greater standardisation of care as far as elective surgical referral is concerned. Referral guidelines have the potential to increase the appropriateness of referral, whilst maintaining the "gate keeper role." Substantial variations in referral rates from primary to secondary care have been found and access to surgery has not been found to be equitable (O'Donnell, 2000; Reynolds *et al.*, 1991; Wilkin and Smith, 1987).

In the UK, NICE guidance for the referral of common conditions to surgical specialties has not been rigorously implemented or evaluated (National Institute for Clinical Excellence, 2001). Two reviews had previously investigated interventions for referral from primary to secondary care in general. Faulkner *et al.* (2003) reported little impact of referral guidelines on rates of referral or health outcomes. Grimshaw *et al.* (2001) found that passively disseminated guidelines had less impact than structured referral sheets. In our systematic review, we found that guidelines on their own did not improve the appropriateness of referral but there were interesting indications that guidelines as part of a wider referral and management package might be valuable (Clarke *et al.*, in press).

We found in our policy analysis and interviews that appropriateness of referral remains an extremely important policy issue in the NHS. It was defined by NHS managers as depending on three hierarchical concepts relating to appropriateness of assessment of clinical necessity; appropriateness of destination and to appropriateness of process (Blundell *et al.*, in press). Demand management was a very prominent concern of NHS managers and contrasted with the more consumerist patient-focused

approach to health care which is also being promulgated centrally. When we undertook this work, practice based commissioning (PBC) was not yet a key issue for primary care trusts but it is clear that the conflict between the advocacy and gate keeping roles are brought into stark relief by PBC.

In a theoretical paper, Davies and Elwyn (2008) suggested three categories of inappropriate referral: those that do not conform to accepted clinical guidance; those made to the wrong service or specialty; and those containing insufficient information, making it difficult to assess urgency or relevance. Our findings support and clarify their conceptual work, giving it an empirical justification. Although individual definitions varied, a **clear need** was perceived for accepted and standard guidance on referral.

Finally, in the survey respondents indicated how in fact they use guidelines in practice – these findings have strong implications for the **format** of any guidelines to be produced requiring short, easy, memorable messages. This accords well with findings on guideline use and format in other studies. (Langley *et al.*, 1998; Young and Ward, 2001; Coleman and Nicholl, 2001; Sturmberg, 1999; Grilli *et al.*; 1999; Gupta *et al.*, 1997).

Whilst not a formal element of this research, we should not forget however the challenge of implementing change once referral guidelines have been developed (Iles and Sutherland, 2001).

In each stage of Phase 1, openness to the possibility of including patients' preferences into referral guidelines was apparent reflecting the "reformation" (Shaw, 2009) which is currently occurring in health care and justifying attempts to include patient preferences as an integral element in referral guidelines.

9.1.3 Conclusions of phase 1 and implications for the development of referral guidelines

The findings of the first phase of the REFER project have a number of practical implications:

1. Referral guidelines need to be developed as part of a more general referral and management package. This could involve the development of structured management sheets or educational interventional material which would strengthen the general practitioners awareness of the intervention. Also, one stop-services and direct access to waiting list could be considered.
2. Current policy developments regarding referral from secondary to secondary care within primary care trusts need to be taken into account including Practice Based Commissioning as well as the establishment of intermediary services to management demand for specialist services and secondary care.
3. Referral guidelines should allow for local variation in the available secondary care services.

4. Referral guidelines should help general practitioners to communicate with their patients about the risk and benefits of referral.
5. Referral guidelines should be concise and contain key messages that are memorable.
6. Referral guidelines should be produced in a language that general practitioners can share with patients.

9.2 REFER project phase 2

In the second phase of the REFER project we demonstrated how referral guidelines can be developed that take into patients' own view on referral into account. Two referral guidelines were developed: one for patients with osteoarthritis of the knee (chapter 7) and one for men with lower urinary tract symptoms (chapter 8). These two conditions were chosen because they are frequently encountered in primary care and there is uncertainty about the appropriateness of referral in many cases.

The guidelines were developed by groups representing patients, general practitioners, surgeons and other health care professionals. Systematic reviews of relevant evidence were considered and formal consensus development methods were used to formulate recommendations for good primary care practice as well as recommendations on the appropriateness of referral.

The members of the guideline development group had to rate their agreement with the appropriateness of referral for a number of case scenarios that described patients according to the severity of symptoms, age, comorbidity as well as their preference for referral.

To determine the representativeness of the guideline development group's view on the appropriateness of referral for patients with these two conditions, we mailed a survey containing a small number of case scenarios to general practitioners, specialists and the public (chapter 9).

9.2.1 Summary of the results of phase 2

Osteoarthritis of the knee

It was the guideline development groups' view that appropriateness of referral only depends on the severity of the knee symptoms and the patients' referral preferences and not on age, comorbidity or body mass. There was consensus that patients with severe knee symptoms who want to be referred should be referred and that patients with moderate or mild symptoms and strong preference against referral should not be referred.

An important observation was that patients' preferences had a greater impact on the groups' ratings of referral appropriateness when symptoms were moderate or severe than when symptoms were mild.

Lower urinary tract symptoms

Also for lower urinary tract symptoms, the guideline development group demonstrated that the appropriateness of referral only depends on symptom severity and referral preferences. Age and prostate size did not influence the group's judgements. As a result, there was consensus on the appropriateness of referral for men with severe lower urinary tract symptoms who want to be referred and the inappropriateness of referral for men with mild symptoms and either no preference or a strong preference against referral.

The groups' judgements seemed to be more responsive to symptom severity when patients did not have a referral preference than when patients had a strong preference for or against referral.

Representativeness of guideline development groups' view

The views of wider groups of general practitioners, specialists and of the public on the appropriateness of referral correspond closely with those of the two guideline development groups. Furthermore, in all three groups the referral preference of patients had a strong impact on the ratings of referral appropriateness and its impact depended on the severity of the symptoms.

9.2.2 Conclusions of phase 2

The development of these two referral guidelines for patients with non-urgent conditions who may benefit from surgery demonstrated that:

1. Formal consensus development methods can be used to elicit explicit statements on the appropriateness of referral of patients with non-urgent conditions according to symptom severity and their referral preference.
2. The appropriateness of referral for patients with non-urgent conditions such as osteoarthritis of the knee and lower urinary tract symptoms depends on the severity of their symptoms as well as on their preferences as to whether they want to be referred or not.
3. Referral guidelines should acknowledge that there can be an interaction between the impact that symptom severity and patient preferences have on referral appropriateness. The impact of patients' preferences was found to be larger when symptoms are severe.
4. Patient characteristics such as age, comorbidity, body mass and prostate size have relatively little impact on referral appropriateness.
5. Decisions on the appropriateness of referral should balance the interests of individual patients (protection of patient autonomy; benefits and harms of specialist management) and those of the population in general population (efficient use of limited resources).
6. Developers of referral guidelines should take into account that there is a potential conflict between the general practitioners' roles of "patient advocate" and "gate keeper".

9.3 Limitations

In the original application the concept of patient preferences is used in two different ways: either as the wish expressed by patients to be referred or as the expression of the values that patients assign to certain health states or their quality of life. When considering the implication of phase 1, the Project Team decided that the focus of phase 2 of the REFER project should be solely on preferences for referral. This shift in focus had an impact on the way the referral guidelines were developed as well as on their evaluation (see 2.1).

Also, a number of limitations of the REFER project need to be acknowledged. First, the systematic review of studies assessing the effectiveness of referral guidelines demonstrated that the evidence base is limited and that the methodological quality of the studies that could be retrieved is poor. There is therefore little evidence that referral guidelines improve the appropriateness of referral. It is important to note that this does not mean that there is evidence that referral guidelines are not effective.

Second, despite strenuous attempts to increase response, the response rate to our survey of general practitioners' views and use of referral guidelines was low (40%). This may have affected the representativeness of our findings, especially if those who did not support the use of referral guidelines were less likely to respond.

Third, the referral guidelines for patients with osteoarthritis of the knee and lower urinary tract symptoms were developed by relatively small groups. As a result, individual members may have had an undue impact on the results. Furthermore, the guideline developers were aware of the aims and objectives of the wider REFER project. All this may have affected the representativeness of their judgements.

Lastly, a survey of a wider group of general practitioners, surgeons and members of the public demonstrated that the judgements of the views of these groups were in close agreement with those of the two guideline development groups. However, the response rate to this survey was low, especially among the general practitioners and surgeons.

9.4 Future research

This is the first time that referral guidelines for non-urgent conditions have been developed that explicitly incorporate patients' preferences for referral. However, the REFER project leaves many questions for future research.

First, the REFER project has not piloted the actual implementation of these guidelines. We do not know how many patients actually have conflicting referral preferences in relation to the severity of their symptoms (e.g. strong preference in favour of referral with mild symptoms or strong preferences against referral with severe symptoms). Without insight in these numbers, it is difficult to envisage what the impact of implementing

the guidelines will be. As a consequence, we do not have evidence on the effects that our referral guidelines will have on health outcomes and costs.

Second, we have not studied what kind of support general practitioners need when they make referral decisions. For example, what is the most appropriate way of presenting the research evidence?

A third issue is that unevaluated and untried methods, including the intermediary clinical assessment and treatment services, are currently being introduced in the NHS to manage the demand for a referral to secondary care the appropriateness of referral. To what extent will these services be able and willing to use guidelines that incorporate patients' preferences?

Lastly, since patient preferences were clearly considered to be integral in decisions about referral appropriateness, more research is now needed to understand what factors determine patients' referral preferences. Do they depend on the type or location of the treatment, the perceived expertise of the practitioner involved, or the actual content of the treatment plan or programme? To what extent do referral preferences reflect patients' expected, desired or anticipated health outcomes?

9.5 Implications for policy and practice

Despite the unanswered questions, the results of the REFER project have a number of implications:

1. Referral guidelines should be developed as part of a wider package (e.g. structured management sheets, educational material) that can support general practitioners.
2. Intermediary services set up to manage demand for specialist services should consider using explicit referral guidelines.
3. Patients' preferences should be incorporated in referral guidelines for non-urgent conditions.
4. Formal consensus development methods should be used to develop referral guidelines that incorporate patients' preferences.
5. Referral guidelines for patients with non-urgent conditions should allow the impact of patients' referral preferences to vary according to symptom severity.
6. Referral of patients with non-urgent conditions such as osteoarthritis of the knee and lower urinary tract symptoms should not depend on age or comorbidity.
7. General practitioners should consider the following guideline for the referral of patients with osteoarthritis of the knee:
 - Patients should be referred if they have severe knee symptoms and have a strong preference in favour of referral.

- Patients should not be referred if they have mild knee symptoms and have a strong preference against referral or no referral preference either way.
 - For all other patient groups, defined according to symptom severity and referral preference, there was no consensus with regard referral.
 - Age, comorbidity, and body mass do not affect the appropriateness of referral.
8. General practitioners should consider the following guideline for the referral of men with lower urinary tract symptoms:
- Patients should be referred if they have severe uncomplicated LUTS and have a strong preference in favour of referral.
 - Patients should not be referred if they have mild uncomplicated LUTS and have a strong preference against referral or no referral preference either way.
 - For all other patient groups, defined according to symptom severity and referral preference, there was no consensus with regard referral.
 - Age and prostate size do not affect the appropriateness of referral.

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Appendix 1: Systematic review - Search strategy

The search strategy was developed using extensive literature scoping, advice from information experts and discussion within the Project Team and with the study Steering Group. In order to maximise the sensitivity of the search, we included both text words and subject headings (MeSH terms). We searched only for papers published from 1980 onwards, but did not impose language restrictions.

The final strategy had three “arms”, which were:

- Terms relating to Primary Care or Primary Care Practitioners
- Terms relating to Referral
- Terms relating to Guidelines

The final search strategy was as follows:

Family Practice [MeSH] OR Primary Health Care [MeSH] OR Physicians, Family [MeSH] OR Primary Care OR “managed care” OR general practi* OR general practitioner OR general practitioners OR family doctor* OR family physician* OR generalist*
AND
Referral and Consultation [MeSH] OR refer OR referr* OR ((recommend* OR request*) AND (Surgical Procedures, Operative [MeSH] OR Surgery [MeSH] OR surgeon* OR surgery[Text Word] OR surgical[Text Word] OR operate[Text Word] OR operative[Text Word] OR operation[Text Word] OR operations[Text Word]))
AND
Practice Guidelines [MeSH] OR Algorithms [MeSH] OR guideline* OR guidance OR tool OR tools OR “algorithm” OR “algorithms” OR protocol OR protocols OR pathway* OR “care standards” OR “treatment standards” OR “preferred practice patterns” OR “decision tree” OR “decision trees” OR “decision aid” OR “decision aids” OR “decision modelling” OR “decision modeling”

Appendix 2: Systematic review – Study selection criteria

SELECTION CRITERIA	INCLUSION CRITERIA	EXCLUSION CRITERIA
Population: Patients	<ul style="list-style-type: none"> Adults (Age 16 years +) 	<ul style="list-style-type: none"> Children (Aged under 16 years)
	<ul style="list-style-type: none"> With a non-urgent condition 	<ul style="list-style-type: none"> With an urgent condition requiring emergency or urgent referral Red flag back symptoms Any evaluation of cancer two-week rule guidelines
	<ul style="list-style-type: none"> Seen in primary care by a primary care practitioner (PCP)/general practitioner (GP) 	<ul style="list-style-type: none"> Seen in primary dental care by general dental practitioner Seen by optician/optometrist Seen in A&E Seen in secondary care
	<ul style="list-style-type: none"> Condition should be amenable to surgical intervention if severe enough Do include: infertility if referral is from primary to secondary care; back pain if surgery is an option; glaucoma if referral is from primary to secondary care and surgery is an option; breast symptoms if non-urgent component 	<ul style="list-style-type: none"> Condition not amenable to surgical intervention
Population: Practitioners	<ul style="list-style-type: none"> Referring practitioner is general practitioner or primary care practitioner 	<ul style="list-style-type: none"> Referring practitioner is not a primary care practitioner (e.g. in referral to tertiary or high dependency care facilities)
	<ul style="list-style-type: none"> Receiving practitioner is a surgeon or practitioner in surgical specialty in secondary care 	<ul style="list-style-type: none"> Receiving practitioner is a someone <i>other than</i> a surgeon or practitioner in a surgical specialty (e.g. social services, complementary therapies, district nursing etc)
Interventions	<ul style="list-style-type: none"> Any guideline(s) or set of rules or protocol which assists primary care practitioners with a decision of whether or not to refer patients to a surgeon or surgical specialty in secondary care for further advice, consultation or treatment 	<ul style="list-style-type: none"> There is no identifiable (repeatable, written) set of rules which could be generalized to GP/PCPs in e.g. another geographic area
	<ul style="list-style-type: none"> Referral for endoscopy or other diagnostic tests if referral is for management of symptoms, not just for investigation 	<ul style="list-style-type: none"> Referral is for diagnostic tests only Back pain if referral is for physiotherapy or imaging
Outcomes	<ul style="list-style-type: none"> Any assessments of appropriateness of referral 	<ul style="list-style-type: none"> Outcomes identified do not fall into the five identified categories of outcome
	<ul style="list-style-type: none"> Any assessments of change in GP/PCP knowledge 	
	<ul style="list-style-type: none"> Any assessments of change in disease status 	
	<ul style="list-style-type: none"> Any assessments of change in health status or quality of life 	
	<ul style="list-style-type: none"> Costs 	
Study designs	<ul style="list-style-type: none"> No study design excluded 	<ul style="list-style-type: none"> No study design excluded
	<ul style="list-style-type: none"> Evaluation of a referral guideline OR study measuring compliance with specific named guideline (comparison of actual practice with guideline) 	<ul style="list-style-type: none"> No evaluation or comparison of actual practice with guideline No specific, clear, identifiable guideline(s) named
	<ul style="list-style-type: none"> Publication must be research based with original data 	<ul style="list-style-type: none"> No original data or research are presented

Appendix 3: GP questionnaire

Survey of General Practitioners in England on the use of referral guidelines for non-urgent conditions

About the REFER questionnaire

Who is carrying out the survey?

- The study is being carried out by the Academic Unit for General Practice in the Centre for Health Sciences at Barts and the London School of Medicine and Dentistry in collaboration with the Royal College of Surgeons for England and the London School of Hygiene and Tropical Medicine.

What is the survey about?

- This is a study about referral guidelines. We want your views on referral guidelines and how you use them.
- Referral guidelines are defined as "any structured paper-based or computer-based guide designed to assist those in primary care in making the decision whether or not to refer a patient to another professional." They may have been developed locally, nationally, or internationally.
- We are particularly interested in your views on referral guidelines that are designed to assist GPs with the decision to refer adult patients to a surgeon for non-urgent conditions.

Why is the survey being carried out?

- The survey is being carried out as part of a 3 year study, the aim of which is to develop guidance to assist GPs in the process of referring patients to surgical specialties in secondary care; in particular providing GPs with support in the involvement of patients in the referral decision. The findings of this survey will inform and influence the way these guidelines are developed.

What will happen to the results?

- The findings of the survey will be used to inform the development of new referral guidelines which will begin in February 2006.

What do I need to do?

- We would like you to complete this short questionnaire, which should take only 5 - 10 minutes of your time. When you have completed the questionnaire please return it at your earliest convenience in the enclosed pre-paid envelope.
- Alternatively, if you would prefer to complete the questionnaire online, please follow the link from www.lshs.qmul.ac.uk/research/gppo/publichealth and enter your unique reference number which you will find in the box on the front page of this questionnaire.
- If you would prefer to take part in the survey over the telephone please call our research team on 0207 882 2481 between the hours of 9am and 5pm, Monday to Friday.
- All completed questionnaires will be treated confidentially and anonymously. Results will not be passed to anyone in a form that allows individuals to be identified.

How to contact us

- If you have any concerns or queries about this questionnaire please contact us on 0207 882 2481 between the hours of 9am and 5pm, Monday to Friday or email n.j.lemaitre@qmul.ac.uk.

1. Your use of guidelines for the referral of adults to a surgeon for non-urgent conditions

1.1 Have you ever used guidelines for the referral of adults to a surgeon for any of the following non-urgent conditions?

(You may tick more than one option)

- | | | | | | |
|------------------------|--------------------------|---|---------------------------------------|--------------------------|----|
| Back pain | <input type="checkbox"/> | 1 | Inguinal Hernia | <input type="checkbox"/> | 9 |
| Osteoarthritis of knee | <input type="checkbox"/> | 2 | Cataract | <input type="checkbox"/> | 10 |
| Varicose veins | <input type="checkbox"/> | 3 | Haemorrhoids | <input type="checkbox"/> | 11 |
| Menorrhagia | <input type="checkbox"/> | 4 | Infertility | <input type="checkbox"/> | 12 |
| Sterilisation | <input type="checkbox"/> | 5 | I have never used referral guidelines | <input type="checkbox"/> | 13 |
| Osteoarthritis of hip | <input type="checkbox"/> | 6 | Can't remember | <input type="checkbox"/> | 14 |
| Prostate problems | <input type="checkbox"/> | 7 | Other Please write in box | <input type="checkbox"/> | 15 |
| Stress Incontinence | <input type="checkbox"/> | 8 | | | |

1.2 Thinking particularly of guidelines for the referral of adults to a surgeon for non-urgent conditions, which of the following options best describes how you use guidelines?

(You may tick more than one option)

- | | | |
|---|--------------------------|----|
| I look at guidelines in most or all individual patient consultations where a referral might be necessary | <input type="checkbox"/> | 1 |
| I look at guidelines when I encounter difficult/unfamiliar circumstances | <input type="checkbox"/> | 2 |
| I never look at guidelines in individual patient consultations | <input type="checkbox"/> | 3 |
| I read guidelines once or twice and rely on memory in order to apply recommendations to individual patients | <input type="checkbox"/> | 4 |
| I read guidelines once or twice for background education and/or to improve my knowledge of conditions | <input type="checkbox"/> | 5 |
| I use guidelines to help me audit my practice | <input type="checkbox"/> | 6 |
| I use guidelines in teaching | <input type="checkbox"/> | 7 |
| Not applicable – I have never used referral guidelines | <input type="checkbox"/> | 8 |
| Don't know | <input type="checkbox"/> | 9 |
| Other Please write in box | <input type="checkbox"/> | 10 |

1.3 Thinking particularly of referral of adults to a surgeon for non-urgent conditions, which of the following options best describes why you use guidelines?

(You may tick more than one option)

- I use guidelines because I believe they help me to make good decisions / Improve quality of care 1
- I use guidelines because I am required to by my local hospital trust / local surgeons 2
- I use guidelines because I am required to by my local PCT (e.g. as part of a "Choose & Book" scheme) 3
- I use guidelines because I am required to by someone else (e.g. Department of Health, NICE, RCGP etc) 4
- I use guidelines because the PCT offers incentives to encourage me to use them 5
- I use guidelines because I believe they will reduce the possibility of litigation 6
- I use guidelines because they help me to explain or share information about treatment decisions with patients 7
- Not applicable – I have never used referral guidelines 8
- Other Please write in box 9

1.4 Thinking particularly of referral to a surgeon for non-urgent conditions, do you think referral guidelines would be helpful for any of the following conditions?

(You may tick more than one option)

- | | |
|---|---|
| Back pain <input type="checkbox"/> 1 | Inguinal Hernia <input type="checkbox"/> 9 |
| Osteoarthritis of knee <input type="checkbox"/> 2 | Cataract <input type="checkbox"/> 10 |
| Varicose veins <input type="checkbox"/> 3 | Haemorrhoids <input type="checkbox"/> 11 |
| Menorrhagia <input type="checkbox"/> 4 | Infertility <input type="checkbox"/> 12 |
| Sterilisation <input type="checkbox"/> 5 | None <input type="checkbox"/> 13 |
| Osteoarthritis of hip <input type="checkbox"/> 6 | Other Please write in box <input type="checkbox"/> 14 |
| Prostate problems <input type="checkbox"/> 7 | |
| Stress incontinence <input type="checkbox"/> 8 | |

1.5 Thinking particularly of referral of adults to a surgeon for non-urgent conditions, which of the following types of support would help you make best use of referral guidelines?

(You may tick more than one option)

- Information telling me what guidelines are available 1
- Expert advice on which are the best available guidelines 2
- General training in how to use guidelines 3
- Good access to paper based guidelines 4
- Good access to electronic or Internet-based guidelines 5
- Technical support to help me find and/or access the best online/electronic guidelines 6
- Technical support to help me use online/electronic guidelines 7
- An Internet source giving links to electronic guidelines 8
- Regular updates telling me when new guidelines are produced 9
- None of the above 10
- Not applicable – I choose not to use referral guidelines 11
- Other Please write in box 12

2 Involving patients in the referral decision

Please indicate the extent to which you agree or disagree with each of the following statements.

	Strongly agree 1	2	→ 3	4	Strongly disagree 5
a. I frequently involve patients in decision making	<input type="checkbox"/>				
b. I feel that sharing decision making with patients is an important principle	<input type="checkbox"/>				
c. I feel my role is to direct patients rather than discuss risk information about treatments	<input type="checkbox"/>				
d. I feel "competent" in involving patients in decision making	<input type="checkbox"/>				
e. I feel confident in discussing risk information about treatments with patients	<input type="checkbox"/>				
f. I have found that patients respond positively to involvement in decision making	<input type="checkbox"/>				
g. Lack of time is a major problem in discussing treatment decisions with patients	<input type="checkbox"/>				
h. Lack of available data is a major problem in trying to share decisions	<input type="checkbox"/>				
i. Many of my patients expect specific information to be provided in discussions about treatments	<input type="checkbox"/>				

3 Any other comments

Please write in the box below anything you would like to add about guidelines for referral of adults to a surgeon for non-urgent conditions.

4 About you

4.1 Are you:

Male 1
Female 2

4.2 To which of the following age groups do you belong?

25 - 34 1
35 - 44 2
45 - 54 3
55 - 64 4
65 or over 5

4.3 How many years is it since you qualified as a GP?

0 - 9 1
10 - 19 2
20 - 29 3
30 or more 4

4.4 Including yourself, how many fully qualified GPs are there in your practice? Please include part-time and salaried GPs.

1 1
2 - 3 2
4 - 5 3
6 - 7 4
More than 7 5

4.5 What is the size of your personal list?

Less than 1000 1
1000 - 1999 2
2000 - 2999 3
3000 or more 4
No personal list 5

4.6 Are you a member of any of the following professional organisations?

RCGP 1
BMA 2
Other professional society/societies 3
(Please state which)

Appendix 4: Referral guideline for osteoarthritis of the knee

Referral guideline

Patients should be referred if they have severe knee symptoms and have a strong preference in favour of referral

Patients should not be referred if they have mild knee symptoms and have a strong preference against referral or no referral preference either way.

For all other patient groups, defined according to symptom severity and referral preference, there was no consensus with regard referral.

Age, comorbidity, and body mass do not affect the appropriateness of referral.

Recommendations for good clinical practice

The referral guideline should be interpreted in the light of following recommendations:

General practitioners should take a detailed medical history and carry out a physical examination to verify the origins of the knee pain.

Results of a knee X-ray need not to be considered.

General practitioners should attempt to reverse surgical risk factors such as smoking and obesity.

General practitioners should provide information about the expected outcome of knee replacement surgery.

Definitions of the patient characteristics

SEVERITY OF OSTEOARTHRITIS OF THE KNEE

With caveat that patients are receiving conservative and non-pharmacological (e.g. physiotherapy, walking aids, etc.) treatment

Examples of MILD limitations of daily activities:

- Patient can **walk** for more than 30 minutes before the onset of severe knee pain.
- Patient does not need help with **self care** (e.g. washing, getting dressed, etc.) because of the knee problem.

Examples of MODERATE limitations of daily activities:

- Patient can **walk** for about 15 to 30 minutes before knee pain becomes severe.
- Patient needs help with some **self care** activities (e.g. washing, getting dressed, etc.) because of the knee problem.

Examples of SEVERE limitations of daily activities:

- Patient can **walk** only for less than 15 minutes (within the house) before knee pain becomes severe.
- Patient needs help with many **self care** activities (e.g. washing, getting dressed, etc.) because of the knee problem.

COMORBIDITY

Examples of patients with ASA grade 2: MILD SYSTEMIC disease:

- **Angina:** Occasional use (2 to 3 times a *month*) of glyceryl trinitrate
- **Hypertension:** Well controlled with *single* (i.e. one type of) antihypertensive medication
- **Diabetes:** Well controlled with oral medication or insulin, without any diabetic complication (e.g. peripheral vascular disease, impaired renal function, or retinopathy)
- **Chronic obstructive pulmonary disease / Asthma:** With productive cough and wheeze, well controlled by inhalers with rare episode of acute chest infection, not limiting lifestyle.
- **Renal disease:** With slightly increase increased creatinine levels (<200 μ mol / L)

Examples of patients with ASA grade 3: SEVERE SYSTEMIC disease:

- **Angina:** Regular use (2 to 3 times a *week*) of glyceryl trinitrate or unstable angina
- **Hypertension:** Requiring *multiple* antihypertensive medications or not well controlled
- **Diabetes:** Not well controlled with oral medication or insulin or with diabetic complication (e.g. peripheral vascular disease, impaired renal function, or retinopathy)
- **Chronic obstructive pulmonary disease / Asthma:** Not well controlled, limiting lifestyle, with high dose of inhaler or oral steroids, with frequent episodes of acute chest infections
- **Renal disease:** Poor renal function (creatinine levels > 200 μ mol / L) or requiring regular dialysis treatment

BODY MASS INDEX (BMI)

Examples of heights and weights combinations for BMI 25 kg/m² and 35 kg/m²

BMI	Height (m)	Weight (kg)
25 kg/m ²	1.50	56.3
	1.60	64
	1.70	72.3
	1.80	81
	1.90	90.3
35 kg/m ²	1.50	78.8
	1.60	89.6
	1.70	101.2
	1.80	113.4
	1.90	126.4

PATIENT PREFERENCES

Strong preference FOR referral:

- Patients strongly favour referral and want the opinion of a specialist about the best possible management of their condition.

Strong preference AGAINST referral:

- Patients are strongly averse to referral.

NO strong referral preference either way:

- Patient only wants to be referred to a specialist if evidence from research and experts indicates that referral is likely to be beneficial.

Appendix 5: Referral guideline for lower urinary tract symptoms

Referral guideline

Patients should be referred if they have severe uncomplicated LUTS and have a strong preference in favour of referral

Patients should not be referred if they have mild uncomplicated LUTS and have a strong preference against referral or no referral preference either way.

For all other patient groups, defined according to symptom severity and referral preference, there was no consensus with regard referral.

Age and prostate size assessed through digital rectal examination do not affect the appropriateness of referral.

Recommendations for good clinical practice

The referral guideline should be interpreted in the light of following recommendations:

General practitioners should verify that the LUTS are uncomplicated and patients with complicated LUTS should always be referred.

Before referral of patients with uncomplicated LUTS, general practitioners should consider lifestyle advice and if that is unsuccessful a therapeutic trial with alpha-blockers should be initiated for at least one week.

Digital rectal examination should be carried out in all patients with LUTS to examine the prostate for nodularity that may be suggestive of cancer.

General practitioners should discuss the need for prostate cancer screening with men with LUTS.

Definitions of the patient characteristics

SEVERITY OF SYMPTOMS

The severity of a patient's symptoms is thought to depend largely on **frequency**, **urgency** and **nocturia**.

Examples of MILD symptoms:

- Need to urinate again in less than 2 hours **1 in 5 times**
- Difficult to postpone urination **1 in 5 times**
- Need to get up to urinate **once** every night.

Examples of MODERATE symptoms:

- Need to urinate again in less than 2 hours **about half the time**
- Difficult to postpone urination **about half the time**
- Need to get up to urinate **twice** every night.

Examples of SEVERE limitations of daily activities:

- Need to urinate again in less than 2 hours **almost always**
- Difficult to postpone urination **almost always**
- Need to get up to urinate **three times** every night.

PROSTATE SIZE

- Prostate size according to the General Practitioner's digital rectal examination

ENLARGED prostate:

- GP considers the prostate to be **enlarged** relative to a man of the same age.

NORMAL prostate:

- GP consider the prostate **not** to be **enlarged** relative to a man of the same age.

PATIENT PREFERENCE

Strong preference FOR referral:

- Patient strongly favours referral and wants the opinion of a specialist about the best possible management of his condition.

Strong preference AGAINST referral:

- Patient is strongly averse to referral.

NO strong referral preference either way:

- Patient only wants to be referred to a specialist if evidence from research and experts indicates that referral is likely to be beneficial.

Appendix 6: Questionnaires to assess representativeness of ratings of referral appropriateness among general practitioners, specialists and the public.

REFER Questionnaire



A survey of general practitioners', orthopaedic surgeons' and members of the public's views on the appropriateness of referral for people with osteoarthritis of the knee ("chronic knee pain")

January 2008

What we would like you to do

This document contains a questionnaire with nine examples of patients with osteoarthritis of the knee (pages 5, 6 and 7).

We would like you to tell us whether you think these patients should be referred by their GP. Taking into account the severity of the symptoms and the patient's preference for referral.

Before you can complete the questionnaire, please read the description of the REFER Project (page 2) and the background information on osteoarthritis of the knee (pages 3 and 4).

Participating in this survey will take about 15 minutes of your time.

Contact details:

Dr Nyokabi Musila
Freepost CEU
Clinical Effectiveness Unit
The Royal College of Surgeons of England
35-43 Lincoln's Inn Field
WC2A 3PE
Tel: 020 7869 6605
Email: refer@rcseng.ac.uk

Clinical leads:

Professor Martin Underwood, GP, Warwick
Professor Andrew McCaskie, consultant orthopaedic surgeon, Newcastle

1 ABOUT THE REFER PROJECT

What is the aim of the REFER Project?

The REFER Project is a 3-year study that aims to develop referral guidelines for patients with non-urgent conditions that can be treated with surgery. An important aspect of this project is how patients' own views on referral can be taken into account.

Who is carrying out the survey?

The study is being carried out by a Project Team based at the Clinical Effectiveness Unit of The Royal College of Surgeons of England and the London School of Hygiene and Tropical Medicine.
The Clinical Project Leads are Martin Underwood, a GP and Andrew McCaskie, a consultant orthopaedic surgeon.

What is the survey about?

A Guideline Development Group including GPs, orthopaedic surgeons, a range of other healthcare professionals, and patients indicated that the severity of patients' symptoms and their preference are the most important factors that determine whether a referral is appropriate or not.

We would like your views on whether the nine example patients with osteoarthritis of the knee should be referred. These patients differ according to the severity of their symptoms and their preference for referral.

What will happen to the results?

The findings of the survey will be used to inform our understanding of how GPs should consider patients' preferences when making referral decisions. The results will be included in the report that describes the referral guideline.

What do I need to do?

We would like you to read the background information before you answer the nine questions about the example patients included in this survey. In total, this should take about 15 minutes of your time.

When you have completed the questionnaire please return it at your earliest convenience in the enclosed pre-paid envelope.

If you would prefer to take part in the survey over the telephone, please call Dr Nyokabi Musila on the REFER Project Team on 020 7869 6605.

All completed questionnaires will be treated in strictest confidence. The names of the participants will never be disclosed. The survey's results will be published in a form that does not allow individual participants to be identified.

2 BACKGROUND INFORMATION ON OSTEOARTHRITIS OF THE KNEE

What is osteoarthritis of the knee?

Osteoarthritis of the knee is a chronic condition which is caused by wear and tear of the cartilage (the tissue that covers the joint surface). Patients are considered to have osteoarthritis of the knee if they are 50 years or older and have chronic knee pain that worsens with use and is not caused by rheumatoid arthritis (chronic inflammation of the joint). Osteoarthritis of the knee often affects the person's quality of life.

Interestingly, studies investigating the progression of osteoarthritis of the knee have shown that there is only a weak link between the extent of the abnormalities that can be seen on an x-ray and the severity of the pain. In other words, a patient who has severe knee pain may show only small abnormalities on a knee x-ray, and patient who experiences hardly any pain may have a knee joint that is severely damaged according to an x-ray.

Summary of the research evidence on the treatment of osteoarthritis of the knee

The treatment aim is to relieve symptoms and thus improve quality of life.

A GP has three options for the management of patients with osteoarthritis of the knee:

- 1. Non-drug treatment:** This is often given in combination with drug treatment. It can include:
 - Physiotherapy. This is used to improve muscle strength, joint stability and mobility.
 - Patient education. This can help to strengthen patients' coping and self management skills. In addition, patients may be advised to lose weight if they are overweight and to avoid activities that make knee pain worse.
- 2. Drug treatment:** A GP can prescribe a number of drugs to relieve the pain. The drugs can be grouped into two types:
 - Non-steroidal anti-inflammatory drugs. These drugs are given to reduce the pain. They include aspirin and ibuprofen. Their most important side effect is that they increase the risk of stomach and bowel bleeding.
 - Opioid analgesics. These drug offer pain relief by directly influencing the central nervous system, and they are most frequently prescribed if other pain killers (see above) do not provide adequate relief. They are addictive. Their most important side effects are drowsiness, vomiting and constipation.
- 3. Referral to an orthopaedic surgeon:** A GP can also refer a patient to an orthopaedic surgeon. An orthopaedic surgeon may:
 - Prescribe a wide range of other treatments (e.g. use of splints, braces, special footwear, acupuncture, electrical stimulation)
 - Provide further advice on the benefits and risks of knee replacement
 - Carry out knee replacement surgery.

Knee replacement is a major surgical procedure.

- About 80% of the patients who had a knee replacement say that they are satisfied with the results one year after their surgery
- Patient with severe osteoarthritis¹ undergoing surgery are likely to have a greater improvement of their symptoms than patients with mild osteoarthritis. However, patients who have surgery before the osteoarthritis becomes too severe have the best overall outcome
- About 1 in 200 patients (0.5%) die in the first three months after surgery, which is lower than the death rate in the general population taking the age and sex of the patients undergoing knee replacement into account
- About 1 in 30 patients (3%) needs a revision of their prosthesis (a second knee replacement) within the first five years after surgery.

¹ See next page for definition of severity

3 IMPORTANT DEFINITIONS

SEVERITY OF OSTEOARTHRITIS OF THE KNEE

Examples of MILD limitations of daily activities:

- Patient can walk for more than 30 minutes before the onset of severe knee pain.
- Patient does not need help with self care (e.g. washing, getting dressed, etc.) because of the knee problem.

Examples of MODERATE limitations of daily activities:

- Patient can walk for about 15 to 30 minutes before knee pain becomes severe.
- Patient needs help with some self care activities (e.g. washing, getting dressed, etc.) because of the knee problem.

Examples of SEVERE limitations of daily activities:

- Patient can walk only for less than 15 minutes (within the house) before knee pain becomes severe.
- Patient needs help with many self care activities (e.g. washing, getting dressed, etc.) because of the knee problem

PATIENT PREFERENCE

Strong preference FOR referral:

Patient strongly favours referral and wants the opinion of a specialist about the best possible management of his condition.

Strong preference AGAINST referral:

Patient is strongly averse to referral.

NO strong referral preference either way:

Patient only wants to be referred to a specialist if evidence from research and experts indicates that referral is likely to be beneficial.

Questionnaire reference number:

4 EXAMPLE PATIENTS

The decision that has to be considered is whether a GP should refer a patient with osteoarthritis of the knee to an orthopaedic surgeon or a healthcare professional (such as orthopaedic nurse specialist or physiotherapist) who is able to put patients on the waiting list for knee replacement.

Important assumptions

Please assume for all example patients that:

- They have not had a previous surgical procedure on any of their knees
- They are already receiving physiotherapy and drug treatment
- They are fully informed by their GPs about all treatment options
- The referral decision has to be made in the context of the resources currently available in the NHS
(Only a limited number of appointments to see an orthopaedic surgeon are available. So by referring one patient another patient may be denied an appointment, or may have to wait longer for one. The average cost of an outpatient appointment to the NHS is £140, and this will increase if further procedures are to be carried out.)

Please read also carefully the definitions of severity of symptoms and the patient preferences on the previous page.

Referral

A patient should be referred if it is likely to be beneficial to a patient, given the best available research evidence as well as the patient's preferences.

PLEASE TICK IN ONE BOX ONLY WHETHER YOU AGREE WITH REFERRAL OF THESE PATIENTS

44

A patient with

- moderate symptoms
- strong preference for referral

should be referred

Strongly disagree										Strongly agree
1	2	3	4	5	6	7	8	9		
<input type="checkbox"/>										

47

A patient with

- severe symptoms
- strong preference for referral

should be referred

Strongly disagree										Strongly agree
1	2	3	4	5	6	7	8	9		
<input type="checkbox"/>										

Questionnaire reference number:

42

A patient with

- severe symptoms
- strong preference against referral

should be referred

Strongly disagree										Strongly agree
1	2	3	4	5	6	7	8	9		
<input type="checkbox"/>										

43

A patient with

- mild symptoms
- strong preference against referral

should be referred

Strongly disagree										Strongly agree
1	2	3	4	5	6	7	8	9		
<input type="checkbox"/>										

45

A patient with

- moderate symptoms
- no referral preference either way

should be referred

Strongly disagree										Strongly agree
1	2	3	4	5	6	7	8	9		
<input type="checkbox"/>										

46

A patient with

- severe symptoms
- no referral preference either way

should be referred

Strongly disagree										Strongly agree
1	2	3	4	5	6	7	8	9		
<input type="checkbox"/>										

47

A patient with

- mild symptoms
- strong preference for referral

should be referred

Strongly disagree										Strongly agree
1	2	3	4	5	6	7	8	9		
<input type="checkbox"/>										

Questionnaire reference number:

48

A patient with

- moderate symptoms
- strong preference against referral

should be referred

Strongly disagree					→					Strongly agree
1	2	3	4	5	6	7	8	9		
<input type="checkbox"/>										

49

A patient with

- mild symptoms
- no referral preference either way

should be referred

Strongly disagree					→					Strongly agree
1	2	3	4	5	6	7	8	9		
<input type="checkbox"/>										

5 ABOUT YOU

5.1 What is your postcode? _ _ _ _ _

5.2 To which of the following age groups do you belong?

25 - 34	<input type="checkbox"/>	1
35 - 44	<input type="checkbox"/>	2
45 - 54	<input type="checkbox"/>	3
55 - 64	<input type="checkbox"/>	4
65 or over	<input type="checkbox"/>	5

5.3 Are you a:

Man	<input type="checkbox"/>	1
Woman	<input type="checkbox"/>	2

5.4 Have you had or do you currently have osteoarthritic of the knee?

Yes	<input type="checkbox"/>	1
No	<input type="checkbox"/>	2
Decline to answer	<input type="checkbox"/>	3

Questionnaire reference number:

5.5 If you have answered Yes to Question 5.4, have you had a knee operation to treat the osteoarthritic of the knee?

Yes	<input type="checkbox"/>	1
No	<input type="checkbox"/>	2

THANK YOU VERY MUCH FOR YOUR TIME

Please return to REFER Project Team using the enclosed pre-paid envelope

FREEB & CEU
Royal College of Surgeons of England
Clinical Effectiveness Unit
London
W 2A 3PE

or call 020 7869 6605 if you prefer to take part over the telephone.

REFER Questionnaire



A survey of general practitioners', urologists' and members of the public's views on the appropriateness of referral for men with uncomplicated lower urinary tract symptoms ("prostatism")

January 2008

What we would like you to do

This document contains a questionnaire with nine examples of men with uncomplicated lower urinary tract symptoms (pages 5, 6 and 7).

We would like you to tell us whether you think these patients should be referred by their GP, taking into account the severity of the symptoms and the patients' preference for referral.

Before you complete the questionnaire, please read the description of the REFER Project (page 2) and the background information on lower urinary tract symptoms (pages 3 and 4).

Participating in this survey will take about 15 minutes of your time.

Contact details:

Dr Nyokabi Musila
Freepost CEU
Clinical Effectiveness Unit
The Royal College of Surgeons of England
35-43 Lincoln's Inn Field
WC2A 3PE
Tel: 020 7889 6605
Email: refer@rcseng.ac.uk

Clinical leads:

Mr Mark Emberton, consultant urologist, London
Dr John Connolly, GP with special interest in urology, Bradford

1 ABOUT THE REFER PROJECT

What is the aim of the REFER Project?

The REFER Project is a 3-year study that aims to develop referral guidelines for patients with non-urgent conditions that can be treated with surgery. An important aspect of this project is how patients' own views on referral can be taken into account.

Who is carrying out the survey?

The study is being carried out by a Project Team based at the Clinical Effectiveness Unit of The Royal College of Surgeons of England and the London School of Hygiene and Tropical Medicine.

The Clinical Project Leads are Mark Emberton, a consultant urologist, London, and John Connolly, a GP with special interest in urology, Bradford.

What is the survey about?

A Guideline Development Group including GPs, urologists, a range of other healthcare professionals, and patients indicated that the severity of patients' symptoms and their preference are the most important factors that determine whether a referral is appropriate or not.

We would like your views on whether the nine example patients with uncomplicated lower urinary tract symptoms should be referred. These patients differ according to the severity of their symptoms and their preference for referral.

What will happen to the results?

The findings of the survey will be used to inform our understanding of how GPs should consider patients' preferences when making referral decisions. The results will be included in the report that describes the referral guideline.

What do I need to do?

We would like you to read the background information before you answer the nine questions included in this survey. In total, this should take about 15 minutes of your time.

When you have completed the questionnaire please return it at your earliest convenience in the enclosed pre-paid envelope.

If you would prefer to take part in the survey over the telephone, please call Dr Nyokabi Musila on the REFER Project Team on 020 7889 6605.

All completed questionnaires will be treated in strictest confidence. The names of the participants will never be disclosed. The survey's results will be published in a form that does not allow individual participants to be identified.

2 BACKGROUND INFORMATION ON LOWER URINARY TRACT SYMPTOMS IN MEN

What are lower urinary tract symptoms in men?

Lower urinary tract symptoms (LUTS) are urinary symptoms that affect between 30% and 60% of men over the age of 40. These symptoms include the need to urinate frequently, a sudden or uncontrollable urge to urinate, difficulty or delay when wanting to urinate, poor urine flow (stream), incomplete emptying of the bladder, dribbling and loss of bladder control.

Benign enlargement of the prostate is the most common cause of LUTS. Therefore, the term 'prostatism'¹ was often used in the past.

For most men, LUTS are chronic symptoms, which will worsen if they are not treated. Some men with LUTS may suddenly be unable to urinate, also called acute urinary retention. This is a very painful condition. It is a medical emergency which needs to be treated immediately by draining the bladder.

What are UNCOMPLICATED LUTS?

A man is considered to have uncomplicated LUTS if he:

- Is aged 40 or above
- has had no experience of being suddenly unable to urinate
- has had no previous operation of the prostate or bladder
- has no signs of prostate cancer according to a digital (finger) rectal examination
- has no urinary incontinence (loss of bladder control)
- has no burning sensation or pain when urinating

Summary of the research evidence on the treatment of LUTS

The treatment aims are:

- to relieve symptoms and thus improve quality of life
- to prevent worsening of LUTS and to reduce the risk of suddenly being unable to urinate (also known as acute urinary retention)

A GP has three options for the management of men with LUTS:

1. **Lifestyle advice:** This is commonly the first type of treatment for a man with mild LUTS. This can include reducing alcohol and coffee intake, avoiding drinking in the evening, and emptying the bladder completely before going to bed.
2. **Drug treatment:** The two most commonly given drugs are:
 - **Alpha-blockers:** These drugs relax the muscles in the prostate and the bladder. They reduce symptoms in about two thirds of men with LUTS within 2 weeks. They also delay the risk of acute urinary retention for about two to three years
 - **Prostate shrinkers:** These drugs are especially effective in men with a large prostate and they take about 6 to 9 months to work. Their great advantage is that they delay the risk of acute urinary retention for at least 6 yearsIn other words, the decision on which drug to use depends on the size of the prostate. However, estimating prostate size by digital (finger) rectal examination can be inaccurate, especially when it is carried out by GPs who have less experience with this examination than urologists. In addition, urologists can use special ultrasound devices to get a more accurate picture of the prostate.
3. **Referral to a urologist / specialist service**
Most GPs would either
 - Prescribe alpha-blockers if a man is still bothered by his symptoms after having had lifestyle advice.
 - Refer to urologist or specialist service¹. A urologist would be able to start drug treatment or carry out a surgical procedure.

¹ See section 4 for definition of specialist service

3 IMPORTANT DEFINITIONS

SEVERITY OF SYMPTOMS

LUTS can disrupt a man's daily activities and have a detrimental effect on the quality of his life. The severity of a patient's symptoms is thought to depend largely on 3 factors:

- (i) how often they need to urinate
- (ii) how difficult they find it to postpone the need to urinate
- (iii) how many times they need to get up at night to urinate

Examples of MILD symptoms:

- Need to urinate again in less than 2 hours sometimes (1 in 5 times)
- Difficult to postpone urination sometimes (1 in 5 times)
- Need to get up to urinate once every night.

Examples of MODERATE symptoms:

- Need to urinate again in less than 2 hours about half the time
- Difficult to postpone urination about half the time
- Need to get up to urinate twice every night.

Examples of SEVERE limitations of daily activities:

- Need to urinate again in less than 2 hours almost always
- Difficult to postpone urination almost always
- Need to get up to urinate three times every night.

PATIENT PREFERENCE

Strong preference FOR referral:

Patient strongly favours referral and wants the opinion of a specialist about the best possible management of his condition.

Strong preference AGAINST referral:

Patient is strongly averse to referral.

NO strong referral preference either way:

Patient only wants to be referred to a specialist if evidence from research and experts indicates that referral is likely to be beneficial.

Questionnaire reference number:

4 EXAMPLE PATIENTS

The decision that has to be considered is whether a GP should refer a patient with uncomplicated LUTS to a specialist service.

Specialist service

A service for men with LUTS which can perform specialised diagnostic tests and/or can deliver specialist expertise in treatment of LUTS.

Important assumptions

Please assume for all patients that:

- the patient has had lifestyle advice
- the patient is fully informed by their GPs about all treatment options
- the referral decision has to be made in the context of the resources currently available in the NHS
(Only a limited number of appointments to see a specialist are available. So by referring one patient another patient may be denied an appointment, or may have to wait longer for one. The average cost of an outpatient appointment to the NHS is £140, and this will increase if further procedures are to be carried out.)

Please read also carefully the definitions of severity of symptoms and the patient preferences on the previous page.

Referral

A patient should be referred if it is likely to be beneficial to a patient, given the best available research evidence as well as the patient's preferences.

PLEASE TICK IN ONE BOX ONLY WHETHER YOU AGREE WITH REFERRAL OF THESE PATIENTS

44

A patient with

- moderate symptoms
- strong preference for referral

should be referred

Strongly disagree	→						Strongly agree	
1	2	3	4	5	6	7	8	9
<input type="checkbox"/>								

47

A patient with

- severe symptoms
- strong preference for referral

should be referred

Strongly disagree	→						Strongly agree	
1	2	3	4	5	6	7	8	9
<input type="checkbox"/>								

Questionnaire reference number:

42

A patient with

- severe symptoms
- strong preference against referral

should be referred

Strongly disagree	→						Strongly agree	
1	2	3	4	5	6	7	8	9
<input type="checkbox"/>								

43

A patient with

- mild symptoms
- strong preference against referral

should be referred

Strongly disagree	→						Strongly agree	
1	2	3	4	5	6	7	8	9
<input type="checkbox"/>								

46

A patient with

- moderate symptoms
- no referral preference either way

should be referred

Strongly disagree	→						Strongly agree	
1	2	3	4	5	6	7	8	9
<input type="checkbox"/>								

48

A patient with

- severe symptoms
- no referral preference either way

should be referred

Strongly disagree	→						Strongly agree	
1	2	3	4	5	6	7	8	9
<input type="checkbox"/>								

41

A patient with

- mild symptoms
- strong preference for referral

should be referred

Strongly disagree	→						Strongly agree	
1	2	3	4	5	6	7	8	9
<input type="checkbox"/>								

Questionnaire reference number:

48

A patient with

- moderate symptoms
 - strong preference against referral
- should be referred

Strongly disagree					→					Strongly agree
1	2	3	4	5	6	7	8	9	10	
<input type="checkbox"/>										

49

A patient with

- mild symptoms
 - no referral preference either way
- should be referred

Strongly disagree					→					Strongly agree
1	2	3	4	5	6	7	8	9	10	
<input type="checkbox"/>										

5 ABOUT YOU

5.1 What is your postcode? _ _ _ _ _

5.2 To which of the following age groups do you belong?

25 - 34	<input type="checkbox"/>	1
35 - 44	<input type="checkbox"/>	2
45 - 54	<input type="checkbox"/>	3
55 - 64	<input type="checkbox"/>	4
65 or over	<input type="checkbox"/>	5

5.3 Are you a:

Man	<input type="checkbox"/>	1
Woman	<input type="checkbox"/>	2

5.4 Have you had or do you currently have uncomplicated lower urinary tract symptoms?

Yes	<input type="checkbox"/>	1
No	<input type="checkbox"/>	2
Decline to answer	<input type="checkbox"/>	3

Questionnaire reference number:

5.5 If you have answered Yes to Question 5.4, have you undergone a surgical procedure to treat the uncomplicated lower urinary tract symptoms?

Yes	<input type="checkbox"/>	1
No	<input type="checkbox"/>	2

THANK YOU VERY MUCH FOR YOUR TIME

Please return to the REFER Project Team using the enclosed pre-paid envelope

FREEPOST CEU
Royal College of Surgeons of England
Clinical Effectiveness Unit
London
WC2A 3PE

or call 020 7869 6605 if you prefer to take part over the telephone.

