QQUIP Quest for Quality and Improved Performance

Patient-focused interventions
A review of the evidence

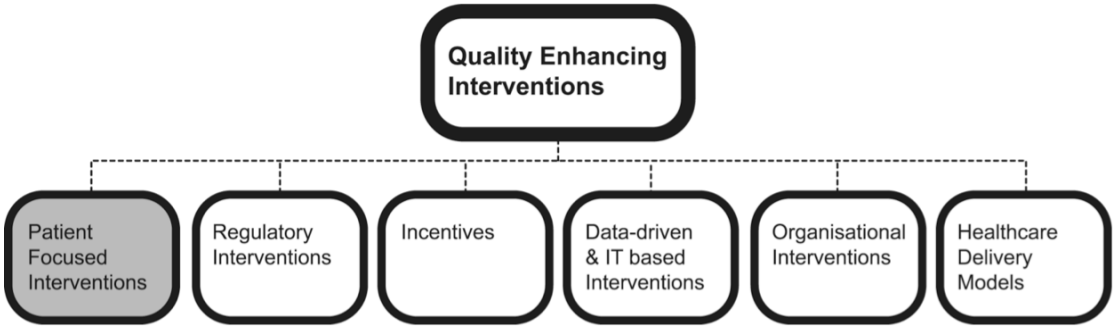
Angela Coulter
Jo Ellins
Picker Institute Europe
August 2006

The Health Foundation

QQUIP and the Quality Enhancing Interventions project

QQUIP (Quest for Quality and Improved Performance) is a five-year research initiative of The Health Foundation. QQUIP provides independent reports on a wide range of data about the quality and performance of healthcare in the UK. It draws on the international evidence base to produce information on where healthcare resources are currently being spent, whether they provide value for money and how interventions in the UK and around the world have been used to improve healthcare quality.

The Quality Enhancing Interventions component of the QQUIP initiative provides a series of structured evidence-based reviews of the effectiveness of a wide range of interventions designed to improve the quality of healthcare. The six main categories of Quality Enhancing Interventions for which evidence will be reviewed are shown below.



All the information generated through QQUIP will be available at www.health.org.uk/QQUIP from autumn 2006.

Published by:

The Health Foundation
90 Long Acre
London WC2E 9RA
Telephone: 020 7257 8000
Facsimile: 020 7257 8001
www.health.org.uk

Registered charity number 286967
Registered company number 1714937

First published 2006

ISBN 0 9548968 1 5

Copyright The Health Foundation and Picker Institute Europe

All rights reserved, including the right of reproduction in whole or in part in any form.

Every effort has been made to obtain permission from copyright holders to reproduce material. The publishers would be pleased to rectify any errors or omissions bought to their attention.

Contents

	Introduction	07
1	Improving health literacy	21
2	Improving clinical decision-making	57
3	Improving self-care	85
4	Improving patient safety	143
5	Improving access to health advice	179
6	Improving the care experience	209
7	Improving service development	249

Patient-focused interventions: introduction

Definition

Patient-focused interventions are those that recognise the role of patients as active participants in the process of securing appropriate, effective, safe and responsive healthcare. There is a growing belief among policy-makers that patients/citizens can contribute to quality improvement at both an *individual* and a *collective* level.

As individuals or family members patients can play a distinct role in their own care by diagnosing and treating minor, self-limiting conditions; by preventing occurrence or recurrence of disease or harm; by selecting the most appropriate form of treatment in partnership with health professionals for more serious illness; and by actively managing long term conditions. Recognising these roles and seeking to strengthen them is seen as fundamental to securing a more patient-centred approach to healthcare delivery.

The collective engagement of patients or citizens can also be mobilised in the drive to monitor and improve quality standards and health outcomes. Fostering high standards of health literacy and a sense of ownership of their health may be the best way to ensure that people adopt healthier lifestyles, helping to meet health and behavioural targets as well as moderating demand for healthcare resources. Regular monitoring of patients' experience of healthcare can provide organisations with a yardstick against which to measure the quality of their services. Offering patients choice and giving providers financial incentives to attract them is also seen as a means of driving up quality standards. Finally, it is believed that patient and public engagement in determining priorities for service development could help to ensure that policy-making keeps in tune with population requirements.

The QQUIP project

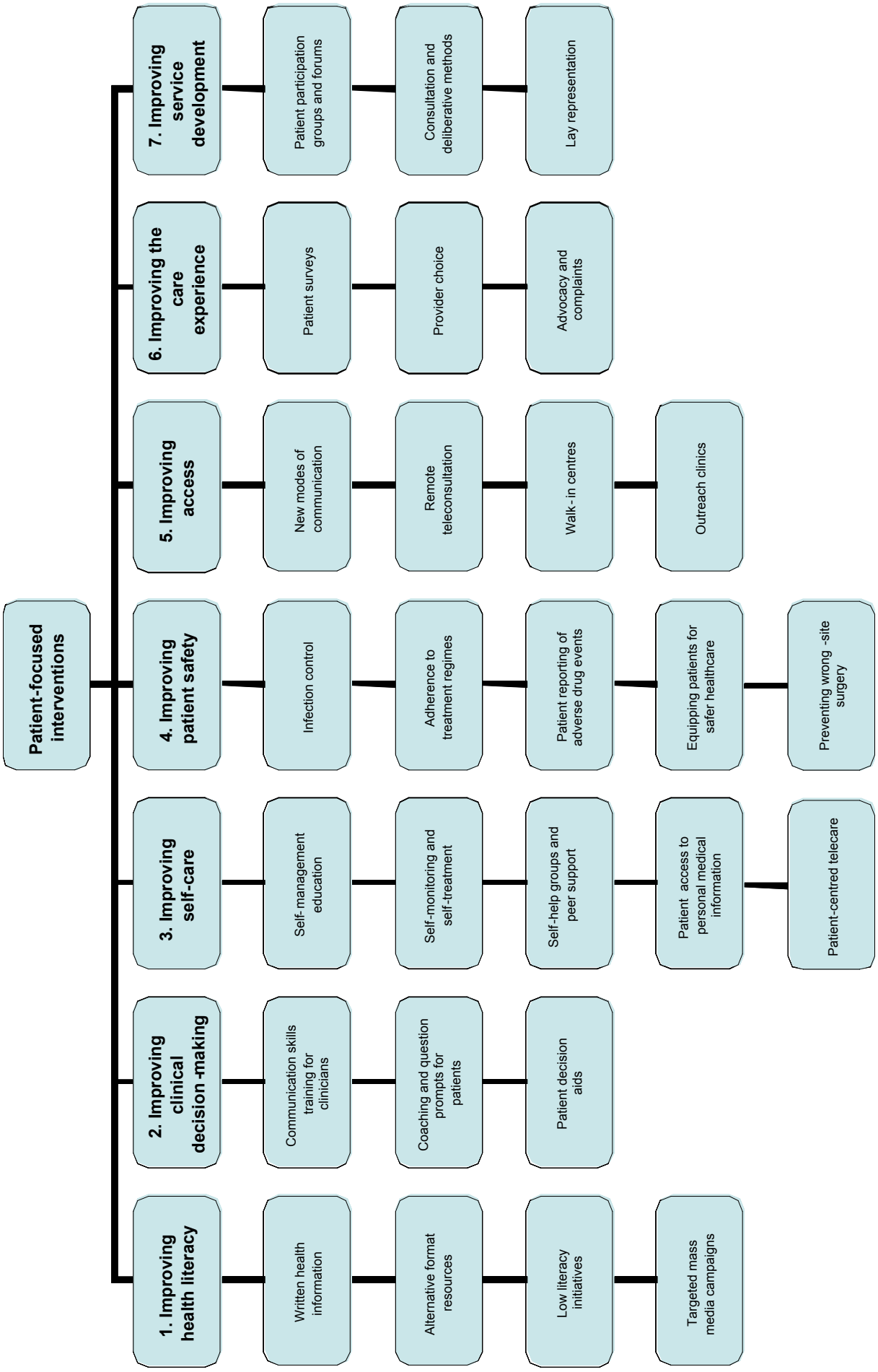
The review forms part of the Health Foundation's programme to build and make public the knowledge base for quality and performance improvement. QQUIP (Quest for Quality and Improved Performance), is a new initiative, coordinated and funded by the Health Foundation, which will collect, analyse and report on a wide range of data about the quality and performance of healthcare provided in the UK. As a contribution to QQUIP, the Picker Institute was asked to produce an overview of the research evidence on the effectiveness of patient-focused interventions.

Patient-focused interventions are generally aimed at one or more of the following seven quality improvement goals:

- improving health literacy
- improving clinical decision-making
- improving self-care
- improving patient safety
- improving access to health advice
- improving the care experience
- improving service development.

This contribution to the QQUIP programme aims to provide a concise and comprehensive overview of the evidence base for each of the above patient-focused interventions. In so doing, we hope to identify best practice and inform decision-making in policy, management, clinical practice and research.

The diagram below gives examples of the types of initiatives covered in this review.


Patient-focused interventions
1. Improving health literacy
Written health information
Alternative format resources
Low literacy initiatives
Targeted mass media campaigns
2. Improving clinical decision -making
Communication skills training for clinicians
Coaching and question prompts for patients
Patient decision aids
3. Improving self-care
Self-management education
Self-monitoring and self-treatment
Self-help groups and peer support
Patient access to personal medical information
Patient-centred telecare
4. Improving patient safety
Infection control
Adherence to treatment regimes
Patient reporting of adverse drug events
Equipping patients for safer healthcare
Preventing wrong -site surgery
5. Improving access
New modes of communication
Remote teleconsultation
Walk- in centres
Outreach clinics
6. Improving the care experience
Patient surveys
Provider choice
Advocacy and complaints
7. Improving service development
Patient participation groups and forums
Consultation and deliberative methods
Lay representation

The challenges of assessing patient-focused interventions

There are a number of methodological difficulties involved in assessing patient-focused interventions, which may affect the reliability of assessments of their effectiveness and its application to policy and practice. First, while experimental conditions are held to be essential for the objective measurement of outcomes, they can bear little resemblance to the typical settings in which interventions are actually delivered. Clinical trials differ in various ways from real-life practice: for example the interventions are often applied by trained specialists following strict protocols; they tend to exclude patients whose personal or medical circumstances might impede their participation; and they are often conducted in specialist rather than community (eg, general practice) settings (Stephenson & Imrie 1998). Many studies also involve participants who are self-selected, thereby avoiding the problems of low levels of interest and motivation. The outcomes of an intervention evaluated under ideal research conditions (efficacy) may well differ from its outcomes when used in the real world (effectiveness); a problem referred to as the efficacy-effectiveness gap. This can limit the generalisability of study findings beyond the research setting to the population at large.

Conventional methods of evaluation, in particular the RCT, are valuable for evaluating interventions when the desired outcomes are relatively simple and unambiguous, but this is not always the case for patient-focused interventions. Strategies to engage patients in their care are frequently complex, involving a combination of elements within a single intervention and there is often a lack of consensus on the most appropriate outcome measures. These interventions may also be most effective when tailored to individual needs and circumstances, rather than being delivered as a standard package. Measuring the global effect of complex interventions may disguise the fact that only some of the elements provide benefit while others are unsuccessful. If patient-focused interventions are going to be efficiently and cost-effectively implemented, information on the relative benefits of the different intervention components is needed. The specific and non-specific effects of an intervention should also be distinguished. For example, a group based education programme may be effective because patients benefit from social interaction and group support, rather than as a result of the educational content per se. Addressing these important issues should be a priority, and guidance for researchers on evaluating complex interventions is available from a number of sources (MRC 2000).

Choosing appropriate criteria for the evaluation of patient-focused interventions is also a major challenge. Researchers currently employ a wide variety of outcome measures, and the lack of standardisation hampers the comparison of findings across studies. Before establishing a core set of measures, the primary aims of patient-focused interventions will have to be agreed. If their purpose is to bring about improvements in health status or in the use of health services, then clinical or service utilisation measures will need to be used. Certainly, the data collected using such measures would be of considerable importance to those planning, managing and delivering healthcare. But are these the outcomes which are most important to patients who are, after all, the focus of the interventions? Patients are more likely to value improvements in their lived experience of illness, which might include quality of life, mobility or psychological well being. The use of patient-centred outcome measures is imperative to assess patients' experience of healthcare and of strategies for quality improvement. Involving patients directly in the design of evaluation studies can be a useful way of ensuring that interventions are assessed using criteria that are relevant and meaningful to patients.

Many studies have included a number of outcome measures to obtain a more complete picture of how well an intervention works. This approach has the potential to reveal how intervention effects vary across different outcome domains. However, showing improvements in some areas does not necessarily indicate that an intervention has achieved its desired goal. For example, self-management education programmes have been largely successful in improving knowledge and coping skills. Better health status or

improved quality of life, which are often the intended purpose of such programmes, have been much harder to demonstrate. Certainly knowledge and coping skills are important in their own right, but research has shown that enhanced patient understanding of health issues does not necessarily lead to positive behavioural change, and that such change does not always result in better health outcomes (Lorig & Holman 2003). Nevertheless, interventions that help to empower patients by building their sense of self-efficacy may be valued even if they do not cause unintended harmful effects.

Methods

Search methodology

For the purposes of this policy overview we aimed to identify evidence on the effectiveness of a broad spectrum of patient-centred interventions. To this end we carried out electronic searches of Medline, Embase, CINAHL, DH-DATA, PsycINFO, AMED, British Nursing Index, Cochrane Library, DARE, King's Fund, National Electronic Library for Health, NHS Research Register, WHO, AHRQ, specialist websites including those of patient organisations, and a reference scan of key papers. The search strategy was based on the above taxonomy of patient-focused interventions, and was restricted to articles written in the English language, published in 1998-2006 (see below for further details on search terms).

Full articles were retrieved for studies that evaluated the effectiveness of patient-focused interventions. We used a hierarchy of evidence classification to determine which studies to include, as follows:

1. Systematic review
2. Individual randomised controlled trial
3. Quasi-experimental study (e.g. experimental study without randomisation)
4. Controlled observational study (e.g. cohort or case-control study)
5. Observational study without control group (e.g. cross-sectional study, before-and-after study or case series).

As our aim was to bring together the best available evidence on patient-focused interventions, we initially searched for high quality systematic reviews. Where rigorous systematic reviews were not found we then searched for well conducted randomised controlled trials. If we found none of these, we moved down the hierarchy to quasi-experimental studies, controlled observational studies, and finally to uncontrolled observational studies. In a few cases we have also included qualitative overviews where we believe these have been conducted to high quality standards. We also carried out a selective review of other relevant papers, including cohort studies, surveys and conceptual papers, which provided background and contextual information.

We have tried to give readers an indication of the strength of evidence on the effectiveness of specific interventions by including information on the type of study and, where possible, its methodological quality. Systematic reviews are very useful if they are carried out to high methodological standards, but their quality cannot be assumed. Organising detailed independent assessments of the methodological quality of each of the reviews and other studies included in this policy overview was beyond the scope of the project and our resources, so we have relied on existing assessments. Reviews carried out for the Cochrane Collaboration, the National Institute of Health and Clinical Effectiveness (NICE) or the NHS Health Technology Assessment programme (NHSTA) are independently assessed according to specified criteria and it is therefore reasonably safe to assume that they have passed a reliable quality threshold. We have therefore indicated the source where this is the case. Some of the other reviews included in our summary have been assessed by the Centre for Reviews and Dissemination (CRD) at the University of York as part of their Database of Abstracts of Reviews of Effects (DARE). We have included a brief summary of their assessments in each case. Where no independent assessment has been found, we have included a note in the text to this effect. For single studies we have simply included a description of the type of study. Almost all of the included studies were published in peer-reviewed journals and therefore subject to some type of independent review, but we do not consider this a reliable guarantee of quality.

Outcomes of interest

The reviews and studies that were identified reported on a wide range of clinical, patient and service-related outcomes. In assessing the effectiveness of patient-focused interventions, we have grouped these into four categories, as follows:

Patients knowledge	For example: • Knowledge of condition and long term complications • Self-care knowledge • Knowledge of treatment options and likely outcomes • Comprehension of information • Recall of information
Patients' experience	For example: • Patient satisfaction • Doctor-patient communication • Quality of life • Psychological wellbeing • Self-efficacy • Patient involvement
Service utilisation and costs	For example: • Hospital admissions • Emergency admissions • Length of hospital stay • GP visits • Cost-effectiveness • Cost to patients • Days lost from work/school
Health behaviour and health status	For example: • Self-care activities • Treatment adherence • Disease severity/activity • Symptom control • Functional ability • Clinical indicators

Search terms

The terms used to search for background information and efficacy studies are outlined below. In all cases, databases were initially searched for the keywords in title, abstract and descriptor fields only. Where this did not identify relevant literature, the strategy was broadened to search the whole document. Our selection was then refined by type of publication, with priority given to systematic reviews, RCTs and review articles.

Health literacy

1. Health literacy
2. Information literacy
3. Low literacy
4. Information
5. Education
6. Informatics
7. Leaflet
8. Patient OR consumer
9. 8 AND (4 OR 5 OR 6 OR 7)
10. Multimedia OR interactive OR audio OR video
11. 10 AND (4 OR 5)
12. Readability
13. Comprehension
14. Simplified
15. Plain language
16. (12 OR 13 OR 14 OR 15) AND (4 OR 5 OR 7)
17. Internet
18. World wide web
19. Online
20. (17 OR 18 OR 19) AND (4 OR 5)
21. Mass media
22. Media campaign
23. Health
24. Screening
25. (21 OR 22) AND (23 OR 24)
26. Digital TV
27. New media
28. (26 OR 27) AND 8 AND 23
29. Underserved
30. Disadvantaged
31. Deprived
32. (29 OR 30 OR 31) AND (4 OR 5)

Clinical decision-making

1. Shared decision making
2. Informed decision making
3. Decision aid
4. Decision support
5. Risk communication
6. Communication skills
7. Training
8. Education
9. 6 AND (7 OR 8)
10. Improv*
11. Communication
12. Interaction
13. 10 AND (11 OR 12)
14. Informed choice
15. Recording OR summary
16. Consultation
17. 15 AND 16
18. Patient participation
19. Patient involvement
20. Sharing
21. Partnership
22. Decision making
23. Treatment decision
24. Management decision
25. (18 OR 19 OR 20 OR 121) AND (22 OR 23 OR 24)
26. Patient centred
27. Consultation
28. Care
29. 26 AND (27 OR 28)
30. Question prompt
31. Question sheet

Self-care

1. Self care
2. Self manage*
3. Self efficacy
4. Patient education
5. Self help
6. Self monitor*
7. Home monitor*
8. Telemonitor*
9. Self diagnos*
10. Self treat*
11. Self medicat*
12. Social support
13. Peer support
14. Mutual support
15. Coping skills
16. Coping behaviour
17. Virtual communit*
18. Telephone support
19. Telecare
20. Telemedicine
21. Home
22. 20 AND 21
23. Patient held record
24. Nursing record system
25. Recording OR summary
26. Consultation
27. 25 AND 26
28. Copying letter
29. Copy*
30. Referral letter
31. 29 AND 30

Patient safety

1. Patient safety
2. Medical error
3. Medical mistake
4. Medical complication
5. Adverse event
6. Adverse drug
7. Side effect
8. Medication safety
9. Diagnostic error
10. Surgical error
11. Wrong site surgery
12. Risk prevention
13. Risk management
14. 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13
15. Patient NEAR involv*
16. Patent NEAR participat*
17. Patient NEAR engage*
18. Patient NEAR role
19. Patient NEAR partner*
20. 15 OR 16 OR 17 OR 18 OR 19
21. 14 AND 20
22. Direct report*
23. Patient report*
24. Consumer report*
25. (22 OR 23 OR 24) AND (5 OR 6 OR 7 OR 8)
26. Patient NEAR adherence
27. Patient Near compliance
28. Hospital acquired infection
29. Handwashing
30. Hand hygiene
31. Infection control
32. 20 AND (28 OR 29 OR 30 OR 31)

Access to health advice

1. Access
2. Care
3. Healthcare
4. Services
5. 1 AND (2 OR 3 OR 4)
6. Increas*
7. Improve*
8. (6 OR 7) AND 1
9. Telephone
10. Email
11. Video
12. Online
13. Consultation
14. Communication
15. Triage
16. (9 OR 10 OR 11 OR 12) AND (13 OR 14 OR 15)
17. Distance medicine
18. Distance communication
19. Remote consultation
20. Teleconsultation
21. Virtual consultation
22. Telemedicine
23. Telephone helpline
24. Telephone advice
25. NHS Direct
26. Walk in centre
27. Walk in service
28. Ambulatory care centre
29. Nurse-led
30. Care
31. 29 AND (13 OR 15 OR 30)
32. Outreach

Care experience

1. Patient choice
2. Consumer choice
3. Provider
4. Doctor
5. Physician
6. Plan
7. Choos*
8. Choice
9. (7 OR 8) AND (3 OR 4 OR 5 OR 6)
10. Choice behaviour
11. Report card
12. Performance report
13. Performance data
14. Performance measure*
15. Performance indicator
16. Performance information
17. Public NEAR disclos*
18. Quality NEAR improve*
19. (7 OR 8 OR 17 OR 18) AND (11 OR 12 OR 13 OR 14 OR 15 OR 16)
20. Patient satisfaction
21. User satisfaction
22. Consumer satisfaction
23. Patient NEAR survey
24. User NEAR survey
25. Consumer NEAR survey
26. Patient feedback
27. Patient evaluation
28. Patient report
29. Patient assessment
30. Patient complaint
31. Complaints system
32. Patient advocacy
33. Health advocacy
34. PALS

Service development

1. Public
2. Patient
3. User
4. Consumer
5. Lay
6. 1 OR 2 OR 3 OR 4 OR 5
7. Involve*
8. Participat*
9. Empower*
10. Represent*
11. 7 OR 8 OR 9 OR 10
12. Delivery
13. Planning
14. Development
15. Provision
16. Decision making
17. Organisational change
18. Change management
19. Needs assessment
20. Ration*
21. Priority setting
22. 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18 OR 19 OR 20 OR 21
23. Health services
24. Healthcare
25. Service
26. Organisation*
27. 23 OR 24 OR 25 OR 26
28. 6 AND 11 AND 22 AND 27
29. Forum
30. Panel
31. Consult*
32. Participation group
33. 6 AND (29 OR 30 OR 31 OR 32)
34. Citizens jury
35. Citizens panel
36. Deliberative
37. 36 AND 22 AND 27

References

Lorig, K.R. & Holman, H. (2003) 'Self-management education: history, definition, outcomes, and mechanisms'. *Ann Behav.Med*, 26 (1): 1-7.

MRC (2000) *A framework for development and evaluation of RCTs for complex interventions to improve health*. London: Medical Research Council.

Stephenson, J. & Imrie, J. (1998) 'Why do we need randomised controlled trials to assess behavioural interventions?'. *BMJ*, 316 (7131): 611-613.

1. Improving health literacy

Health literacy: summary of findings

- Health literacy is fundamental to patient engagement. If individuals do not have the capacity to obtain, process and understand basic health information, they will not be able to look after themselves effectively or make appropriate health decisions.
- There has been little research into the prevalence of health illiteracy in the UK. Estimates of inadequate health literacy in the US have suggested that the problem is significant, affecting around 90 million adults, with potentially serious consequences for their health.
- Despite various initiatives to improve the quality and availability of health information, studies indicate that patients and the public want more information than they currently receive and that health professionals tend to overestimate the amount of information they supply.
- There are concerns about the accessibility, quality, readability, reliability and usefulness of much printed and electronic consumer health information. Various checklists have been devised to assess the quality of such material.
- The internet has become an important source of health information, but a 'digital divide' has been widely documented, with access and use more prevalent among younger, more affluent and more advantaged groups.
- Written information (e.g. leaflets) used as an adjunct to professional consultation and advice has been shown to improve health knowledge and recall, particularly when it is personalised to the individual. Few other beneficial effects have been demonstrated and there is no evidence of improvement in health behaviour or health status.
- Alternative format resources, such as websites, can also improve knowledge and studies have demonstrated high user satisfaction and beneficial effects on self-efficacy and health behaviour. There is some evidence of greater health benefit for disadvantaged groups when access barriers are overcome. Harm arising from unreliable websites may be under-reported.
- Initiatives designed to specifically target low literacy groups have had mixed results, with some studies showing beneficial effects on knowledge and behaviour, but there have been relatively few attempts to test the effect of these initiatives on reducing health inequalities.
- Targeted mass media campaigns have been shown to increase awareness, but the effects may be short-lived. There is some evidence of impact on utilisation of services, but little evidence of beneficial effect on health behaviour, although two studies showed that the mass media could be effective in influencing smoking behaviour among young people.
- There is a clear need for more research into the prevalence of low health literacy and its effects. Development and evaluation of effective interventions should be a priority.

Health literacy: introduction

Health literacy is a relatively new term, first used in a 1974 paper entitled 'Health Education as Social Policy'. In early definitions, health literacy was narrowly conceived as the ability to read and comprehend written medical information and instructions.

More recently, an expanded understanding of the nature, dimensions and context of health literacy has emerged. A useful definition is offered by Kickbusch, who states that health literacy is "*the ability to make sound health decisions in the context of everyday life – at home, in the community, at the workplace, the health care system, the market place and the political arena*" (Kickbusch et al 2005). A range of competencies are encompassed by this definition, including:

- basic health knowledge
- reading, comprehending and evaluating health information
- application of health preventing, promoting and self-care behaviours
- verbal communication with health professionals
- health decision-making
- health advocacy and activism.

The role of health information and education in bringing about improved health literacy is emphasised by Nutbeam, who proposes that there are three levels of health literacy (Nutbeam 2000).

Health literacy level and educational goal	Content of educational activity	Example of activity
Functional health literacy: basic skills in reading and writing to be able to function effectively in a health context	Transmission of factual information on health risks and health services utilisation	Patient information leaflets, traditional health education
Interactive health literacy: more advanced cognitive, literacy and social skills to actively participate in health care	As above plus opportunities to develop skills in a supportive environment	School health education programmes
Critical health literacy: the ability to critically analyse and use information to participate in action to overcome structural barriers to health	As above plus provision of information on the social and economic determinants of health, and opportunities to achieve policy and/or organisational change	Community-based development programmes

Source: Nutbeam (2000).

According to Nutbeam's model, health literacy is not simply a matter of being able to read and make sense of health information, but is also an essential empowerment strategy. Being able to effectively access and use health information is the foundation for individuals to have active and informed involvement in their healthcare and in decisions relating to this. Achieving greater health literacy in the population is, therefore, integral to improving the health of disadvantaged populations and to tackling health inequalities.

Importantly, health literacy is not simply the application of general literacy skills to healthcare settings. Rather, it is a set of functional skills which are *context specific*. In

other words, an individual may be capable of understanding everyday sources of information, but struggle to make sense of health-related materials which routinely contain unfamiliar vocabulary or concepts. Basic literacy strategies will need to be supplemented by specific initiatives to identify and target those with communication difficulties arising from low health literacy.

Health literacy: what is the extent and impact of low health literacy?

To date, there has been little research into health literacy in the UK. In the US, it is estimated that 90 million adults have inadequate health literacy, which impairs their ability to navigate complex healthcare systems, to comprehend and act upon health information and to effectively self-manage their health problems (Ad Hoc Committee on Health Literacy 1999). Although health literacy does not straightforwardly correlate with other (e.g. socioeconomic) inequalities in health, low health literacy appears to be particularly prevalent among lower socioeconomic groups, ethnic minorities, the elderly and those with chronic conditions or disabilities (Andrus & Roth 2002, Sihota & Lennard 2004).

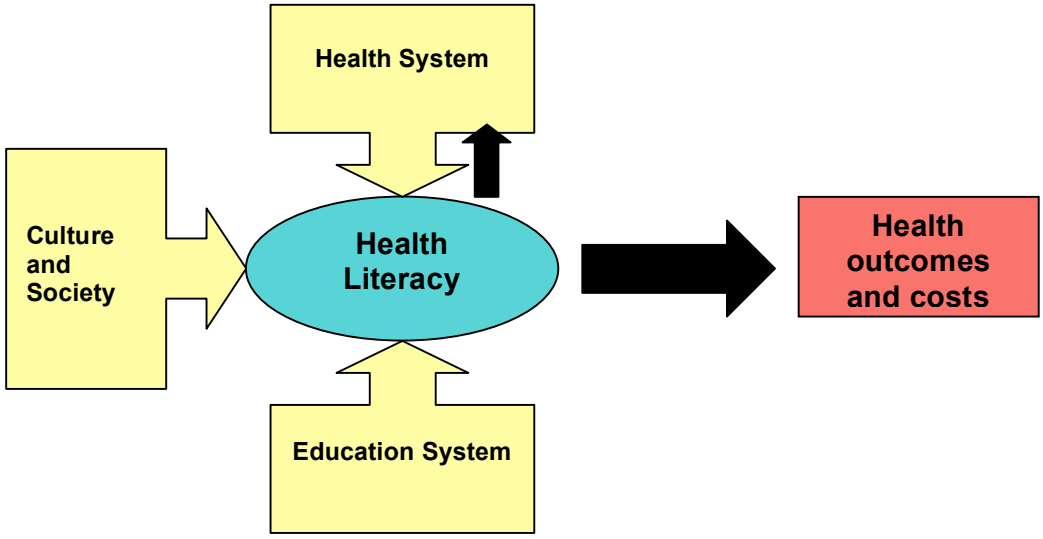
Inadequate health literacy can have profound health and financial consequences (Ad Hoc Committee on Health Literacy 1999, Institute of Medicine 2004, Sihota & Lennard 2004). Research has reported that patients with low health literacy:

- have poorer health status
- are at greater risk of hospitalisation and have longer hospital visits
- have higher rates of admission to emergency services
- are less likely to adhere to prescribed treatments and self-care plans
- have more medication and treatment errors
- have less knowledge of disease management and health-promoting behaviours
- have decreased ability to communicate with healthcare professionals and share in decision-making
- are less able to make appropriate health decisions
- make less use of preventive services
- incur substantially higher healthcare costs.

Reviewing the evidence, the American Medical Association found that health literacy is a stronger predictor of health status than age, income, employment status, education level, race or ethnic group (Ad Hoc Committee on Health Literacy 1999).

Health literacy: what types of intervention target health literacy?

Health literacy is the outcome of a complex array of individual and social processes. The US Institute of Medicine (IOM) has identified three broad factors that contribute to health literacy, each of which constitutes a potential site for intervention: culture and society, health systems and the education system (Institute of Medicine 2004).



Source: Institute of Medicine (2004).

For the purposes of this policy review we are specifically interested in those interventions which fall under the IOM's categories of 'health system' and 'culture and society'. Such interventions are broad in range and include those being newly developed in the area of consumer informatics and internet health applications. We have classified these interventions into four types:

- written health information
- alternative format resources
- low literacy initiatives
- targeted mass media campaigns.

The related topics of self-management education and health advice are addressed in detail elsewhere in this report.

Types of health literacy intervention: examples

Written health information

The *Toolkit for Producing Patient Information* was developed by the Department of Health in collaboration with the Patient Information Forum, Royal National Institute for the Blind and Plain English Campaign (www.nhsidentity.nhs.uk/patientinformationtoolkit). The aims of the toolkit are:

- to improve standards of written information by making sure that the material produced is clear, concise, relevant, accurate and in everyday language
- to increase confidence in NHS information among patients, their carers and people who use NHS services
- to make it easier for NHS organisations to produce high quality information
- to make sure information for patients supports NHS values and communication principles.

The toolkit offers practical advice on writing information for patients, including checklists and a series of leaflet templates.

Types of health literacy intervention: examples (cont.)

Alternative format resources

CHESS (Comprehensive Health Enhancement Support System) is an internet-based patient information and support system, developed at the University of Wisconsin-Madison. The system offers a range of services including personalised health information, social support networks, and decision-making and problem-solving tools. Currently, CHESS modules are available on the following topics: breast cancer, prostate cancer, smoking cessation, heart disease, asthma, menopause, dementia and care giving.

In 2001-2 the NHS conducted a series of pilot projects assessing the feasibility and effectiveness of delivering health information and advice via interactive digital TV platforms (DiTV). Subsequently, in late 2004, the government launched *NHS Digital TV*. The service provides:

- information on NHS services
- an encyclopaedia of illnesses, conditions, treatments and tests
- self-care advice on treating common health problems and advice on healthy living.

The written information is illustrated by images and video clips.

Low literacy initiatives

The California Health Literacy Initiative (CHLI) is the largest statewide health literacy project in the US. The CHLI's stated purpose is *"to inform and partner with individuals and organizations to craft collective, lasting solutions which will positively impact the health and well-being of individuals with low-literacy skills, their families, and their communities."* As well as engaging in advocacy and awareness-raising activities, the CHLI coordinates a resource centre for health literacy information and training (http://cahealthliteracy.org).

Targeted mass media campaigns

Developing Patient Partnerships (DPP) was established in the UK in 1997 by the Department of Health and British Medical Association (www.dpp.org.uk). DPP designs and conducts health education campaigns with the following objectives:

- to promote the responsible use of health services
- to encourage better communication between patients and health professionals
- to offer advice and support to patients and the public in self-care.

Your Life! magazine was launched in 2004 by the Department of Health and Dr Foster, an independent healthcare information provider. The consumer-style glossy magazine targets younger women in low income groups with specially tailored information on health promotion and local NHS services. Your Life! is available free of charge in many areas of England through GP surgeries, high street retailers and leisure outlets.

Health literacy: what do patients and the public want?

The delivery of high quality and appropriately targeted consumer health information is central to the achievement of health literacy. Patients need such information in order to (Coulter et al 1999):

- understand what is wrong
- gain a realistic idea of prognosis
- make the most of consultations
- understand the processes and likely outcomes of possible tests and treatments
- assist in self-care
- learn about available services and sources of help
- provide reassurance and help to cope
- help others understand
- legitimise seeking help and their concerns
- learn how to prevent further illness
- identify further information and self-help groups
- identify the 'best' healthcare providers.

Studies indicate that patients want more information than they currently receive and that health professionals frequently overestimate the amount of information they supply (Richards 1998). In order to overcome this gap in the provision of consumer health information five key issues must be taken into consideration. These are:

- information needs
- accessibility
- quality
- readability and comprehensibility
- usefulness.

Information needs

Patient information needs are highly diverse and so cannot be straightforwardly identified and defined. Such needs are shaped by demographic characteristics including age, gender and socio-economic status, as well as the patient's particular circumstances, beliefs, preferences and styles of coping (Consumers Association 2003). There are also important differences due to patients' skills and abilities, with particular needs arising from low literacy, auditory/visual impairment and non-English speaking. The type of information that is sought by an individual patient is likely to change during the course of their illness (Detmer et al 2003). Patient reports indicate that, in the initial stages following diagnosis, there is a preference for practical information to support care decisions, including information on treatment options and their likely outcomes. More in-depth and specific information needs emerge later, when the patient's focus often turns to issues of self-care and long term prognosis.

Research points to the importance of tailoring information to patients' needs and characteristics. In comparison to general information, personalised materials tend to produce better health and service-related outcomes and are more highly valued by patients themselves (Jones et al 1999, Kreuter et al 1999). Computer-based systems are one means by which a tailored approach to consumer health information provision may be achieved, using the patient's medical record. Efforts to evaluate the impact of targeted health information are underway, and findings from published research are described below.

Accessibility

There has been a marked proliferation in consumer health information in recent years. Above all, this has been driven by the rapid expansion of the internet as an information source. There are currently more than 580 million people worldwide using the internet, and over 16 million in the UK alone (Powell et al 2003). In surveys, 60-80% of internet users report going online for health information. Numerous internet and computer-based information tools have been developed for consumer use, in some cases combining information delivery with additional services such as decision aids or virtual support groups. Key initiatives include:

• Canadian Health Network	http://www.canadian-health-network.ca/
• CHESS (Comprehensive Health Enhancement Support System)	http://chess.chsra.wisc.edu/Chess
• DIPEx (Database of Patient's Experiences of Illness)	http://www.dipex.org/
• HealthFinder	http://www.healthfinder.gov/
• NeLH (National electronic Library for Health)	http://www.nelh.nhs.uk/
• NHS Direct Online	http://www.nhsdirect.nhs.uk/

The potential of the internet to effectively disseminate consumer health information is limited, however, by disparities in both access to and ability to use computer technology. A 'digital divide' has been widely documented, with rates of computer (and internet) use highest among the young, affluent and employed and far lower in low income, low literacy and ethnic minority groups and in the disabled and elderly (Powell et al 2003). Rather than facilitating the empowerment of new categories of healthcare consumer, the internet appears to be largely reinforcing existing patterns of information-seeking behaviour (Wilkins & Navarro 2001). This is taken as further evidence of the operation of an 'inverse information law', whereby those with the greatest need for health information are least able to access it.

The concept of 'information therapy', developed by Donald Kemper and Molly Mettler of US organisation Healthwise, represents a promising strategy to enhance consumer accessibility to health information (Kemper & Mettler 2002). Noting that *"information is as important to a patient's health as any drug, medical test, or surgery"*, Kemper and Mettler argue that people need access to accurate, evidence-based information as part of their treatment. Hence they propose that information should be *prescribed* to patients at every point along the healthcare continuum. Rather than health information being about the care process, on this view information is itself a key component of that process.

Quality

Along with accessibility, the quality of consumer health information is another major area of concern. Studies evaluating consumer health information materials have reported that they are of variable and often poor quality (see box below).

Quality of consumer health information
Strength of evidence studies have been carried out on both written and internet consumer health information. Criteria for evaluating information quality commonly include: accuracy, completeness/scope, readability, design and aesthetics, author/sponsor disclosure, authority of source and recency.

Written information
Coulter and colleagues assessed the quality of patient information materials relating to ten health problems or treatments (Coulter et al 1998). Their key findings were as follows:

- often the information contained inaccuracies and misleading statements. The most common problem in this respect was an overly optimistic view of treatment, emphasising benefits and understating risks and side-effects
- very few materials met patients' information needs adequately. In particular, information on causes and consequences of conditions, prevalence, recovery time and treatment outcome probabilities was poorly presented or absent
- many materials failed to indicate the sources or strength of the evidence on which they were based
- few materials were felt to contain balanced and comprehensive information with which to support shared decision-making.

Internet information
Smart and Burling systematically reviewed internet patient information on radiological procedures (Smart & Burling 2001). Twenty eight websites were included, most being operated by medical institutions. Their review concluded that:

- information quality was variable; only one website reached the maximum eight marks and five achieved only one mark
- few sites provided the level of detail a patient needs to achieve a good understanding of radiological procedures
- the readability level of nearly half the websites was high, to the extent that the materials were likely to be incomprehensible to patients with lower literacy.

Eysenbach and colleagues undertook a systematic review of research evaluating the quality of internet consumer health information (Eysenbach et al 2002). Seventy nine studies met their inclusion criteria, evaluating 5,941 websites and 1,329 web pages. They reported that:

- the majority of studies (70%) concluded that quality is a problem with regard to internet health information
- accuracy scores varied according to the criteria used; in studies that used more rigorous criteria, approximately 30-35% of websites were reported to contain inaccurate information
- levels of inaccuracy varied according to the particular type of information; for example, 45.5% of diet and 88.9% of nutrition websites were found to contain inaccurate information, compared with only 4% and 5.1% for prostate and breast cancer sites respectively.

Various initiatives are being developed and implemented to facilitate consumer access to high quality health information. Broadly, these initiatives are either focused on the activities of information providers, using mechanisms such as accreditation and certification, or the activities of information users, through the development of critical appraisal skills.

- **Provider-focused: e.g. accreditation and certification schemes**
    - Health on the Net Foundation Code of Conduct (HON Code): http://www.hon.ch/
    - URAC Health Web Site Accreditation: http://webapps.urac.org/websiteaccreditation/default.htm
    - MedCERTAIN certification and rating (MedPICS): www.medcertain.org.
- **Consumer-focused: e.g. critical appraisal tools and checklists**
    - DISCERN quality criteria for consumer health information: http://www.discern.org.uk/
    - European Commission's quality criteria for health related websites: http://europa.eu.int/information_society/eeurope/ehealth/quality/index.htm
    - Critical Appraisal Skills Programme (CASP) for consumers: http://www.phru.nhs.uk/casp/casp.htm.

Readability and comprehensibility

Most consumer health information is produced in text format. To be effectively communicated, this type of information needs to be presented in such a way so as to be readable and comprehensible. Various formulas have been designed to assess readability, which assign a score for text difficulty and an equivalent reading grade level. Most formulas, including the commonly used Flesch-Kincaid and Fry formulas, calculate readability on the basis of two criteria:

- the number of difficult words (defined by the number of syllables in a word)
- the number and average length of sentences.

Using these formulas, research has shown that many consumer information materials are written at above average reading ability, making them difficult for many people to comprehend. This mismatch between material and reader has been documented for patient information leaflets (Smith et al 1998), internet health materials (Berland et al 2001), medication inserts (Kirkpatrick 1999) and informed consent forms (Paasche-Orlow et al 2003).

Nonetheless, there are problems associated with the use of readability formulas in the development and evaluation of consumer health information. In narrowly focusing on quantifiable criteria, readability formulas fail to address important subjective aspects of the text and reading process (Eysenbach et al 2002). Reading comprehension is influenced by the tone and style of language, cultural sensitivity and the reader's skills, knowledge, interest and motivation, yet none of these factors are measured by readability formulas. Therefore simply revising text to improve readability, in accordance with standard formulas, will not necessarily lead to improvements in comprehension (Atkinson 2003). It has also been pointed out that, during the course their illness, some patients become very familiar with complex medical terminology (Meade & Smith 1991). In these cases, readability formulas may lead to a simplification of language which is unnecessary and potentially patronising.

Usefulness

The usefulness of consumer health information refers to its relevance and ability to help patients understand their situation and make appropriate decisions. Much of the literature already cited points to areas of disparity between the type of information that patients seek and what is available to them. For example, the evaluation by Coulter and

colleagues (outlined above) found that patient information materials often failed to provide adequate information on several topics of relevance to patients. Similarly, a systematic review of patient information leaflets on hypertension concluded that few contained the full range of information that is considered important by the target population (Fitzmaurice & Adams 2000). Another study found that education materials specifically designed for low income women did not include cost information, yet this was the issue that was of greatest concern to the group (Davis et al 1998).

One explanation for these findings is that patients themselves are often not involved in developing and/or evaluating information materials produced for their use (Coulter et al 1998). Differences between patients and healthcare professionals in their estimation of what constitutes useful material may also play a role. In one study, patients and physicians were asked to rate the importance of information contained in diabetes literature (Reid et al 1995). While physicians chose information on disease pathophysiology, patients indicated a preference for information on treatments and prognosis. This indicates the importance of producing consumer health information based on specific research into what patients need, rather than on what health professionals think patients need.

Health literacy: what strategies have been tried and by whom?

From the literature, three key objectives of health literacy interventions can be identified. These are:

- to provide patients with timely and appropriate health information materials to enhance health knowledge, skills and behaviours, and to enable informed health decisions
- to encourage the appropriate and effective use of healthcare services, including greater uptake of preventive and screening services
- to tackle inequalities in health and healthcare access by targeting information and education at low literacy, hard-to-reach and disadvantaged groups.

Various organisations have undertaken efforts to address health literacy issues. In particular, major health literacy initiatives are being pursued across North America. For example, the Canadian Public Health Association (CPHA) has identified the achievement of health literacy as one of its nine major goals. To fulfil this commitment, the CPHA established the National Literacy and Health Program which aims to promote awareness among health professionals of the links between literacy and health. The programme offers services to help health professionals serve low literacy individuals more effectively, focusing in particular on plain language information and clear oral communication. In the US, the American Medical Association became the first national medical organisation to adopt a policy on health literacy. The association's philanthropic arm, the AMA Foundation, campaigns to improve health literacy through its Health Literacy Grants and Awards Program; by distributing health literacy resources to physicians; and in supporting the work of the Partnership for Clear Health Communication. In 2004 the US National Institutes of Health and Agency for Healthcare Research and Quality announced a new federal grants programme entitled 'Understanding and Promoting Health Literacy'. The programme aims to advance understanding of the relationship between health literacy and health behaviours, health outcomes, treatment and service utilisation, and of effective health literacy interventions and preventions.

Through its annual Patient Information Award, the British Medical Association is actively supporting efforts to improve the delivery of health information to patients and consumers. The award aims to encourage the production and dissemination of accessible, high quality materials to enhance patients' understanding of health issues and their ability to participate in care decisions. There has also been a longstanding commitment in the UK to informing and involving patients in healthcare, through the implementation of health education and promotion programmes. In particular, this has been pursued in the activities of Health Education Authority and its successor organisations the Health Development Agency and, latterly, National Institute for Health and Clinical Excellence.

Also in the UK, the 'Skilled for Health' campaign was jointly launched in 2003 by the Department for Health and the Department for Education and Skills. The campaign aims to demonstrate the links between better basic skills and improved health and to develop health-related learning materials for use with key groups: teenage parents, people with long term medical conditions, the elderly and ethnic minorities. Six local projects were launched in 2004 for phase two of the initiative.

Public debate and policy in the UK, however, has been more strongly focused on the provision of health information than on health literacy. Indeed, the drive to deliver high quality consumer health information is a central component of government policy for the National Health Service. In 1997 the New Labour government outlined its programme for the reform of the service in *The New NHS: Modern, Dependable* (Department of Health 1997). This identified the role of improved information provision in enabling people to take better care of themselves, thus potentially relieving some of the burden on NHS services. In 1998, an information strategy for the NHS was unveiled, followed in 2001 by

an implementation plan outlined in *Building the Information Core* (Department of Health 2001). A series of information initiatives have been introduced as a result of these policies, including NHS Direct Online, NHS Direct Digital TV and the National Electronic Library for Health. In 2004, the government restated its commitment to improving the quality and accessibility of consumer health information with the announcement of a three-year programme of action (see box).

Better information, better choices, better health: putting information at the centre of health (Department of Health 2004)

The strategy is underpinned by a series of principles, as follows:

People should:

- Have access to accurate, high quality, comprehensive information delivered in the way they want
- Have their personal information needs considered and discussed at every contact with health care professionals
- Receive as much support as they want to access and understand information
- Be empowered to ask questions and be involved as far as they want in making decision about, for example, the benefits and risks of action, and how any risks can be mitigated.

To support these principles, the strategy aims specifically to:

- **Embed information as an integral part of delivering healthcare through the entire healthcare system**. Information should be delivered in tandem with care provision and not as an 'add-on', in primary care, secondary care and specialist services.
- **Drive up health outcomes for disadvantaged groups**. Helping people in these groups to access, understand and act upon information will help narrow health inequalities and overcome many barriers to improving personal health and using health services.
- **Set out a single approach to information**. Clarity over what information is to be made available nationally will allow local NHS organisations to plan and commission information with confidence and without costly duplication.
- **Empower people to get the right information at the right time**. Timely personalised information will help people make choices to improve their health and help those providing care to give the advice people need when they need it.
- **Help people to confidently participate in healthcare decisions**. Understanding what is happening or likely to happen will help give people the confidence to communicate their preferences and concerns to health professionals.
- **Make information more effective**. The process of delivering information to people is just as important as the information itself. How it is explained directly impacts on how it is received and acted upon.
- **Make communications central to how we care for people**. New and more effective ways of reaching disadvantaged groups will include making information available in new environments (the home, shops, schools, workplaces) and in more accessible formats, for instance plain language, audio, translations, magazines, TV, radio and face to face with trusted community members.

Health literacy: what works?

1. Written health information

It is widely recognised that patients often forget things that are told to them during their consultation (Kenny et al 1998). Furthermore, the limited time available for consultations restricts the extent to which doctors can directly deliver advice and information on important aspects of care. Written health information is seen as a useful adjunct to verbal communication and, in recent years, there has been a marked proliferation in the availability of patient information leaflets and other printed materials (Coulter et al 1998).

Recognising the importance of written health information, numerous good practice guidelines have been produced. The major recommendations made across these guidelines are summarised below.

Producing effective consumer health information

Good practice guidelines for producing consumer health information recommend the following principles:

- actively involve patients in the development and evaluation of information materials
- before preparing the materials, consider the information needs of the target population. Where possible, information should be tailored to the individual patient's circumstances and concerns
- written information should be presented in plain English and be at a reading level which is suitable for the target population
- materials should reflect cultural diversity and be made available in non-English languages
- information should be accurate, non-biased and include a clearly stated evidence-base
- language should be non-alarmist, non-patronising and in the active voice
- avoid the use of unnecessarily long words, technical jargon and acronyms
- where possible, make use of illustrative diagrams and other appropriate visual aids
- present information clearly and in short blocks of text. Question and answer formats, sub-headings and bullet points are helpful to divide long sections of text
- include a publication date so that readers can gauge whether the information is up-to-date
- provide a list of contacts where patients can obtain further information if required
- make information available in a variety of mediums and from a range of sources
- the timing of information dissemination is crucial to its effectiveness. Bear in mind that patient's information needs are likely to change over the course of their illness.

Examples of best practice in patient information include:

- *Lymphomas* by the Lymphoma Association
  http://www.lymphoma.org.uk/support/
- *Understanding breast reconstruction* by Cancer BACUP
  http://www.cancerbacup.org.uk/Treatments/Surgery/Breastreconstruction
- *How to cope with hospital admission* by MIND
  http://www.mind.org.uk/Information/Booklets/How+to/hospitaladmission.htm
- *Your child's general anaesthetic* by the Royal College of Anaesthetists
  http://www.youranaesthetic.info/child/
- Avert website
  http://www.avert.org/

We identified eight systematic reviews of the effectiveness of patient information, although in many of the individual studies included in these reviews information was delivered as part of a broader intervention combining a number of different approaches. A key issue in developing effective strategies for delivering information is whether there are additional benefits from tailoring materials to the individual in question. Two RCTs are also reported below, as they address the specific impact of personalised versus general information on patient outcomes.

Forbes and colleagues (1999) reviewed the evidence for the effectiveness of interventions to improve cervical cancer screening rates (Forbes et al 1999). Included studies could involve a range of interventions such as: invitations, reminders, education, message framing, counselling, risk factor assessment, making screening procedures easier or more acceptable, and removal of financial barriers or use of economic incentives. Six of the studies assessed educational approaches, involving printed materials (3 studies), video/slide presentations (1), face-to-face visits (3). Printed materials did not increase screening rates, but there was evidence to support the use of video/slide presentations and face-to-face visits. The strongest evidence of improvement was for invitation letters.

Strength of evidence: Cochrane systematic review.

Jones and colleagues (1999) compared general and personalised computer-based information for patients with cancer (Jones et al 1999). This RCT involved 525 patients, receiving treatment for cancer in western Scotland, who were randomised to receive general computer information, personalised computer information or printed booklets. Those offered personalised materials were more likely to use them, find them relevant, show them to others and feel that they had learn something new. A computer information system was found to be 40% of the cost of printed booklets. Personalised computer information was far more expensive in the trial, largely because of the time spent manually extracting data from patient records. However, the authors note that there would be no extra cost if personalised materials could be generated using an electronic patient medical record.

Strength of evidence: Single randomised controlled trial.

McDonnell (1999) conducted a systematic review to determine the effectiveness of providing information to patients prior to undergoing surgery or other invasive procedures (McDonnell 1999). Eighteen controlled studies were included, with length of stay (LOS) and anxiety the most commonly reported outcomes. Of the ten studies which measured LOS, only three found statistically significant effects: two reported significantly shorter LOS and one significantly longer LOS in the intervention group. Six studies measured patient anxiety, with only one study reporting significantly lower anxiety levels in the intervention group. The author concludes that there is insufficient evidence to establish the effectiveness of preparatory preoperative information.

Strength of evidence: Systematic review – review based on clear inclusion/exclusion criteria and thorough search of the published literature; however, search restricted to English language publications, excluded unpublished literature and did not report details of individual study quality (CRD).

Forster and colleagues (2001) examined the effectiveness of information and/or education strategies for stroke patients and/or their carers (Forster et al 2001). This Cochrane review identified nine studies, six of which evaluated the provision of information and the remaining three evaluated a programme of educational lectures. There was some evidence that information combined with education was more effective than information alone. The provision of information only had no effect on mood, perceived health status or patient/carer quality of life. Two trials measured satisfaction, with no significant difference between intervention and control groups. In one study, combined information and education was reported to improve family functioning.

Strength of evidence: Cochrane systematic review.

McPherson and colleagues (2001) conducted a systematic review to determine effective methods of information delivery to cancer patients (McPherson et al 2001). Ten studies met the inclusion criteria, covering a variety of interventions including audiotapes, audiovisual aids, interactive media and, primarily, written information. Written information was found to enhance recall and knowledge, and patients and their families valued practical information booklets or packages. Most of the studies failed to demonstrate the effectiveness of the interventions on psychological outcomes, although this may be because the interventions were intended to have an educational rather than a counselling function. Two important findings from the review are that: i) cancer patients are a heterogeneous population whose information needs differ according to their preferences and coping styles; and ii) tailoring information to the patient reduces the amount, increases the relevance and enhances recall of information provided.

Strength of evidence: Systematic review – review question and inclusion criteria stated but some processes not clearly reported; review was limited by the scarcity of papers that met the RCT inclusion criteria (CRD).

Johnson and colleagues (2003) reviewed the evidence comparing verbal information with verbal plus written information for patients being discharged from hospital settings to home (Johnson et al 2003). They were specifically concerned with trials examining information on disease/condition management; specific care related to procedures; medication; when to seek attention; and who to seek attention from and how. Two trials met the inclusion criteria (one in the US, the other in Canada), both of which involved parents of children who were being discharged from hospital (one a burns unit, the other an emergency department). Intervention groups in both trials had increased knowledge and satisfaction; one trial measured return visits to hospital, and found a significantly

higher rate of return visits in the control group. However, this trial did not find a difference between the groups in terms of need to phone a doctor for advice following discharge.

Strength of evidence: Cochrane systematic review.

Horey and colleauges (2004) systematically reviewed the effectiveness of providing information to pregnant woman about caesarean birth (Horey et al 2004). Two RCTs met the inclusion criteria, both attempting to reduce the number of caesarean births by encouraging vaginal delivery. One study (USA) compared a prenatal education and support programme with a brief pamphlet; in the other (Finland) all participants received two sessions to discuss childbirth, and the intervention group were given additional sessions and the option to discuss possible interventions with a midwife. Neither study reported on knowledge or decision-making outcomes. No differences between control and intervention groups were found for clinical outcomes (e.g. vaginal birth, elective/scheduled caesarean, and attempted vaginal delivery) or psychological outcomes.

Strength of evidence: Cochrane systematic review.

McDonald and colleagues (2004) examined whether preoperative education improves postoperative outcomes and patient satisfaction, and reduces patient anxiety (McDonald et al 2004). This Cochrane review was specifically concerned with the effects of education – including patient information – for those facing total hip or total knee replacement surgery. Nine studies were identified, which involved education given verbally or in a written or audiovisual form. Overall, the studies found that education is effective in improving preoperative anxiety, but has no significant impact on patient satisfaction, length of hospital stay, mobility outcomes or postoperative pain. The authors note that one possible explanation for these findings is that the trials typically involved an active comparator, which is likely to result in smaller effect sizes. One study did find that preoperative education reduced length of stay; this study was conducted with patients who had poor levels of social support and functioning who received a complex, combined intervention including skills training and individually tailored support programmes. This suggests that there may be additional benefits to patients with greater need.

Strength of evidence: Cochrane systematic review.

Johansson and colleagues (2005) assessed the impact of preoperative education for orthopaedic patients (Johansson et al 2005). Their systematic review identified eleven studies, with most involving written materials alone or in combination with other methods. Control groups generally received usual care. Common outcome measures included pain, knowledge and anxiety. All but one of the studies reported at least one positive effect, with knowledge and performance of exercises most frequently improved. Patients receiving preoperative information also felt more empowered than controls and two studies found that they used less postoperative pain medication. Findings were generally mixed for the other outcomes measured (including patient anxiety and experience of pain).

Strength of evidence: Systematic review, no independent assessment found.

Jones and colleagues (2006) compared various different approaches to delivering information to cancer patients (Jones et al 2006). They were particularly interested in the impact of information on psychological wellbeing, which is known to be negatively affected by the experience of cancer. Four hundred patients were recruited, and were

randomised into eight groups defined by binary factors (personalised versus general information; patient interactively selecting information versus automatic production; and receive versus not receive anxiety management advice). The amount of information that was automatically produced was much higher than the amount that patients chose for themselves. Participants who received automatically produced booklets were more likely to find the information useful and more satisfied with what they had received. However some patients did perceive automatically produced booklets to be overwhelming. More patients with personalised materials felt that these told them something new and that the information was relevant to their situation. They were also more likely to show their information to others and to think that it helped them in discussing their cancer or its treatment. There was no significant difference according to the three intervention factors in terms of changes in anxiety or depression.

Strength of evidence: Single randomised controlled trial.

Summary of known effects of written health information

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Health knowledge and recall of information improved. Evidence suggests recall is most improved with personalised information. The combination of written and verbal information has greater impact on knowledge outcomes than verbal information alone.
Patients' experience, including communication and psychological outcomes	Little evidence of effect on psychological outcomes, but possible improvement in family functioning. Mixed overall results in relation to patient satisfaction, but higher levels of satisfaction reported for combined written and verbal information (compared with verbal information only). Some evidence that patients' sense of control is improved by preoperative information.
Health services utilisation and cost	Mixed results for impact of pre-operative information on length of hospital stay. No impact on screening rates and effect on health inequalities unknown. Computer generated information less costly than printed leaflets.
Health behaviour and health status	No effect on health status. Impact on health behaviour not known.

2. Alternative format resources

With advances in information technology, alternative methods for making health information accessible to consumers have been developed. Foremost among such developments is the internet, through which patients can receive health information and advice, form virtual health communities and support groups, and participate in e-health commerce. As with the internet, many of the technologies in this category are interactive resources, thus allowing patients to assume greater control over the information gathering process. Research on alternative format resources has largely focused on the same outcomes used in the evaluation of written patient information (e.g. knowledge/recall, health behaviours, health status and health services utilisation). However, given the unregulated nature of the internet, another major consideration is whether there is any *harm* associated with the use of health information accessed in this way.

Bessell and colleagues (2002) explored the impact of online health services and information on patient decision-making, attitudes, knowledge, satisfaction and health outcomes and utilisation (Bessell et al 2002). Their systematic review of the literature identified 10 comparative studies, including controlled studies, before and after studies and interrupted time series. The studies provide evidence supporting the effectiveness of internet-based educational programmes, with positive effects reported for behavioural change, social support and patient attitudes. While there is a lack of evidence as to the impact of the internet on health service utilisation, the study results indicate possible benefits with regard to cost effectiveness of health service provision and workflow practices. There was no available evidence for the effect of the patient internet use on health outcomes.

Strength of evidence: Systematic review – review had a defined question and searched a range of databases but it is unclear whether a formal validity assessment was conducted to exclude study designs prone to bias (CRD).

Crocco and colleagues (2002) examined the potential for harm arising from the use of internet health information (Crocco et al 2002). Only three articles met the eligibility criteria, which described individual or small case studies. The authors suggest the possibility of underreporting of cases of harm associated with use of internet health information.

Strength of evidence: Systematic review – appropriately broad inclusion criteria, methodology well described and individual cases identified and described appropriately; as the authors state, a review of cases posted on the Internet itself would probably have been a better starting point (CRD).

Gustafson and colleagues (2002) reviewed the research evidence for the computer-based Comprehensive Health Enhancement Support System (CHESS), focusing particularly on underserved populations including African Americans and the elderly (Gustafson et al 2002). While the *level* of CHESS use doesn't vary greatly between different populations, there are important differences in *type* of use. The underserved tend to use CHESS for information and analysis services rather than computer-mediated communication services such as discussion groups. Research has shown that underserved groups benefit more from their use of CHESS. The authors suggest that this is likely to be because the underserved have more to gain from health information and also due to their different style of use.

Strength of evidence: Research review.

Nicholas and colleagues (2002) were commissioned by the UK Department of Health to evaluate four pilot projects exploring the feasibility and effectiveness of health information and advice services supplied to the public via digital interactive television (DiTV) (Nicholas et al 2002). The pilot projects consisted of: Flextech Living Health, Communicopia (NHS Direct), Channel Health and DKTV (A Different Kind of Television). Sixty seven per cent of Living Health Users and 90% of Communicopia viewers said they felt better informed about a condition after using the service. DiTV was also found to lead to improvements in health; for example, one third of Living Health users and 62% of Communicopia users said that the information they found either 'helped' or 'helped a lot' in improving their condition. The authors suggested that DiTV may reduce utilisation of health services; for example, 53% of Living Health users said they used information to substitute a visit to their doctor. Twenty seven per cent of Communicopia users said that they would use the service to find information on subjects that they would not want to discuss with their doctor. Use of DiTV services varied according to the users' technological literacy; older patients were less enthusiastic and more anxious about DiTV than younger ones. User satisfaction with the four services was varied, but overall was fairly high.

Strength of evidence: Multi-method evaluation.

Treweek and colleagues (2002) systematically reviewed evidence from randomised controlled trials for the effectiveness of computer-generated patient education materials (Treweek et al 2002). Three studies met the eligibility criteria, all of which involved interventions for preventive care. The primary outcome measure was effect on professional practice, which included delivery of information, cost, time spent with patients, prescribing, referrals and other clinical activities. All three studies reported improvements in some areas, but gains were modest overall. One study (Lowensteyn et al. 1998) reported on health outcomes, with the intervention group demonstrating greater reductions in cholesterol which resulted in significant improvement in both cardiovascular age and predicted eight-year coronary risk compared to controls.

Strength of evidence: Systematic review – clear review question, extensive database search and well described procedure but no formal validity assessment; as the authors acknowledge, the evidence presented was very limited (CRD).

Eysenbach (2003) conducted a systematic review of literature on cancer patients' use of the internet and its impact on health outcomes (Eysenbach 2003). Twenty four surveys were identified, which included responses from a total of 8,679 patients with cancer. Four types of internet use were identified: communication (email), community (virtual support groups), content (health information) and e-commerce. From the available evidence, the effect of electronic support groups (ESGs) is unclear, although recent studies indicate that ESGs can increase perceived social support and decrease loneliness. The overwhelming majority of studies of information provision to cancer patients have evaluated printed materials and computer-based personalised information rather than internet information. Of the little research available for internet information, findings indicate that it has positive effects on self-efficacy and task behaviour, empowers patients to make health-related decisions and improves confidence in the doctor-patient encounter. However, patients reported feeling overwhelmed by the sheer volume of internet output and confused by conflicting medical information on cancer treatment.

Strength of evidence: Systematic review, no independent assessment found.

Scott and colleagues (2003) assessed the evidence for interventions designed to improve communication with children and adolescents about their cancer. Nine studies met their inclusion criteria, two of which involved computer-based educational programmes. One of these studies found improved knowledge and understanding immediately after completion of computer-assisted instructional programme (but retention of knowledge was not measured). The other compared a CD-Rom with a book for children with leukaemia, and reported that the CD-Rom group felt more in control of their health and more satisfied overall. While there was no difference in children's understanding of the events associated with leukaemia, those in the CD-Rom group gave more detailed accounts of these events.

Strength of evidence: Cochrane systematic review.

Eysenbach and colleagues (2004) examined the evidence for the impact of virtual communities (social networks formed or facilitated through electronic media) on social and health outcomes (Eysenbach et al 2004). Thirty eight studies met the inclusion criteria, only six of which solely evaluated virtual communities. The remainder involved complex approaches where the virtual community was an adjunct to a broader intervention. The studies reported mixed results for the impact of virtual communities on levels of depression and social support measures. Reported effects on health service utilisation were also variable. With one exception, the studies failed to demonstrate any positive effects of virtual communities on health status and health behaviours. The author notes that, in the studies reviewed, there was no evidence that virtual communities had negative or harmful effects.

Strength of evidence: Systematic review, no independent assessment found.

Nicholas and colleagues (2004) were commissioned by the Department of Health to conduct an evaluation of the use and impact of digital health information platforms (Nicholas et al 2004). The four-year evaluation included three types of service: touch-screen information kiosks, health websites on the internet and digital interactive television (DiTV). Touch-screen kiosks were not found to have strong effects on health outcomes; the kiosks helped users to understand their condition better, but did not lead to improvements in their condition or help them in physician consultations. Overall, take-up of kiosks was low (17%, compared to around 30% for the internet and DiTV), which may be explained by their often poor integration into the health environment. Use of the internet was associated with positive outcomes, with users reporting better understanding of health problems (93%), access to information not provided by their doctor (51%) and changes in health-related behaviour (38% of users subsequently took more exercise; impact on smoking and drinking habits was far lower). As with kiosks, there was no evidence that people used the internet as a substitute for visiting their doctor. Users of the digital health platforms were most likely to be women under the age of 55; the elderly made comparatively little use of the online systems, due to problems operating the technology and a preference for receiving advice directly from medical professionals. Lower income groups were twice as likely to use DiTV services compared with the internet, while the internet was most likely to be used by more affluent and educated groups. The evaluation of the four digital television services is summarised in detail above (Nicholas et al. 2002).

Strength of evidence: Multi-method evaluation.

Nguyen and colleagues (2004) collected evidence on internet-based patient education and support interventions (Nguyen et al 2004). Seventeen studies reported outcomes data – seven provided computer equipment to participants, and the remaining ten only

included people with existing internet access. The studies involved various different clinical populations, including those with diabetes, breast cancer, HIV/AIDS, chronic back pain, chronic heart failure, or who wanted to lose weight. Reports of user satisfaction were generally positive, and some interventions were associated with moderate improvements in health and service outcomes. Quality of life was not improved, and the findings for perceived social support were mixed.

Strength of evidence: Systematic review, no independent assessment found.

Wantland and colleagues (2004) conducted a meta-analysis of studies comparing web-based with non web-based interventions on behavioural change outcomes (Wantland et al 2004). Twenty two articles were identified, involving a total of 11,754 participants; the interventions were mostly educational or instructional in content. The studies involved a range of internet-based approaches and participant groups, and measured many different knowledge and/or behaviour change outcomes. Effect sizes varied from -0.01 to 0.75, with outcomes improved by web-based interventions in 16 of the 17 studies in which effect sizes were reported. A non web-based intervention was favoured in one study, but the difference did not reach statistical significance.

Strength of evidence: Systematic review, no independent assessment found.

Gaston and Mitchell (2005) systematically identified trials of approaches to improve information giving to patients with advanced cancer (Gaston & Mitchell 2005). They identified nine controlled and three uncontrolled trials, involving various interventions such as audiotaping consultations, summary letters or videos. Consultation tapes have a small but significant effect on patient knowledge and satisfaction. Summary letters can also be effective, but patients tend to prefer the audiotape format. There is some evidence that written information can decrease levels of anxiety. Take home materials can also be shared with friends and family, thereby increasing levels of practical and emotional support. Two of the studies compared videotape with standard written information, coming to opposite conclusions about the added value of the videotape format.

Strength of evidence: Systematic review, no independent assessment found.

Murray and colleagues (2005) conducted a Cochrane systematic review to assess the effects of interactive health communication applications (ICHAs) for people with chronic disease (Murray et al 2005). ICHAs were described as ‘computer-based, usually web-based, packages for patients that combine health information with at least one of social support, decision support, or behaviour change support’. Twenty four RCTs met their inclusion criteria which examined the following conditions: AIDS/HIV (2 studies); Alzheimer’s/memory loss (2); asthma (6); cancer (3); diabetes (6); eating disorders (1); encopresis (1); obesity (2); and urinary incontinence (1). Primary outcome measures included: knowledge, social support, self-efficacy, emotional outcomes, behavioural outcomes and clinical outcomes. ICHAs were found to improve knowledge, social support, health behaviours and clinical outcomes. There was insufficient data to determine impact on emotional outcomes or cost-effectiveness. Results indicated probable positive effects on self-efficacy, but more data is needed to clarify this.

Strength of evidence: Cochrane systematic review.

Santo and colleagues (2005) reviewed the evidence for the use of audiotapes in communicating health information (Santo et al 2005). They were specifically concerned

with audiotape recordings of health information, delivered as educational interventions for patients and carers. Thirty one studies met the inclusion criteria. The main outcomes measured were: knowledge/recall, behavioural change, anxiety, self-care and satisfaction. Overall, the studies reported mixed results for many of the outcomes, including knowledge/recall and anxiety. Positive effects were consistently reported for self-care measures and patient satisfaction. A few studies found that patients appreciated receiving recorded information even where this did not lead to an increase in knowledge or recall. Two studies indicated that audiotapes can decrease consultation times and phone calls to health professionals and reduce overall health costs.

Strength of evidence: Systematic review, no independent assessment found.

Wofford and colleagues (2005) identified 26 trials of computer-assisted patient education in the office setting (Wofford et al 2005). They were specifically concerned with the delivery of educational messages using multimedia techniques, e.g. use of graphics and/or audio. Commonly reported outcomes included clinical indicators, knowledge, health attitudes, shared decision-making, health services utilisation and costs. Generally knowledge and self-efficacy were improved, but evidence for health, psychological and cost outcomes were mixed.

Strength of evidence: Systematic review, no independent assessment found.

Summary of known effects of alternative format resources

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Health knowledge mainly improved, but results mixed.
Patients' experience, including communication and psychological outcomes	High user satisfaction, and some evidence that audiotapes preferred over standard written materials. Beneficial effects on self-efficacy and task behaviour, involvement in decisions and confidence in doctor-patient consultations. Some evidence of improved social support, particularly with interactive health communication applications.
Health services utilisation and cost	Some evidence of greater benefit for under-served groups, but older people may find access and use more difficult. Tape-recordings of consultations may reduce follow ups and costs.
Health behaviour and health status	Some evidence of beneficial impact on health behaviour, particularly with web-based educational interventions. Harm may be under-reported. Clinical outcomes improved with interactive health communication applications.

3. Low literacy initiatives

Low literacy initiatives may employ any of the strategies described in the three other categories. Where low literacy initiatives differ is in specifically targeting such strategies towards groups who lack adequate health literacy skills. Most often, low literacy initiatives have involved designing or revising patient information or educational materials in order to enhance comprehension among people with health literacy problems. Considerable use has been made of non-written media to communicate health information including pictograms, videotape formats and interactive computer systems. Most of the evidence for low literacy initiatives currently comes from North America, where there are major funding opportunities for research of this kind. In addition to studies specifically involving low literacy patients, we have also described a number of important trials with groups that are at greater risk of low health literacy (e.g. impoverished populations, ethnic minorities).

Moudgil and colleagues (1999) conducted a randomised controlled trial to evaluate the impact of asthma education on economically disadvantaged white European and Indian groups (Moudgil et al 2000). The study was based in community settings, specifically in districts with high ethnicity and socioeconomic deprivation in inner city Birmingham. Patients from both populations were randomised either to receive individually tailored asthma self-management plans and literature (printed in English or the appropriate ethnic dialect) or to be in the control group which received neither. The intervention reduced the number of hospital admissions (10 versus 30), GP consultations (341 vs. 476), prescriptions of oral steroids (92 vs. 177) and antibiotics (220 vs. 340). However, when the data were analysed by ethnicity, only in the white European group were differences between control and intervention groups statistically significant.

Strength of evidence: Single randomised controlled trial.

Strydom and Hall (2001) tested a specially designed information leaflet intended to improve knowledge of psychotropic medication in patients with intellectual disability (Strydom & Hall 2001). Fifty four patients were recruited, randomised either to receive verbal medication information from a nurse or psychiatrist, or to receive the verbal information plus an information leaflet. Medication knowledge and understanding in patients was significantly lower in the intervention group, and the authors note that information leaflets may actually confuse people with cognitive disabilities. There were no significant differences between the groups in terms of satisfaction with either their medication or clinician.

Strength of evidence: Single randomised controlled trial.

Eakin and colleagues (2002) conducted a systematic review of the effectiveness of diabetes self-management programmes targeting disadvantaged populations (Eakin et al 2002). Ten controlled studies met the eligibility criteria, with nine describing interventions delivered in group-based sessions. The studies provide some evidence for the short term effectiveness of self-management programmes with regard to dietary patterns and weight loss, blood glucose control and physical activity. Only two studies reported on changes in diabetes knowledge and neither found significant intervention effects. There was evidence of the maintenance of short term effects, except in the case of weight loss. Of two studies which reported on long term psychosocial outcomes, neither found a significant difference between groups. Given that people from disadvantaged groups face barriers in attending group-based meetings, the authors suggest that alternative modalities for the delivery of self-management education should be evaluated.

Strength of evidence: Systematic review – clearly stated review question and study selection criteria but search limited to MEDLINE and English language publications; no information given on the literature selection, validation and data extraction processes (CRD).

Mansoor and Dowse (2003) examined the impact of pictogram information on the acquisition and comprehension of drug information in low literacy patients (Mansoor & Dowse 2003). Sixty participants were randomly allocated to a group either receiving text-only information or text and pictogram information. They were then asked to read a patient information leaflet (PIL) and medicine label for nystatin suspension (used in the prevention and treatment of thrush). The group receiving the pictograms demonstrated significantly greater comprehension of the PIL and medicine label. Patients also showed a clear preference for the pictogram information.

Strength of evidence: Single randomised controlled trial.

Anderson and colleagues (2004) conducted an RCT of pain management education in underserved African American and Hispanic cancer patients (Anderson et al 2004). They enrolled 97 patients, and those randomised to intervention received a culturally specific video and booklet on pain management. The control group received a video and booklet on nutrition. A nurse met with patients from both groups to discuss the materials. They found no statistically significant difference between the groups for pain intensity and pain interference, quality of life, pain control or functional status. There was a significant decrease in the worst ratings of pain among African American intervention patients at initial follow-up, but this had not been sustained by subsequent assessments. The authors found that more than 50 of the sample were receiving inadequate pain medication.

Strength of evidence: Single randomised controlled trial.

Berkman and colleagues (2004) conducted a systematic review for the AHRQ of interventions designed to mitigate the effects of low literacy on health outcomes (Berkman et al 2004). Twenty studies were identified which evaluated various types of interventions including low literacy educational materials and consent forms, videotapes and interactive multimedia programmes. Only one study (Davis et al. 1998) measured the effects on a literacy intervention on health service utilisation; this reported that an intervention consisting of a twelve minute educational video, verbal recommendation and brochure significantly improved mammography uptake at six months (but not at 24 months) compared with a verbal recommendation alone and a combination of recommendation and brochure. While many studies reported the effectiveness of interventions in improving knowledge, they did not measure whether this also improved literacy-associated disparities in health. Several studies measured effects on health behaviours, with positive results reported for smoking, exercise and medication compliance but not for dietary behaviours. None of the eligible studies addressed the effects of literacy interventions on the costs of healthcare or disparities in health service use.

Strength of evidence: Systematic review, no independent assessment found.

Fitzgibbon and colleagues (2004) evaluated a combined dietary and breast health intervention in young, low acculturated Latino women (Fitzgibbon et al 2004). The intervention was tailored to make it culturally relevant to the target population, and was specifically designed to reduce fat and increase fibre intake, and increase proficiency of

and reduce anxiety about breast self-examination. The project was conducted at a family health centre in Chicago, serving a primarily immigrant Latino population. The intervention group were offered 16 90-minute sessions that provided information on diet and early detection of breast cancer, and just over half of the group randomised to intervention attended eight or more of these sessions. At eight month follow-up, the intervention group was found to have significantly lower fat intake and increased frequency and proficiency of breast self-examination. No statistically significant differences were found for fibre intake.

Strength of evidence: Single randomised controlled trial.

The Institute of Medicine (2004) overviewed the evidence for current health literacy interventions taking place within, or sponsored by, health systems (Institute of Medicine 2004). The majority of health literacy interventions involved revising patient information materials using simplified language and/or visual aids. Most studies evaluating this type of intervention reported positive outcomes in areas such as patient satisfaction, preference and anxiety; however, similar improvements in patient comprehension were not shown. Findings from studies of technology-based low literacy interventions are mixed; some show positive outcomes in areas such as knowledge and self-care ability, while others show no effect. Simply converting text versions of patient education materials into an alternative format (e.g. CD-ROM) leads to improvements in satisfaction but not in knowledge. Studies evaluating complex health literacy interventions produced variable results, although there is evidence to support the combined use of simplified written materials and verbal presentation. Research has shown that tailored print communications can improve health behaviour outcomes but that effectiveness is largely restricted to patients who were already considering making a behavioural change. There is also evidence that computer-generated tailored information can enhance patient knowledge and satisfaction, while decreasing decisional conflict.

Strength of evidence: Research review.

Gerber and colleagues (2005) evaluated a multimedia diabetes educational intervention in patients with low health literacy levels (Gerber et al 2005). A total of 244 patients were enrolled from five clinics in Chicago, and were randomised to either receive the intervention or standard care (control). Health literacy testing found that 56% of the intervention group, and 55% of the control group, had low health literacy. The intervention consisted of a personal computer with touch screen, run as a kiosk which was placed in waiting areas. It included audio/video sequences to communicate information, provide psychological support and promote diabetes self-management skills. There was a significant increase in the intervention group in their perceived susceptibility to diabetes complications, with the greatest increase found in those with low health literacy. However, there were no significant differences between the groups in clinical outcomes, self-efficacy, knowledge or medical care.

Strength of evidence: Single randomised controlled trial.

Griffiths and colleagues (2005) reported on the first trial of a lay-led self-management programme with South Asian adults in East London (Griffiths et al 2005). The intervention was based on the Chronic Disease Self Management Programme, adapted for cultural appropriateness to the participant group. The intervention improved self-efficacy and self-management behaviour in participants attending at least three of the six weekly sessions, but there were no significant differences between the groups in terms of communication outcomes or utilisation of healthcare services. The authors reported difficulties both in recruiting to the programme, and retaining participants for the six week duration.

Strength of evidence: Single randomised controlled trial.

Harmsen and colleagues (2005) tested an educational intervention intended to improve intercultural doctor-patient communication, and thereby decrease inequalities of care (Harmsen et al 2005). Thirty eight GPs in the Rotterdam region were invited to participate, who had practice lists with at least 25% non-Western patients, and a total of 986 consultations were finally included. The intervention targeted both GPs (who were educated about cultural differences and received two and a half days training in intercultural communication) and patients (who received videotaped instructions on how to communicate with their GP in a direct way). The primary outcome was mutual understanding (measured using the Mutual Understanding Scale), with patients' satisfaction and perceived quality of care also assessed. At six months, there was no difference between the control and intervention group in primary or secondary outcomes. However, there was a significant improvement in mutual understanding and quality of care in the non-Western patients in the intervention group. There was also a small, but non-significant change, in the non-Western group in terms of consultation satisfaction and perceptions that the GP had been considerate. The improvement in the non-Western intervention patients was largely accounted for by those who could be described as partly traditional/modern.

Strength of evidence: Single randomised controlled trial.

Holmes-Rovner and colleagues (2005) described the development and evaluation of a plain language decision aid for men with prostate cancer (Holmes-Rovner et al 2005). The decision aid was tested in a convenience sample of 60: 20 receiving the paper version, 20 the internet version and 20 the audio version. The men completed a survey about their experience of using the aid, the results of which were compared with historical controls. While knowledge was not found to be any higher in the decision aid group, there was increased awareness that radiation therapy has side effects. There was also significantly greater discussion of treatment options compared to the control group. The decision aid was found to be universally clear and helpful, and 72% of men who received it said that they were more likely to take an active role in their treatment decision. Additionally, the research identified several principles of plain language that were particularly important to the target group including: translations of medical language, the emotional difficulties of choices and the use of attractive layout and illustrations. The provision of numbers of show frequency of side effects was also considered essential.

Strength of evidence: Survey evaluation, compared with historical controls.

Summary of known effects of low literacy initiatives

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Mixed results for knowledge and comprehension. Some evidence of a worsening in understanding for patients with intellectual disabilities. Pictograms assist comprehension and are preferred by patients.
Patients' experience, including communication and psychological outcomes	Some evidence of improved satisfaction, particularly with non-written interventions. Improvements in intercultural communication with an educational

	intervention targeted at both doctors and patients. Low literacy decision aid increased discussion of options and patients' perceived role in decision-making. Mixed results for self-efficacy.
Health services utilisation and cost	No change in rates of utilisation and impact on health inequalities unknown.
Health behaviour and health status	Some evidence of improved health and self-care behaviors, but no improvement in health status.

4. Targeted mass media campaigns

The mass media is a major and influential source of consumer information. It is no surprise, then, that it is widely used for the dissemination of health information to patients and the general public. This category is specifically concerned with the use of mass media for targeted health communication, rather than with media reporting of health issues. A strength of mass media campaigns is their potential to reach large sections of the population. This broad reach is achieved through traditional mass media vehicles such as television, radio, newspapers, posters, leaflets and booklets, as well as emerging interactive mass media applications. The evidence outlined below pertains to a variety of informational and educational campaigns aiming to improve health knowledge, health behaviours and the effective use of healthcare services.

HealthWhich? (1998) evaluated the information campaigns conducted by the Doctor Patient Partnership (DPP) to encourage responsible use of NHS services (Health Which? 1998). They conducted ten focus groups and 72 in-depth interviews to determine the public's opinion on nine DPP campaigns. Five of the campaigns were said by patients to contain confusing messages. Most felt that the DPP campaigns lacked relevance, because they felt they were already using NHS services responsibly. People often failed to detect the overall message from the campaign materials. By contrast, the DPP's Home Healthcare Guide was very popular with patients, and was reported to contain the type of health-related information people wanted.

Strength of evidence: Multi-method evaluation.

Marcus and Crane (1998) reviewed the published evidence for cervical cancer screening interventions (Marcus & Crane 1998). Over 200 studies were identified which broadly fell into two categories: interventions designed to increase the number or proportion of women screened for cervical cancer, and interventions designed to reduce loss to follow up among women with abnormal Pap smear. The studies involved mass media campaigns, community outreach strategies, patient letters and opportunistic screening. With regard to mass media campaigns, several studies reported little or no effect. Where effects did occur, they tended to be short in duration. The evidence indicates that mass media campaigns are most effective at raising awareness and creating a positive background context in which other interventions can be successfully deployed. Therefore, mass media campaigns are likely to be most effective when used in combination with other approaches (e.g. community outreach workers).

Strength of evidence: Systematic review, no independent assessment found.

Sowden and Arblaster (2000) conducted a Cochrane systematic review of mass media interventions for preventing the uptake of smoking in young people (Sowden & Arblaster 2000). Six studies met the inclusion criteria, all using a controlled trial design. Two of the studies concluded that mass media was effective in influencing smoking behaviour; both of the campaigns described in these studies had a solid theoretical basis, used formative research in designing campaign messages and were relatively intensive over longer periods of time.

Strength of evidence: Cochrane systematic review.

Grilli and colleages (2002) assessed the effect of mass media (including targeted campaigns and editorial coverage) on the use of health services (Grilli et al 2002). Their Cochrane systematic review included 20 articles, the majority of which evaluated planned media campaigns concerning the use of drugs, medical or surgical procedures and

diagnostic tests. The campaigns were conducted through a variety of media (including radio, television, newspapers, posters and leaflets) and varied considerably in length (from one week to four years). The only permitted outcome measure was direct impact on health services utilisation by healthcare providers or patients. All studies, except one, concluded that mass media was effective, although when the data were re-analysed fewer studies were found to produce positive results. The available data did not allow the authors to draw conclusions about the specific characteristics of successful campaigns, differences in the effect of planned campaigns and unplanned coverage, or potential differentials in the influence of mass media on consumers and health professionals.

Strength of evidence: Cochrane systematic review.

Black and colleagues (2002) conducted a systematic review of the literature on the effectiveness of community-based strategies to increase women's participation in cervical cancer screening (Black et al 2002). Nineteen studies were included in the review; mass media campaigns were most commonly evaluated, either alone or in combination with other interventions. Seventeen of the 19 studies measured outcomes in terms of Pap smear rates and, of these, twelve reported statistically significant improvements compared to controls (although in some studies the actual difference was small). Of the four studies of mass media campaigns alone, the only one that was effective targeted a definite sub-population with tailored material. All five studies that combined mass media campaigns with other interventions were effective at increasing Pap smear rates or early cancer detection. The studies do not provide conclusive evidence as to the sustainability of effects.

Strength of evidence: Systematic review, no independent assessment found.

Stone and colleagues (2002) systematically reviewed the literature on the relative effectiveness of interventions to increase use of adult immunization and cancer services (Stone et al 2002). Eighty one studies were included in the analysis, all of which involved a usual care or control group. The interventions studied were: patient reminders, feedback, education, financial incentives, regulatory interventions, organisational change and media campaigns. Organisational change and patient financial incentives were most effective; patient education was found to be one of the least effective interventions, although it was consistently moderately effective in increasing screening participation. Media campaigns could not be reliably assessed due to insufficient data.

Strength of evidence: Systematic review, no independent assessment found.

Summary of known effects of targeted mass media campaigns

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Effective in awareness-raising.
Patients' experience, including communication and psychological outcomes	Home healthcare guides are popular.
Health services utilisation and cost	Some impact on utilisation; raise awareness of screening but not effective on their own in increasing uptake.
Health behaviour and health status	Can reduce smoking among young people.

Health literacy: what looks promising for future R&D?

Although health literacy issues are being given increasing prominence, the above evidence review demonstrates that there are considerable gaps in what is known about how to raise standards of health literacy. There is a need for continued research in this area, in particular focusing on the impact of interventions on literacy-related disparities. To this end, trials must be designed to measure and stratify outcomes according to health literacy level.

In addition to the above, future research should focus on the following important issues:

- identify the factors mediating and moderating the relationship between health literacy and patient outcomes
- reliable assessment of the impact of health literacy interventions on health status, behaviours and knowledge, and health service utilisation. Greater use of comparative methods for evaluating the relative effectiveness of different approaches
- establish the most effective ways of delivering health information and education, paying particular attention to communication with low literacy, hard-to-reach and disadvantaged groups
- identify the characteristics of successful mass media campaigns, and investigate how and in what ways impact is enhanced by combining mass media campaigns with other strategies (e.g. mailings, outreach programmes)
- assess the cost-effectiveness of health literacy strategies
- investigate the impact of interventions for improving the quality of health information, such as the development of critical appraisal skills training and tools for consumer use.

References

Ad Hoc Committee on Health Literacy (1999) 'Health literacy: report of the Council on Scientific Affairs, American Medical Association'. *JAMA*, 281 (6): 552-557.

Anderson, K.O. et al (2004) 'Pain education for underserved minority cancer patients: a randomized controlled trial'. *J Clin Oncol*, 22 (24): 4918-4925.

Andrus, M.R. & Roth, M.T. (2002) 'Health literacy: a review'. *Pharmacotherapy*, 22 (3): 282-302.

Atkinson, T. (2003) *Plain language and patient education: a summary of current research. Research briefs on health communication*. Montreal: The Centre for Literacy.

Berkman, N.D. et al (2004) *Literacy and health outcomes. Evidence Report/Technology Assessment No. 87*. Rockville, MD: Agency for Healthcare Research and Quality.

Berland, G.K. et al (2001) 'Health information on the Internet: accessibility, quality, and readability in English and Spanish'. *JAMA*, 285 (20): 2612-2621.

Bessell, T.L. et al (2002) 'Do Internet interventions for consumers cause more harm than good? A systematic review'. *Health Expectations*, 5 (1): 28-37.

Black, M.E. et al (2002) 'A systematic literature review of the effectiveness of community-based strategies to increase cervical cancer screening'. *Can.J Public Health*, 93 (5): 386-393.

Consumers Association (2003) *Patient information: what's the prognosis? Policy Report*. London: Consumers' Association.

Coulter, A. et al (1998) *Informing patients: an assessment of the quality of patient information materials*. London: King's Fund.

Coulter, A. et al (1999) 'Sharing decisions with patients: is the information good enough?'. *British Medical Journal*, 318: 318-322.

Crocco, A.G. et al (2002) 'Analysis of cases of harm associated with use of health information on the internet'. *JAMA*, 287 (21): 2869-2871.

Davis, T.C. et al (1998) 'A polio immunization pamphlet with increased appeal and simplified language does not improve comprehension to an acceptable level'. *Patient Educ Couns*, 33 (1): 25-37.

Department of Health (1997) *The New NHS: modern, dependable*. London: The Stationary Office.

Department of Health (2001) *Building the Information Core - Implementing the NHS Plan*. London: Department of Health.

Department of Health (2004) *Better information, better choices, better health. Putting information at the centre of health*. London: Department of Health.

Detmer, D.E. et al (2003) *The informed patient: study report*. Cambridge: Cambridge University Health.

Eakin, E.G. et al (2002) 'Reaching those most in need: a review of diabetes self-management interventions in disadvantaged populations'. *Diabetes/Metabolism Research and Reviews*, 18 (1): 26-35.

Eysenbach, G. (2003) 'The impact of the Internet on cancer outcomes'. *CA Cancer J Clin*, 53 (6): 356-371.

Eysenbach, G. et al (2004) 'Health related virtual communities and electronic support groups: systematic review of the effects of online peer to peer interactions'. *BMJ*, 328 (7449): 1166.

Eysenbach, G. et al (2002) 'Empirical studies assessing the quality of health information for consumers on the world wide web: a systematic review'. *JAMA*, 287 (20): 2691-2700.

Fitzgibbon, M.L. et al (2004) 'Results of mujeres felices por ser saludables: A dietary/breast health randomized clinical trial for latino women'. *Annals of behavioral medicine*, 28 (2): 95-104.

Fitzmaurice, D.A. & Adams, J.L. (2000) 'A systematic review of patient information leaflets for hypertension'. *J Hum.Hypertens.*, 14 (4): 259-262.

Forbes, C. et al (1999) 'Interventions targeted at women to encourage the uptake of cervical screening'. *Cochrane.Database.Syst.Rev*, (1).

Forster, A. et al (2001) 'Information provision for stroke patients and their caregivers'. *Cochrane.Database.Syst.Rev.*, CD001919 (3).

Gaston, C.M. & Mitchell, G. (2005) 'Information giving and decision-making in patients with advanced cancer: A systematic review'. *Social Science and Medicine*, 61 (10): 2252-2264.

Gerber, B.S. et al (2005) 'Implementation and evaluation of a low-literacy diabetes education computer multimedia application'. *Diabetes Care*, 28 (7): 1574-1580.

Griffiths, C. et al (2005) 'Randomised controlled trial of a lay-led self-management programme for Bangladeshi patients with chronic disease'. *British Journal of General Practice*, 55: 831-837.

Grilli, R. et al (2002) 'Mass media interventions: effects on health services utilisation'. *Cochrane.Database.Syst.Rev.*, CD000389 (1).

Gustafson, D.H. et al (2002) 'CHESS: 10 years of research and development in consumer health informatics for broad populations, including the underserved'. *International Journal of Medical Informatics*, 65 (3): 169-177.

Harmsen, H. et al (2005) 'The effect of educational intervention on intercultural communication: results of a randomised controlled trial'. *Br J Gen Pract*, 55 (514): 343-350.

Health Which? (1998) 'DPP not getting message across says Health Which?'. *Press Release, www.which.net*.

Holmes-Rovner, M. et al (2005) 'Evidence-based patient choice: a prostate cancer decision aid in plain language'. *BMC Med Inform Decis.Mak.*, 5 (1): 16.

Horey, D. et al (2004) 'Information for pregnant women about caesarean birth'. *Cochrane.Database.Syst.Rev.*, CD003858 (1).

Institute of Medicine (2004) *Health Literacy: a prescription to end confusion*. Washington DC: The National Academies Press.

Johansson, K. et al (2005) 'Preoperative education for orthopaedic patients: Systematic review'. *JAN Journal of Advanced Nursing*, 50 (2): 212-223.

Johnson, A. et al (2003) 'Written and verbal information versus verbal information only for patients being discharged from acute hospital settings to home'. *Cochrane.Database.Syst.Rev.*, CD003716 (4).

Jones, R. et al (1999) 'Randomised trial of personalised computer based information for cancer patients'. *British Medical Journal*, 319: 1241-1247.

Jones, R.B. et al (2006) 'Effect of different forms of information produced for cancer patients on their use of the information, social support, and anxiety: randomised trial'. *BMJ*, 332 (7547): 942-948.

Kemper, D.W. & Mettler, M. (2002) *Information therapy: prescribed information as a reimbursable medical service*. Boise,ID: Healthwise Inc.

Kenny, T. et al (1998) 'A PIL for every ill? Patient information leaflets (PILs): a review of past, present and future use'. *Family Practice*, 15 (5): 471-479.

Kickbusch, I. et al (2005) *Enabling healthy choices in modern health societies*. Presentation given to the 8th European Health Forum Badgastein: 5-8 October 2005.

Kirkpatrick, M. (1999) 'Using the readability assessment instrument to evaluate patient medication leaflets'. *Drug Information Journal*, 33 (2): 557-563.

Kreuter, M.W. et al (1999) 'One size does not fit all: the case for tailoring print materials'. *Ann Behav.Med*, 21 (4): 276-283.

Mansoor, L.E. & Dowse, R. (2003) 'Effect of pictograms on readability of patient information materials'. *Ann Pharmacother.*, 37 (7-8): 1003-1009.

Marcus, A.C. & Crane, L.A. (1998) 'A review of cervical cancer screening intervention research: implications for public health programs and future research'. *Prev.Med*, 27 (1): 13-31.

McDonald, S. et al (2004) 'Pre-operative education for hip or knee replacement'. *The Cochrane Library*, (1).

McDonnell, A. (1999) 'A systematic review to determine the effectiveness of preparatory information in improving the outcomes of adult patients undergoing invasive procedures'. *Clinical Effectiveness in Nursing*, 3: 4-13.

McPherson, C.J. et al (2001) 'Effective methods of giving information in cancer: a systematic literature review of randomized controlled trials'. *J Public Health Med*, 23 (3): 227-234.

Meade, C.D. & Smith, C.F. (1991) 'Readability formulas: cautions and criteria'. *Patient Education and Counseling*, 17: 153-158.

Moudgil, H. et al (2000) 'Asthma education and quality of life in the community: a randomised controlled study to evaluate the impact on white European and Indian subcontinent ethnic groups from socioeconomically deprived areas in Birmingham, UK'. *Thorax*, 55 (3): 177-183.

Murray, E. et al (2005) 'Interactive Health Communication Applications for people with chronic disease'. *Cochrane.Database.Syst.Rev.*, CD004274 (4).

Nguyen, H.Q. et al (2004) 'Internet-based patient education and support interventions: a review of evaluation studies and directions for future research'. *Comput.Biol.Med*, 34 (2): 95-112.

Nicholas, D. et al (2004) *A summary report of the research project: The web, the kiosk, digital TV and the changing face of consumer health information provision: a national impact study. April 2000-March 2004*. London: City University.

Nicholas, D. et al (2002) *First steps towards providing the nation with health care information and advice via their television sets. Summary report*. London: City University.

Nutbeam, D. (2000) 'Health literacy as a public health goal: a challenge for contemporary health education and communication strategies into the 21st century'. *Health Promotion International*, 15 (3): 259-267.

Paasche-Orlow, M.K. et al (2003) 'Readability standards for informed-consent forms as compared with actual readability'. *N Engl J Med*, 348 (8): 721-726.

Powell, J.A. et al (2003) 'The doctor, the patient and the world-wide web: how the internet is changing healthcare'. *J R Soc Med*, 96 (2): 74-76.

Reid, J.C. et al (1995) 'Why people don't learn from diabetes literature: influence of text and reader characteristics'. *Patient Educ Couns*, 25 (1): 31-38.

Richards, T. (1998) 'Partnership with patients'. *BMJ*, 316 (7125): 85-86.

Santo, A. et al (2005) 'Exploring the value of audiotapes for health literacy: a systematic review'. *Patient Educ.Couns.*, 58 (3): 235-243.

Sihota, S. & Lennard, L. (2004) *Health literacy: being able to make the most of health*. London: National Consumer Council.

Smart, J.M. & Burling, D. (2001) 'Radiology and the internet: a systematic review of patient information resources'. *Clin Radiol.*, 56 (11): 867-870.

Smith, H. et al (1998) 'Evaluation of readability and accuracy of information leaflets in general practice for patients with asthma'. *BMJ*, 317 (7153): 264-265.

Sowden, A.J. & Arblaster, L. (2000) 'Mass media interventions for preventing smoking in young people'. *Cochrane.Database.Syst.Rev.*, CD001006 (2).

Stone, E.G. et al (2002) 'Interventions that increase use of adult immunization and cancer screening services: a meta-analysis'. *Ann Intern.Med*, 136 (9): 641-651.

Strydom, A. & Hall, I. (2001) 'Randomized trial of psychotropic medication information leaflets for people with intellectual disability'. *J Intellect.Disabil.Res.*, 45 (Pt 2): 146-151.

Treweek, S.P. et al (2002) 'Computer-generated patient education materials: do they affect professional practice? A systematic review'. *J Am.Med Inform Assoc*, 9 (4): 346-358.

Wantland, D.J. et al (2004) 'The effectiveness of Web-based vs. non-Web-based interventions: a meta-analysis of behavioral change outcomes'. *J Med Internet.Res*, 6 (4): e40.

Wilkins, S.T. & Navarro, F.H. (2001) 'Has the Web really empowered health care consumers? The truth is customers may not have changed as much as we think'. *Mark.Health Serv*, 21 (3): 5-9.

Wofford, J.L. et al (2005) 'The multimedia computer for office-based patient education: a systematic review'. *Patient Educ Couns*, 59 (2): 148-157.

2. Improving clinical decision-making

Shared decision-making: summary of findings

- Most patients expect to be given information about their condition and the treatment options and they want clinicians to take account of their preferences. Some expect to be actively engaged in the decision-making process, or even to take decisions themselves. This type of partnership approach to clinical decision-making is known as shared or informed decision-making, evidence-based patient choice or concordance. Informed consent and risk communication are closely related concepts.

- The desire for participation in clinical decision-making has been found to vary by age, educational status and disease severity. There may also be important ethnic or cultural differences. However, these factors have been found to explain only part of the variance. Individuals tend to express different role preferences depending on the circumstances, so clinicians need to ask patients what role they want to play instead of making assumptions based on observable characteristics.

- The evidence suggests that true shared decision-making is not widely practised. Doctors often fail to explore patients' values and preferences and risk communication is often poorly expressed by doctors and not well understood by patients.

- Communication skills training should be the main mechanism by which clinicians learn about and gain competencies in the principles and practice of shared decision-making, but the extent to which it is explicitly included in medical curricula is not known. There is evidence that such training can be effective in improving communication skills.

- Coaching for patients in communication skills and question prompts can have a beneficial effect on knowledge and information recall. These interventions also empower patients to become more involved in decisions, but there is no evidence of effect on satisfaction, mood or treatment outcomes.

- Decision aids for patients improve knowledge and information recall and lead to increased involvement in the decision-making process. Patients using decision aids experience less decisional conflict. Decision aids have also been shown to have some impact on health services utilisation leading in some cases to reduced cost, but no effect on health outcomes has been demonstrated.

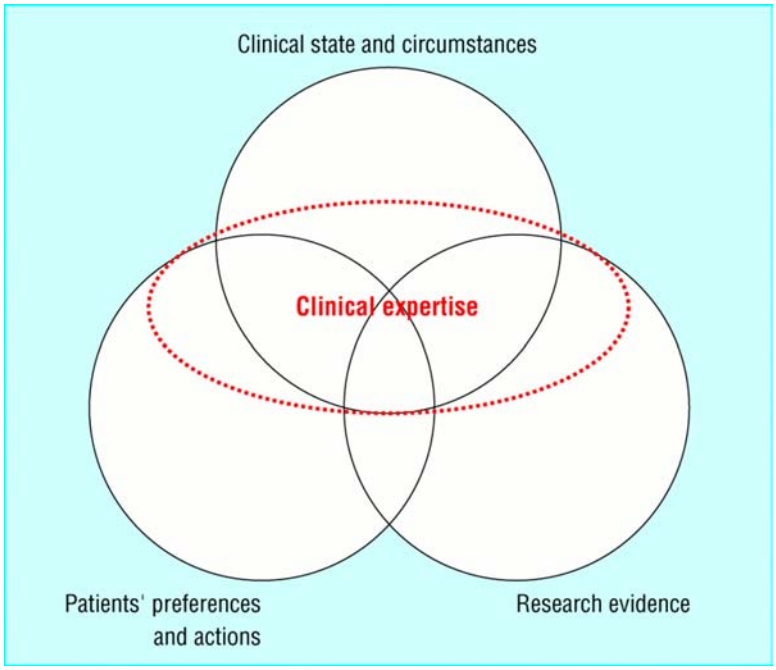
- In spite of policy commitments and evidence of benefit, initiatives to promote shared decision-making, better risk communication and fully informed decision-making have not been widely implemented. Well planned strategies are required which should include training for clinicians and high quality evidence-based decision aids for patients.

Shared decision-making: introduction

Failures in communication of information about illness and treatment are the most frequent source of patient dissatisfaction (Coulter & Cleary 2001, Grol et al 2000). The traditional model of decision-making assumed that doctors and patients shared the same goals, that only the doctor was sufficiently informed and experienced to decide what should be done, and that patient involvement should be confined to giving or withholding consent to treatment. However, this paternalistic approach now seems seriously outdated. Many, if not most, patients nowadays expect to be given information about their condition and the treatment options, and they want clinicians to take account of their preferences. Some expect to go further: to be actively engaged in the decision-making process, or even to take the decisions themselves. This type of partnership or patient led approach has been referred to variously as *shared* or *informed decision-making*, *evidence-based patient choice* or *concordance*. Although subtle distinctions between these concepts have been posited by various authors, these need not concern us here. For the purpose of this evidence review we will refer to the general approach as shared decision-making.

Shared decision-making has been defined as *"a process in which patients are involved as active partners with the clinician in clarifying acceptable medical options and in choosing a preferred course of clinical care"* (Sheridan et al 2004).

Other definitions have emphasised the values-based nature of clinical decision-making, which ideally incorporates patients' preferences as well as research evidence and knowledge of the patient's clinical state (see figure below).



An updated model for evidence based decisions (Haynes et al 2002)

For example, the definition provided by O'Connor and her colleagues, *"the process of interacting with patients who wish to be involved in arriving at an informed, values-based choice among two or more medically reasonable alternatives (which may include 'watchful waiting')"*, highlights the voluntary nature of the process, the scientific basis ("medically reasonable"), the emphasis on values clarification in addition to information provision, and the possibility of arriving at a decision not to undergo treatment (O'Connor et al 2004).

Closely related concepts include informed consent and risk communication. The doctrine of informed consent derives from the ethical principle of autonomy (ensuring that patients' beliefs and preferences are respected and they are supported in making choices), but medical ethics also requires doctors to take account of beneficence (doing good and avoiding harm) and justice (treating all patients equally). In its guidance on informed consent the UK General Medical Council (GMC) placed great stress on the autonomy principle, stating that all registered doctors must *"respect patients' autonomy – their right to decide whether or not to undergo any medical intervention even where a refusal may result in harm to themselves or in their own death. Patients must be given sufficient information, in a way that they can understand, in order to enable them to exercise their right to make informed decisions about their care"* (General Medical Council 1999).

Risk communication involves providing factual information about probabilities, usually in a quantified form, and confronting uncertainties. It is a key component of seeking informed consent and the shared decision-making process.

Shared decision-making: what is the rationale?

When choosing a treatment or preventive procedure the aim is to select options that increase the likelihood of desired health outcomes and minimise the chance of undesired consequences. In modern clinical practice there are often multiple options for treating a problem and these decisions are sometimes 'close calls', i.e. the benefit/harm ratios are uncertain or marginal (O'Connor et al 2003b). In these circumstances the best choice depends on how an individual patient values the potential benefits and harms of the alternatives. In shared decision-making the intention is that both the process of decision-making and the outcome – the treatment decision – will be shared.

The partnership approach to decision-making takes as its starting point the notion that two types of expertise are involved. The doctor is, or should be, well informed about diagnostic techniques, the causes of disease, prognosis, treatment options, and preventive strategies, but only the patient knows about his or her experience of illness, social circumstances, habits and behaviour, attitudes to risk, values and preferences. Both types of knowledge are needed to manage illness successfully, so both parties should be prepared to share information and take decisions jointly. Shared information is an essential prerequisite, but the process also depends on a commitment from both parties to engage in a negotiated decision-making process. The clinician must provide the patient with information about diagnosis, prognosis and treatment options, including outcome probabilities, and the patient must be prepared to discuss their values and preferences. The clinician must acknowledge the legitimacy of the patient's preferences and the patient has to accept shared responsibility for the treatment decision.

Patients cannot express informed preferences unless they are given sufficient and appropriate information, including detailed explanations about their condition and the likely outcomes with and without treatment. There is a professional and moral consensus about the clinical duty to obtain informed consent, but a legal requirement to do so extends only to surgical procedures and entry into clinical trials. In surgical practice obtaining informed consent is often viewed as an essentially passive activity where the goal is to obtain the patient's signature to indicate agreement to the treatment. Doctors tend to talk about "consenting the patient", using it as a transitive verb to denote something that's done *to* the patient instead of *with* them, a passive rather than an active, participative decision-making process.

The GMC has detailed the information that patients may want to know, before deciding whether to consent to treatment or an investigation (see box).

Informed consent (General Medical Council 1999)

- Details of the diagnosis and prognosis, and the likely prognosis if the condition is left untreated.
- Uncertainties about the diagnosis including options for further investigation prior to treatment.
- Options for treatment or management of the condition, including the option not to treat.
- The purpose of a proposed investigation or treatment; details of the procedures or therapies involved, including subsidiary treatment such as methods of pain relief; how the patients should prepare for the procedures; and details of what the patient might experience during or after the procedure including common and serious side effects.
- For each option, explanation of the likely benefits and the probabilities of success; and discussion of any serious or frequently occurring risks, and of any lifestyle changes which may be caused by, or necessitated by, the treatment.
- Advice about whether a proposed treatment is experimental.
- How and when the patient's condition and any side effects will be monitored and re-assessed.
- The name of the doctor who will have overall responsibility for the treatment and, where appropriate, names of the senior members of his or her team.
- Whether doctors in training will be involved, and the extent to which students may be involved in an investigation or treatment.
- A reminder that patients can change their mind about a decision at any time.
- A reminder that patients have a right to seek a second opinion.
- Where applicable, details of costs or charges which the patient may have to meet.

So according to the GMC patients ought to be informed about uncertainties, in addition to known facts about the options they face. Summarising what is known about treatment outcomes, especially when the evidence is conflicting or incomplete, is a challenging task for most clinicians. How realistic is it to expect them to carry it out adequately in the face of the other conflicting pressures of a busy clinic? Achieving truly *informed* consent requires excellent communication skills and effective educational resources. If this is to be achieved, clinicians will require training and decision aids.

Shared decision-making: when it is appropriate?

There is considerable debate about when, and to what extent, patients should be encouraged to participate in decisions. Many advocates of shared decision-making suggest it should be restricted to *preference-sensitive* decisions, i.e. those where the patient's values ought to guide the choice. It is seen as being most relevant in situations of uncertainty, in which two or more clinically reasonable alternatives exist and where the patient has indicated a desire to participate in the decision-making process (Whitney et al 2004). Informed consent, on the other hand, is perceived to be appropriate, and indeed necessary, for all decisions of significant risk even if there is only one treatment possibility. Even in these situations the patient has to choose between two courses of action, to accept or reject the treatment. McNutt has argued that the concept of *shared* decision-making is a misnomer because physicians should never make choices *for* patients (McNutt 2004). Instead they should play the role of navigator, communicating risk and outcome probabilities and helping patients to make informed medical decisions for themselves. Others draw attention to the fact that some patients prefer to remain uninformed and to delegate decision-making responsibility to the doctor (Leydon et al 2000). Either way, it is important to determine what role the patient wants to play in the process and to tailor information-giving and decision-making style to their requirements (Dowie 2002).

Clinical decision-making is a complex process involving several steps (Charles et al 1999, Elwyn et al 1999):

- recognise and clarify the problem
- identify potential solutions
- discuss options and uncertainties
- provide tailor-made information
- check understanding and reactions
- check decision-making role preference
- explore the patient's views
- agree a course of action
- implement the chosen course of action
- arrange follow up
- evaluate the outcome.

If patients are to participate actively in the process, they require information and decision support. Given the short consultation times experienced in most busy clinics, it is often unrealistic to expect clinicians to provide full information about the risks and benefits of all treatment options. Relevant and accessible information is not always available to clinicians, let alone to lay people (Coulter et al 1999), and doctors may not be sufficiently skilled in risk communication to convey probabilities in a manner that is comprehensible to their patients. Information packages for risk communication and patient decision aids are a potential solution to this problem.

Shared decision-making: what do patients and the public want?

There is plenty of evidence that many patients want more information than they are currently given (Coulter & Magee 2003), but this does not necessarily mean they want to participate in decision-making. Some have argued that the desire for greater involvement is restricted to a minority group of young, white, middle class patients, but the evidence does not support this. The desire for participation has been found to vary according to age, educational status and disease severity, but these factors explain only part of the variance.

An age-related trend has been found in a number of studies – younger and better educated people are more likely to want to play an active role (Krupat et al 2000, O'Connor et al 2003a, Robinson & Thomson 2001). Despite the association between age and decision-making preferences, age on its own is not a reliable predictor of a patient's preferred role (Kennelly & Bowling 2001). Older people are particularly likely to suffer from the presumption that they are incapable of taking decisions or unwilling to face choices about their medical care. Care of patients at the end of life is a case in point. National guidance requires that do-not-rescuscitate orders should not be applied without first discussing the issue with patients and/or their relatives, yet there is evidence that this does not happen in two thirds of cases (Bowling & Ebrahim 2001).

People's preferences may vary according to the stage in the course of a disease episode and the severity of their condition. Surveys of healthy populations tend to elicit much more positive responses about involvement in decision-making than surveys of people with life threatening conditions. For example, an Australian population survey found that more than 90% preferred an active role in decisions about diagnostic tests or treatments (Davey et al 2002), whereas a British study of the decision-making role preferences of cancer patients found that 48% of those with breast cancer and only 22% of those with colorectal cancer wanted to be involved (Beaver et al 1999).

There may also be important cultural differences. A population survey carried out in eight European countries found significant variations in response to a question about who should take the lead in making treatment choices (Coulter & Magee 2003). Respondents were asked to select one of five responses: the patient alone, the patient after consultation with the doctor, the doctor and patient together, the doctor after discussion with the patient, or the doctor alone. While 91% of respondents from Switzerland, 87% of those from Germany and 74% of those from the UK felt the patient should have a role in treatment decisions, either sharing responsibility for decision-making with the doctor or being the primary decision-maker, the proportion of Polish patients who felt the same way was only 59% and in Spain it was only 44%.

A 1998 review of studies exploring the extent to which patients wanted to participate in decisions confirmed the variation in results but concluded that patients should be informed of treatment alternatives and involved in treatment decisions when more than one effective alternative exists (Guadagnoli & Ward 1998). The only way to find out patients' preferred role is to ask them. But their responses may be influenced by previous experience. Some patients may assume a passive role because they have never been encouraged to participate and remain unaware of alternatives. There is also an apparent illogicality about asking patients to indicate their preferred role in decision-making before they have been informed about the nature of the choices they face (Elwyn et al 1999).

Shared decision-making: what happens in practice?

Despite the expectation of involvement on the part of many patients, the evidence suggests that true shared decision-making is not the norm. For example, a study involving observation of 62 GP consultations found little evidence that doctors and patients participated in a way that led them to develop an active consensus about the preferred treatment (Stevenson et al 2000). Doctors often fail to explore patients' values and preferences, tending to focus on the disease rather than the person (Corke et al 2005), but failure to do so can lead to misunderstandings and non-adherence to treatment recommendations (Britten et al 2000).

Braddock and colleagues (1999) studied 1,057 audiotaped encounters among 59 primary care physicians and 65 general and orthopaedic surgeons in the USA, during the course of which 3,552 clinical decisions were taken (Braddock et al 1999). Only 9% of these met accepted standards of completeness for informed decision-making. Among the elements of informed decision-making studied, discussion of the nature of the intervention occurred in 71% of cases and patients' preferences were discussed in 21%, but alternative treatments were mentioned in only 11% of consultations, risks and benefits of the alternatives in 6%, uncertainties associated with the decision in 4%, and assessment of the patient's level of understanding took place in only 1.5% of the consultations.

Stevenson and her colleagues reviewed 134 papers reporting observational studies of communication between patients and practitioners about medicine-taking (Stevenson et al 2004). They were specifically interested to find out if patients were encouraged to share their beliefs, experiences and preferences and if a truly two-way communication took place. They found that most patients are happy to discuss their concerns, but health professionals do not always encourage them to do so. Patients often fail to disclose to professionals that they have not taken the medicines as recommended and patients do not always voice their preferences. Doctors tend to dominate discussion in the consultation and patients tend to take a passive role. When providing information, doctors rarely assess patients' understanding of it, despite an awareness of the importance of doing so. They found scant evidence of shared decision-making.

The national patient surveys carried out among patients in NHS organisations in England consistently reveal gaps between patients' desire for involvement and their experience. For example, 47% of the 85,773 respondents to the 2004 national adult inpatient survey indicated that they would have liked more involvement in decisions about their treatment and care, as did 32% of the 102,383 respondents to the 2004 primary care survey. Of those prescribed medicines in primary care in 2004 (n=62,998), 41% would have liked more involvement in the choice of medication and 39% would have liked more information about medication side-effects.

Ford and her colleagues carried out a series of interviews designed to elicit doctors' and nurses' attitudes to providing evidence-based information to patients and involving them in decisions (Ford et al 2002). Perceived barriers included:

- concern about knowledge gaps and limitations of the research evidence
- concern about lack of skills in risk communication
- belief that many patients could not cope with the information and/or would not want to take responsibility for decision-making
- fear that patients would tend to choose the most expensive or unaffordable options
- concern about lack of technical support for shared decision-making, i.e. non-availability of risk communication tools or decision aids
- concern about time constraints within the consultation
- concern about disrupting or undermining the doctor-patient relationship.

Studies have found variations in doctors' attitudes towards a more egalitarian relationship with patients, ranging from protective paternalism through enlightened self interest (Elwyn et al 1999). There is some evidence that attitudes are changing, particularly among GPs, and many doctors are becoming more favourably disposed to the idea, but theoretical support does not automatically lead to changes in practice. For example, a study involving 20 GPs found strong support for the notion of shared decision-making, but video analysis of their consultations showed they were not practising it (Stevenson 2004).

Shared decision-making: what strategies have been tried and by whom?

A number of organisations and official bodies are enthusiastically promoting greater patient involvement in treatment decisions. Organisations in the US and Canada have been particularly active in this regard. For example, the Institute of Medicine's 2001 report on the quality of American healthcare, *Crossing the Quality Chasm* stated:

> *"Patients should be given the necessary information and the opportunity to exercise the degree of control they choose over health care decisions that affect them. The health system should be able to accommodate differences in patient preferences and encourage shared decision making"* (Committee on Quality of Health Care in America 2001).

The US Preventive Services Task Force also sees shared decision-making as essential for 'preference-sensitive' decisions, i.e. those involving *"interventions that have net benefit for some but not for others"* (Sheridan et al 2004). Kaiser Permanente aims to promote self-care, self-management and shared decision-making throughout their services (Doyle et al 2002), and several other North American organisations have played a key role in promoting the idea, including:

• HealthWise in Idaho	www.healthwise.org
• Center for Information Therapy in Washington DC	www.informationtherapy.org
• Foundation for Informed Medical Decision Making in Boston	www.findm.org
• HealthDialog in Boston	www.healthdialog.com
• CHESS system, developed at the University of Wisconsin-Madison	www.chsra.wisc.edu
• Ottawa Health Research Institute	www.ohri.ca/DecisionAid
• Department of Clinical Epidemiology and Biostatics at McMaster University in Canada	www.mcmaster.ca

The UK General Medical Council, which promotes good practice standards for all doctors, says in its major standards document, *Good Medical Practice,* that doctors must respect the right of patients to be fully involved in decisions about their care (General Medical Council 2001). The Health Service Ombudsman, who is responsible for investigating patients' complaints, has drawn attention to the need to give patients information about treatment options and to communicate risk in a way that patients can understand (Health Service Ombudsman 2004). The Department of Health's plans for 2005-8 state that patients should receive timely and suitable information and should be "*encouraged to express their preferences and supported to make choices and shared decisions about their own healthcare*" (Department of Health 2004b). In 2004, they announced a new information strategy aimed at ensuring that this commitment becomes a reality (Department of Health 2004a). The British Medical Association is also trying to encourage more emphasis on good communication (BMA Board of Medical Education 2004). They note that progress has been made, particularly with regard to communication skills training at undergraduate level, but a more sustained commitment is needed.

Shared decision-making: what outcomes are important?

There has been some debate in the literature about the primary aims of shared decision-making and hence which criteria and outcome measures are most appropriate when evaluating the effects of interventions designed to promote it. The following list of possibilities has been suggested (Entwistle et al 1998):

- information provision
- patients' acquisition of skills
- patients' knowledge and emotions
- how decisions are made
- quality of decisions
- professional-patient relationships
- use of healthcare
- health status of patients
- patient satisfaction
- organisation and cost of health services.

In practice the outcome measures used in randomised controlled trials have tended to focus on patients' experience of the decision process, the type of treatments undergone, health outcomes and economic variables (Kennedy 2003). Impact on decisional conflict (psychological uncertainty related to feeling uninformed) has been commonly used as an outcome measure. Patient satisfaction and anxiety have also been frequently studied. But Bekker and colleagues have argued that since raised levels of anxiety are associated *both* with more effective decision strategies *and* with stressful health interventions, anxiety is an inappropriate outcome measure (Bekker et al 2003b). In a separate paper the same authors argued that patient satisfaction was also problematic, because reduced satisfaction could be interpreted as a favourable outcome if it resulted from a more realistic evaluation of treatment options (Bekker et al 2003a).

The extent to which treatment choices are consistent with patients' values has been less frequently studied, yet some have argued that this should be the primary outcome (Sepucha et al 2004). An appropriate measure of decision quality would focus on the extent to which patients acquire relevant knowledge and on the level of agreement between their relative preferences for the salient outcomes of each treatment option and the treatment or management plan they eventually choose. Depending on the patients' particular values and the clinical circumstances, informed decisions could either be *for* major medical intervention or *against* it. The goal to increase treatment or screening rates may be appropriate in certain instances, for example where there is under-use of effective options or gaps in care. However, appropriate reductions in uptake can also confer important health benefits. In particular, reducing unnecessary use of aggressive and expensive options may lead to fewer adverse patient events, as well as freeing up health resources for re-allocation to other areas of patient care.

Shared decision-making: what works?

This review of the evidence focuses on three strategies for improving communication and involving patients more actively in decisions about their care:

- communication skills training for clinicians
- coaching and question prompts for patients
- patient decision aids.

1. Communication skills training for clinicians

Most medical and nursing schools offer communications skills training for undergraduates, and postgraduates and doctors are expected to learn about and gain competencies in the principles of shared decision-making. The General Medical Council's recommendations on undergraduate medical education state that graduates must know about and understand the principles of good communication, including how to take account of patients' own views and beliefs when suggesting treatment options, and that they should involve patients in developing management plans (General Medical Council 2003). Doctors undertaking pre-registration house officer training are expected to practice skills in involving patients in decisions about themselves (General Medical Council 1997). Finally, the draft curriculum for the foundation years in postgraduate education and training developed by the Modernising Medical Careers team expects that trainees will learn to help patients express preferences and make personal choices about treatment and care (Curriculum Committee of the Academy of Medical Royal Colleges and Modernising Medical Careers Implementation Group in the Department of Health 2004).

So shared decision-making is, at least in theory, firmly on the curriculum. But what is the evidence that these skills can be taught?

Hulsman and colleagues (1999) identified 14 studies evaluating communication skills training for clinically experienced physicians who have finished their undergraduate medical education (Hulsman et al 1999). The training was delivered by instruction (13 studies), modelling (8), skill practice (9), feedback (9) and discussion (11). Outcomes measured included receptive behaviours, information behaviours, and interpersonal and affective behaviours. Physicians generally self-reported improvements in their communicative behaviour, however the interventions were found to have limited effects when assessed by behavioural observations or impact on patient outcomes. Overall, positive effects were found on half or less of the observed behaviours. The interventions had no effect on health status, and findings for patient compliance and psychosocial health were mixed.

Strength of evidence: Systematic review – comprehensive review of studies, however search restricted to Medline and PsycLIT, and to English language publications; no formal validity assessment, although studies were classified according to their design (CRD).

Lewin and colleagues (2001) carried out a Cochrane review to evaluate the effects of interventions that aim to promote patient-centred approaches in clinical consultations (Lewin et al 2001). Patient-centred care was defined as a philosophy of care that encourages: (a) shared control of the consultation and of decisions about management of health problems, and/or (b) a focus on the patient as a whole person and their individual preferences in a social context (in contrast to a focus on disease or body parts). Seventeen studies met the inclusion criteria. Ten studies evaluated training for health professionals only, while the remainder looked at multi-faceted interventions with training as one of several components. They found fairly strong evidence that some interventions

can lead to significant increases in the patient-centredness of consultations. Training healthcare providers in patient-centred approaches can impact positively on patient satisfaction. Few studies evaluated health behaviour or health status outcomes.

Strength of evidence: Cochrane systematic review.

van Dam and colleagues (2003) identified eight studies that tested the effects of interventions to modify provider-patient interaction and consultation style on patient diabetes self-care and diabetes outcomes (van Dam et al 2003). They found that training providers (GPs and nurses) in a more patient-centred consulting style did not lead to better health outcomes or improved self-care, but helped GPs to help their patients set realistic goals. Coupled with prompts, guidelines, feedback and medical education training also improves the quality of diabetic care. Other interventions that focused on patients directly – such as guided preparation prior to consultations, group education, group consultations and automated telephone management – were more effective than interventions aimed at providers. They concluded that patient-focused behavioural interventions show good efficacy and efficiency and improve patient self-care and diabetes outcomes.

Strength of evidence: Systematic review, no independent assessment found.

Griffin and colleagues (2004) systematically reviewed evidence for the outcomes of interventions to alter the professional-patient interaction (Griffin et al 2004). They found eleven studies that tested interventions directed at health professionals, including six trials of communication skills training programmes. In three studies professionals were provided with either a note or questionnaire completed by patients prior to the consultation, and all showed a significant improvement in functional status or patient anxiety. Three of the six trials of communication skills training reported significant improvements in health outcomes; two reported better health outcomes in the comparison group. However, almost half of the interventions delivered via practitioners were associated with at least one worsened outcome in the intervention group.

Strength of evidence: Systematic review – clear review question and inclusion criteria, validity assessment conducted, but unpublished data not sought; authors made conservative conclusions which were generally consistent with the data presented (CRD).

Stevenson and colleagues (2004) reviewed four studies that evaluated training sessions for doctors and five for pharmacists (Stevenson et al 2004). The doctors' training sessions were found to lead to improvements in doctors' general communication with patients and in patients' medication knowledge. The interventions targeted at pharmacists led to improvements in their communication skills and decreases in the number of medicines prescribed and the cost of medicines. The pharmacists' interventions also resulted in an improvement in patients' knowledge, adherence, satisfaction and health outcomes, and a decrease in medication-related problems. Interventions targeted at the pharmacist directly, rather than patients, were more likely to encourage practice improvements.

Strength of evidence: Systematic review, no independent assessment found.

Edwards and colleagues (2004) reported a study designed to evaluate the effects of training GPs in shared decision-making and the use of simple risk communication aids (Edwards et al 2004). A cluster randomized controlled trial with crossover was carried out with the participation of 20 GPs in urban and rural practices in Wales. No statistically

significant changes in patient-based outcomes were found. The authors concluded that patients can be more involved in treatment decisions, and risks and benefits of treatment options can be explained in more detail, without adversely affecting outcomes. A second paper from this study reported that the intervention led to an increase in patient involvement in decision-making and clinicians using the risk communication tools perceived significantly higher patient and clinician agreement on treatment, patient satisfaction with information, clinician satisfaction with decisions made, and general overall satisfaction with the consultation, than those who were exposed to the shared decision-making skills workshops (Elwyn et al 2004).

Strength of evidence: Single randomised controlled trial.

Cohen and colleagues (2004) carried out an economic evaluation as part of the above mentioned cluster randomized crossover trial which involved training 20 GPs in the use of risk communication tools, shared decision-making competences, or both (Cohen et al 2004). Cost of training was assessed by prospective monitoring of resources used and data on prescribing, referrals, investigations and follow up consultations were also collected. Training cost £1,218 per practitioner which increased the cost of a consultation by £2.89. The authors concluded that unless training has a major influence on consultation length, it is unlikely to have any substantial impacts on cost.

Strength of evidence: Single randomised controlled trial.

Fellowes and colleagues (2004) organised a Cochrane review to assess whether communication skills training is effective in changing health professionals' behaviour in cancer care with regard to communication with patients (Fellowes et al 2004). Three randomised trials were included in their review, involving 347 health professionals who attended either an intensive three day course or a modular course. Assessments were by means of observation of clinician-patient communication with patients, role plays with oncology nurses, simulated patient interviews and patient questionnaires. Outcomes included a variety of indicators of communication style. The authors concluded that training programmes were effective in improving some areas of cancer care professionals' communication skills. They were unable to draw conclusions on the comparative efficacy of the different programmes.

Strength of evidence: Cochrane systematic review.

Gysels and colleagues (2004) carried out a systematic review for the National Institute of Clinical Excellence (NICE) to assess the effectiveness of different training methods used in communication training courses for health professionals caring for cancer patients (Gysels et al 2004). They identified 47 studies including four RCTs, evaluating 13 interventions. The training objectives were directed towards improving the medical interview, assessment of psychological distress among patients, imparting distressing information, counselling, problem solving, assessment of patients need for information, knowledge, awareness and general skills. The interventions made use of a variety of educational methods, including instruction, modelling, role play, feedback and discussion and lasted between a few days and six months. All the courses were residential. Outcome measures included behavioural assessments using independent instruments, patient outcomes and health professionals' self-reports. Twelve studies that aimed to enhance objective communication skills achieved positive outcomes; three studies that examined the effects of training on clinical practice found that the interventions failed to change clinical practice unless behavioural components were integrated; and the studies that dedicated their interventions partially or totally to attitude generally showed positive results. The authors concluded that the best results are to be expected from a training

programme that is carried out over a longer period of time. Learner-centred programmes using several methods (including a didactic component focused on theoretical knowledge, practical rehearsal and constructive feedback from peers and skilled facilitators) proved to be very effective. Small groups encouraged more intensive participation.

Strength of evidence: NICE Technology Appraisal.

Summary of known effects of communications skills training

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Improved patient knowledge.
Patients' experience, including communication and psychological outcomes	Communication improved; greater involvement in decision-making. Patient satisfaction improved and anxiety reduced.
Health services utilisation and cost	Some evidence of reduction in number and cost of prescriptions. Training in risk communication and shared decision-making largely cost-neutral.
Health behaviour and health status	Better medication adherence, but mixed effects on health outcomes. No effect on diabetes outcomes.

2. Coaching and question prompts for patients

In addition to interventions aimed primarily at clinicians, various studies have evaluated attempts to empower patients to take a more active role in the consultation. These have included coaching in how to raise issues and express preferences, question cards that act as prompts on appropriate questions to ask the doctor, encouragement to keep diaries or lists of topics for discussion, and summaries or audiotapes of the main points discussed for the patients to review later.

Rowe and colleagues (2002) identified eight trials evaluating patient-focused interventions aimed at improving communication between health professionals and women in maternity care (Rowe et al 2002). The interventions included four trials in which women were provided with extra information about ante-natal testing in a variety of formats. These were valued by the women and appeared to reduce anxiety, but they had no effect on uptake. Communication skills training for midwives and doctors improved their information-giving about antenatal tests. Three trials of patient-held maternity records demonstrated that these can increase women's involvement in and control over their care. The final trial involved providing a set of leaflets designed to promote informed choice to five maternity units coupled with a one-off training course for staff. There was no effect on the primary outcome measure of informed choice or on other relevant outcomes such as satisfaction and feeling in control.

Strength of evidence: Systematic review – clearly stated review question and selection criteria, reasonably comprehensive literature search, and appropriately cautious conclusions (CRD).

Scott and colleagues (2003) carried out a Cochrane review of randomised and non-randomised controlled trials that had evaluated the effects of providing recordings (e.g. audiotapes) or summaries (e.g. letter with reminders of key points) of consultations to people with cancer (Scott et al 2003). Twelve studies were included in the review. In seven of the studies between 83% and 96% of participants found recordings or summaries valuable. Five out of nine studies reported better recall of information as a result and four out of seven found that participants in the intervention groups were more satisfied with the information they received. There was no evidence of any impact on anxiety or depression. One study measure quality of life outcomes, but found no effect.

Strength of evidence: Cochrane systematic review.

Griffin and colleagues (2004) systematically reviewed evidence for the outcomes of interventions to alter the professional-patient interaction (Griffin et al 2004). They identified 35 studies, which described interventions targeted at patients (11 studies), professionals (16) or both (8). Eleven studies specifically evaluated communication skills training programmes, and these are described in detail above. The patient focused interventions were delivered prior to consultation, and often involved an interview with patients, the provision of written information/question cards to them, or an opportunity for patients to note issues or concerns that should be raised with the clinician. All were intended to encourage patients to take a more active role in the forthcoming clinical encounter. The intervention was associated with improvement of at least one health-related outcome in 18 out of 35 studies. Four studies were deemed to be of high methodological quality, and an impact on health-related outcomes was reported in three of these. Thirty trials measured effects on the process of consultation, and these were significantly improved in the intervention group in the 22 cases. Findings for satisfaction, length of consultation and patient knowledge were mixed. Generally more positive effects were found for interventions aimed at patients; almost half of the interventions targeted at health professionals were associated with the worsening of at least one outcome.

Strength of evidence: Systematic review – clear review question and inclusion criteria, validity assessment conducted, but unpublished data not sought; authors made conservative conclusions which were generally consistent with the data presented (CRD).

Harrington and colleagues (2004) carried out a review of patient-focused interventions designed to increase participation in consultations (Harrington et al 2004). They identified 20 studies, most of which were conducted in the USA, mostly in primary care or outpatient settings. Eleven of the studies were randomised controlled trials. They included written interventions, face-to-face coaching and videotapes, mainly designed to promote question-asking, raising concerns, and requesting clarification or checking understanding. Overall, half of the interventions resulted in increased patient participation, with slightly more significant results found for bids for clarification than for question-asking. However, of the ten written interventions, only two reported a significant increase in question-asking. Patient satisfaction was the most commonly measured outcome, but few significant improvements were found. However there were significant improvements in other outcomes, including perceptions of control over health, preferences for an active role, recall of information, adherence to recommendations, attendance and clinical outcomes.

Strength of evidence: Systematic review, no independent assessment found.

Stevenson and colleagues (2004) reviewed intervention studies designed to improve communication about medicines, two of which sought to improve psychiatric patients' communication skills (Stevenson et al 2004). These led to an increase in patients' knowledge about medicines and better adherence to treatment recommendations, but there was no impact on the extent to which patients reported problems or symptoms, made medication requests or on their sense of control. Seven papers included in this systematic review focused on patient-pharmacist interactions. Two of these were designed to encourage patients to ask questions and these were found to be partially effective. The use of advertisements to encourage patients to ask questions had a positive impact on pharmacists' communication but no significant impact on patients' question asking behaviour, the amount of information provided, or the duration of the interaction. When patients were asked to write down the questions they wished to ask, they asked more questions and had longer consultations. However, there was no significant impact on the information provided by pharmacists and no impact on satisfaction, medication knowledge or adherence.

The same review included five interventions that focused on interactions between patients and nurses or medical assistants, two involving telephone services and three involving face to face discussion of medicines with a nurse. The telephone services had some positive effects, with people feeling better informed about their medicines and more likely to contact the clinic with specific queries. The three interventions in which patients discussed their medicines with a nurse face-to-face indicated that this may lead to patients being more likely to have subsequent discussions with the doctor and being more likely to take their medicines and attend appointments.

Strength of evidence: Systematic review, no independent assessment found.

Gaston and Mitchell (2005) identified 13 studies evaluating interventions to encourage patient participation in decision-making (Gaston & Mitchell 2005). These indicated that question prompt sheets can increase the number of patient questions asked without increasing anxiety or the length of consultations. Prompt sheets are most effective when

referred to and endorsed by health professionals, and more beneficial than the provision of generalised information prior to professional-patient consultations.

Strength of evidence: Systematic review, no independent assessment found.

Koh and colleagues (2005) conducted a systematic review to identify trials examining the effectiveness of audio recording consultations for parents of critically sick babies (Koh et al 2005). Research has shown that parents in intensive care units often find it difficult to understand, remember and adjust to information given to them. Nonetheless, the authors were unable to identify any randomised or quasi-randomised studies assessing interventions of this type.

Strength of evidence: Cochrane systematic review.

Summary of known effects of coaching and question prompts for patients

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Some evidence of improved knowledge and recall.
Patients' experience, including communication and psychological outcomes	Increased involvement and question-asking, and increased perception of control. Prompt sheets more effective than generalised information, and patient-focused approaches more effective than those targeted at health professionals. Mixed results for satisfaction.
Health services utilisation and cost	Length of consultation unchanged, even where question asking increases. No impact on uptake of ante-natal tests. Mixed results in relation to medication adherence and clinic attendance.
Health behaviour and health status	Mixed results in relation to treatment outcomes.

3. Patient decision aids

Patient decision aids are standardised evidence-based tools intended to facilitate the process of making informed values-based choices about disease management and treatment options, prevention or screening (O'Connor et al 2004). They are designed to supplement rather than to replace patient-practitioner interaction. The content is usually based on reviews of clinical research and studies of patients' information needs. They use a variety of media to present the information in an accessible form to patients including leaflets, audiotapes, workbooks, decision boards, computer programmes, interactive videos, websites, structured interviews, and group presentations. They do not set out to be didactic or prescriptive. Instead they aim to help patients clarify their values and preferences and weigh up the potential benefits and harms of alternative courses of action. Most decision aids incorporate three key elements: information provision and risk communication, values clarification, and guidance or coaching in deliberation and communication. There are more than 400 decision aids listed on the Cochrane register (www.ohri.ca/decisionaid) covering a wide range of conditions and treatment options. A number of these have been evaluated in clinical trials and more trials are currently in progress.

An international group of researchers led by Professor Annette O'Connor of the University of Ottawa and Professor Glyn Elwyn of the University of Cardiff (the International Patient Decision Aid Standards Collaboration - IPDAS) has been developing a set of criteria to help patients judge the quality of decision aids, using a Delphi process to determine priorities. This group has reviewed the evidence on communicating risk and presenting probabilities. While more empirical testing of the different methods is required, the box below summarises current understanding of the most fruitful approaches:

Presenting probabilities: IPDAS recommendations (IPDAS Collaboration 2005)

- Use of numbers or graphics to quantify risk leads to more accurate understanding than words such as "rare", "high" and "probable".
- It is easier to understand the number of times something happens in a group (event rates) than other ways of presenting probabilities.
- It is easier to understand when the same denominator is used.
- Visual aids should use consistent scales and denominators.
- It is easier to compare options when probabilities are presented using the same time frames.
- Patients feel differently about options when negative framing (e.g. probability of dying) and positive framing (e.g. probability of living) is used, so it is best to use both.
- Very small chances of unfamiliar events are hard to comprehend, so it helps to make comparisons with more familiar situations (e.g. dying from crossing the street, being struck by lightening etc).

We identified ten systematic reviews which had collated evidence on the effectiveness of decision aids for patients faced with a choice of treatments or screening decisions. The main findings are outlined below:

Bekker and colleagues (1999) identified 547 controlled studies published in 1991-6 evaluating interventions that may affect informed patient decision-making (Bekker et al 1999). A total of 251 studies were in general medicine, 114 cancer, 108 genitourinary medicine, 61 primary care, 31 paediatrics, 31 obstetrics and gynaecology, 15 mental health, eleven surgery, ten dentistry and seven in genetics. The decision under study was lifestyle change in 357 studies, screening in 114, treatment in 107, participation in

the consultation in 51, and 26 other types of decisions. Out of all these studies only five were theory driven, assessed measures associated with informed decision-making, and used a low risk of bias design. The authors concluded that there was a paucity of well-designed, theoretically driven and adequately operationalised research assessing informed patient decision-making.

Strength of evidence: Systematic review – fairly well-conducted review; clear objectives and inclusion/exclusion criteria; comprehensive literature search but English language studies only; data extraction process is well reported; conclusions seem to follow from the results (CRD).

Molenaar and colleagues (2000) carried out a limited systematic review of 30 controlled and non-controlled studies (Molenaar et al 2000). Most were conducted in Canada or the US and they covered decisions about cancer, benign prostatic hyperplasia, chronic respiratory disease, heart disease, prevention and screening. The authors concluded that decision aids were feasible for use in consultations, improved patients' knowledge of the treatment options and outcomes, were acceptable to patients and helped to increase agreement between their values and the decisions made.

Strength of evidence: Systematic review – a poor review; inclusion criteria were not clearly addressed; literature search limited to one database only; quality of included studies not formally assessed and inclusion/exclusion criteria unclear; heterogeneity not assessed formally. Conclusions appear to follow from the results but, as stated by the authors, should be viewed with caution because of methodological limitations in the review process (CRD).

Edwards and colleagues (2000) identified 96 studies that looked at whether risk-communication interventions are associated with changes in patient knowledge, attitudes and behaviours (Edwards et al 2000). The methodological quality of the studies was variable, but they concluded that risk communication interventions generally had positive effects. Interventions addressing treatment choices were associated with larger effects than those in other contexts, e.g. prevention or screening. Interventions using individual risk estimates were associated with larger effects than those using more general risk information.

Strength of evidence: Systematic review, no independent assessment found.

Estabrooks and colleagues (2001) combined data from twelve studies, eight of which were randomized controlled trials and four were well-conducted observational studies (Estabrooks et al 2001). The studies covered a range of decision topics including benign prostate disease, ischaemic heart disease, flu vaccine, hepatitis B vaccine, genetic screening for breast cancer, Down syndrome screening, hormone replacement therapy and breast cancer treatment. They found that decision aids improved patients' knowledge and had some impact on the decision-making process, but did not influence treatment preferences.

Strength of evidence: Systematic review – broad review question; inclusion criteria clearly defined; quality threshold applied; comprehensive search strategy, but English language only; thorough review process; sound conclusions (CRD).

Jepson and colleagues (2001) found six controlled trials focusing on informed choice in antenatal and prostate specific antigen (PSA) screening (Jepson et al 2001). Uptake in the intervention groups was significantly higher than control for HIV testing, the same for

Down's syndrome screening, and lower for cystic fibrosis screening. In the two trials of prostate screening the effects were inconsistent. The authors concluded that there was insufficient evidence to determine whether the provision of information about potential benefits and harms of screening affected uptake.

Strength of evidence: Systematic review, no independent assessment found.

Whelan and colleagues (2001) carried out a systematic review to describe and evaluate the use of decision aids for cancer patients (Whelan et al 2001). They identified 61 unique studies, including 18 randomised controlled trials, five non-randomised trials and various other study designs. More decision aids had been developed for patients with breast and prostate cancer than for other types of cancer. Decision aids increased patients' knowledge and involvement in decision-making. Anxiety and depression scores were not increased. Among men making decisions about prostate cancer screening, significantly fewer decided to proceed with screening after receiving a decision aid.

Strength of evidence: Systematic review, no independent assessment found.

Edwards and colleagues (2003) looked at studies that assessed the effects of different types of individualised risk communication (i.e. information that is personalised to specific risk groups instead of presenting figures for the population as a whole) for patients who are deciding whether to participate in screening (Edwards et al 2003). They identified 13 randomised controlled trials, ten of which addressed breast screening. Individualised information was associated with an increased uptake of screening. However the two studies that provided the most detailed risk estimates were the only ones to show a reduction in uptake of tests.

Strength of evidence: Cochrane systematic review.

O'Connor and colleagues (2003) organised an extensive systematic review of randomised controlled trials of decision aids for the Cochrane Collaboration (O'Connor et al 2003c). They identified 34 trials published up to the end of 2002 that looked at decision aids aimed at helping patients to make treatment or screening decisions. In comparison to usual care, decision aids were found to increase patient involvement in decision-making by 30% (95% CI 10-50%), knowledge scores increased by 19 points out of 100 (13-24), the proportion of patients with realistic perceptions of the chances of benefits and harms improved by 40% (10-90), decisional conflict scores reduced by nine points out of 100 (6-12), the proportion of patients who remained undecided reduced by 57% (30-70), and agreement between patients' values and the treatments chosen increased. These improvements were achieved without harmful effects on satisfaction or anxiety levels. The review reported screening and treatment uptake rates in 16 trials, of which seven focused on decisions about major elective surgery. Six of the seven trials demonstrated 21-44% reductions in use of more invasive surgical options, without adverse effects on health outcomes.

These authors also found that more detailed decision aids performed better than simpler ones in respect of knowledge increases, realistic perceptions of likely benefits and harms of treatments and agreement between values and choice. Few of the trials published to date have included measures of cost-effectiveness, but among the three British trials that did include economic measures, decision aids were found to be cost-effective in one and would have been cost-neutral in two others if less expensive delivery methods (e.g. the internet) had been used.

Strength of evidence: Cochrane systematic review.

Briss and colleagues (2004) looked for studies that evaluated interventions to improve decision-making about cancer screening (Briss et al 2004). They reviewed 15 studies looking at the use of small media, counselling, group education, provider-oriented strategies, or combinations of these, to promote informed decision-making. The interventions helped to improve patients' knowledge and promoted greater accuracy of risk perceptions, but few studies looked at whether they resulted in an appropriate level of participation in decision-making or whether decisions were consistent with patients' preferences or values.

Strength of evidence: Systematic review, no independent assessment found.

Evans and colleagues (2005) systematically reviewed evidence for the impact of decision aids for PSA testing (Evans et al 2005). They identified eleven evaluations (ten conducted in the USA, one in Canada), involving seven different PSA decision aids. This included four RCTs – a pooled analysis of their findings showed a 3.5% reduction in the number of patients having a PSA test at twelve months, a statistically significant finding. Generalised to the population, this suggests that for every 1,000 men 40 fewer will undergo a PSA test as a consequence of using a decision aid. The greatest reduction in PSA rates was reported in a trial of a video-based intervention. Decision aids were also associated with a short-term improvement in knowledge of PSA or prostate cancer, although these effects were reduced at longer-term follow up.

Strength of evidence: Systematic review, no independent assessment found.

Summary of known effects of decision aids

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Knowledge improved.
Patients' experience, including communication and psychological outcomes	Involvement in decision-making process increased and decisional conflict reduced. Improved match between values and treatment chosen. No effect on anxiety or depression. Mixed results in relation to patient satisfaction.
Health services utilisation and cost	Individualised risk information generally increases uptake of screening, except for prostate cancer screening where it is appropriately reduced. Some evidence of reduction in use of elective surgical procedures, leading to greater cost-effectiveness.
Health behaviour and health status	Some evidence of improvements in health status, but mixed results. No evidence of negative effects.

Shared decision-making: what looks promising for future R&D?

Despite strong organisational commitment in favour of the policy and fairly strong evidence of benefit, widespread implementation of innovations designed to improve clinical decision-making and promoter greater patient involvement has yet to occur. Barriers include lack of awareness, lack of knowledge and skills, concerns about time and resource pressures, and negative attitudes among some clinicians because of possible loss of power, loss of face or loss of income (Billings 2004, Graham et al 2003, Holmes-Rovner et al 2000).

Greater emphasis should be placed on overcoming these barriers in well planned implementation strategies. These should be incorporated into existing educational curricula and clinical governance or quality improvement plans and carefully evaluated as they are rolled out.

The leaders of the Cochrane Collaboration on Decision Aids have outlined a strategy to encourage wider implementation of shared decision-making involving the following steps (O'Connor et al 2004):

- setting quality standards to inform the development and use of decision aids
- improving access by compiling and managing a clearing house of decision aids
- organising training for clinicians in the principles and practice of shared decision-making
- providing decision support alongside established patient education programmes
- offering financial incentives to provide decision support to patients
- making decision aids freely available on the internet
- offering decision support via nurse led call centres
- establishing demonstration projects to test the feasibility and effects of providing decision support in a wide range of settings.

Implementation strategies should take account of change management principles derived from research on translating evidence into practice. These will need to find ways of addressing the structural and attitudinal barriers that currently inhibit the adoption of best practice.

References

Beaver, K. et al (1999) 'Decision-making role preferences and information needs: a comparison of colorectal and breast cancer'. *Health Expectations*, 2: 266-276.

Bekker, H. et al (1999) 'Informed decision making: an annotated bibliography and systematic review'. *Health Technology Assessment*, 3 (1).

Bekker, H.L. et al (2003a) 'Understanding why decision aids work: linking process with outcome'. *Patient Education and Counseling*, 50: 323-329.

Bekker, H.L. et al (2003b) 'Is anxiety a suitable measure of decision aid effectiveness: as systematic review?'. *Patient Education and Counseling*, 50: 255-262.

Billings, J. (2004) 'Promoting the dissemination of decision aids: an odyssey in a dysfunctional health care financing system'. *Health Affairs*, Suppl Web Exclusive: 128-132.

BMA Board of Medical Education (2004) *Communication skills education for doctors: an update*. London: British Medical Association.

Bowling, A. & Ebrahim, S. (2001) 'Measuring patients' preferences for treatment and perceptions of risk'. *Quality in Health Care*, 10 (suppl. 1): i12-i18.

Braddock, C.H. et al (1999) 'Informed decision making in outpatient practice: time to get back to basics'. *Journal of the American Medical Association*, 282 (24): 2313-2320.

Briss, P. et al (2004) 'Promoting informed decisions about cancer screening in communities and healthcare systems'. *American Journal of Preventive Medicine*, 26 (1): 67-80.

Britten, N. et al (2000) 'Misunderstandings in prescribing decisions in general practice: qualitative study'. *British Medical Journal*, 320: 484-488.

Charles, C. et al (1999) 'Decision-making in the physician-patient encounter: revisiting the shared treatment decision-making model'. *Social Science and Medicine*, 49: 651-661.

Cohen, D. et al (2004) 'Resource effects of training general practitioners in risk communication skills and shared decision making competences'. *Journal of Evaluation in Clinical Practice*, 10 (3): 439-445.

Committee on Quality of Health Care in America (2001) *Crossing the quality chasm: a new health system for the 21st century*. Washington: National Academy Press.

Corke, C.F. et al (2005) 'How doctors discuss major interventions with high risk patients: an observational study'. *British Medical Journal*, 330: 182-184.

Coulter, A. & Cleary, P.D. (2001) 'Patients' experiences with hospital care in five countries'. *Health Affairs*, 20 (3): 244-252.

Coulter, A. et al (1999) 'Sharing decisions with patients: is the information good enough?'. *British Medical Journal*, 318: 318-322.

Coulter, A. & Magee, H. (2003) *The European Patient of the Future*. Maidenhead: Open University Press.

Curriculum Committee of the Academy of Medical Royal Colleges and Modernising Medical Careers Implementation Group in the Department of Health (2004) *Curriculum for the foundation years in postgraduate education and training*. London: Academy of Medical Royal Colleges.

Davey, H.M. et al (2002) 'Medical tests: women's reported and preferred decision-making roles and preferences for information on benefits, side-effects and false results'. *Health Expectations*, 5 (4): 330-340.

Department of Health (2004a) *Better information, better choices, better health. Putting information at the centre of health*. London: Department of Health.

Department of Health (2004b) *Health and social care standards and planning framework for 2005/6-2007/8*. London: Department of Health.

Dowie, J. (2002) 'The role of patients' meta-preferences in the design and evaluation of decision support systems'. *Health Expectations*, 5 (1): 16-27.

Doyle, L. et al (2002) 'Strengthening self-care, self-management, and shared decision-making practices throughout Kaiser Permanente'. *The Permanente Journal*, 6 (2): 53-56.

Edwards, A. et al (2004) 'Patient-based outcome results from a cluster randomized trial of shared decision making skill development and use of risk communication aids in general practice'. *Family Practice*, 21 (4): 347-354.

Edwards, A. et al (2000) 'The effectiveness of one-to-one risk communication interventions in health care: a systematic review'. *Med Decis.Making*, 20 (3): 290-297.

Edwards, A. et al (2003) 'Effects of communicating individual risks in screening programmes: Cochrane systematic review'. *BMJ*, 327 (7417): 703-709.

Elwyn, G. et al (1999) 'Towards a feasible model for shared decision making: focus group study with general practice registrars'. *British Medical Journal*, 319: 753-756.

Elwyn, G. et al (2004) 'Achieving involvement: Process outcomes from a cluster randomized trial of shared decision making skill development and use of risk communication aids in general practice'. *Family Practice*, 21 (4): 337-346.

Entwistle, V.A. et al (1998) 'Evaluating interventions to promote patient involvement in decision-making: by what criteria should effectiveness be judged?'. *Journal of Health Services Research and Policy*, 3 (2): 100-107.

Estabrooks, C. et al (2001) 'Decision aids: are they worth it?'. *Journal of Health Services Research and Policy*, 6 (3): 170-182.

Evans, R. et al (2005) 'Reduction in uptake of PSA tests following decision aids: systematic review of current aids and their evaluations'. *Patient Educ.Couns.*, 58 (1): 13-26.

Fellowes, D. et al (2004) 'Communication skills training for health care professionals working with cancer patients, their families and/or carers'. *Cochrane.Database.Syst.Rev*, CD003751 (2).

Ford, S. et al (2002) 'Barriers to the evidence-based patient choice (EBPC) consultation'. *Patient Education and Counseling*, 47: 179-185.

Gaston, C.M. & Mitchell, G. (2005) 'Information giving and decision-making in patients with advanced cancer: A systematic review'. *Social Science and Medicine*, 61 (10): 2252-2264.

General Medical Council (1997) *The new doctor*. London: GMC.

General Medical Council (1999) *Seeking patients' consent: the ethical considerations*. London: GMC.

General Medical Council (2001) *Good Medical Practice*. London: GMC.

General Medical Council (2003) *Tomorrow's doctors*. London: GMC.

Graham, I.D. et al (2003) 'A qualitative study of physicians' perceptions of three decision aids'. *Patient Education and Counseling*, 50: 279-283.

Griffin, S.J. et al (2004) 'Effect on health-related outcomes of interventions to alter the interaction between patients and practitioners: a systematic review of trials'. *Ann Fam.Med*, 2 (6): 595-608.

Grol, R. et al (2000) 'Patients in Europe evaluate general practice care: an international comparison'. *British Journal of General Practice*, 50: 882-887.

Guadagnoli, E. & Ward, P. (1998) 'Patient participation in decision-making'. *Social Science and Medicine*, 47 (3): 329-339.

Gysels, M. et al (2004) 'Communication training for health professionals who care for patients with cancer: a systematic review of effectiveness'. *Support.Care Cancer*, 12 (10): 692-700.

Harrington, J. et al (2004) 'Improving patients' communication with doctors: a systematic review of intervention studies'. *Patient Educ.Couns*, 52 (1): 7-16.

Haynes, R.B. et al (2002) 'Physicians' and patients' choices in evidence based practice'. *British Medical Journal*, 324: 1350.

Health Service Ombudsman (2004) *1st Report, 2003/04 session*. Health Service Ombudsman.

Holmes-Rovner, M. et al (2000) 'Implementing shared decision-making in routine practice: barriers and opportunities'. *Health Expectations*, 3: 182-191.

Hulsman, R.L. et al (1999) 'Teaching clinically experienced physicians communication skills. A review of evaluation studies'. *Med Educ.*, 33 (9): 655-668.

IPDAS Collaboration (2005) *International patient decision aid standards (IPDAS) collaboration*. Canada: University of Ottawa.

Jepson, R.G. et al (2001) 'Increasing informed uptake and non-uptake of screening: evidence from a systematic review'. *Health Expectations*, 4: 116-126.

Kennedy, A.D.M. (2003) 'On what basis should the effectiveness of decision aids be judged?'. *Health Expectations*, 6: 255-268.

Kennelly, C. & Bowling, A. (2001) 'Suffering in deference: a focus group study of older cardiac patients' preferences for treatment and perceptions of risk'. *Quality in Health Care*, 10 (Suppl. 1): i23-i28.

Koh, T.H. et al (2005) 'Audio recordings of consultations with doctors for parents of critically sick babies'. *Cochrane Database Syst Rev*, (1): CD004502.

Krupat, E. et al (2000) 'The practice orientations of physicians and patients: the effect of doctor-patient congruence on satisfaction'. *Patient Educ Couns*, 39 (1): 49-59.

Lewin, S.A. et al (2001) 'Interventions for providers to promote a patient-centred approach in clinical consultations'. *Cochrane.Database.Syst.Rev.*, CD003267 (4).

Leydon, G.M. et al (2000) 'Cancer patients' information needs and information seeking behaviour: in depth interview study'. *British Medical Journal*, 320: 909-913.

McNutt, R.A. (2004) 'Shared medical decision making: problems, process, progress'. *Journal of the American Medical Association*, 292 (20): 2516-2518.

Molenaar, S. et al (2000) 'Feasibility and effects of decision aids'. *Med Decis Making*, 20 (1): 112-127.

O'Connor, A. et al (2003a) 'A survey of the decision-making needs of Canadians faced with complex health decisions'. *Health Expectations*, 6 (2): 97-109.

O'Connor, A.M. et al (2003b) 'Risk communication in practice: the contribution of decision aids'. *British Medical Journal*, 327: 736-740.

O'Connor, A.M. et al (2004) 'Modifying unwarranted variations in health care: shared decision making using patient decision aids'. *Health Aff.(Millwood.)*, Suppl Web Exclusive: VAR63-VAR72.

O'Connor, A.M. et al (2003c) 'Decision aids for people facing health treatment or screening decisions'. *Cochrane.Database.Syst.Rev.*, CD001431 (2).

Robinson, A. & Thomson, R.G. (2001) 'The potential use of decision analysis to support shared decision making in the face of uncertainty: the example of atrial fibrillation and warfarin anticoagulation'. *Quality in Health Care*, 9: 238-244.

Rowe, R.E. et al (2002) 'Improving communication between health professionals and women in maternity care: A structured review'. *Health Expectations*, 5 (1): 63-83.

Scott, J.T. et al (2003) 'Recordings or summaries of consultations for people with cancer'. *Cochrane.Database.Syst.Rev.*, CD001539 (2).

Sepucha, K. et al (2004) 'Policy support for patient-centred care: the need for measurable improvements in decision quality'. *Health Affairs*, October 2004: VAR 54-VAR.62.

Sheridan, S.L. et al (2004) 'Shared decision making about screening and chemoprevention: A suggested approach from the U.S. Preventive Services Task Force'. *American Journal of Preventive Medicine*, 26 (1): 56-66.

Stevenson, F.A. (2004) 'General practitioners' views on shared decision making: a qualitative analysis'. *Patient Education and Counseling*, 50: 291-293.

Stevenson, F.A. et al (2000) 'Doctor-patient communication about drugs: the evidence for shared decision making'. *Social Science and Medicine*, 50: 829-840.

Stevenson, F.A. et al (2004) 'A systematic review of the research on communication between patients and health care professionals about medicines: the consequences for concordance'. *Health Expectations*, 7 (3): 235-245.

van Dam, H. et al (2003) 'Provider-patient interaction in diabetes care: effects on patient self-care and outcomes A systematic review'. *Patient Education and Counseling*, 51 (1): 17-28.

Whelan, T.J. et al (2001) *Impact of cancer-related decision aids: an evidence report*. Hamilton, Ontario: McMaster University Evidence-based Practice Center.

Whitney, S. et al (2004) 'A typology of shared decision making, informed consent, and simple consent'. *Annals of Internal Medicine*, 140 (1): 54-59.

3. Improving self-care

Self-care: summary of findings

- Improving self-care is a major goal of policy and service development across various national and organisational settings. In the UK, the centrepiece of the government's activities is the Expert Patient Programme (EPP), a lay led self-management course based on the Chronic Disease Self-Management Program developed by Kate Lorig at Stanford University.

- Self-care interventions vary considerably in their objectives, content, method of delivery, duration and target population. To talk of the effectiveness of 'self-care interventions' (or even of 'self-management education') is, therefore, misleading.

- There are significant limitations in the evidence base for self-care interventions; the following areas have not been adequately evaluated:
    - long term outcomes
    - cost-effectiveness
    - comparative effectiveness of different self-care strategies
    - which components of complex interventions provide greatest benefit.

- Many published studies lack adequate descriptions of the interventions evaluated and the study context, which hampers replication and the implementation of strategies in clinical practice.

- Two assumptions that have often been made in self-care research are not well supported by the evidence: that providing patients with health information leads to behaviour change, and that behaviour change necessarily produces improved health outcomes.

- Information-only patient education has limited effectiveness, and improvements on outcomes other than knowledge have not been found. Educational programmes teaching practical self-management skills are more effective than the provision of information alone.

- Studies of self-management education, including the Lorig model replicated by the EPP, have produced mixed findings. However, self-management education has been associated with improvements in knowledge, coping behaviour, adherence, self-efficacy and symptom management. There is also some evidence of a reduction in health service utilisation and cost, and enhanced patient quality of life.

- While self-management education leads to short term improvements in health behaviour and dimensions of health status, these effects tend to diminish over time. By contrast, quality of life effects are more likely to be sustained beyond the intervention period.

- Most studies of condition-specific education programmes have involved people with asthma, diabetes or arthritis. Combined with regular practitioner review and patient action plans, asthma self-management education can lead to improvements in health services utilisation, quality of life, and self-efficacy. Moderately enhanced lung function has also been demonstrated in children and adolescents with asthma. In patients with arthritis, self-management education has only a small and short term impact on key outcomes such as pain and functional disability.

- As part of a combined intervention, self-management education has been associated with greater blood glucose control and a reduction in diabetic complications in patients with Type 1 diabetes. Better health outcomes (blood glucose control and blood pressure) are reported for group-based educational approaches for patients with Type 2 diabetes.

- Although no consistent pattern has been found between intervention characteristics and strength of outcomes, the following factors are associated with larger effect sizes: longer intervention (twelve weeks or more) and higher intensity programmes; regular review by health professionals; focus on specific rather than general educational topics; participative rather than didactic teaching methods; multi-component approaches, and involvement of family or other informal carers.

- In contrast to the large body of evidence for self-management education, relatively few studies have been conducted of other self-care interventions such as self-monitoring, patient-centred telecare and support groups.

- The key findings from studies of other intervention strategies are:

    - *Self monitoring*: the evidence does not support blood glucose self-monitoring in patients with diabetes, but studies have shown that self-monitoring of blood pressure and anticoagulant therapy produces outcomes similar to those of professionally managed care. Self-monitoring is cost neutral for hypertensive patients, and leads to significant cost savings in the case of anticoagulation therapy.

    - *Self-help and support groups*: participation in self-help and support groups has not been shown to have any major effects on health behaviour or status. However, participants report benefits from the sharing of information, experiences and practical solutions. Support group interventions have been shown to be beneficial to carers by improving their confidence, coping ability, family functioning and reducing the perceived burden of care.

    - *Facilitating patient access to personal medical information*: patient-held records are generally found to be useful by patients, and increase their sense of control. Recording consultations improves understanding, and the uptake and recall of information. Neither intervention has shown to benefit clinical or behavioural outcomes.

    - *Patient-centred telecare*: home-based telecare can reduce patients' sense of isolation and improve self-efficacy, quality of life, patient empowerment and psychological outcomes. Impact on service use and cost-effectiveness is unclear, but financial savings may be made where 'virtual visits' substitute for routine home care. There is less evidence for impact on health status, but benefits in terms of depressive symptoms have been reported.

Self-care: introduction

At its most basic, self-care refers to the practices undertaken by individuals towards maintaining health and managing illness. A more comprehensive definition of self-care is offered by the Department of Health, as:

> *"the actions individuals and carers take for themselves, their children, their families and others to stay fit and maintain good physical and mental health; meet social and psychological needs; prevent illness or accidents; care for minor ailments and long term conditions; and maintain health and wellbeing after an acute illness or discharge from hospital"* (Department of Health 2005b).

It is often forgotten that most healthcare, perhaps as much as 85%, is self-care (Vickery et al 1983). In looking after themselves and their family members lay people provide a far greater quantity of healthcare than do health professionals. Hannay used the metaphor of an iceberg to illustrate the point that health professionals, even those working in 'first contact' care such as general practice, see only a small fraction of the afflictions that could potentially trigger a consultation (Hannay 1979). Self-care also incorporates the actions that people take to prevent ill health, for example avoiding unhealthy behaviours and adopting healthy ones. However, in this chapter we focus on lay people's involvement in management of ill health in partnership with health professionals and other sources of support. This collaborative dimension is reflected in the definition offered by Dean, who states that self-care involves *"decisions to seek advice in lay, professional and alternative care networks, as well as evaluation of decisions regarding action based on that advice"* (Dean 1986).

On the above definitions, self-care entails people's active involvement in all aspects of their own healthcare and that of their families. Nonetheless, the concept is most closely associated with the day-to-day management of health problems by people with long term and chronic illnesses such as diabetes, asthma and arthritis. The terms self-care and self-management are often used interchangeably, although they are not strictly the same.

A range of interventions have been developed and implemented to improve patient self-care, with self-management education being the most common and well known. Although self-management education is often considered to be an aspect of patient education, these two activities can clearly be distinguished from one another on a number of dimensions (see below).

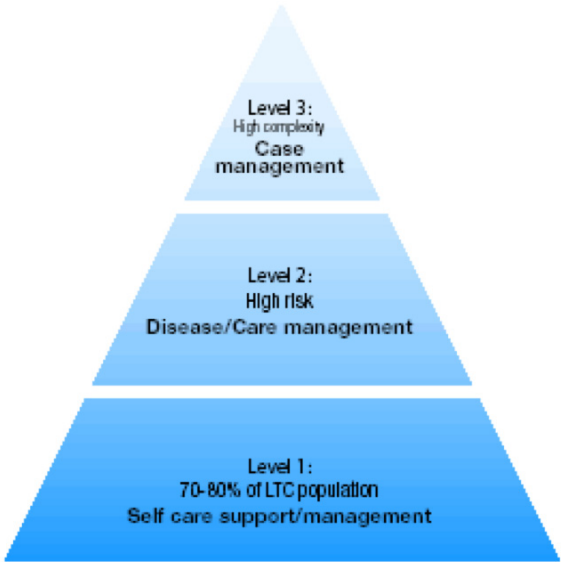
	Traditional patient education	**Self-management education**
What is taught?	Information and technical skills about the disease	Skills for how to act on problems
How are problems formulated?	Problems reflect the inadequate control of the disease	The patient identifies problems he/she experiences that may or may not be related to the disease
Relation of education to the disease	Education is disease specific and teaches information and technical skills related to the disease	Education provides problem-solving skills that are relevant to the consequences of chronic conditions in general
What is the theory underlying the education?	Disease specific knowledge creates behaviour change, which in turn produces better clinical outcomes	Greater patient confidence in his/her capacity to make life-improving changes (self-efficacy) yields better clinical outcomes
What is the goal?	Compliance with the behaviour change taught to	Increased self-efficacy to improve clinical outcomes

	the patient to improve clinical outcomes	
Who is the educator?	A health professional	A health professional, peer leader or other patients, often in group settings

Source: Bodenheimer et al (2002).

Fundamentally, patient education and self-management interventions differ in terms of the role they see for the patient in achieving change. Whereas patient education focuses on delivering knowledge and technical skills to patients to enable them to follow medical advice, self-management education is premised on the goal of empowering patients to take active control of their illness and apply problem-solving skills to meet new challenges (Bodenheimer et al 2002). This distinction is reflected in the methods by which each of these interventions is delivered: patient education is taught through a conventional didactic approach and self-management education through participatory learning techniques.

Support for self-management is strongly emphasised in service delivery models designed to improve the quality, coordination and efficiency of care for chronically ill patients. This includes the three-tier NHS and Social Care Long Term Conditions Model, recently launched by the Department of Health (see diagram).



NHS and Social Care Long Term Conditions Model: Delivery System (Department of Health 2005c)

The goal of self-management support is to enable patients to perform three sets of tasks: i) medical management of their illness (e.g. taking medication, adhering to a special diet); ii) carrying out normal roles and activities; and iii) managing the emotional impact of their illness (Lorig & Holman 2003).

Self-care: what is the rationale?

The growing burden of chronic disease has exposed significant limitations in traditional care delivery systems and models. In the UK alone, an estimated 17 million people live with at least one chronic illness, with prevalence highest among older age groups (Department of Health 2005c). The care needs of the chronically ill differ substantially from those of acute care patients for whom healthcare services were originally designed. These specific needs arise from the ongoing and often complex task of managing not just the physical aspects of chronic illness but its broader impact on the individual's emotional, psychological and social functioning.

Chronic care patients are frequent and long term users of healthcare services; according to the Department of Health, 80% of GP consultations, 60% of hospital bed days and two thirds of emergency admissions are related to chronic conditions (Department of Health 2004). Nonetheless, most of the day-to-day management of these conditions is carried out by patients and their families in the home or other non-medical settings: self-care is an inevitable feature of chronic illness. Under these circumstances a hierarchical model, in which the patient is passive recipient of care services, is unfeasible. Rather, the effective management of chronic illness entails an active partnership between healthcare professional and patient, combining professional expertise and lay experiential knowledge (Von Korff et al 2002). In this collaborative approach, the health professional's principal role is to encourage, facilitate and support the patient in their self-care activities.

Early efforts to enhance patient involvement in chronic illness focused on providing general information on conditions and treatment options, which was delivered as a component of clinical care (Newman et al 2001). However, although information is important to improving self-care, it is by no means sufficient. An array of competencies can be developed by individuals to actively participate in managing their condition. These range from technical skills such as medical self-monitoring, through to strategies to overcome obstacles in daily living including problem solving techniques (Lorig & Holman 2003). Not in all cases will support for self-care be sought from, or be most appropriately provided by, professionals from within the healthcare team. Indeed, there is an important role for voluntary and community-based organisations in offering information, mutual aid and forms of emotional and social support (Campbell et al 2004).

The principles of self-care are developed in a number of theoretical models, mostly developed with the fields of psychology and behavioural science. Of these, it is Bandura's self-efficacy theory that is most widely referred to (Bandura 1997). Self-efficacy refers to an individual's belief in their capacity to successfully learn and perform a specific behaviour. A strong sense of self-efficacy leads to a feeling of control, and willingness to take on and persist with new and difficult tasks. When applied to health, this theory suggests that patients are empowered and motivated to manage their health problems when they feel confident in their ability to achieve this goal. On this view, interventions for improving self-care should focus on confidence building, and equipping patients with the tools (knowledge and skills) to set personal goals and develop effective strategies for achieving them.

Self-care: what do patients and the public want?

There is much public enthusiasm for the concept of 'expert patients', people who are proactive managers of their chronic conditions. Patient organisations have been at the forefront of efforts to get self-management recognised as a key component of healthcare. For example, the Long Term Medical Conditions Alliance (LMCA), a coalition of patients' organisations in the UK, piloted the Californian self-management education programmes organised by their members that led to the later EPP initiative by the Department of Health. Certainly, policymakers have been keen advocates of self-care, framing it as a key element in the shift towards user-focused services and patient empowerment (Department of Health 2001). However, this move was not without its critics. Even given the use of patient-centred language some have interpreted this policy agenda as a device to transfer the costs and responsibility for care onto the patient (Bradley & Blenkinsopp 1996, Dean & Kickbush 1995). Reservations have also been expressed by health professionals, in particular about whether there is sufficient capacity to adequately support patients in self-managing their own care.

Aside from the above concerns, is it the case that patients actually want to be more actively involved in managing their care? Many studies have probed patients' views of shared decision-making, but preferences for self-management have not been as widely explored. However, a 2005 survey of the population in England indicates that there is interest for both practicing self-care and leading healthy lifestyles (Department of Health 2005a). Of those with long term health conditions, 90% reported interest in playing a greater role in treating minor ailments, and 87% were interested in more actively managing their chronic condition. Additionally, there is evidence that strategies for supporting self-care are welcomed by patients and can lead to improvements in their experience. For example, one study found that patients were extremely positive about the government's plans to move towards a system of patient-accessible electronic medical records (Health Which? and National Programme for Information Technology 2003). In particular, patients appreciated the opportunity to records their wishes on their medical record, and to directly access test results and prescription information. Importantly, patients are more willing and motivated to assume responsibility for aspects of their care, such as managing their medication regimes, when they feel assured that professional support is available to them should they need it (e.g. Fitzmaurice et al 2002).

Patient views of self-care are not, however, universally positive. A study of guided self-management plans for asthma reported that participants were generally ambivalent about their usefulness and relevance, and few patients made consistent use of their own plan (Jones et al 2000). For less seriously affected patients, there was a mismatch between their understanding of their asthma (as an acute problem requiring intermittent care) and the image of asthma advanced by the self-management plan (as a chronic condition that needs regular monitoring and management). Difficulties have been reported in recruiting and/or retaining patients in trials of self-care interventions. For example, 76% of patients approached to participate in a study of self-management of warfarin treatment declined the invitation (Murray et al 2004). Many of the systematic reviews of self-management education outlined below comment that drop-out rates are relatively high, with up to 50% of enrolees failing to complete trials in some instances. The factors associated with trial attrition, and characteristics of patients most likely to drop out, are in need of further investigation so that interventions can be targeted to achieve the best results.

The type and level of support that is needed by patients who are self-managing chronic health problems has also been examined in recent research. A national population survey, conducted in 2005, found considerable variation in the UK population in terms of knowledge, confidence and skills for self-management (Ellins & Coulter 2005). It concluded that successful support strategies must be tailored to meet individual needs and targeted towards those groups who are having greatest difficulty taking care of their health. While needs vary, there are also important general themes that should inform an

effective and patient-centred strategy for supporting self care. A series of interviews with people with long term conditions identified three such themes, namely (Corben & Rosen 2005):

- good relationships between patients and professionals
- clear accessible information and signposting
- flexibility of service provision to fit in with patients' other commitments.

Self-care: what strategies have been tried and by whom?

The growing prevalence and impact of long term medical conditions has propelled the concept of self-care to prominence across a wide range of countries and health systems. The UK has been active in developing and promoting self-care initiatives, principally through the establishment of the Expert Patient Programme. Enhancing self-care was identified as one of the core components of delivering a patient-centred service in the NHS plan, unveiled in 2000 (Secretary of State for Health 2000). Many of the current National Service Frameworks (NSFs) strongly emphasise the role of the individual and their family in their own care; a resource pack to assist with the implementation of the NSFs has been distributed to all GP practices in England, which includes a section on 'Chronic disease management and self-care'. Published in January 2005, *Supporting People with Long Term Conditions* (Department of Health 2005c) outlined a service delivery model for chronically ill patients, in which support for self-care was one of the three core elements (see box).

NHS and social care model for improving care for people with long term conditions (Department of Health 2005c).

Different interventions should be used for patients with different degrees of need. The NHS and Social Care Long Term Conditions Model sets out a delivery system that matches care with need.

Level 3: Case management – requires the identification of the very high intensity users of unplanned secondary care. Care for these patients is to be managed using a community matron of other professional using a case management approach, to anticipate, co-ordinate and join up health and social care.

Level 2: Disease specific care management – this involves providing people who have a complex single need or multiple conditions with responsive, specialist services using multi-disciplinary teams and disease specific protocols and pathways, such as the National Service Frameworks and Quality and Outcomes Framework.

Level 1: Supported self care – collaboratively helping individuals and their carers to develop the knowledge, skills and confidence to care for themselves and their condition effectively.

Local health and social care partners should ensure self care and self management are priorities in local planning and commissioning and should mainstream activities to support self care. The new primary care contracting arrangements – including new GSM, PMS, PCTMS and the new pharmacy contract – will give PCTs real options for sourcing the best services to support self care.

Self care is one of the key pillars of The NHS Improvement Plan vision for a patient-centred care system and is an important strand to the Government's overall strategy for health. Supporting self care is essential to sustaining delivery of the PSA target in order to produce better health outcomes, slow disease progression, ensure better management of the sudden deteriorations often associated with long term conditions and result in improved quality of life for people.

The cornerstone of government's efforts to promote self-care is the Expert Patient Programme (EPP), launched in England and Wales in September 2001. Pilot courses began in 26 PCTs in April 2002, but by the end of the pilot phase (April 2004) almost 300

PCTs had implemented courses or were officially committed to the programme. The 2006 community health white paper promised an increase in EPP capacity from 12,000 to 100,000 course places per year by 2012, with a trebling of investment to achieve this target (Department of Health 2006). It also announced the creation of a not-for-profit community interest company to market and deliver the programme. Pilots are also underway of an online version of the EPP course.

The EPP is based on the chronic disease self-management programme (CDSMP) developed by Kate Lorig and colleagues at the Patient Education Research Center at Stanford University, California. The CDSMP is a generic, lay led, community-based self-management course run over six weekly (two and a half hour) sessions. The programme aims to build patients' skills, resources and confidence towards better managing their long term condition; the subjects covered in the courses include (Lorig et al 1999b):

- cognitive skills
- relaxation and fatigue symptom management
- anger, fear and frustration management
- the role of healthy eating and exercise
- communication skills
- managing medication
- managing depression
- planning for the future and making an action plan
- problem solving
- making informed treatment decisions
- working in partnership with the health professional team.

The precursor of these generic courses were educational programmes focusing on coping with specific conditions, such as arthritis, asthma or diabetes. For example, drawing on condition specific courses developed at Stanford University and elsewhere, patient groups in the UK organised their own disease self-management programmes. These include 'Challenging Arthritis' and the 'Self-Management Training Programme', developed by Arthritis Care and the Manic Depression Fellowship respectively. Such initiatives have been supported by the LMCA's Living Well Project, launched in 2001. This project set out with four major aims, to:

- create a central co-ordination centre to support organisations, professionals and individuals interested in lay-led self-management
- increase the number of organisations delivering lay-led self-management programmes among LMCA members from 13 to 20
- develop a system of professional development and support for volunteer tutors
- create a corps of ten Assessor Tutors (to monitor the quality of courses delivered).

Disease-specific educational programmes have also been developed and/or run by health professionals, usually delivered in hospital settings. These have been particularly strong in the area of diabetes, where the DESMOND and DAFNE patient education programmes have been developed for people with type 1 and type 2 diabetes respectively. Under recommendations from the National Institute of Health and Clinical Excellence, all PCTs are expected to provide patient education courses as part of their diabetes service.

A national evaluation of the EPP has recently been completed by the National Primary Care Research and Development Centre at the Universities of Manchester and York. This included a randomised controlled trial to assess clinical and cost-effectiveness, a qualitative study of patients' expectations and experiences and a process analysis. Results of the qualitative research and process analysis were published in 2005 (Kennedy et al 2005), the key findings are summarised below.

National evaluation of the Expert Patients Programme: key findings

- The EPP was most quickly established in PCTs that were already running similar initiatives, and where someone acted as a 'product champion' and implementer.

- The high degree of voluntary sector involvement in the EPP makes it more difficult for connections to be made with existing NHS services for managing long term conditions.

- Benefits of a generic course were identified by participants – including providing support for those with poorly recognised chronic conditions that are not well supported by health professionals. However many felt that they would have benefited more from a condition specific course, and such courses are likely to be more easily integrated with local NHS services and existing chronic disease initiatives.

- When evaluating the courses, participants most valued the social support generated through sharing experiences, practical exchange of ideas and reduction in social isolation. However, it is not clear that the structured EPP course is the best way to meet this social support need, particularly given that courses only run over six sessions.

- Two types of course attendees were identified:
    - the majority of people went to share their experiences and make a contribution to improving the lives of others with long term conditions. They viewed the EPP as a reinforcement of their existing self-management behaviour rather than as an opportunity to learn anything new
    - a minority of people practiced ad hoc self-care, and did not already see themselves as 'experts'. They needed opportunities to improve their self-management skills, and had less access to other resources and support.

- Recruiting sufficient numbers to run courses had not always been possible, leading to cancellation. Although hard-to-reach groups (including ethnic minorities) stand to benefit most from the EPP, particular difficulties were encountered in targeting and engaging people from these groups.

- A survey of those who declined to attend found the following reasons:
    - a lack of perceived need
    - low expectations of what the course was seen to offer
    - lack of familiarity and receptivity to the principles and values of lay-led self-management training
    - lack of confidence in ability to take part

- Most health professionals did not engage with, and actively direct their patients to, EPP courses. This was the result of cultural and practical barriers, including a lack of common guidelines for direct referral to the EPP. The support of health professionals is essential for long term success and mainstreaming across the NHS.

In addition to the national evaluation, much research has also been conducted into the Stanford self-management programmes on which the EPP is based. Findings indicate that the programmes lead to moderate short term improvements in some domains including health behaviours, self-efficacy and use of health services (Lorig et al 1999a, Lorig et al 2001). Although it has been claimed that self-management education improves health outcomes (Department of Health 2001), the current evidence for its effects on dimensions of health status is mixed. Whether short term improvements are sustained over the longer period is also unclear, as almost all studies have measured outcomes at a maximum of six months. A recent RCT of a mail-delivered arthritis self-management intervention measured outcomes at one, two and three years (Lorig et al 2004). In the earlier assessments, improvements in disability, role function, self-efficacy, global severity and doctor visits were observed. By three years, there were no statistically significant differences between intervention and usual care groups in any of the outcomes measured.

While the EPP has been the main focus of the government's efforts to encourage self-care, other initiatives are broadly supportive of this goal. Moves to reclassify certain prescription-only products to pharmacist prescribed or general sales list (which can be sold in any retail outlet) is improving patients' access to medicines and their ability to self-medicate less serious ailments. A self-help guide has been produced by NHS Direct, providing information and advice about how to treat common health problems at home. Developments in IT are also playing a role – NHS HealthSpace, for example, is an online service for storing and accessing personal health information. It is intended that patients will eventually be able to electronically access to their own medical records via this service.

Beyond the UK, self-care is central to policy and service developments in various other national and organisational settings. In Australia, the Sharing Health Care Initiative aims to *"improve health-related quality of life for people with chronic diseases, to encourage people to use the health care system more effectively and to enhance collaboration between individuals, their families and health care professionals in the management of chronic conditions."* Twelve demonstration projects were conducted and evaluated, one in each of the eight states/territories and four smaller projects focusing on self-management in indigenous communities. The projects involved a number of different approaches including coaching techniques and the lay led self-management courses developed at Stanford University. National evaluation of the Initiative found:

- improvements in the majority of indices including health status and increased symptom control
- reduced GP visits and overnight hospital stays
- major changes occurred within the first six to eight months and were sustained
- consistent improvements arose in those projects with active involvement of health professionals and GPs.

In 1994, Health Canada set up the Self-Care Project, which has been carried out in the following four stages:

- **a framework for supporting self-care**: a exploratory study of the ways in which health professionals stimulate and support self-care
- **workshops for physicians and nurse educators**: workshops to identify ways of increasing knowledge and skills in promoting self-care practices through training and support
- **workshops and pilot projects**: a series of workshops organised around particular themes (e.g. heart health, stress management for women) and pilot projects in clinical care, education and research
- **networking and partnership building**: nine demonstration projects in clinical and educational settings, aiming to promote self-care by fostering changes in

attitude and behaviour among healthcare professionals. The establishment of the Supporting Self-Care Network.

The Self-Care Project diverges from the approach taken in the UK in two important respects: i) it has a strong focus on health professionals, in particular the role that they can play in supporting and promoting self-care; and ii) it has adopted a multidisciplinary framework that brings together clinical, educational, research and consumer interests.

Healthcare providers in North America have moved towards a model of care that recognises and encourages active patient participation. The approach developed by US health maintenance organisation Kaiser Permanente considers patients to be co-producers of their health and healthcare, rather than simply consumers of health services. On this basis, Kaiser has sought to encourage patients to become more actively involved in and educated about their healthcare, including offering self-management education programs in chronic disease and pain management. To improve care for patients with chronic disease, the Medicare Modernization Act (passed in 2003) established a disease management model, entitled the Chronic Care Improvement Program. A key goal of the Program is to encourage and support patients in self-care activities. Each enrolled patient receives an individualised care management plan that includes self-care education and the use of technologies for home health monitoring. The Program has been piloted in patients with congestive heart failure, complex diabetes and chronic obstructive pulmonary disease.

Website addresses

- **Expert Patients Programme**
  www.expertpatients.nhs.uk
- **Sharing Health Care Initiative**
  www.chronicdisease.health.gov.au/sharing.htm
- **Self-Care Project**
  http://www.hc-sc.gc.ca/hppb/healthcare/supporting.htm
- **Supporting Self-Care Network**
  www.supportingselfcare.ca
- **Medicare Chronic Care Improvement Program**
  http://www.cms.hhs.gov/medicarereform/ccip/
- **Challenging Arthritis (Arthritis Care)**
  www.arthritiscare.org.uk/contact/contacts_courses.cfm
- **Self Management Training Programme (Manic Depression Fellowship)**
  http://www.mdf.org.uk/self_management.php
- **The Living Well Project**
  www.lmca.org.uk/docs/self_man1.htm

Self-care: what outcomes are important?

There is some disagreement as to what the core outcome measures for the evaluation of self-care interventions should be. Clinical outcomes are commonplace, and include disease symptoms, pain and health status. Patient-centred outcomes, such as functional status and quality are life, are also widely used. Given that a stated aim of many interventions, in particular self-management education, is to improve self-care practices and use of health services, it is unsurprising that behaviour change is often measured. However, it has been suggested that researchers often falsely assume a simple causal relationship between behavioural change and other (e.g. clinical) outcomes (Newman et al 2004). The problem with this assumption is illustrated by studies showing that clinical and/or symptomatic improvements can occur in the absence of behaviour change, and that positive behaviour change does not necessarily predict improvements in health status. On this basis, Lorig and Holman propose that the beneficial effects of self-management education arise not from its impact on self-management behaviour but, rather, from its enhancement of patients' sense of self-efficacy (Lorig & Holman 2003).

Complications also arise with the use of psychological outcome measures. While levels of depression and anxiety tend to be higher in chronic care patients compared with the general population, not all patients recruited into trials of self-care interventions have poor psychological wellbeing (Newman et al 2004). This may explain why positive psychological effects are most consistently found in studies of psychoeducational approaches, as these are usually conducted among patients who are experiencing symptoms of depression and/or anxiety (Steed et al 2003).

The following outcomes have been most frequently measured in trials of self-care interventions:

- disease status: e.g. blood glucose control (diabetes) and lung function (asthma)
- severity and control of pain
- patient quality of life
- self-efficacy and self-management behaviours: e.g. self-monitoring, symptom management and diet/exercise
- knowledge of the condition and its treatment
- functional status and disability
- medication use, adherence and tolerance
- psychological wellbeing
- coping skills
- health service utilisation and cost
- school/work absenteeism
- patient satisfaction
- long term complications.

Self-care: what works?

Considerable data has been collected on the effect of self-care interventions. Where possible, we have only reported evidence from systematic reviews. However, for areas in which systematic reviews have not been undertaken or are limited in scope, the findings from individual studies have also been included.

1. Self-management education

The majority of research into self-care interventions has focused on self-management education programmes. Such programmes broadly aim to empower and equip people with chronic conditions to cope with and day-to-day manage their health problems, but employ an array of different approaches to this end. There have been a large number of studies conducted into the effectiveness of self-management education programmes, and the findings from 46 systematic reviews are described below. The reviews have been grouped as follows:

- information-only patient education and self-help resources
- asthma self-management education
- diabetes self-management education
- arthritis/rheumatic disease self-management education
- hypertension self-management education
- COPD self-management education
- computer-based self-management education.

In some cases, reviews have not focused on specific clinical conditions or types of educational intervention. These are presented in a final category, entitled ‘miscellaneous self-management education’.

a) Information-only patient education and self-help resources

Bower and colleagues (2001) systematically reviewed the literature, to identify studies evaluating clinical and/or cost-effectiveness of self-help interventions for anxiety and depression (Bower et al 2001). Self-help was defined as: a) a therapeutic intervention administered through text, audiotape, videotape, computer text, or through group meetings or individual exercises; and b) designed to be conducted predominantly independently of professional conduct. Eight controlled studies met their inclusion criteria; all involved written interventions (e.g. self-help booklets) and some also included face-to-face or telephone support (either combined with the written materials or as a separate intervention). Trial participants had anxiety, anxiety and depression, stress or chronic fatigue. Outcomes measured included psychiatric symptoms, physical function, health service utilisation, coping, knowledge of disorder and satisfaction with treatment. The methodological quality of the studies was relatively low; only one study conducted a power evaluation and only one (not the same study) stated an a priori outcome. Effect sizes for the various outcomes were mixed (varying from -0.18 to 1.18), but all studies reported significant improvements in at least one outcome. The mean effect size was calculated for six of the eight studies, and was 0.41 (CI 0.09 – 0.72). The studies provide no evidence on the long term effects of self-help interventions.

Strength of evidence: Systematic review – a well conducted systematic review, using a thorough search strategy, although limited to English language publications (CRD).

Morrison and colleagues (2001) reviewed the effectiveness of printed patient education materials in chronic illness (Morrison 2001). They identified eight controlled trials, which compared printed education materials (delivered alone, not in combination with other interventions) with usual care. The primary outcomes were patient knowledge and behaviour. Studies of arthritis and back pain reported statistically significant differences between control and intervention groups in patient knowledge (actual difference: 14-15% arthritis and 7% back pain). For back pain, an RCT and a quasi-RCT reported on provider visits; the RCT found no difference between groups whereas the quasi-RCT found a significant reduction in provider visits in the intervention group. Four studies evaluated education materials for hypertensive patients; the interventions did not have significant effects either on patient knowledge or adherence (measured by prescription filling or appointment keeping).

Strength of evidence: Systematic review – clearly stated aims and inclusion criteria but no description of methods used to select studies or assess validity; searches were limited to a small number of databases and to English language publications (CRD).

Gibson and colleagues (2002) conducted a Cochrane systematic review of controlled trials of information-only asthma patient education programmes (Gibson et al 2002). Such programmes are limited to the provision of information on asthma, its causes and treatment, and do not attempt to influence self-management skills, behaviours or attitudes. Twelve trials met the inclusion criteria, which were found to be of variable quality. Information-only asthma education did not have a significant effect on rates of hospitalisation, doctor visits, lung function, medication use or days lost from normal activity. In two studies, an improvement in perceived asthma symptoms was reported after patient education. One study found asthma education to be associated with decreased emergency room visits.

Strength of evidence: Cochrane systematic review.

Lancaster and Stead (2002) examined the effectiveness of different forms of self-help materials for smoking cessation (Lancaster & Stead 2002). They were specifically concerned with the impact of structured self-help materials, rather than basic smoking cession information. Sixty trials were identified; 33 compared materials to no intervention or standard materials and the remainder compared tailored or targeted materials or compared other variations of programmes. The content and format of the materials differed substantially, with the American Lung Association 'Freedom from Smoking in 20 days' manual the most commonly used approach. A pooled analysis of eleven trials comparing self-help to no intervention produced an effect that just reached statistical significance. The studies found no benefit for adding self-help materials to face-to-face advice or nicotine replacement therapy. The evidence showed that tailored materials were more effective than standard literature, and the largest effect sizes were for trials that compared tailored materials to no intervention.

Strength of evidence: Cochrane systematic review.

Thompson and colleagues (2003) performed a systematic review of different methods of giving dietary advice for reducing cholesterol levels in adults (Thompson et al 2003). Specifically, this Cochrane review compared advice given by dieticians with other health professionals or self-care resources. Twelve studies were identified, seven of which compared dietician advice with self-help resources. The self-help resources were generally information-only, in the form of leaflets. There was no statistically significant difference between effects for dietician advice and use of self-help resources. One trial compared dietician advice, nurse advice and self-help resources; there were no significant differences between the groups at follow up, and the improvement in cholesterol levels in all three groups was small. Another trial considered the relative cost-effectiveness of dietician advice versus self-help resources, finding that the former was five times more expensive ($370) than the latter ($80). Given that efficacy is similar for the two approaches, this suggests that self-help resources may be the most cost-effective intervention.

Strength of evidence: Cochrane systematic review.

Anderson and colleagues (2005) found eleven trials of self-help books for depression, and conducted a meta-analysis with six of these (Anderson et al 2005). All the trials were of low methodological quality, and participants were self-selected and generally highly educated. The trials included in the meta-analysis all involved the US publication 'Feeling Good'. This found a significant improvement in depressive symptomatology after four weeks; longer term effects were not measured.

Strength of evidence: Systematic review, no independent assessment found.

van Boeijen and colleagues (2005) reviewed evidence for self-help manuals for anxiety disorders in primary care (van Boeijen et al 2005). Six RCTs were identified, which evaluated self-help manuals to be used by the patient themselves or with limited assistance by a therapist. Effects were measured using psychiatric and global symptom checklists. Four studies compared manuals with a waiting list or usual care; two showing significant effects for the manual. The remaining two studies compared different types of manual-based interventions (one compared manuals with increasing levels of therapist contact and the other compared manuals with and without CBT). These found that the more time spent guiding patients on the use of the manual, the greater the effectiveness. In two studies, longer term outcomes were measured; these suggest that effects are sustained for up to three years. Effect sizes varied considerably, and were higher in studies of longer duration.

Strength of evidence: Systematic review, no independent assessment found.

Griffiths and Christensen (2006) reviewed evidence from RCTs of internet interventions for mental disorders and related conditions (Griffiths & Christensen 2006). Criteria for the inclusion of studies were that they: i) involved a self-help website for a condition treated by clinical psychologists; b) tested the efficacy of a self-help psychoeducational or skills training intervention; c) employed a randomised controlled trial design; and d) incorporated a control group that was not subjected to an active treatment intervention. Sixteen papers, describing fifteen studies, were found. These focused on depression (3 studies), anxiety disorders or symptoms (5), eating disorders or their risk factors (3), stress (1), insomnia (1), headache (1) and encopresis (1). All the studies involved cognitive behavioural or behavioural interventions, with one reporting on the effectiveness of information alone. Outcomes were not consistently improved across the studies, or within them (where multiple outcomes were used). However, the studies do indicate some modest benefits from internet interventions in terms of symptoms, behaviour and knowledge. Where user satisfaction was measured, this was consistently positive.

Strength of evidence: Systematic review, no independent assessment found.

Mataix and Marks (2006) reviewed the evidence for self-help for people with obsessive-compulsive disorder (Mataix & Marks 2006). Their search found no RCTs of self-help manuals or groups. Evidence of benefit was found in three uncontrolled studies of real-time telephone support, one uncontrolled study of computer-based education, and two uncontrolled studies and one RCT of interactive computer-aided self-help. Compliance with and outcomes of the interactive computer intervention was enhanced by brief, scheduled support from a clinician.

Strength of evidence: Systematic review, no independent assessment found.

Montgomery and colleagues (2006) collected evidence for media-based behavioural interventions for children with behavioural problems (Montgomery et al 2006). These interventions aim to help parents or carers to better understand their child's problem, and to develop appropriate strategies to use with their child (in this case cognitive behavioural). Media-based approaches provide information and advice through a range of media, including audiotapes, books, computer programmes, leaflets, manuals, videotapes or a combination of these. Eleven studies were found, with written information to convey behavioural skills the most frequently used method. The interventions had moderate effects on children's behaviour when compared to no treatment, and as an adjunct to medication.

Strength of evidence: Cochrane systematic review.

Stefano and colleagues (2006) evaluated self-help interventions for patients with binge eating disorder and bulimia nervosa (Stefano et al 2006). They searched for studies on self-help involving books, manuals or audiovisual materials, and found nine relevant studies. Overall, self-help significantly improved remission rates when compared to a waiting list control. However, when the findings for guided and unguided interventions were separately compared to control, they did not reach statistical significance. The researchers point to a number of problems with the studies reviewed including: self-selected samples, preponderance of female patients, varying trial durations, different levels of training for interventionists, and a lack of follow up data in some cases.

Strength of evidence: Systematic review, no independent assessment found.

Summary of known effects of information-only patient education and self-help resources

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Evidence of improved knowledge in arthritis and back pain, but not hypertension.
Patients' experience, including communication and psychological outcomes	Not known.
Health services utilisation and cost	No effect on utilisation; dietary self-help resources more cost-effective than specialist advice, and produce similar outcomes.
Health behaviour and health status	Moderate (short-term) effects on health behaviours and symptoms in some studies, but conflicting results. Evidence of better outcomes with brief scheduled support from a clinician.

b) Asthma self-management education

Powell and Gibson (2002) evaluated various modalities for delivering asthma self-management in a Cochrane review (Powell & Gibson 2002). Specifically, they reviewed studies that: i) optimised asthma control through inhaled corticosteroid use by regular medical review or optimised asthma control by individualised written action plans; ii) used written self-management plans based on peak expiratory flow self-monitoring compared with symptom self-monitoring; iii) compared different options for the delivery of optimal self-management programmes. Fifteen trials met the inclusion criteria. Studies in the first two categories reported equivalent effects for the different types of self-management programmes being compared. In the final category, self-management programmes that omitted regular review or which were low intensity were associated with poorer outcomes. One study reported no difference in healthcare utilisation or lung function between self-management programmes with verbal instruction and written action plans.

Strength of evidence: Cochrane systematic review.

Gibson and colleagues (2003) investigated whether health outcomes were influenced by asthma self-management programmes combined with regular practitioner review (regular medical review and a written action plan) (Gibson et al 2003). Written action plans are a set of rules that patients follow to alter therapy, dependent either on peak expiratory flow monitoring or symptom levels. This Cochrane review included 36 controlled trials which compared self-management education with usual care. Self-management education led to improvements across a range of outcome measures: reduction in hospitalisations (relative risk (RR) 0.64, CI 0.50 – 0.82), unscheduled visits to the doctor (RR 0.68, CI 0.56 – 0.81), days off work/school (RR 0.79, CI 0.67 – 0.93), nocturnal asthma (RR 0.67, CI 0.56 – 0.79) and quality of life (standard mean difference 0.29, CI 0.11 – 0.47). No significant effects were observed for changes in lung function. Programmes that allowed patients to self-adjust their medication using a written action plan were most effective.

Strength of evidence: Cochrane systematic review.

Toelle and Ram (2003) conducted a Cochrane systematic review to determine whether a written asthma self-management plan increases medication adherence and improves outcomes (Toelle & Ram 2003). Seven RCTs met the inclusion criteria, which reported on outcomes such as medication adherence, hospitalisation, emergency department visits, oral corticosteroid use, lung function, days lost from work/school, unscheduled doctor visits and respiratory tract infections. The studies did not provide consistent evidence that written plans produce better outcomes than no written plan. Some studies found that one type of plan (peak flow or symptom based) had greater effectiveness in some outcome areas, although the evidence did not consistently favour one approach over another.

Strength of evidence: Cochrane systematic review.

Wolf and colleagues (2003) conducted a Cochrane review of the findings of 32 controlled clinical trials of asthma self-management programmes in children and adolescents (Wolf et al 2003). The studies covered a range of interventions delivered in group, individual or combined format; of between one and 26 sessions; using either symptoms or peak-flow as the basis for management; and focusing on prevention, attacks or social skills. Self-management education was associated with small to moderate improvements in lung function (0.50, CI 0.25 – 0.75), self-efficacy (0.36, 0.15 –

0.57), number of days of restricted activity (-0.29, -0.33 – -0.09) and school absenteeism (-0.14, -0.23 – -0.04). Education was associated with a small reduction in number of visits to emergency departments, but had no effect on hospitalisations. Effects on utilisation outcomes were stronger for moderate-severe asthma than mild-moderate asthma. Sub-group analysis showed that individual self-management programmes had the greatest reductions in morbidity outcomes, whereas reductions in hospitalisations were greater for group programmes.

Strength of evidence: Cochrane systematic review.

Summary of known effects of asthma self-management education

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Not known.
Patients' experience, including communication and psychological outcomes	Improved quality of life.
Health services utilisation and cost	Some evidence of reduced emergency hospital visits, hospitalisations and unscheduled doctor visits.
Health behaviour and health status	Mixed findings for impact on lung function.

c) Diabetes self-management education

Corabian and Harstall (2001) considered evidence for the effects of formal patient education programmes, designed to promote self-management, in adults with type 2 diabetes (Corabian & Harstall 2001). Such programmes were delivered in either individual or group sessions, and their content was determined by the educator. Three meta-analyses, seven primary studies and seven systematic reviews were identified. The literature consistently supported patient education as a component of diabetes care. From the meta-analyses the following observations were made: lower quality studies tended to produce higher effect sizes; knowledge and skill performance was more improved in patient education programmes of longer duration; knowledge and skill effects continued to improve over the longer term (to at least one year), however weight loss improvements depleted over the same time period; improvements in metabolic control peaked at between one and six months and then declined after six months, the opposite trend occurred with psychological outcomes; effect sizes for knowledge and disease status were smaller for those over the age of 40 compared to younger patients. The authors note that knowledge and skills are necessary but not sufficient to ensure good diabetes control in the long term. From the evidence available, it was not possible to concretely establish whether patient education is effective at promoting self-management in the long term to prevent/delay diabetic morbidity and mortality or improve patient quality of life. There was no consistent pattern of effect based on type of intervention, duration, setting or other characteristics, thus it was not possible to identify which intervention strategy is most effective for improving diabetes control. A number of barriers to diabetes self-management were identified including patient characteristics, socio-environmental context, the disease itself, and patients' interaction with diabetes care and education providers.

Strength of evidence: Systematic review – literature search was well defined but limited to English and French language publications, inclusion/exclusion criteria not clearly reported, no validated tool was used to assess quality; the absence of firm conclusions regarding patient education and highlighting of the need for further research were appropriate (CRD).

Hampson and colleagues (2001) conducted a systematic review of the effects of psychosocial and educational interventions (which aim to improve knowledge, skills and self-management) for adolescents with type 1 diabetes (Hampson et al 2001). Sixty four studies, describing 62 interventions, met the inclusion criteria. A narrative description of all 64 studies was completed, as well as a meta-analysis of results from the RCTs. The studies covered a wide variety of interventions, the most common being skills training, followed by dietary interventions, emotional/psychological interventions and family-related interventions. In many cases, the individual delivering the intervention was not specified; where the professional was named, these were most likely to be nurses (32.3%), psychologists (32.3%) or doctors (27.4%). Effects were measured across a number of outcomes, with the greatest number of reports for glycaemic control. Twelve RCTs used glycaemic control as an outcome measure, reporting an average effect size of 0.33. However, there was significant heterogeneity between the individual results of these RCTs which was eliminated when two studies which produced large effect sizes were removed. Without these two studies, the mean improvement in glycaemic control was reduced substantially (from 0.33 to 0.08). Improvements in psychosocial outcomes were larger than those for blood glucose control (mean effect size 0.37).

Reporting on economic outcomes was minimal, but the studies did provide tentative evidence that psychosocial and educational interventions can lead to a reduction in health services utilisation. Of twelve studies that focused on individuals with poor metabolic control, only two showed significant reductions in hospitalisation after intervention. There is no robust evidence to determine the cost-effectiveness of psychosocial and educational interventions in diabetes.

Strength of evidence: NHS Health Technology Assessment systematic review.

Norris and colleagues (2001) reviewed evidence for the effectiveness for self-management training in type 2 diabetes (Norris et al 2001). Seventy two studies, reported in 84 articles, were included; the purpose of the interventions were broadly categorised as knowledge/information, lifestyle behaviours, skill development and coping skills. Where follow up was short (less than six months) self-management training was associated with improvements in knowledge, frequency or accuracy of blood glucose self-monitoring, self-reported dietary habits and glycaemic control. Variable effects were reported for lipids, physical activity, weight and blood pressure. In studies with longer follow up, interventions that used regular enforcement were sometimes more effective in improving glycaemic control. The studies showed no evidence of effectiveness for disease-related events or mortality.

Strength of evidence: Systematic review – the review question was broad, incorporating studies with differing interventions, time scales, patients and outcomes; complete retrieval of available articles was unlikely given restrictions in the search strategy; poor reporting of the details of included studies (CRD).

Valk and colleagues (2001) systematically reviewed the effectiveness of patient education for the prevention of foot ulceration in patients with diabetes mellitus (Valk et al 2002). This Cochrane review identified eight RCTs, of generally poor methodological quality. Four trials compared intensive with brief educational interventions, and two of

these reported on clinical endpoints. One trial, which studied high-risk patients, found a one year reduction in incidence of ulcers (odds ratio (OR) 0.28) and amputations (OR 0.32); in the other study, no difference between control and intervention groups was found at seven year follow up. Foot ulceration was not significantly different between groups in a trial evaluating a diabetes education programme which included issues of foot care. In another trial, where patient education was delivered as part of a complex intervention targeted at doctors and patients, the number of serious foot lesions was improved in the intervention group after one year (OR 0.41). Foot care knowledge was found to be significantly improved in two studies; in another, foot care knowledge was significantly worse but foot care behaviour was significantly improved in the education group.

Strength of evidence: Cochrane systematic review.

Loveman and colleagues (2002) examined the clinical and cost-effectiveness of patient education models for diabetes (Loveman et al 2003). The review was limited to educational interventions concerned with the dissemination of knowledge and skills, using a number of approaches which can be carried out by the normal range of personnel involved in diabetes care. Trials that evaluated specialised psychological interventions such as cognitive behavioural or psychoanalytical therapy were excluded, as were educational interventions targeting a specific aspect of diabetes care (e.g. foot care). The authors identified 24 controlled trials, either comparing education with a control group or with another educational intervention. For type 1 diabetes, the three studies that tested education as part of a broader package of care showed positive results for diabetes control and reductions in complications. One study used a design that allowed for the independent evaluation of patient education; the results of this study indicated that education alone was not effective. There were several studies of educational interventions in type 2 diabetes, which produced mixed results. While some studies had positive results, many others reported few or no effects on diabetes control and compilations. Data were insufficient for a cost-effectiveness analysis of education interventions only, although there is evidence supporting cost-effectiveness where education is delivered as part of a package of care that also includes treatment intensification.

Strength of evidence: NHS Health Technology Assessment systematic review.

Norris and colleagues (2002) systematically reviewed the effectiveness and cost-effectiveness of diabetes self-management education in community settings (Norris et al 2002b). The studies provided data for a number of different interventions, differing in terms of content, educator, follow up period and method of delivery. The outcomes of interest were classified as physiological, knowledge, skills, psychosocial outcomes and healthcare system outcomes. Self-management education had beneficial effects on glycaemic control for: adults in community gathering settings, and children and adolescents in home settings. Few studies reported on non-physiological outcomes in community and home settings; while there was some evidence of improvement in these outcomes the findings weren't consistently positive. The evidence was insufficient to assess the effectiveness of self-management education delivered in recreational camps and the workplace.

Strength of evidence: Systematic review, no independent assessment found.

Norris and colleagues (2002) performed a meta-analysis of RCT data for the effects of diabetes self-management education on glycaemic control (Norris et al 2002a). Thirty one studies met their inclusion criteria, which entirely or mostly evaluated self-

management education in people with type 2 diabetes. The review collected data on diabetes self-management education regardless of type, setting, educator, method of delivery, duration or intensity. When outcomes were measured on completion of the intervention, self-management education was found to improve glycaemic control (average change of 0.76%, CI 0.34 – 1.18). Increased contact time between educator and patient increased the effect of self-management education. However, effects were not sustained between one to three months following completion of the intervention. There was significant heterogeneity between the results of the trials, which may be explained by differences between the interventions evaluated.

Strength of evidence: Systematic review – clear review question, several relevant sources searched (although search limited to English language publications); methods used for study selection, validity assessment and data extraction not described; given significant heterogeneity of results, meta-analysis may not have been appropriate (CRD).

Gary and colleagues (2003) reported results from a meta-analysis of RCTs evaluating the effects of behavioural and educational interventions on body weight and glycaemic control in people with type 2 diabetes (Gary et al 2003). The meta-analysis was conducted with the findings of 18 RCTs, involving a total of 2,720 patients. The interventions varied substantially in terms of content, frequency and setting, leadership, mode of instruction, topics, follow up and outcomes. Nurses were most often involved in delivering the intervention (39%), with dieticians (26%), physicians (17%) and other professionals (13%) also reported as interventionists. The main topic of most interventions was diet (70%); topics also covered included exercise (57%), medications (35%) and self-monitoring (26%). Blood glucose levels were significantly reduced compared with controls (pooled effect size -0.43). The largest effect sizes were reported in studies with higher quality scores, larger sample sizes, physician interventionists and in which the topic areas focused on medications and exercise. Group and individual approaches produced similar results. Educational interventions produced small, but non-significant, weight loss effects.

Strength of evidence: Systematic review, no independent assessment found.

NICE (2003) reported evidence for the clinical and cost effectiveness of structured patient education in diabetes care (NICE 2003). Education was defined in terms of three main objectives: i) control of vascular risk factors; ii) management of diabetes-associated complications; and iii) quality of life. Education for people with type 1 diabetes was evaluated in four studies; only one measured education alone, and found no significant impact on blood glucose levels. The remaining studies, which measured education as part of an intensified treatment programme, found improvements in blood glucose levels and diabetes complications over the short and long term. Treatment intensification programmes, however, were also associated with increased frequency of hypoglycaemic episodes. Eight studies focused on the effects of general self-management education for people with type 2 diabetes. In only three of these were significant differences in blood glucose levels between control and intervention groups reported; in all three studies, the intervention was delivered over a long period and had the shortest time between the end of the intervention and follow up. The studies provide some evidence that general self-management education can improve body mass index, use of medications, quality of life and diabetes knowledge. Seven trials of focused self-management education in people with type 2 diabetes were reviewed. No differences were found for blood pressure, body mass index or weight, cholesterol or triglyceride levels. Two trials tested interventions that combined exercise with dietary education, both reporting significant improvements in blood glucose levels. One of these studies also measured quality of life, which was found to be significantly improved in the intervention group compared with control. Two cost-effectiveness analyses were identified, both from the USA and limited in terms of their

generalisability. One reported that a behavioural intervention addressing diet and exercise was more cost-effective than a general educational intervention in adults with type 2 diabetes. The second found that a dietary self-management programme led to improvements in intermediate health outcomes in adults with type 1 and 2 diabetes, at a cost of $137 per person. A cost-utility analysis of the DAFNE (Dose Adjustment for Normal Eating) programme was submitted to NICE, which reported a cost saving of £2,679 over ten years. A re-evaluation of this data, based on more conservative assumption of intervention effects, came to a reduced net saving of £536.

Strength of evidence: NICE Technology Appraisal.

Sarkisian and colleagues (2003) assessed the effectiveness of self-care interventions for improving glycaemic control or health-related quality of life in older African American or Latino adults with diabetes (Sarkisian et al 2003). Eight RCTs were identified, which evaluated the following: educational group sessions, exercise classes, diet counselling sessions, support group meetings, weekly pharmacist appointments, diabetic education, follow up phone calls, standard or nutritional diabetic education programmes, group discussions, one-to-one diabetic education and bicultural community health work. Outcomes of interest were: glycaemic control, diabetes-related symptoms or self-rated quality of life. Out of the eight trials, five reported improved glycaemic control. However, where a six-month follow up was conducted, improvements were not sustained in two studies and were only partially sustained in a third. Four trials reported on quality of life; only in one was there a difference in end scores between intervention and control groups (this was a very small trial, involving only 24 patients in total). Positive trials had the following characteristics: poor glycaemic control at baseline; intervention was tailored either culturally or to age; use of group counselling or support; involvement of family. The authors raise concerns about the methodological quality of the trials; many had high drop-out rates and only one conducted analysis on an intention-to-treat basis.

Strength of evidence: Systematic review – clear review question and relevant sources searched, but search was limited to English language publications, and inclusion criteria and methods used to extract data and assess validity were not clearly described; authors conclusions supported by the evidence presented in the review (CRD).

Steed and colleagues (2003) carried out a systematic review of the psychosocial outcomes of education, self-management and psychological interventions in diabetes (Steed et al 2003). Educational interventions are those where patients only receive information; self-management interventions aim to promote adherence by teaching practical or psychosocial skills, or by addressing attitudes and beliefs; and psychological interventions primarily address negative mood states. Thirty six studies were included, with 54% conducted with type 2 diabetic patients, 11% with type 1, and 35% with both. The interventions evaluated typically contained a number of components (with an average of three components); the most common element was general education, which was included in 75% of the studies. Five studies evaluated effects on psychological well-being, with only one reporting that the intervention (self-management) led to significant improvements in both negative and positive mood. In four out of the six RCTs that measured depression outcomes, the intervention led to improvements compared to control; three of these studies were conducted with psychological interventions (and with patients that had high baseline levels of stress and/or depression). Anxiety was improved in only two out of seven RCTs, which evaluated psychological stress management and an educational intervention. Improvements in quality of life were not found using generic measures, but were reported in studies measuring disease specific quality of life; improvements in this outcome were most common for self-management interventions. In all but one study, short term quality of life effects were sustained at longer term follow up; this contrasts with findings for glycaemic control, where effects tend to regress over time.

Methodological problems, including small sample sizes and poor description of the interventions, limit the interpretation of results and the conclusions that can be drawn from them.

Strength of evidence: Systematic review, no independent assessment found.

Ellis and colleagues (2004) reported a meta-analysis of the effect of diabetes patient education on glycaemic control (Ellis et al 2004). Twenty-one RCTs describing 28 educational interventions were identified, involving a total of 2,439 patients. The interventions varied with regard to teaching method, content, intervention duration, number of sessions and overall time period. For example, the studies included the following teaching methods: didactic, goal setting (dictated and negotiated), situational problem solving and cognitive re-framing. In the majority of the interventions (n=20), study participations were patients with type 2 diabetes. There was a statistically significant (but modest) difference in glycaemic control between intervention and control groups at initial follow up and at 24 weeks. Interventions that were performed face-to-face, used cognitive reframing teaching methods or which included exercise an educational component, were most successful at improving glycaemic control. The authors note that their meta-analysis is limited by the small number of available studies.

Strength of evidence: Systematic review, no independent assessment found.

Deakin and colleagues (2005) assessed the effectiveness of group-based self-management strategies for people with type 2 diabetes (Deakin et al 2005). Outcomes of interest were clinical, lifestyle and psychosocial, in both short term (four to six months) and long term (more than twelve months) follow up. To be included in the review, the sessions had to be delivered to groups of six people or more. Fourteen publications, involving eleven different studies, were identified. These described a range of different approaches, varying in intensity, their location, the person delivering the programme, and whether or not family members also participated. Group-based training led to a significant short term lowering of systolic blood pressure. It also reduced the need for diabetes medication, and significantly improved fasting blood glucose levels, glycated haemoglobin, and diabetes knowledge at both short and longer term follow up. There was also evidence of improved self-efficacy, self-management, treatment satisfaction and quality of life (at longer term follow up only). Effectiveness does not appear to vary according to whether the course was delivered in primary or secondary care, who delivered it (as long as they were adequately trained) or the size of the group.

Strength of evidence: Cochrane systematic review.

Summary of known effects of diabetes self-management education

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Knowledge improved.
Patients' experience, including communication and psychological outcomes	Mixed evidence for quality of life and psychological outcomes. Psychological interventions improve depression in patients with high baseline levels. Better self-efficacy and self-management with group-based approaches.

Health services utilisation and cost	Insufficient evidence to draw firm conclusions.
Health behaviour and health status	Type 1 diabetes: combined approaches (involving treatment intensification) lead to short term improvements in blood glucose control and diabetic complications. Type 2 diabetes: best evidence is for group-based approaches which improve blood glucose levels and systolic blood pressure. Better use of medicines. Improved foot care with carefully targeted interventions.

d) Arthritis/rheumatic disease self-management education

Astin and colleagues (2002) performed a meta-analysis of 25 RCTS evaluating psychological interventions in the treatment of rheumatoid arthritis (Astin et al 2002). The studies evaluated the following interventions: multimodal cognitive behavioural approaches with components such as relaxation, imagery and cognitive coping skills; multicomponent with a biofeedback element; traditional psychotherapeutic interventions (group based and individual); patients' writing or speaking about difficult emotions or stressful experiences. The outcomes measured in the studies included: pain, functional disability, psychological status, coping, self-efficacy and tender joints. The follow up periods ranged from two to 18 months. When measured post intervention, there were significant improvements in pain (effect size 0.22), functional disability (0.27) and self-efficacy (0.35) compared with control. However, effect sizes were far smaller (and non-significant) at follow up: pain=0.06, functional disability=0.12 and self-efficacy=0.20. Conversely, tender joints were found to be significantly improved at follow up (0.30) but not at post-treatment (0.15). In the case of psychological outcomes (usually depression) and coping, both were significantly improved at post-treatment (0.15 and 0.46) and follow up (0.33 and 0.52). While there was no significant relationship between trial quality and effect sizes, the authors note that effect sizes for pain and disability were smaller in higher quality trials than in lower quality studies, and for psychological outcomes were larger in higher quality trials than in lower quality studies. Effectiveness was greater in studies involving patients who had been chronically ill for less than 11.5 years and where the interventions were of shorter duration.

Strength of evidence: Systematic review – clearly stated aims and inclusion criteria; several sources were searched and publication/reporting bias was assessed, although the method used to select the studies was not described; validity was assessed, scored and reported using a validated scale; data were appropriately combined in a meta-analysis (CRD).

Riemsma and colleagues (2003) assessed the effects of patient education programmes on health status in adults with rheumatoid arthritis (Riemsma et al 2003). Patient education was defined as formal structured instruction on rheumatoid arthritis and on ways to manage arthritis symptoms; studies that used psycho-behavioural methods were also included. Thirty one RCTs were identified in this Cochrane review in which patient education was provided as an adjunct to usual medical care; the studies were generally of low methodological quality. The interventions evaluated were categorised as information only, counselling or behavioural treatment (e.g. behavioural instruction, skills training and biofeedback). Overall, patient education was found at initial follow up to have small but significant effects on disability, joint counts, patients global assessment, psychological status and depression. No intervention effects were observed for anxiety

and disease activity, and improvements in pain scores were small (and non-significant). By final follow up, the improvements associated with patient education had not been sustained. The evidence in favour of patient education is largely account for by the effects of behavioural treatments, given that neither information only nor counselling interventions produced significant effects either at initial or final follow up.

Strength of evidence: Cochrane systematic review.

Savelkoul and colleagues (2003) identified 14 controlled studies of active coping interventions in patients with rheumatic disease (Savelkoul et al 2003). Specifically these studies reported on group interventions, intended to teach patients active coping skills for general problems (e.g. stresses of daily life) rather than to cope with pain. The interventions differed in terms of aims, content and duration. They were broadly categorised as i) self-management: in which illness self-management skills are taught; ii) education support groups: which include teaching self-management skills in an atmosphere of educational support; and iii) cognitive-behavioural interventions: aimed at improving the patients' way of dealing with pain and stress. Outcome measures included knowledge, physical status, psychological status, health-related behaviours and health service utilisation. Only three trials measured effects on coping specifically, with only one reporting significantly improved effects in the intervention group compared with controls. Out of four studies measuring social support effects, only one reported improvements for the intervention. Where quality of life was measured in terms of life satisfaction, no intervention effects were found. Thirteen studies measured quality of life by asking patients about their functional health status and in six of these the intervention produced positive effects. There were no characteristics that obviously differentiated these six positive studies from the remaining seven which measured quality of life in this way.

Strength of evidence: Systematic review – a well-conducted systematic review and the authors' conclusions are likely to be reliable (CRD).

Warsi and colleagues (2003) performed a meta-analysis of controlled trials of arthritis self-management education programs to evaluate their effect on pain and disability (Warsi et al 2003). Seventeen trials met the inclusion criteria, with a combined total of 4,114 patients. The mode of delivery varied, with six interventions delivered in an individual format, nine in group format and one in a combination of both. The majority of the interventions were developed using a theoretical model, in most cases this was social cognitive theory (of which self-efficacy theory is part). The type of intervention also differed between studies, from patient education leaflets through to the Stanford Arthritis Self-Management Programmes. Although self-management education was associated with statistically significant improvements in pain and disability, the actual effect sizes in both these areas were small: pain (0.12, CI 0.00 – 0.24), disability (0.07, CI 0.00 – 0.15). Qualitative analysis did not identify any specific characteristics which differentiated studies reporting statistically significant positive effect sizes from those with non-significant findings. Studies with the largest effect sizes also had the largest trial drop-out rates.

Strength of evidence: Systematic review – clear review question, but only two databases searched and studies limited to English language; no discussion of reasons for high drop-out rates or possible influence on results; significant heterogeneity in results for pain outcomes (CRD).

Niedermann and colleagues (2004) focused on the long term effects of educational or psychoeducational interventions for patients with rheumatoid arthritis (Niedermann et al 2004). Patient education is defined as: any combination of learning experience designed

to facilitate voluntary adoption of behaviour conducive to health. Psychoeducational approaches are described as combining teaching intervention activities with behavioural intervention activities to improve coping and change behaviour. Eleven studies were identified which provided data on a variety of interventions (seven were broadly categorised as classic educational programmes to teach knowledge and specific skills, while the remaining four evaluated cognitive behavioural therapy); program durations; outcome measures; and follow up periods. Of these studies, seven were rated as being of high quality. At a minimum, long term follow up was taken as six months, but some studies had follow ups of up to 15 months. Educational interventions led to short and longer term improvements in knowledge and compliance (e.g. with prescribed medication or exercise regimes), but had no effect on health status, pain relief or disability. Psychoeducational interventions produced short term improvements in coping behaviour, and two of the four studies involving these interventions showed a positive effect on physical or psychological health outcomes in the long term. Three studies measured impact on self-efficacy (two educational, one psychoeducational), reporting mixed results. The studies of higher methodological quality were less likely to observe positive intervention effects than those of lower quality. The highest quality study (of cognitive behavioural therapy) found only modest improvements in outcomes and no long term effects.

Strength of evidence: Systematic review, no independent assessment found.

Summary of known effects of arthritis self-management education

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Knowledge improved.
Patients' experience, including communication and psychological outcomes	Mixed results for quality of life and self-efficacy. Evidence of improved psychological outcomes and coping behaviour.
Health services utilisation and cost	Not known.
Health behaviour and health status	Small improvements in pain, functional disability and joint counts, which are not sustained over the longer term. No impact on disease activity.

e) Hypertension self-management education

Boulware and colleagues (2001) conducted a systematic review and meta-analysis of evidence for patient-centred behavioural interventions to improve blood pressure in patients with hypertension (Boulware et al 2001). Behavioural interventions were categorised as one of the following: i) counselling techniques; ii) self-monitoring of blood pressure; or iii) structured training courses. Counselling was defined as individual or group discussion and teaching with a personalised approach, set in a non-classroom format in which individuals or group members might often share their personal experiences. Training courses were defined as curriculum-based courses, aimed at teaching several people at once, that were less personal than group counselling and usually occurred in a classroom setting with one or more curriculum leaders. Fifteen studies reported on these interventions, with the majority evaluating counselling

approaches (n=10); self-monitoring and training interventions were each evaluated in one study. The studies varied in terms of setting, duration, leadership and sample size. Counselling led to significant improvements in blood pressure compared with usual care. Neither self-monitoring nor training were found to produce statistically significant improvements over usual care in blood pressure, and combining counselling with these other approaches did not lead to greater improvements (except in one study).

Strength of evidence: Systematic review – the aims of the review were well described and the literature search (for English language publications only) was comprehensive; several key features of the included studies were not adequately described (e.g. methodology, patient characteristics and results); given the problems with the review, the authors conclusions may not be valid (CRD).

Fahey and colleagues (2003) systematically reviewed interventions to improve control of blood pressure in hypertensive patients (Fahey et al 2003). Fifty nine RCTs were identified, evaluating one of the following interventions: i) self-monitoring; ii) educational interventions directed to the patient; iii) educational interventions directed to the health professional; iv) health professional-led care; v) organisational interventions aimed at improving the delivery of care; and vi) appointment reminder systems. The outcomes of interest were mean systolic and diastolic blood pressure, control of blood pressure, and proportion of patients followed up at clinic. Antihypertensive drug therapy, combined with an organised system of regular review, was found to be the most effective intervention at reducing blood pressure. The effects of the other interventions were variable (see below for the evidence on self-monitoring). There was substantial heterogeneity in results among the trials for the remaining groups of interventions. None produced large reductions in systolic or diastolic pressure. The authors comment that educational interventions, directed at either professionals or patients, are unlikely by themselves to have an impact on blood pressure control.

Strength of evidence: Cochrane systematic review.

Summary of known effects of hypertension self-management education

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Not known.
Patients' experience, including communication and psychological outcomes	Not known.
Health services utilisation and cost	Not known.
Health behaviour and health status	Blood pressure improved with counselling approaches, but no effect with patient education, self-monitoring or training interventions.

f) COPD self-management education

Monninkhof and colleagues (2003) conducted a Cochrane systematic review to investigate the value of self-management education for patents with chronic obstructive

pulmonary disease (COPD) (Monninkhof et al 2003). Twelve articles were included, describing eight RCTs and one controlled trial comparing self-management education with usual care. The studies evaluated a wide range of interventions, from written educational materials alone, to more active self-management education programmes involving personal action plans. Outcomes measured included: health-related quality of life (QoL), COPD symptoms, use of medications, hospitalisations, emergency room visits, doctor/nurse visits, days lost from work and lung function. The results for QoL were mixed; a meta-analysis of data for disease specific QoL found that self-management education groups had better scores, but the difference with control groups did not reach statistical significance. Self-management education had no significant effect on hospital admissions, emergency room visits, days lost from work, symptom severity and lung function. Self-management education led to appropriately increased use of oral steroids and antibiotics, and reduced the need for rescue medication.

Strength of evidence: Cochrane systematic review.

Turnock and colleagues (2005) assessed the efficacy of action plans in the management of COPD (Turnock et al 2005). Action plans provide guidelines on how to recognise exacerbations, and define when to alter medication or visit healthcare providers; their aim is to encourage early intervention. Three randomised trials met the inclusion criteria, all involving an intervention which combined an action plan and information booklet. In one, patients also received an educational session with a nurse experienced in respiratory disease. Booklets supplied with the action plans covered topics including smoking cessation, controlling breathlessness, nutrition, exercise, clearing mucus from the lungs, medications and provided contact details of community support services. In all three studies the primary outcomes were hospital admission, healthcare utilisation and use of medications; a number of secondary outcomes were also measured. Actions plans did not have an impact on healthcare utilisation, quality of life, lung function, functional capacity, symptom scores, mortality, anxiety or depression. They did significantly improve medication usage and self-management. The number and length of exacerbations were not measured in any of the trials.

Strength of evidence: Cochrane systematic review.

Summary of known effects of COPD self-management education

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Not known.
Patients' experience, including communication and psychological outcomes	No significant impact on quality of life or psychological outcomes.
Health services utilisation and cost	No effect on hospitalisation admissions and emergency hospital visits.
Health behaviour and health status	Lung function and symptom severity unchanged. Medication usage and self-management improved with action plans.

g) Computer-based self-management education

Kaltenhaler and colleagues (2002) conducted a systematic review of the clinical and cost-effectiveness evidence for computerized cognitive behaviour therapy (CCBT) in anxiety and depression (Kaltenthaler et al 2002). CCBT can involve problem solving, psycho-education and self-help, and there is minimal contact with a therapist given that the intervention is delivered via a computer (or interactive telephone system). The authors identified trials which compared CCBT to either therapist led CBT or usual care, and in which CCBT was delivered either alone or as part of a package. The main outcomes of interest were psychological symptoms; interpersonal and social functioning; quality of life; preference, satisfaction and acceptability; and cost-effectiveness. Sixteen trials reporting on clinical outcomes and 13 reporting on cost outcomes were reviewed. The majority of studies comparing CCBT with therapist led CBT found the two approaches to be equally effective; one study found therapist led CBT to be of greater effectiveness than CCBT in patients hospitalised for depression. Four studies reported CCBT to be more effective than usual care. CCBT appears to reduce therapist time compared to therapist led CBT. None of the cost-effectiveness studies provided data for CCBT so a modelling analysis was undertaken. Problems with this data, however, prevented any concrete conclusions about cost-effectiveness being made.

Strength of evidence: NHS Health Technology Assessment systematic review.

Murray and colleagues (2004) conducted a Cochrane systematic review to assess the effects of interactive health communication applications (ICHAs) for people with chronic disease (Murray et al 2005). ICHAs were described as "computer-based, usually web-based, packages for patients that combine health information with at least one of social support, decision support, or behaviour change support." Twenty four RCTs met their inclusion criteria which examined the following conditions: AIDS/HIV (2 studies); Alzheimer's/memory loss (2); asthma (6); cancer (3); diabetes (6); eating disorders (1); encopresis (1); obesity (2); and urinary incontinence (1). Primary outcome measures included knowledge, social support, self-efficacy, emotional outcomes, and behavioural and clinical outcomes. ICHAs were found to improve knowledge, social support, health behaviours and clinical outcomes. There was insufficient data to determine impact on emotional outcomes or cost-effectiveness. Results indicated probable positive effects on self-efficacy, but more data is needed to clarify this.

Strength of evidence: Cochrane systematic review.

Summary of known effects of computer-based self-management education

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Knowledge improved.
Patients' experience, including communication and psychological outcomes	Enhanced social support, and some evidence of improved self-efficacy.
Health services utilisation and cost	Reduced therapist time with cognitive CBT, although impact on costs unknown.
Health behaviour and health status	Improved health behaviours and clinical outcomes with ICHAs.

h) Cancer self-management education

Rehse and Pukrop (2003) conducted a meta-analysis of 37 controlled studies of psychosocial interventions in adult cancer patients (Rehse & Pukrop 2003). Specifically, they analysed the effects of such interventions on patients' quality of life. The interventions evaluated were classified under one of the following four headings: i) patient education programmes primarily providing medical or procedural information; ii) professionally guided support groups of cancer patients providing mutual help; iii) coping skills training, utilising techniques including biofeedback, behaviour modification and reinforcement schedules; and iv) psychotherapeutic interventions including psychotherapy and counselling. The overall effect size was 0.31, indicating a positive but moderate impact on quality of life. Effect sizes were greater for patient education; male only samples; interventions of longer duration (at least twelve weeks); where QoL measurements were based on patient self-reports; where QoL referred to functional rather than emotional adjustment; and in studies that had higher than average methodological quality scores. A multivariate analysis found that, when all other variables were controlled for, duration of intervention was the only predictor of improved outcomes that remained significant. There were no significant differences between the effect sizes for social support, coping skills training and psychotherapy.

Strength of evidence: Systematic review – a broad review, using several sources to identify relevant literature; details of the design and characteristics of the included studies were not reported and there was no indication of what control groups were (making it difficult to assess generalisability of findings) (CRD).

Summary of known effects of cancer self-management education

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Not known.
Patients' experience, including communication and psychological outcomes	Moderate improvement in quality of life.
Health services utilisation and cost	Not known.
Health behaviour and health status	Not known.

i) Miscellaneous self-management education

Crow and colleagues (1999) investigated the nature and extent of the placebo effect, and how it might be harnessed to improve the quality of healthcare (Crow et al 1999). Specifically, they tested the hypothesis that changes in health status attributed to placebos are achieved by manipulating treatment-related outcome expectations (beliefs that treatment will have positive or negative effects on health status) and patient-related self-efficacy expectations (beliefs that one can carry out the actions necessary for successful management of a disease or coping with the treatment). Outcome expectancy

can be enhanced by the provision of accurate information about the success of treatment, and self-efficacy expectancy can be enhanced by skills training. The authors concluded that self-efficacy is most likely to be improved through self-management education teaching specific skills rather than simply imparting knowledge. They found little evidence on cost-effectiveness of self-management interventions. Given that outcomes are improved when patients are more actively involved in the medical encounter, training patients and practitioners in techniques that facilitate patient involvement in consultations is also justified.

Strength of evidence: NHS Health Technology Assessment systematic review.

Cooper and colleagues (2001) overviewed findings from existing meta-analyses of patient education in chronic disease (Cooper et al 2001). Education was described as any intervention aimed to provide a patient with information and skills about diet, exercise and/or stress management for self-care. Twelve meta-analyses were selected for review, reporting altogether on 565 independent trials. The main results were: i) knowledge: patient education was found to have significant and large effects for knowledge; ii) psychological effects: only three out of the twelve meta-analyses reported on psychological outcomes, finding relatively small effects; iii) physical effects: the meta-analyses reported moderate but variable effect sizes, with trials using shorter follow ups reporting the greatest effects; and iv) self-care effects: of the eight meta-analyses reporting on self-care outcomes, all found positive but small effects associated with patient education. While a key intention of the review was to evaluate effects by intervention type, this was not possible due to inadequate descriptions of interventions being evaluated. Four of the meta-analyses had conducted sub-group analysis, which showed that effects were smallest for didactic approaches and psychosocial strategies, and larger for combined interventions and enhanced education methods using social learning and behavioural modification exercises. Few of the trials included in the meta-analyses measured outcomes beyond six months. Where longer term effects were measured, these were frequently lower than at post treatment or short term follow up. Overall, the development of interventions was not guided by appropriate theoretical models of behaviour.

Strength of evidence: Systematic review, no independent assessment found.

de Ridder and Schreurs (2001) identified 35 controlled studies of interventions aiming to help chronically ill patients cope with their condition (De Ridder & Schreurs 2001). The studies were of the following chronic conditions: AIDS, asthma, cancer, cardiovascular disease, chronic pain, diabetes and rheumatoid arthritis. In all of the studies, a cognitive behavioural approach was adopted. While both problem-focused (e.g. self-management, lifestyle skills) and emotion-focused (e.g. relaxation, distraction) coping strategies were represented, interventions of the former kind prevailed. Generic and disease specific outcomes measures were used to evaluate effects on coping. Generally, the studies produced positive findings. However, small study sizes limit the conclusions that can be drawn from this. In some cases, the mediating role of coping on patient outcomes was evaluated by assessing the impact of the intervention on coping, and the impact of coping on the desired endpoint. Strong associations were observed in both sets of relationships. Due to variations across the studies, and the multi-component nature of many of the interventions evaluated, it was not possible to determine which coping strategies or components of multi-faceted interventions lead to the greatest improvements.

Strength of evidence: Systematic review – the search strategy was limited to two databases and no attempt was made to assess the validity of included studies; key aspects of the review process (e.g. data extraction) were not reported (CRD).

Barlow and colleagues (2002) reviewed the evidence for self-management approaches in patients living with chronic illness (Barlow et al 2002). They note that while many self-management approaches involve multiple components, insufficient descriptions make it difficult to establish which elements contribute to effectiveness. The outcomes measured in the trials were broadly classified as being: physical, psychological and social health status; knowledge of condition and its treatment; laboratory tests; use of medication; self-efficacy; self-management behaviours; use of healthcare resources; and cost. Available evidence indicates that self-management approaches can lead to improvements in knowledge, symptom management, self-management behaviours, self-efficacy and some aspects of health status (e.g. depressive symptoms). There does not appear to be any difference in effectiveness according to type of approach (e.g. group-based versus individualised). RCTs of asthma self-management programmes show that they are effective in increasing knowledge, compliance with medication and symptom management compared with usual care. Evaluations of multi-component asthma self-management programmes report improvements in compliance, symptom management, lung function and days hospitalised. In diabetic patients, self-management programmes are effective in terms of self-management behaviours, in particular blood glucose monitoring.

Strength of evidence: Systematic review, no independent assessment found.

Warsi and colleagues (2004) evaluated the effectiveness of patient self-management programmes for chronic diseases (Warsi et al 2004). Seventy one controlled trials were included in their analysis, and were classified into the following five groups: arthritis, asthma, diabetes, hypertension and miscellaneous. Data were abstracted on the following characteristics of educational programmes: duration of education, number of sessions or contacts, background training of educators, setting of the educational program, educational format (individual vs. group), method of education (written, audiotape, videotape, telephone, or face-to-face), and use of a formal syllabus. Overall, effect sizes for the self-management education programmes were small to moderate (0.01 – 0.46). The only intervention characteristic that correlated with improved outcomes was face-to-face approaches. Self-management programmes were associated with improvements in blood glucose levels for diabetic patients (0.46, CI 0.17 – 0.74), systolic blood pressure for hypertensive patients (0.20, CI 0.01 – 0.39) and frequency of asthma attacks (0.59, CI 0.35 – 0.83). Increased benefits of self-management education for diabetic and hypertensive patients correlated with improvements in medication compliance. Pooled analysis of data for arthritis self-management programmes did not find any significant effects.

Strength of evidence: Systematic review, no independent assessment found.

Chodosh and colleagues (2005) conducted a systematic review and meta-analysis of evidence for self-management programmes in older adults (Chodosh et al 2005). Fifty three studies contributed to their meta-analysis: 26 involving diabetes patients, 14 osteoarthritis and 13 hypertension. The self-management programmes were found to have significant but generally moderate effects on clinical outcomes. The pooled effect size (PES) for blood glucose in the diabetes studies was -0.36, but was -0.62 for programmes that primarily focused on diet and education. There was no evidence of an effect on weight loss. The osteoarthritis studies produced a PES of -0.06 for both pain and function, a finding of trivial clinical significance. The PES from hypertension studies was -0.39 for systolic blood pressure and -0.51 for diastolic blood pressure. An assessment of possible publication bias indicated that the positive results for both diabetes and hypertension should be treated with caution.

Strength of evidence: Systematic review – a generally well-conducted review and the authors' conclusions are likely to be reliable (CRD).

Summary of known effects of miscellaneous self-management education

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Knowledge improved.
Patients' experience, including communication and psychological outcomes	Self-efficacy improved through programmes teaching specific self-management skills. Enhanced patient self-care and coping behaviour.
Health services utilisation and cost	Not known.
Health behaviour and health status	Some evidence of improvements in health status, which may result from enhanced medication compliance. Better diabetes control with self-management programmes focusing on diet and exercise.

2. Self-monitoring and self-treatment

Technological developments are enabling patients to have greater involvement and autonomy in care practices that were previously conducted by healthcare professionals. This includes devices for home self-monitoring of health status and treatment regimens, and diagnostic kits for self-testing. Patients' role in their care is also being enhanced by moves to reclassify medicines from prescription-only status, which allows for greater self-medication to treat minor illnesses. Eight systematic reviews are described below, which report on studies evaluating either medical self-monitoring or medication self-management. We have also included two individual RCTs of blood pressure and anticoagulation self-monitoring, as these report data from cost-effectiveness analyses that are not reported in the systematic reviews. Our extensive literature search identified no published data on the outcomes of self-testing kits and self-medication.

Coster and colleagues (2000) reviewed the clinical and cost-effectiveness evidence for different methods of monitoring blood glucose control in diabetes mellitus (Coster et al 2000). Eight RCTs were identified for self-monitoring in type 2 diabetes, and eight for self-monitoring in type 1. Overall the quality scores for the studies were low, indicating poor trial conduct and reporting. The studies for diabetes type 2 compared the effects of blood or urine monitoring with no self-monitoring, or blood glucose self-monitoring with urine glucose self-monitoring. These studies varied considerably in terms of trial duration, study regimens and evaluation methods. Of the six trials that compared self-monitoring with no regular monitoring, five found no difference between intervention and control groups. A meta-analysis of four of these RCTs was conducted, which confirmed that self-monitoring does not have effects either on blood glucose control or body weight. None of the trials that compared blood with urine self-monitoring found a difference between these two approaches with regard to blood glucose control. Four trials reported on patient quality of life, with none finding significant intervention effects. The majority of studies involving patients with type 1 diabetes compared blood testing with urine testing (n=6), one study compared blood testing with no testing and another evaluated different frequencies of blood testing. In only one study did self-monitoring lead to improved blood glucose control; this study was conducted in children, where the control group performed urine testing. In most studies, patients reported a preference for blood glucose monitoring over urine testing. One study of diabetes type 1 evaluated cost-effectiveness, reporting that blood testing was more costly than urine testing (although the authors caution against generalising the results of this trial).

Strength of evidence: NHS Health Technology Assessment systematic review.

Fitzmaurice and colleagues (2002) compared outcomes for patient self-management of oral anticoagulation therapy with routine primary care management (Fitzmaurice et al 2002). Forty nine patients were randomised either to self-management or routine primary care management. The intervention group received two training sessions of between one and two hours in duration. For a six month period, patients in the intervention group were required to perform an INR test every two weeks or one week following dosage adjustment. They also had daytime access to medical advice and regular support from their practice nurse and GP. There were no significant differences between the two groups with regard to INR control. No serious adverse events were recorded for the intervention group; one patient in the control group suffered a fatal retroperitoneal haemorrhage. The cost of anticoagulant management was much lower for the self-management than the routine management group (£90 vs. £425 per patient/per year).

Strength of evidence: Single randomised controlled trial and cost-effectiveness analysis.

Fahey and colleagues (2003) identified 15 RCTs of blood pressure self-monitoring interventions (Fahey et al 2003). Self-monitoring was associated with a significant reduction in diastolic blood pressure and a non-significant trend towards improved blood pressure control. It was not possible to draw any firm conclusion about effects on systolic blood pressure as there was significant heterogeneity in the study findings.

Strength of evidence: *Cochrane systematic review.*

Siebenhofer and colleagues (2003) conducted a systematic review of RCTs comparing self-management of oral anticoagulation therapy with routine care (Siebenhofer et al 2004). The outcomes of interest were: anticoagulation control, major bleedings, recurrent thromboembolism and treatment-related quality of life. Four studies met the inclusion criteria, but one was excluded from analysis due to concerns over bias. The remaining three studies showed that self-management of oral anticoagulation is equivalent to specialist management, and superior to routine care by general practitioners. In two studies, significant improvements in treatment-related quality of life were reported for self-management. For the remaining outcomes of interest, the data were insufficient to draw any firm conclusions.

Strength of evidence: *Systematic review, no independent assessment found.*

Cappuccio and colleagues (2004) evaluated the effect of blood pressure self-monitoring on blood pressure control (Cappuccio et al 2004). Their meta-analysis was based on 18 RCTs: six based in outpatient clinics, eight in community settings and GP clinics, and four in mixed settings. Outcomes of interest were: change in blood pressure and change in the proportion of people with blood pressure above target. When compared with usual blood pressure monitoring in the healthcare system, self-monitoring was associated with better control of hypertension and greater achievement of blood pressure targets. However, in clinical terms, the actual size of the difference between control and interventions groups was relatively small.

Strength of evidence: *Systematic review, no independent assessment found.*

Farmer and colleagues (2005) evaluated the feasibility, acceptability and cost-effectiveness of diabetes telemedicine applications (Farmer et al 2005). Such applications are designed to support recording and interpretation of blood glucose measurements by patients to improve glycaemic control and outcomes. A systematic review identified 16 clinical trials, the majority of which involved people with type 1 diabetes. Nine studies measured glycated haemoglobin levels, only one of which showed a significant improvement following intervention. Other studies did show some clinical benefits, but changes did not reach statistical significance. Four trials measured patients' sense of being in control of their diabetes, but no effects were observed. There was insufficient evidence to support the cost-effectiveness of telemedicine interventions for self-monitoring.

Strength of evidence: *Systematic review, no independent assessment found.*

McManus and colleagues (2005) evaluated the clinical and cost effectiveness of self-monitoring of blood pressure control among patients with hypertension (McManus et al 2005). Four hundred and forty one patients were enrolled in the RCT, allocated to usual care (blood pressure monitoring at their general practice) or to receive an intervention consisting of patient-held targets and a machine for self-monitoring their own blood pressure. At six months, there was a significant difference between the control and

intervention groups in systolic blood pressure; however this difference was not found at one year follow up. No difference was found in terms of diastolic blood pressure, anxiety, health behaviours or numbers of prescribed drugs. Patients in the intervention group rated self-monitoring more highly than monitoring by a doctor or nurse, and consulted less frequently than those in the control group. Self-monitoring was not significantly more costly than usual care (£251 versus £240).

Strength of evidence: Single randomised controlled trial and cost-effectiveness analysis.

Welschen and colleagues (2005) systematically reviewed the evidence for self-monitoring of blood glucose in patients with type 2 diabetes who are not taking insulin (Welschen et al 2005). Six RCTs were identified; four compared self-monitoring with usual care and two compared blood glucose with urine self-monitoring (one involving a third usual care group). Only two of the trials reported significantly improved blood glucose, one of which combined self-monitoring with education on diet and lifestyle. No differences between control and intervention groups were found for quality of life, wellbeing or patient satisfaction. The authors note that a limitation of three of the four unsuccessful trials was that no standard instructions were provided to patients about adjusting their behaviour and changing their lifestyle and/or medication to modify their glucose levels.

Strength of evidence: Cochrane systematic review.

Heneghan and colleagues (2006) conducted a systematic review and meta-analysis of evidence for self-monitoring of oral anticoagulation (Heneghan et al 2006). Fourteen trials were identified, involving a total of 3409 patients, which compared self-monitoring and routine anticoagulation. Trials were conducted in various countries and patient groups, and had durations of between two months and two years. Combined analysis of trial outcomes found that self-monitoring leads to a one third reduction in death from all causes. It also improves both the benefits and harms of anticoagulation, including a 55% reduction in thomboembolism. The authors note that trials often included education and training, and that these may have contributed to the observed effects (two trials found that education alone was more effective than routine care).

Strength of evidence: Systematic review, no independent assessment found.

Jansen (2006) examined the effectiveness of self-monitoring blood and urine glucose in type 2 diabetes (Jansen 2006). Thirteen RCTs were identified, which were included in a meta-analysis. Self-monitoring blood glucose led to a reduction in glycated haemoglobin of 0.40 percentage points. This reduction was more than doubled when the intervention involved regular feedback. However, the clinical significance of this reduction is unclear. Self-monitoring of blood glucose was found to produce better results than self-monitoring of urine glucose.

Strength of evidence: Systematic review, no independent assessment found.

Summary of known effects of self-monitoring

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Not known.
Patients' experience, including	Mixed results for quality of life. Diabetes

communication and psychological outcomes	self-monitoring has no impact on patients' perceived sense of control or wellbeing.
Health services utilisation and cost	Diabetic urine testing more costly than blood testing. Anticoagulant self-monitoring less costly than specialist management, and cost of blood pressure self-monitoring equal to usual care. Reduced consultation with blood pressure self-monitoring.
Health behaviour and health status	Health outcomes of self-monitoring at least equal to routine care, and some evidence that is it equivalent to specialist management.

3. Self-help groups and peer support

Self-help and peer support groups have multiple functions. They are an opportunity to obtain information and practical assistance, as well as being a forum to share experiences and feelings with people in a similar situation. Large numbers of groups and programmes have been set up by, and for, not only patients but also their caregivers, partners and families. As only three systematic reviews have been located, the findings from four controlled trials are also summarised below.

Schwartz (1999) compared a coping skills group intervention with peer telephone support in patients with multiple sclerosis (MS) (Schwartz 1999). One hundred and thirty six patients were randomised, and 123 were assessed at two years. The coping skills group met weekly for a two hour session led by a health professional; patients attended eight sessions, which were designed to teach methods of dealing with MS problems and goal setting. After the eight sessions, pairs of patients telephoned each other once a month for ten months. For the telephone peer support intervention, lay people with MS were trained to provide non-directive support, and 15 minute telephone calls were made monthly for one year. The main outcome measures were neurological disability and neuropsychological performance, role performance, adaptability and wellbeing. The groups did not differ on any of the main outcomes, and both deteriorated in neuropsychological functioning and self-efficacy in completing daily activities. The coping skills group were less likely to cope by blaming others.

Strength of evidence: Single randomised controlled trial.

Ritchie and colleagues (2000) conducted a randomised controlled trial of a telephone peer support intervention for parents of children with chronic conditions (Ritchie et al 2000). One hundred and thirty seven parents of children aged seven or under with cystic fibrosis, spina bifida or diabetes, were enrolled. The intervention consisted of a one hour telephone support group meeting held weekly over a twelve week period. The groups were facilitated by peers with older children (7-13 years) with the same chronic conditions. Participants' perceptions of the group's impact were recorded in weekly diaries and in interviews conducted at three points over the six month trial period. Most of the parents (85%) were satisfied with the support group, and often reported benefiting from the opportunity to share solutions and compare feelings. Many parents felt they have received important information and affirmational and/or emotional support from participation in the group. The group had positive effects on parents' coping abilities; most parents described having more confidence handling the day-to-day demands of their child's condition, and about half reported feeling more comfortable with their situation, feeling more relaxed, having an increased sense of confidence or having a change in perspective. Even parents who felt they already had a good level of knowledge and understanding reported learning new information and ideas about their child's condition and caregiving. Over 70% of parents described positive effects on their existing relationships, and one third stated that the group resulted in an improved relationship and/or communication with their spouse.

Strength of evidence: Single randomised controlled trial.

Bordeleau and colleagues (2003) evaluated the effects of group psychosocial support in women with metastatic breast cancer (Bordeleau et al 2003). Two hundred and thirty five women were randomised to either a control group or to participate in weekly, 90 minute, therapist-led support group. Both groups received educational material and medical/psychosocial care when necessary. There were no significant differences between the groups with regard to global quality of life, functioning or symptom status.

There was a significant deterioration in both groups during the study period in dimensions of functioning (global, physical functioning, role functioning and cognitive functioning) and in various symptom domains (dyspnea, appetite loss and fatigue), which was not unexpected in metastatic breast cancer patients.

Strength of evidence: Single randomised controlled trial.

Campbell and colleagues (2004) systematically reviewed the evidence on peer support programmes for cancer patients (Campbell et al 2004). Twenty one studies, involving 17 different programmes, met their inclusion criteria. While high participant satisfaction was consistently reported, many studies had low response rates and did not elicit feedback from non-respondents or drop-outs. Telephone and internet support groups offer anonymity to patients, and were reported to be of particular benefit to those with less common forms of cancer, to homebound patients, to geographically distant patients and to those desiring privacy. Patients reported benefiting from the provision and exchange of information that support programmes offered, and the non-randomised studies found that patients had a better understanding of their cancer experience and were more informed as a result of their involvement in these programmes. There were three randomised trials (all of group-based peer support programmes), none of which found that peer support groups led to significant improvements in quality of life. In all three studies, peer group support had a marginally negative effect on certain outcomes including mental health, physical functioning, negative affect, general health, depression and anxiety, life satisfaction, self competency and social competency. One study, involving patients with Hodgkin's Disease, reported a decrease in activity levels among peer support group participants.

Strength of evidence: Systematic review, no independent assessment found.

Chien and colleagues (2004) conducted a randomised controlled trial of a mutual support group for caregivers of family members with schizophrenia (Chien et al 2004). Fourty eight caregivers, from two psychiatric outpatient clinics in Hong Kong, were randomised either to the support group (meeting for twelve two hour sessions) or to routine family support services. Outcomes measured were burden of care, family functioning, and need and use of support services. The number and duration of patient hospitalisations was also recorded. The support group led to significant improvements, compared with control, in burden of care and family functioning. Differences in support service utilisation were not found. There was also a significant reduction in duration of hospitalisations in the intervention group, but no difference with controls in the number of hospitalisations. Participants attending the support group reported feeling less guilty and frustrated and having a better understanding of their relative's condition. There were no significant differences post-intervention between the groups in terms of the carer's physical health.

Strength of evidence: Single randomised controlled trial.

Eysenbach and colleagues (2004) examined the effects of virtual communities (social networks formed or facilitated through electronic media) on social and health outcomes (Eysenbach et al 2004). Thirty eight studies met the inclusion criteria, only six of which evaluated virtual communities alone; the remainder involved complex interventions of which the virtual community was only one part. The studies reported variable results for the impact of virtual communities on levels of depression, social support measures and health service utilisation. With one exception, the studies failed to demonstrate any positive effects on health status and health behaviours. Conversely, there was no evidence that virtual communities had negative or harmful effects.

Strength of evidence: Systematic review, no independent assessment found.

van Dam and colleagues (2005) assessed the effectiveness of social support interventions for patients with type 2 diabetes (van Dam et al 2005). Six RCTs were identified involving a range of interventions such as group consultations, peer group sessions, telephone peer contact, internet-based peer communication or personal coach support. Overall, the studies provided evidence that social support interventions can improve self-care and outcomes of diabetes care. Specifically, knowledge and perceived social support were increased, but the evidence for clinical outcomes was mixed. One trial found that increased social support led to greater benefits in women, but had negative effect in men. This is taken by the authors as a potential indication of the differential impact of social support by gender.

Strength of evidence: Systematic review, no independent assessment found.

Summary of known effects of self-help and peer group support

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Some evidence of improved knowledge.
Patients' experience, including communication and psychological outcomes	Improvement in carer's experience and coping abilities. Mixed effects on psychological wellbeing. Enhanced sense of social support, although effects by differ by gender.
Health services utilisation and cost	Possible reduction in length of stay, but no effect on hospitalisation rates.
Health behaviour and health status	Little evidence of beneficial effect on health status and some (weak) evidence of negative effects.

4. Facilitating patient access to personal medical information

Substantial amounts of information accrue during the care experience, relating to the patient's condition, its treatment, the conduct and findings of investigations and tests, check-ups, self-management techniques and instructions for emergencies. Patients' involvement in their care can be improved by facilitating their access to this personal medical information. The reviews and trials summarised in this section pertain to two interventions of this type: medical records that are held by the patient and audiotape recordings of clinical consultations. While initiatives to copy referral letters to patients are also relevant, no research has yet been undertaken to evaluate their impact.

Drury and colleagues (2000) conducted a randomised controlled trial of the use of patient-held records (PHRs) in cancer care (Drury et al 2000). Six hundred and fifty patients, with any type of cancer, were randomised either to receive the PHR or to usual care. Assessment was conducted at three months, with the following outcomes measured: i) patients' satisfaction with communication and participation in their care; ii) health status; iii) emotional functioning; and iv) cognitive functioning. There were no statistically significant differences between control and intervention groups in any of the outcomes measured.

Strength of evidence: Single randomised controlled trial.

Warner and colleagues (2000) evaluated patient-held shared care records in patients with long term mental illness (Warner et al 2000). Ninety patients were recruited to participate in the twelve month trial and randomised either to receive the shared care record or to control. Key outcomes were psychiatric morbidity, patient satisfaction with services, hospital admissions and outpatient clinic attendance. The PHR did not lead to significant improvements in any of the outcomes measured.

Strength of evidence: Single randomised controlled trial.

Williams and colleagues (2001) recruited 501 cancer patients into a randomised controlled trial of PHRs (Williams et al 2001). Effects on health-related quality of life (QoL), patients' and healthcare professionals' views and preferences, and NHS resource use were measured. There were no significant differences between control and intervention groups with regard to QoL, resource use, difficulty understanding what was happening to them and recalling information. However, the PHR did have a significant impact on helping patients prepare for meetings with healthcare staff and feel more in control.

Strength of evidence: Single randomised controlled trial.

Cornbleet and colleagues (2002) conducted a randomised controlled trial PHRs in patients with advanced cancer and palliative care needs (Cornbleet et al 2002). Two hundred and thirty one patients participated, and were randomised either to receive a PHR or to control. Data were collected between four and six months for effects on professional-patient communication, satisfaction with communication and acceptability to carers (lay and professional). PHRs had no significant effect on patient communication with healthcare professionals or on their satisfaction with this communication. Seventy four patients were followed up in the intervention group, of whom 86% said that someone had made use of the PHR. The majority of healthcare professionals surveyed felt that PHRs had been of benefit. Impressions of PHRs were more positive among community-based than hospital practitioners.

Strength of evidence: Single randomised controlled trial.

Lecouturier and colleagues (2002) evaluated a PHR for patients newly diagnosed with lung or colorectal cancer (Lecouturier et al 2002). The two outcomes measured in this RCT were patient satisfaction and patients' and healthcare professionals' views of PHRs. Eighty six per cent of control patients, compared with 58% of intervention patients were very satisfied with the information received, a difference of statistical significance. Fifty three per cent of intervention patients found the PHR helpful and 69% reported that it would be useful to them in the future.

Strength of evidence: Single randomised controlled trial.

Currell and Urquhart (2003) conducted a Cochrane systematic review of nursing record systems (Currell & Urquhart 2003). A nursing record system is described as a record of care planned with and/or given to individual patients by qualified nurses (or other caregivers under the direction of a qualified nurse). Eight controlled studies were identified. Three studies of patient-held records and two of computerised nursing information reported no effects (positive or negative) on patient outcomes. The computerised interventions, however, were shown to increase the time spent on care planning. Another study, of a paediatric pain management sheet, showed a positive effect on children's pain intensity.

Strength of evidence: Cochrane systematic review.

Lester and colleagues (2003) evaluated the effectiveness of PHRs for patients with schizophrenia receiving shared care (Lester et al 2003). Two hundred and one patients were recruited and were randomised to intervention (receive PHR) or control. The outcomes of interest were patient satisfaction and schizophrenic psychopathology. The PHR had no significant effect on either of the primary outcomes or on use of health services.

Strength of evidence: Single randomised controlled trial.

Scott and colleagues (2003) conducted a Cochrane systematic review of the effects of providing recording or summaries of their consultations to people with cancer and their families (Scott et al 2003). Twelve controlled trials met the inclusion criteria, measuring a variety of outcomes. Between 83% and 96% of patients who were given recordings or summaries of their consultations found them valuable and in four out of seven studies participants were more satisfied with recorded/summarised information. Out of nine studies that evaluated impact on recall of information, five reported an improvement in patients receiving recordings or summaries. There was no evidence of effect on anxiety or depression. One study evaluated impact on quality of life, but found no effect.

Strength of evidence: Cochrane systematic review.

Brown and Smith (2004) evaluated the effects of giving women their own case notes to carry during pregnancy (Brown & Smith 2004). Three RCTs were identified, involving a total of 675 women. In each of the trials, the intervention groups were given their complete antenatal records to carry, while control groups were given a card with abbreviated information and no clinical follow up or clinical progress information. Women who held their own records were significantly more likely to feel in control, but there was

no difference in satisfaction with care between intervention and control groups. Women in the intervention group preferred to hold their own records in subsequent pregnancies, with women in the control group significant less likely to want to hold their notes in the future. In one trial, 25% of notes held by the hospital were lost or mislaid, while there was no loss by women holding their own notes. No difference in loss/misplacement was observed in the two other trials. No significant differences between groups were found in any of the secondary outcome measures including partner's involvement, health-related behaviours, breastfeeding practices, number of women needing analgesia during birth and perinatal and maternal outcomes. The number of women having assisted birth or caesarean sections was higher in the intervention group (relative risk 1.83, CI 1.08 – 3.12).

Strength of evidence: Cochrane systematic review.

Koh and colleagues (2005) conducted an extensive systematic review, to identify trials examining the effectiveness of audio recording consultations for parents of critically sick babies (Koh et al 2005). Research has shown that parents in intensive care units often find it difficult to understand, remember and adjust to information given to them. Nonetheless, the authors were unable to identify any randomised or quasi-randomised studies evaluating interventions of this type.

Strength of evidence: Cochrane systematic review.

Liddell and colleagues (2004) examined the efficacy of providing patients with an audiotape of their consultation in the general practice setting (Liddell et al 2004). One hundred and eighty patients were recruited, 95 randomised to receive an audiotape of their consultation and the remaining 85 to act as controls. Sixty one per cent of patients in the intervention group listened to the recording of their consultation and, of these, two thirds rated the tape as 'useful' or 'very useful'. Nearly half of the people who listened to their tape reported that this improved their understanding of the consultation, and 24% noticed information that they had not heard during the consultation. After one week, the intervention was found to have no effect on adherence to GP advice or anxiety about the condition.

Strength of evidence: Single randomised controlled trial.

Ross and colleagues (2004) assessed the impact of patient-accessible electronic medical records on patient care and clinic operations (Ross et al 2004). One hundred and seven patients with congestive heart failure were enrolled in a randomised controlled trial. The intervention group received software consisting of an electronic medical record, an educational guide and a messaging system enabling communication between patient and clinic staff. After twelve months, the intervention did not have any impact on self-efficacy or health status, but did improve general adherence to medical advice. Patients in the intervention group reported greater satisfaction with doctor-patient communication, although the difference did not reach statistical significance. There was significantly greater utilisation of emergency health services in the intervention group.

Strength of evidence: Single randomised controlled trial.

Summary of known effects of facilitating patient access to personal medical information

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Audiotape recordings of consultations improve understanding and increase uptake and recall of information.
Patients' experience, including communication and psychological outcomes	Patient-held records increase sense of control, but mixed results for impact on doctor-patient communication. Recording consultations has no effect on anxiety or quality of life.
Health services utilisation and cost	Some evidence of increased resource use with patient-held records, and that maternity records less likely to be mislaid.
Health behaviour and health status	Little evidence of beneficial effect on health behaviour or health status. Pain intensity reduced with a paediatric pain management sheet. Better adherence to medical advice among patients with heart failure.

5. Patient-centred telecare

While most professional care continues to be delivered in face-to-face encounters, opportunities now exist for remote care and monitoring using telemedicine systems. Telemedicine refers to "the use of telecommunications technology for medical diagnostic, monitoring, and therapeutic purposes when distance separates the users" (Hersh et al 2001b). On this definition, telemedicine can involve remote communications between professionals and the transmission of clinical data within healthcare systems. In this section, however, we are only concerned with home-based telecare interventions intended to empower patients in their own care. Six systematic reviews were found, and two RCTs are also described.

Currell and colleagues (2000) identified five studies of interventions designed to support home care and patient self-management of chronic conditions (Currell et al 2000). Care was delivered to patients remotely using telemedicine technologies and applications. As part of this, patients were required to self-monitor their blood pressure, ECG, blood glucose or heart rate and then transmit the data remotely using telephone or computer modems. The studies did not indicate the telemedicine has a detrimental effect on patient care, but there was also little evidence that it improves patient outcomes. In one study conducted with hypertensive patients, the intervention was associated with a significant improvement in medication adherence in patients who were non-adherent at baseline. Data were insufficient to draw any conclusions about the cost-effectiveness of telemedicine interventions.

Strength of evidence: Cochrane systematic review.

Hersh and colleagues (2001) assessed the impact of telemedicine interventions on clinical outcomes (Hersh et al 2001a). While they identified a large number of telemedicine studies, only 19 of these focused on home-based telemedicine. Eight of the studies evaluated home monitoring of diabetes, and found that this had little or no impact on blood glucose control. The remaining trials showed modest benefits in general chronic disease management and for patients with hypertension and AIDS, including reduced social isolation and increased decision-making confidence. There was little evidence of impact on health services use, although a videophone for paediatric home ventilator patients did significantly reduce the number of unscheduled hospital visits and hospital admission days compared with historical controls.

Strength of evidence: Systematic review – clearly stated research question, efforts made to locate all relevant research and descriptive synthesis appropriate; but exclusion/inclusion criteria not presented and quality assessment incomplete (CRD).

Howells and colleagues (2002) investigated the impact of a negotiated telephone support (NTS) intervention on self-efficacy for self-management in patients with type 1 diabetes (Howells et al 2002). The NTS intervention was developed using the principles of problem solving and social learning. Seventy nine people were randomised either to: i) continued routine management; ii) continued routine management plus NTS; iii) annual clinic attendance with NTS. The outcomes measured were blood glucose levels, self-efficacy, barriers to adherence, problem solving and diabetes knowledge. Participants in the two intervention groups received an average of 16 telephone calls per year, with a mean duration of nine minutes. At one year follow up, the intervention groups were significantly improved in terms of self-efficacy, but there was no difference between the three groups in glycaemic control.

Strength of evidence: Single randomised controlled trial.

Hailey and colleagues (2003) conducted a systematic review of telemedicine, which found 19 studies of telehome care applications (Hailey et al 2003). Telephone-based approaches were most commonly used, with other strategies including telerehabilitation for individuals with spinal cord injury and cardiovascular disorders. Six of the studies involved cardiovascular patients, five diabetes patients and three asthma patients. Home care and monitoring applications provide convincing evidence of benefit, with health outcomes improved in many trials and service use reduced in a small number. Four of the studies included economic analyses, all of which found significant cost savings associated with telemedicine.

Strength of evidence: Systematic review, no independent assessment found.

Jennett and colleagues (2003) assessed the socio-economic impact of telehealth (Jennett et al 2003). They searched for evidence across a range of telehealth applications, and found 63 studies of home-based interventions. These generally involved populations with two or more of the following: chronic heart failure, chronic obstructive pulmonary disease, asthma, diabetes, anxiety and wound care. Socio-economic benefits of home-based telehealth included greater quality of life and patient empowerment, which may result from enhanced feelings of independence and security. There is also evidence for reduced utilisation of services (hospital days and clinic visits). In addition, the studies provide some evidence of cost savings to patients, home care agencies and the healthcare system overall. In patients with diabetes, telehealth can improve the quality of home care, including self-monitoring and self-care, and lead to better blood glucose control. COPD telehealth applications can lead to substantial reductions in hospital readmissions, emergency hospital visits and the overall cost of care. Most economic evaluations have examined the financial outcomes of replacing home care visits with telehealth services. These report similar or reduced costs for telehealth compared to usual care.

Strength of evidence: Systematic review, no independent assessment found.

Louis and colleagues (2003) conducted a systematic review of telemonitoring for the management of heart failure (Louis et al 2003). Telemonitoring was defined as “home monitoring of patients using special telecare devices in conjunction with a telecommunication system.” Eighteen observational studies, and six RCTs, were identified. Patient acceptance of, and compliance with, telemonitoring was high. The observational studies found a significant reduction in hospitalisations and readmission rates. However, many of these studies combined telemonitoring with other strategies (e.g. patient education, automated medication reminders) and it is difficult to determine how much of the impact was due to telemonitoring. Two out of four RCTs which measured hospitalisations and readmission rates reported benefits with telemonitoring. There was also some evidence of improved quality of life and health status. Cost-effectiveness analyses generally produced positive results. For example, one study evaluated the incorporation of video consultations into a routine home health care programme. It found total means costs of $1948 in the intervention group and $2674 in the control group. This difference was mainly account for by a reduction in hospitalisations in the telemonitoring group.

Strength of evidence: Systematic review, no independent assessment found.

Glueckauf and Ketterson (2004) reviewed studies of telehealth interventions for individuals with chronic illness (Glueckauf & Ketterson 2006). Nine studies met the inclusion criteria, including three which evaluated home-based telephone systems (the

other studies involved videoconferencing and internet-based education systems). These systems were used to inquire about patients' health, deliver educational and health promotion messages, provide support, and to transmit results of home self-monitoring activities. In all three studies, there were significant improvements on key health and psychosocial outcomes including glycaemic control and depressive symptomatology. One study evaluated the impact of an automated telephone service for patients with diabetes which focused on self-care. This had a significant positive impact on clinical endpoints (glycaemic control) and psychosocial functioning, anxiety and self-efficacy.

Strength of evidence: Systematic review, no independent assessment found.

Montori and colleagues (2004) conducted a randomised controlled trial to evaluate telecare feedback for diabetic patients with inadequate glycaemic control (Montori et al 2004). All participating patients were asked to monitor their blood glucose four times a day and transmit the data at least every two weeks via a modem. Patients in the intervention group received automatic feedback from a study nurse within 24 hours of transmitting their data. The intervention produced a small, but statistically significant, improvement in glucose control. In addition to the RCT, two reviewers also conducted a meta-analysis of existing data on telecare. The findings from eight studies were analysed, which showed that there is no significant difference in glucose control between telecare and usual care.

Strength of evidence: Single randomised controlled trial.

Summary of known effects of patient-centred telecare

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Not known.
Patients' experience, including communication and psychological outcomes	Some evidence of reduced social isolation and improved self-efficacy, quality of life, patient empowerment and psychological outcomes.
Health services utilisation and cost	Mixed evidence for impact on service use. Some cost savings reported, particularly where 'virtual visits' substituted for routine home healthcare.
Health behaviour and health status	Mixed evidence for impact on diabetic outcomes. Improved depressive symptoms.

Self-care: what looks promising for future R&D?

A great deal of research has been conducted into the effectiveness of interventions for improving self-care, most of which has focused on self-management education programmes. However, there are important limitations in the evidence produced by such research. Most importantly, the majority of trials have tended to measure only short term outcomes, typically conducting assessments at six months or less. Consequently, little is known about whether, and the extent to which, initially observed effects are sustained over a longer time period. The cost-effectiveness of self-care interventions also needs further investigation, as financial considerations have been largely overlooked in existing research and development. Additionally, studies have usually been conducted in specialist research settings, rather than the usual community-based settings where self-care initiatives would be typically delivered. This leaves open the question of whether implementing self-care interventions in routine care is feasible.

The following recommendations address the above gaps in the evidence base, as well as identifying other important areas for future research:

- longer term measurement of outcomes, in order to establish whether and the extent to which intervention effects are sustained beyond the initial follow up period
- comparative research to evaluate the relative clinical and cost-effectiveness of different strategies for improving self-care
- use of research designs enabling the independent measurement of components of complex, multidimensional interventions
- research into the circumstances and groups for which self-care interventions are most beneficial
- further evaluation of the relationship between dimensions of self-care (e.g. self-management behaviours, self-efficacy) and health status outcomes
- expansion of the current focus on a small number of chronic diseases (in particular diabetes, arthritis and asthma) to assess the generalisability of trial findings to the chronic care population in general
- further evaluation of self-care interventions for which evidence is most lacking, including home telecare, patient support groups and self-monitoring
- development and evaluation of integrated models of self-care with stronger emphasis on professional support provided in general practice and other primary care settings.

Notwithstanding the above gaps in the research, there is already considerable evidence to guide the effective development and implementation of self-care strategies for patients with chronic illness. Efforts should be focused on providing opportunities for patients to develop practical skills and the confidence for self-managing their health problems, as this approach has been shown to be of greater effectiveness than the provision of information alone. Hands on, participative leaning styles, rather than traditional didactic methods, are most suitable to this approach. If given the right tools and support, patients can be empowered to set their own self-management goals and devise appropriate strategies for meeting these. However, while the objective is greater patient autonomy and control over their health, the role of heath professionals and other agencies in guiding patients through this process is essential. Many of the studies reviewed above point to the importance of regular contact between patients and those in the supporting role.

References

Anderson, L. et al (2005) 'Self-help books for depression: how can practitioners and patients make the right choice?'. *Br J Gen Pract*, 55 (514): 387-392.

Astin, J.A. et al (2002) 'Psychological interventions for rheumatoid arthritis: a meta-analysis of randomized controlled trials'. *Arthritis Rheum.*, 47 (3): 291-302.

Bandura, A. (1997) *Self-Efficacy: The exercise of control*. New York: W.H. Freeman.

Barlow, J. et al (2002) 'Self-management approaches for people with chronic conditions: a review'. *Patient Educ.Couns*, 48 (2): 177-187.

Bodenheimer, T. et al (2002) 'Patient self-management of chronic disease in primary care'. *JAMA*, 288 (19): 2469-2475.

Bordeleau, L. et al (2003) 'Quality of life in a randomized trial of group psychosocial support in metastatic breast cancer: overall effects of the intervention and an exploration of missing data'. *J Clin Oncol*, 21 (10): 1944-1951.

Boulware, L.E. et al (2001) 'An evidence-based review of patient-centered behavioral interventions for hypertension'. *American Journal of Preventive Medicine*, 21 (3): 221-232.

Bower, P. et al (2001) 'The clinical and cost-effectiveness of self-help treatments for anxiety and depressive disorders in primary care: a systematic review'. *Br J Gen Pract*, 51 (471): 838-845.

Bradley, C. & Blenkinsopp, A. (1996) 'Over the counter drugs. The future for self medication'. *BMJ*, 312 (7034): 835-837.

Brown, H.C. & Smith, H.J. (2004) 'Giving women their own case notes to carry during pregnancy'. *Cochrane.Database.Syst.Rev.*, CD002856 (2).

Campbell, H.S. et al (2004) 'Cancer peer support programs - do they work?'. *Patient Education & Counseling*, 55: 3-15.

Cappuccio, F.P. et al (2004) 'Blood pressure control by home monitoring: meta-analysis of randomised trials'. *BMJ*, 329 (7458): 145.

Chien, W.T. et al (2004) 'A randomized controlled trial of a mutual support group for family caregivers of patients with schizophrenia'. *Int J Nurs Stud.*, 41 (6): 637-649.

Chodosh, J. et al (2005) 'Meta-analysis: chronic disease self-management programs for older adults'. *Ann Intern Med*, 143 (6): 427-438.

Cooper, H. et al (2001) 'Chronic disease patient education: lessons from meta-analyses'. *Patient Educ.Couns.*, 44 (2): 107-117.

Corabian, P. & Harstall, C. (2001) *Patient diabetes education in the management of adult type 2 diabetes. Health Technology Assessment 23.* Alberta: Canada: Alberta Heritage Foundation for Medical Research.

Corben, S. & Rosen, R. (2005) *Self-management for long-term conditions*. London: King's Fund.

Cornbleet, M.A. et al (2002) 'Patient-held records in cancer and palliative care: a randomized, prospective trialt'. *Palliat.Med*, 16 (3): 205-212.

Coster, S. et al (2000) 'Monitoring blood glucose control in diabetes mellitus: a systematic review'. *Health Technology Assessment*, 4 (12).

Crow, R. et al (1999) 'The role of expectancies in the placebo effect and their use in the delivery of health care: a systematic review'. *Health Technology Assessment*, 3.

Currell, R. & Urquhart, C. (2003) 'Nursing record systems: effects on nursing practice and health care outcomes'. *Cochrane.Database.Syst.Rev.*, CD002099 (3).

Currell, R. et al (2000) 'Telemedicine versus face to face patient care: effects on professional practice and health care outcomes'. *Cochrane.Database.Syst.Rev.*, CD002098 (2).

De Ridder, D. & Schreurs, K. (2001) 'Developing interventions for chronically ill patients: is coping a helpful concept?'. *Clin Psychol Rev.*, 21 (2): 205-240.

Deakin, T. et al (2005) 'Group based training for self-management strategies in people with type 2 diabetes mellitus'. *The Cochrane Library*, (1).

Dean, K. (1986) 'Self-care behavior: Implications for aging'. In Dean, K. et al (eds), *Self-Care and Health in Old Age: Health behavior implications for policy and practice*. London: Croon Helm.

Dean, K. & Kickbush, I. (1995) 'Health related behaviour in health promotion: utilizing the concept of self-care'. *Health Promotion International*, 10 (1): 35-40.

Department of Health (2001) *The Expert Patient: a new approach to chronic disease management for the 21st century*. London: Department of Health.

Department of Health (2004) *Improving Chronic Disease Management*. London: Department of Health.

Department of Health (2005a) *Public attitudes to self care: baseline survey*. London: Department of Health.

Department of Health (2005b) *Self Care - A Real Choice*. London: Department of Health.

Department of Health (2005c) *Supporting People with Long Term Conditions. An NHS and Social Care Model to support local innovation and integration*. London: Department of Health.

Department of Health (2006) *Our health, our care, our say: a new direction for community services*. London: Department of Health.

Drury, M. et al (2000) 'Patients with cancer holding their own records: a randomised controlled trial'. *Br J Gen Pract*, 50 (451): 105-110.

Ellins, J. & Coulter, A. (2005) *How engaged are people in their healthcare? Findings of a national telephone survey*. Oxford: Picker Institute.

Ellis, S. et al (2004) 'Diabetes patient education: a meta-analysis and meta-regression'. *Patient Education and Counseling*, 52 (1): 97-105.

Eysenbach, G. et al (2004) 'Health related virtual communities and electronic support groups: systematic review of the effects of online peer to peer interactions'. *BMJ*, 328 (7449): 1166.

Fahey, T. et al (2003) 'Interventions used to improve control of blood pressure in patients with hypertension'. *Cochrane.Database.Syst.Rev.*, CD005182 (1).

Farmer, A. et al (2005) 'A systematic review of telemedicine interventions to support blood glucose self-monitoring in diabetes'. *Diabetic medicine : a journal of the British Diabetic Association*, 22 (10): 1372-1378.

Fitzmaurice, D.A. et al (2002) 'A randomised controlled trial of patient self management of oral anticoagulation treatment compared with primary care management'. *J Clin Pathol.*, 55 (11): 845-849.

Gary, T.L. et al (2003) 'Meta-analysis of randomized educational and behavioral interventions in type 2 diabetes'. *Diabetes Educ*, 29 (3): 488-501.

Gibson, P.G. et al (2003) 'Self-management education and regular practitioner review for adults with asthma'. *Cochrane Database Syst.Rev.*, CD001117 (1).

Gibson, P.G. et al (2002) 'Limited (information only) patient education programs for adults with asthma'. *Cochrane.Database.Syst.Rev.*, CD001005 (2).

Glueckauf, R. & Ketterson, T. (2006) 'Telehealth interventions for individuals with chronic illness: research review and implications for practice'. *Professional Psychology: Research and Practice*, 35 (6): 615-627.

Griffiths, K. & Christensen, H. (2006) 'Review of randomised controlled trials of internet interventions for mental disorders and related conditions'. *Clinical Psychologist*, 10 (1): 16-29.

Hailey, D. et al (2003) *Recent studies on assessment of telemedicine: systematic review of study quality and evidence of benefit*. Alberta, Canada: Institute of Health Economics.

Hampson, S.E. et al (2001) 'Effects of educational and psychosocial interventions for adolescents with diabetes mellitus: a systematic review'. *Health Technology Assessment*, 5 (10): 1-79.

Hannay, D.R. (1979) *The symptom iceberg - a study of community health*. London: Routledge and Kegan Paul.

Health Which? and National Programme for Information Technology (2003) *The public view on electronic health records*. http://www.dh.gov.uk/assetRoot/04/05/50/46/04055046.pdf.

Heneghan, C. et al (2006) 'Self-monitoring of oral anticoagulation: a systematic review and meta-analysis'. *Lancet*, 367 (9508): 404-411.

Hersh, W.R. et al (2001a) 'Clinical outcomes resulting from telemedicine interventions: a systematic review'. *BMC Med Inform Decis.Mak.*, 1 (1): 5.

Hersh, W.R. et al (2001b) 'Telemedicine for the Medicare population'. *Evid.Rep.Technol.Assess.(Summ.)*, 24: 1-6.

Howells, L. et al (2002) 'A randomized control trial of the effect of negotiated telephone support on glycaemic control in young people with Type 1 diabetes'. *Diabet.Med*, 19 (8): 643-648.

Jansen, J.P. (2006) 'Self-monitoring of glucose in type 2 diabetes mellitus: a Bayesian meta-analysis of direct and indirect comparisons'. *Curr Med Res Opin*, 22 (4): 671-681.

Jennett, P.A. et al (2003) 'The socio-economic impact of telehealth: a systematic review'. *J Telemed.Telecare.*, 9 (6): 311-320.

Jones, A. et al (2000) 'Qualitative study of views of health professionals and patients on guided self management plans for asthma'. *British Medical Journal*, 321: 1507-1510.

Kaltenthaler, E. et al (2002) 'A systematic review and economic evaluation of computerised cognitive behaviour therapy for depression and anxiety'. *Health Technol.Assess.*, 6 (22): 1-89.

Kennedy, A. et al (2005) *How has the EPP been delivered and accepted in the NHS during the pilot phase*. Manchester: National Primary Care Research and Development Centre, University of Manchester.

Koh, T.H. et al (2005) 'Audio recordings of consultations with doctors for parents of critically sick babies'. *Cochrane Database Syst Rev*, (1): CD004502.

Lancaster, T. & Stead, L.F. (2002) 'Self-help interventions for smoking cessation'. *Cochrane database of systematic reviews (Online)*, (3): CD001118.

Lecouturier, J. et al (2002) 'Evaluation of a patient-held record for patients with cancer'. *Eur J Cancer Care (Engl)*, 11 (2): 114-121.

Lester, H. et al (2003) 'A cluster randomised controlled trial of patient-held medical records for people with schizophrenia receiving shared care'. *Br J Gen Pract*, 53 (488): 197-203.

Liddell, C. et al (2004) 'Giving patients an audiotape of their GP consultation: a randomised controlled trial'. *Br J Gen Pract*, 54 (506): 667-672.

Lorig, K.R. et al (1999a) 'Evidence suggesting that a chronic disease self-management program can improve health status while reducing utilization and costs: a randomized trial'. *Medical Care*, 37 (1): 5-14.

Lorig, K.R. et al (1999b) *The chronic disease self-management workshop leader's manual*. Palo Alto: California: Stanford Patient Education Research Center.

Lorig, K.R. & Holman, H. (2003) 'Self-management education: history, definition, outcomes, and mechanisms'. *Ann Behav.Med*, 26 (1): 1-7.

Lorig, K.R. et al (2004) 'Long-term randomized controlled trials of tailored-print and small- group arthritis self-management interventions'. *Medical Care*, 42 (4): 346-354.

Lorig, K.R. et al (2001) 'Effect of a self-management program on patients with chronic disease'. *Effective Clinical Practice*, 4: 256-262.

Louis, A.A. et al (2003) 'A systematic review of telemonitoring for the management of heart failure'. *Eur J Heart Fail.*, 5 (5): 583-590.

Loveman, E. et al (2003) 'The clinical and cost-effectiveness of patient education models for diabetes: a systematic review and economic evaluation'. *Health Technology Assessment*, 7 (22).

Mataix, D. & Marks, I. (2006) 'Self-help with minimal therapist contact for obsessive-compulsive disorder: a review'. *European Psychiatry*, 21 (2): 75-80.

McManus, R.J. et al (2005) 'Targets and self monitoring in hypertension: randomised controlled trial and cost effectiveness analysis'. *BMJ*, 331 (7515): 493.

Monninkhof, E.M. et al (2003) 'Self-management education for chronic obstructive pulmonary disease'. *Cochrane.Database.Syst.Rev.*, CD002990 (1).

Montgomery, P. et al (2006) 'Media-based behavioural treatments for behavioural problems in children'. *Cochrane Database Syst Rev*, (1): CD002206.

Montori, V.M. et al (2004) 'Telecare for patients with type 1 diabetes and inadequate glycemic control: a randomized controlled trial and meta-analysis'. *Diabetes Care*, 27 (5): 1088-1094.

Morrison, A. (2001) 'Effectiveness of printed patient educational materials in chronic illness: a systematic review of controlled trials'. *Journal of Managed Pharmaceutical Care*, 1 (1): 51-62.

Murray, E. et al (2005) 'Interactive Health Communication Applications for people with chronic disease'. *Cochrane.Database.Syst.Rev.*, CD004274 (4).

Murray, E. et al (2004) 'Training for patients in a randomised controlled trial of self management of warfarin treatment'. *BMJ*, 328 (7437): 437-438.

Newman, S. et al (2001) 'What is meant by self-management and how can its efficacy be established?'. *Rheumatology (Oxford)*, 40 (1): 1-4.

Newman, S. et al (2004) 'Self-management interventions for chronic illness'. *Lancet*, 364 (9444): 1523-1537.

NICE (2003) *Guidance on the use of patient-education models for diabetes. Technology Appraisal Guidance 60*. London: National Institute for Clinical Excellence.

Niedermann, K. et al (2004) 'Gap between short- and long-term effects of patient education in rheumatoid arthritis patients: a systematic review'. *Arthritis Rheum.*, 51 (3): 388-398.

Norris, S.L. et al (2001) 'Effectiveness of self management training in type 2 diabetes: a systematic review of randomized controlled trials'. *Diabetes Care*, 24 (3): 561-587.

Norris, S.L. et al (2002a) 'Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control'. *Diabetes Care*, 25 (7): 1159-1171.

Norris, S.L. et al (2002b) 'Increasing diabetes self-management education in community settings. A systematic review'. *Am J Prev.Med*, 22 (4 Suppl): 39-66.

Powell, H. & Gibson, P.G. (2002) 'Options for self-management education for adults with asthma'. *Cochrane.Database.Syst.Rev.*, (1): CD004107.

Rehse, B. & Pukrop, R. (2003) 'Effects of psychosocial interventions on quality of life in adult cancer patients: meta analysis of 37 published controlled outcome studies'. *Patient Educ.Couns.*, 50 (2): 179-186.

Riemsma, R.P. et al (2003) 'Patient education for adults with rheumatoid arthritis'. *Cochrane.Database.Syst.Rev.*, CD003688 (2).

Ritchie, J. et al (2000) 'Parents' perceptions of the impact of a telephone support group intervention'. *Journal of Family Nursing*, 6 (1): 25-45.

Ross, S.E. et al (2004) 'Providing a web-based online medical record with electronic communication capabilities to patients with congestive heart failure: randomized trial'. *J Med Internet Res.*, 6 (2): e12.

Sarkisian, C.A. et al (2003) 'A systematic review of diabetes self-care interventions for older, African American, or Latino adults'. *Diabetes Educ*, 29 (3): 467-479.

Savelkoul, M. et al (2003) 'Stimulating active coping in patients with rheumatic diseases: a systematic review of controlled group intervention studies'. *Patient Educ Couns*, 50 (2): 133-143.

Schwartz, C.E. (1999) 'Teaching coping skills enhances quality of life more than peer support: results of a randomized trial with multiple sclerosis patients'. *Health Psychol.*, 18 (3): 211-220.

Scott, J.T. et al (2003) 'Recordings or summaries of consultations for people with cancer'. *Cochrane.Database.Syst.Rev.*, CD001539 (2).

Secretary of State for Health (2000) *The NHS Plan: a plan for investment, a plan for reform*. London: Stationery Office.

Siebenhofer, A. et al (2004) 'Systematic review of studies of self-management of oral anticoagulation'. *Thrombosis and Haemostasis*, 91 (2): 225-232.

Steed, L. et al (2003) 'A systematic review of psychosocial outcomes following education, self-management and psychological interventions in diabetes mellitus'. *Patient Educ Couns*, 51 (1): 5-15.

Stefano, S.C. et al (2006) 'Self-help treatments for disorders of recurrent binge eating: a systematic review'. *Acta Psychiatrica Scandinavica*, 113 (6): 452-459.

Thompson, R.L. et al (2003) 'Dietary advice given by a dietitian versus other health professional or self-help resources to reduce blood cholesterol'. *Cochrane.Database.Syst.Rev.*, (3): CD001366.

Toelle, B.G. & Ram, F.S. (2003) 'Written individualised management plans for asthma in children and adults'. *Cochrane.Database.Syst.Rev.*, (2): CD002171.

Turnock, A.C. et al (2005) 'Action plans for chronic obstructive pulmonary disease'. *Cochrane database of systematic reviews (Online)*, (4): CD005074.

Valk, G.D. et al (2002) 'Patient education for preventing diabetic foot ulceration. A systematic review'. *Endocrinol.Metab Clin North Am*, 31 (3): 633-658.

van Boeijen, C.A. et al (2005) 'Efficacy of self-help manuals for anxiety disorders in primary care: a systematic review'. *Fam.Pract*, 22 (2): 192-196.

van Dam, H.A. et al (2005) 'Social support in diabetes: a systematic review of controlled intervention studies'. *Patient Educ.Couns.*, 59 (1): 1-12.

Vickery, D.M. et al (1983) 'Effect of a self-care education program on medical visits'. *Journal of the American Medical Association*, 250 (21): 2952-2956.

Von Korff, M. et al (2002) 'Organising care for chronic illness'. *BMJ*, 325 (7355): 92-94.

Warner, J.P. et al (2000) 'Patient-held shared care records for individuals with mental illness. Randomised controlled evaluation'. *Br J Psychiatry*, 177: 319-324.

Warsi, A. et al (2003) 'Arthritis self-management education programs: a meta-analysis of the effect on pain and disability'. *Arthritis and Rheumatism*, 48 (8): 2207-2213.

Warsi, A. et al (2004) 'Self-management education programs in chronic disease'. *Archives of Internal Medicine*, 164: 1641-1649.

Welschen, L.M. et al (2005) 'Self-monitoring of blood glucose in patients with type 2 diabetes who are not using insulin'. *Cochrane.Database.Syst.Rev.*, (2): CD005060.

Williams, J.G. et al (2001) 'Pragmatic randomised trial to evaluate the use of patient held records for the continuing care of patients with cancer'. *Qual Health Care*, 10 (3): 159-165.

Wolf, F.M. et al (2003) 'Educational interventions for asthma in children'. *Cochrane.Database.Syst.Rev.*, CD000326 (1).

4. Improving patient safety

Patient safety: summary of findings

- The role patients can play in improving the safety of their care has been recognised only recently, and research into this issue is still in its early stages.

- Patients want greater openness and honesty from healthcare professionals, including full disclosure of medical errors and adverse events that have affected them.

- The extent to which patients can contribute to safety improvement will depend on various factors including demographic characteristics, perceived vulnerability to harm and confidence in challenging health professionals. Patient-focused safety initiatives must not be seen as a substitute for efforts targeted at changing professional behaviour or addressing systemic problems, but rather work alongside them.

- Throughout the process of care, patients have the potential to ensure the safety of their care and prevent the occurrence of errors. This includes:
    - making informed choices about providers
    - helping to reach an accurate diagnosis
    - sharing decisions about treatments and procedures
    - contributing to safe medication use
    - participating in infection control initiatives
    - checking the accuracy of medical records
    - observing and checking care processes
    - identifying and reporting treatment complications and adverse events
    - practising effective self-management, including treatment monitoring
    - shaping the design and improvement of services.

- Successful partnerships with patients to reduce errors and improve safety can only occur in environments where patient involvement is valued and supported. Issues of health literacy must also be tackled before information about safety and risk can be effectively communicated to patients and acted upon by them.

- Patient involvement in hospital infection campaigns has been shown to have positive effects. Encouragement to patients to ask health workers if they have washed their hands, in combination with the increased provision of handwashing facilities, leads to significant improvements in hand hygiene compliance.

- Various strategies for improving patient adherence to treatment have been evaluated. Of these, the most effective involve simplifying dosing regimens. Other interventions – such as patient education, information and counselling – have produced less conclusive and robust results. Educational interventions and information provision are unlikely to be effective on their own. There is a lack of data on the longer term impact of patient adherence interventions.

- Few studies of other patient-focused patient safety strategies have been conducted. There is mixed evidence for the role of patient safety information in adverse event prevention, and the impact of direct patient reporting to adverse event monitoring systems is unknown. There is evidence that patients do not always comply with requests to mark the correct surgical site.

- Much can be done – both in research and practice – to improve patient involvement in patient safety. Particular attention should be paid to improving means of communicating with and listening to patients on matters of safety, and enhancing the availability and quality of safety information for patients and the public.

Patient safety: introduction

The public inquiry into failures in the performance of surgeons involved in heart surgery on children at the Bristol Royal Infirmary between 1984 and 1995 made 198 recommendations on how to prevent failures in the future. Central to the recommendations was a belief that enhancing the patient's or parent's role might help to prevent the occurrence of errors and ameliorate the adverse effects of unintended harm (Secretary of State for Health 2001). The report urged doctors to:

- involve patients (or their parents/carers) in decisions
- keep patients (or carers) informed
- improve communication with patients (or carers)
- provide patients (or carers) with counselling and support
- gain informed consent for all procedures and processes
- elicit feedback from patients (or carers) and listen to their views
- be open and candid when adverse events occur.

This chapter looks at the potential for enhancing the patient's role in patient safety, at what is being done currently and with what effect, and considers possible future developments. First, however, we describe the nature of the problem and relevant definitions and concepts.

Central to the field of patient safety are several concepts with multiple definitions and often interrelated meanings. Patient safety itself is usually defined in a negative sense, as the absence of error or injury. For example, the influential Institute of Medicine (IOM) report *To Err is Human* defined patient safety as *"the freedom from accidental injury due to medical care or from medical errors"* (Institute of Medicine 2000). The definition offered by the National Patient Safety Agency is more positive in tone, and also emphasises the procedural dimensions of safety improvement. It describes patient safety as:

> *"the process by which an organisation makes patient care safer. This should involve: risk assessment; the identification and management of patient-related risks; the reporting and analysis of incidents; and the capacity to learn from and follow-up on incidents and implement solutions to minimise the risk of them recurring"* (National Patient Safety Agency 2003).

Both of the above definitions specifically focus on safety and error within the context of healthcare organisations. While such organisations may be of particular significance, safety considerations also arise in other settings such as nursing homes, ambulatory care and patient self-management (Shojania et al 2001).

Closely related to the concept of patient safety, and to an extent integrated into it, is that of *medical error*. As with patient safety, a commonly used definition is that provided by the IOM: *"An error is the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning)"* (Institute of Medicine 2004b). Importantly, the IOM states that error can occur either through taking inappropriate action (errors of commission) or through failure to act (errors of omission). It has been suggested that medical error should be distinguished from negligence or malpractice, insofar as the first is accidental while the latter are deliberate violations of a rule or standard of behaviour (Fallowfield & Fleissig 2003). Medical errors cannot be reliably defined or identified by their outcome, as they do not in all cases lead to observable injury to the patient (Leape 1994). The term 'near miss' is used to describe situations that did not cause harm to patients, but could have done.

Conversely, incidents in which the person receiving healthcare was harmed are referred to as 'adverse events' (Wilson et al 1996). Leape and colleagues identified a range of

factors that contribute to adverse patient events, categorising them as diagnostic, treatment, preventive and other (Leape et al 1993) (see box).

Types of medical error (Leape et al 1993)

Diagnostic
- Error or delay in diagnosis
- Failure to employ indicated tests
- Use of outmoded tests or therapy
- Failure to act on results of monitoring or testing

Treatment
- Error in the performance of an operation, procedure or test
- Error in the administering of a treatment
- Error in the dose or method of using a drug
- Avoidable delay in treatment or in responding to an abnormal test
- Inappropriate (not indicated) care

Preventive
- Failure to provide prophylactic treatment
- Inadequate monitoring or follow up of treatment

Other
- Failure of communication
- Equipment failure
- Other system failure

Also central to debates about patient safety are the concepts of clinical risk and clinical governance. These concepts draw attention to the wider context of patient safety, specifically to the factors that increase the likelihood that patients will be unintentionally harmed by their healthcare. Risks are both inherent in healthcare – all medicines, for example, can cause unwanted and harmful side effects – and can arise due to the actions of people, system faults and budgetary pressures, and interactions between these (BMA 2002). Within the broad framework of clinical governance, systems and procedures for the identification, management and reduction of clinical risks are a major element. Therefore clinical governance, and risk management in particular, are important vehicles for promoting patient safety.

Patient safety: what is the frequency and nature of adverse patient events?

Reviewing data on the incidence and impact of medical errors, the IOM declared that the American medical system itself is a leading cause of death and injury (Institute of Medicine 2000). American research has reported that between 2.9% and 5.4% of patients admitted to hospital suffer an adverse event. In the majority of cases – 53% in a study in Utah and Colorado – the adverse events were deemed to have been preventable (Thomas et al 1999). In the US it has been estimated that at least 44,000 deaths annually, and possibly as many as 98,000, are the result of medical errors.

UK figures show that around 10% of inpatients suffer an adverse event; when extrapolated to the general population, this suggests that there are 850,000 cases of medical injury to NHS inpatients each year (Department of Health 2000). According to the Department of Health, the direct costs of such adverse events are likely to be in excess of £2 billion; expenditure on medical negligence claims is approximately a further £400 million annually. Around half of all patient safety incidents occurring in NHS hospitals are thought to be preventable (National Audit Office 2005). By contrast with the acute sector, little is known about error and safety in primary care and other non-acute settings. A recent review of evidence on this topic found wide variations in reported rates of medical errors: anywhere between five and 80 per 100,000 consultations (Sandars & Esmail 2003). However, these figures are likely to underestimate the actual extent of error as they are based on voluntary reporting methods, which are known to identify only a fraction of cases.

Among inpatients, approximately half of all adverse events are associated with surgical procedures (Weingart et al 2000). Beyond the hospital setting, many common errors are related to the administration and use of medicines. Not all adverse drug events (ADEs) occur as the result of medical error; even used properly, medicines are capable of producing harmful side effects. Nonetheless, the risks of medicine use are increased by misprescribing, administration of the wrong drug or dose, overlooked allergies and drug interactions, insufficient monitoring and inadequate communication of essential information to patients. A US study in two tertiary care hospitals reported rates of actual and potential ADEs of 6.5% and 5.5% respectively (Bates et al 1995). Twenty eight per cent of all ADEs, and 42% of serious and life threatening ADEs, were judged to have been preventable.

Adverse drug events can also occur, and be perpetuated, as a result of patients' non-compliance with medication recommendations (Barber 2002). Indeed, there are many ways in which patients can actively – although not always consciously – contribute to error and harm. Intrinsic patient factors, including age and language abilities and lifestyle habits such as smoking and alcohol consumption, can act as risk factors for adverse events. Patients' attitudes to treatment, their manner of interacting and communicating with staff, and responsibility for their own care are also influential. With the shift towards patients taking a more active role in the care process, strategies for preventing errors and improving safety will increasingly need to focus on the role to be played by patients themselves.

An explanatory framework developed by Vincent and colleagues (Vincent et al 1998) recognises patient characteristics as one of the seven major causes of adverse events (see box). However, the framework's originators point out that such 'human' factors (which would also include the actions of individual doctors) are frequently overemphasised in the reporting of adverse events, to the neglect of systemic sources of error. In complex and dynamic healthcare environments, adverse events are generally the result of chains of events in which human error plays only a part. The approach taken by Vincent and colleagues – and replicated in other leading contributions to the patient

safety field (e.g. Department of Health 2000, Institute of Medicine 2000) – highlights how *latent failures* within healthcare systems create circumstances in which individuals are more prone to error. These failures, which principally arise through managerial decisions and actions, become embedded in the structure and function of the healthcare system; they may include inadequate equipment, stressful environments and heavy workloads. This systems-oriented approach points to the dual importance of tackling individual human error and the diffuse conditions which give rise to lapses in standards of care and patient safety.

Factors influencing clinical practice and contributing to adverse events (Coulter 2002a, Vincent et al 1998)

Framework	Contributory Factors	Examples of Problems that Contribute to Errors
Institutional	• Regulatory context • Medicolegal environment	Insufficient priority given by regulators to safety issues; legal pressures against open disclosure, preventing the opportunity to learn from adverse events
Organisational and management	• Financial resources and constraints • Policy standards and goals Safety culture and priorities	Lack of awareness of safety issues on the part of senior management; policies leading to inadequate staffing levels
Work environment	• Staffing level and mix of skills • Patterns in workload and shift • Design, availability and maintenance of equipment • Administrative and managerial support	Heavy workloads, leading to fatigue; limited access to essential equipment; inadequate administrative support, leading to reduced time with patients
Team	• Verbal communication • Written communication • Supervision and willingness to seek help • Team leadership	Poor supervision of junior staff; poor communication among different professions; unwillingness of junior staff to seek assistance
Individual staff member	• Knowledge and skills • Motivation and attitude • Physical and mental health	Lack of knowledge or experience; long term fatigue and stress
Task	• Availability and use of protocols • Availability and accuracy of test results	Unavailability of test results or delay in obtaining them; lack of clear protocols and guidelines
Patient	• Complexity and seriousness of condition • Language and communication • Personality and social factors	Distress; language barriers between patients and caregivers

Patient safety: what do patients and the public want?

If patients are to play a role in ensuring the delivery of safer healthcare, safety improvement programmes should be informed by and take account of patients' preferences, values and expressed needs. Surveys reveal that patients want more openness about and disclosure of medical errors (Hobgood et al 2002, Witman et al 1996). A survey conducted by the Department of Health found that, of patients who had been affected by medical injury (Chief Medical Officer 2003):

- 34% wanted an apology or explanation
- 23% wanted an enquiry into the causes
- 17% wanted support in coping with the consequences
- 11% wanted financial compensation
- 6% wanted disciplinary action.

When medical errors occur, patients seek not only to be told about the incident but also to receive information on what happened, why it happened, how its consequences can be mitigated and how recurrences can be prevented. Honest disclosure of such information has been found to increase patient satisfaction and trust, and reduce the likelihood of legal action being commenced (Mazor et al 2004).

There is, however, a disparity between patients' preferences for receiving notification and information about medical errors and current disclosure practices. A recent US survey reported that, of patients who had experienced a medical error, 70% were not informed of the mistake by the health professional involved (Kaiser Family Foundation & AHRQ 2004). In a study of attitudes to disclosure, 92% of patients felt that they should be informed of adverse events, compared to only 60% of doctors (Hingorani et al 1999). Another study highlighted the gap between doctors' beliefs about disclosure of medical errors and what they actually do; 32% of doctors surveyed said they would give the patient full details of a medical error, but 70% felt that they *ought* to do so (Vincent 1998).

Certainly patients are keen to know about errors that affect them, but do they also want to be involved in safety improvement efforts? Little is known about the specific role that patients and the public envisage for themselves in preventing errors and promoting safety. However, the desire of some patients for greater involvement in their healthcare, including participation in decisions about treatment, is well documented (e.g. Coulter & Magee 2003). Organisations of patients and consumers working to improve patient safety have been established, most notably the US-based Consumers Advancing Patient Safety. Additionally, NHS patient surveys show that patients want more information on safety-related topics such as medicine side effects and understanding test results.

Patients' willingness and ability to become involved in patient safety is likely to depend on demographic characteristics, such as age and ethnicity, as well as issues around perceived vulnerability to harm and confidence in challenging professionals (Koutantji et al 2005). It will also be influenced by the nature and complexity of the patients' condition and its treatment, and the level of technical knowledge required to understand these.

Patient safety: what can patients do to ensure safe care?

The patient safety movement has historically overlooked the role of the patient (Vincent & Coulter 2002), and disregarded the various ways in which patients already contribute to the safe delivery of their care. By understanding patients in a passive sense, as the victims of errors and safety failures, the many ways in which they can actively partner with healthcare providers to make care safer have been neglected. If patients are to meaningfully contribute to this domain, it will be essential to recognise and address the barriers to this. For example, enabling and supporting patients in patient safety may place additional burdens on staff and healthcare resources. This, along with the fear of an increased risk of litigation, may discourage healthcare professionals from working towards greater patient involvement (Vincent & Coulter 2002, Wilson & Smith 2001).

Once it is recognised that patients have an essential role in promoting safety, various opportunities for their involvement in improvement initiatives can be identified. Throughout the process of care, patients have the potential to make valuable and important contributions, including:

- making informed choices about providers
- helping to reach an accurate diagnosis
- sharing decisions about treatments and procedures
- contributing to safe medication use
- participating in infection control initiatives
- checking the accuracy of medical records
- observing and checking care processes
- identifying and reporting treatment complications and adverse events
- practising effective self-management (including treatment monitoring)
- shaping the design and improvement of services.

Each of the above roles patients might play in ensuring the safety of their care is outlined in detail below. For a small number of these areas, specific interventions to facilitate or encourage patient involvement have been developed and evaluated. Studies reporting on the effectiveness of these interventions are described in the later ‘What Works?’ section.

Making informed choices about providers

During many recent high-profile medical scandals, such as that at the Bristol Royal Infirmary, it has emerged that individual clinicians and/or professional bodies have been aware of lapses in patient safety long before action was taken to investigate and address them. Had the patients involved known about potential dangers to their safety, they would probably have chosen to go to a different provider. Patients can make safer choices about their care when comparative information on the safety of organisations and services is produced for their use (Vincent & Coulter 2002). Such information is already available in the US, including The Leapfrog Group’s online database containing quality and safety ratings for hospitals across the country (www.leapfroggroup.org). The advice given to American healthcare consumers is to choose hospitals and doctors that perform high numbers of the procedure concerned, as these generally have better outcomes for their patients. Similar efforts are now underway in England, where the Department of Health is preparing information to inform patients’ choices as part of the Choose and Book scheme (Department of Health 2004).

Helping to reach an accurate diagnosis

The information that patients can provide to doctors – about their symptoms, concerns, and medical and treatment history – is important in establishing early and accurate diagnosis. As with all types of medical error, poor communication and the misunderstandings that can arise from this are a major cause of error in diagnosis.

Failure to listen to what the patient is saying about their symptoms, or dismissing their concerns too hastily can lead to misdiagnosis. A patient-centred consulting style increases the likelihood that important information will be shared. For most patients this means a sympathetic doctor, who listens and encourages them to discuss their problems (Britten et al 2000). However, research has shown that consultations are not always consistent with patients' preferences. Respondents to the national patient surveys in England have reported problems in this regard: in 2004, 26% of emergency patients said staff did not always listen carefully to what they were saying; 32% of outpatients said they had not received a clear explanation of treatment risks; and 32% of inpatients and 47% of primary care patients said they would have liked more involvement in decisions about their care (Picker Institute Europe 2005). Barriers to effective communication relate not only to doctors' and patients' interpersonal skills and their attitudes towards the value of communication. Organisational constraints, above all the restricted time available for consultations, also hamper the full and open exchange of information between doctors and their patients (BMA 2004).

Sharing decisions about treatments and procedures

As discussed in Chapter 2, when deciding on the best way to treat or manage a condition the aim is to maximise the likelihood of desired health outcomes and minimise the chance of undesired consequences. When there is more than one possible course of action, it is important that the patient is informed about the potential benefits and harms of each option and that their values and preferences guide the decision. They cannot be said to have given their informed consent if they have not been fully informed about the risks and involved in the decision. Failure to involve patients in this way can lead to unrealistic demands, over-treatment (with consequent increased risks), and ultimately to disillusion. If patients are encouraged to believe there is an effective pill for every ill, or that surgery is risk free, it is no wonder that they sometimes find the reality disappointing (Coulter 2002b).

Contributing to safe medication use

Medication errors are a leading cause of adverse events in healthcare. In the US it is estimated that medication errors account for nearly 20% of all incidents that endanger patient safety, and are responsible for 7,000 deaths each year and thousands more patients injuries (Institute of Medicine 2000). Implementing strategies to reduce the occurrence of preventable medication errors is, therefore, a major element of patient safety initiatives. In the hospital environment, patients can contribute to such strategies if they are kept informed about medication management, and are encouraged to speak up if they notice changes in the way they are given or respond to their medicines (Koutantji et al 2005). The growing emphasis on managing illness in community settings, and on patient self-management of chronic conditions, means that patients often have a central role in the administration of medicines. Patients' medication knowledge and adherence can be enhanced through the provision of information about the appropriate use, purpose and effects (including side effects) of their medicines (Lowe et al 1995). Greater access to, and more patient-friendly, medicines information is imperative. A patient led review of the mandatory patient information leaflets accompanying prescription medicines found that they excessively used technical and medical jargon; were poorly written and designed; and contained too much – and sometimes contradictory – information (Consumers Association 2000). In view of this, it was suggested that patients should be involved in the development and review of medicines information for their use.

Participating in infection control initiatives

Infections acquired in hospitals and other healthcare settings are a major patient safety problem. In addition to causing substantial morbidity and mortality, they also prolong hospitalisations, increase resource utilisation and drive up costs. It is estimated that, at

any one time, approximately one in eleven patients in English hospitals will contract an infection during their stay (National Audit Office 2000). A common source of transmission is direct contact with an infected patient or member of healthcare staff. Although not all hospital acquired infection is preventable, research indicates that up to 50% of cases can be avoided through improved hand hygiene practices among healthcare workers. Patients can encourage compliance with hand hygiene by asking staff who are treating them if they have washed their hands beforehand. In a recent survey of patients, conducted by the National Patient Safety Agency (NPSA), 71% thought that patients should be involved in helping staff improve hand hygiene (National Patient Safety Agency 2004). Whether patients will feel confident and comfortable directly challenging staff over this sensitive issue in real life situations is questionable, and the same NPSA survey reported that only 26% of patients would be willing to raise concerns in practice. Fear of consequences, and of being perceived as a nuisance by busy staff, were suggested by patients as factors that may discourage them from asking about hand hygiene. This points to the importance of utilising techniques that reassure patients about the acceptability and importance of speaking up.

Checking the accuracy of medical records

Until recently medical records were seen as the property of the clinician, rather than the patient. Few patients saw their notes and those that asked to do so were often actively discouraged or reprimanded. Attitudes are slowly changing, but patient-held records are still a rarity. Studies examining the effects of giving patients access to their records have generally produced positive results (Drury et al 2000, Elbourne et al 1987, Jones et al 1999). Holding their records and reading them can increase patients' knowledge of their health state and their sense of shared responsibility for their own healthcare. It can also help to increase the accuracy of the records. One British general practice discovered errors in more than 30% of medical records when patients were encouraged to review their notes (Pyper et al 2001). Accurate records are a pre-requisite for safe care.

Observing and checking care processes

Patients can be asked to check the details of their treatment as a safety measure. It is common for staff to ask patients their name and address to reduce the risk of administering a treatment to the wrong person. Unfortunately, the reason for this information check is not always clearly explained to the patient, who is sometimes left feeling confused about why they are repeatedly asked to provide the same information. The reasons for this procedure should be explained. Recognising this, one US organisation has produced a booklet for patients describing when and why staff will check information with them to ensure they are given the correct surgery (VA National Center for Patient Safety 2006). Patients can also be asked to confirm the surgical site (e.g. left leg or right leg?). They, or their carers, can be encouraged to speak up if they notice changes in medication type or dose, or if they suspect that equipment is malfunctioning, although challenging staff could prove quite daunting for many patients. Patients who are well-informed about clinical standards and guidelines and feel sufficiently empowered can draw attention to any lapses when they occur, for example, when bedbound patients are not turned frequently enough to avoid pressure sores, or if diabetic patients' blood glucose levels are not regularly monitored. In theory, patients who know what to expect during a treatment episode can play a key role in coordinating their care and ensuring that staff perform to high quality standards. In practice, such a strategy is unlikely to succeed unless it is actively encouraged by staff.

Identifying and reporting treatment complications and adverse events

One of the key principles of patient safety is that, while it is not always possible to prevent adverse healthcare events, much can be learned from reporting and analysing their occurrence. An understanding of the incidence, nature and causes of medical errors

leading to adverse events is essential to their prevention (Department of Health 2000). Various incident reporting systems have been established, including a number of national programmes for the reporting of adverse drug reactions such as the UK Medicine and Healthcare Products Regulatory Agency's (MHRA) Yellow Card Scheme. The usefulness of such systems is weakened by the generally low levels of reporting to them. This problem could be improved if patients themselves were able to directly submit reports.

There is evidence that patients report suspected adverse events far earlier than health professionals, which suggests that patient involvement may also reduce the time taken to identify and respond to safety problems (Egberts et al 1996). It has also been suggested that patients are more likely to report potentially embarrassing or distressing side effects to an anonymous scheme than directly to a health professional (van Grootheest et al 2003). Systems for patient reporting of adverse drug reactions operate in both Sweden and the USA, and the MHRA is currently piloting a patient equivalent of the Yellow Card scheme. Additionally, patients (and family members) can more immediately contribute to their own safety by alerting health professionals to suspected adverse events or to deterioration in their condition. Prompt response from health professionals to such patient observations can help to minimise the occurrence of harm.

Practising effective self-management (including treatment monitoring)

The role that patents play in the delivery of their healthcare is both significant and – with the trend towards greater intermediate, home and self-care – on the increase. The quality and outcomes of care can be enhanced by motivating, equipping and supporting patients in self-management. In the case of chronic illness, effective self-management is not only desirable but essential. There is evidence that patients can contribute to the safe delivery of care through their own active and informed involvement. Patient self-monitoring of anticoagulation therapy, for example, is associated with a reduction in the incidence of complications and adverse treatment outcomes (Douketis 2001). Complications and adverse events after discharge from hospital can be avoided if time is taken to explain to patients how they can monitor their progress and response to treatments, and when they can resume their normal activities. Discharge planning should begin at the earliest possible opportunity and be based on the individual's specific needs and circumstances. Providers need to anticipate any problems that might occur following discharge and educate patients about appropriate courses of action. Safe discharge can also be encouraged by supervising patients in self-administration of medicines or the use of medical devices during their hospital stay.

Shaping the design and improvement of services

The concept of latent failures – described above – captures how safety problems can be embedded within the structure of healthcare organisations. A recent report by the Department of Health and Design Council emphasised the significance of design to improving patient safety (Department of Health & Design Council 2003). If potential sources of error are not anticipated and addressed during the development and implementation of services, as has often been the case, patient safety problems are effectively 'designed into' the system. The alternative is to place safety considerations at the centre of service design, which involves (Nolan 2000):

- designing the system to prevent errors
- designing procedures to make errors visible when they do occur so that they may be intercepted
- designing procedures for mitigating the adverse effects of errors when they are not intercepted.

Such an approach, as the Department of Health/Design Council report highlighted, must be informed by a thorough understanding of the views and experiences of all those who interact with and use healthcare facilities. This can help to achieve a better

understanding of the complex environments in which care is delivered and errors occur, as well as ensure that solutions are responsive to and guided by the needs of the different groups involved.

Across the spectrum of patient care there are opportunities for patients to take a role in improving safety and minimising risk and error. The drive for greater patient involvement must work alongside and complement, rather than act as a substitute for, efforts targeted towards the actions of healthcare professionals and system-level risks and vulnerabilities. Patients can be encouraged to raise concerns about safety issues, draw attention to risks and adverse events, provide diagnostic information and share decisions about appropriate treatments. However, genuine forms of patient involvement will only be achieved within a safety culture that appreciates the value of patient contributions, and is supportive of these. A culture of this kind will be developed by promoting the principles of openness and honesty, and by enhancing trust and communication between doctors and patients. As part of this, improvements must be made in the way that health professionals share important safety-related information with their patients. This includes not only committing to full disclosure of medical errors and adverse events, but also finding effective methods for discussing complex and technical issues such as risk and outcome probabilities.

As well as constructing an environment supportive of patient involvement, the problem of low health literacy also needs to be prioritised. As we outlined in Chapter 1, people with low health literacy face difficulties in understanding and using basic health information. Where such information pertains to safety issues, such as in the informed consent procedure, a lack of patient comprehension can potentially increase the risk of medical error. On the issue of informed consent, several studies have shown that consent forms require a reading level which is above that of the average patient (e.g. Hopper et al 1998). Though patients may formally give ‘informed consent’ by signing the form, if they do not fully understand the risks and benefits of the procedure they have agreed to their consent is not truly informed. Many potential threats to patient safety may have their origins in miscommunication arising from low health literacy, including (Institute of Medicine 2004a):

- failure to get accurate medical histories
- poor health knowledge and understanding of health conditions
- poor treatment adherence
- medication errors
- lower utilisation of preventive and other healthcare services
- poor patient satisfaction.

Health literacy considerations should be paramount in the production and dissemination of safety-related information, education materials and documentation.

Patient safety: what strategies have been tried and by whom?

Patient safety is increasingly being recognised as one of the most important issues in healthcare delivery around the world. Various factors have drawn attention to this issue, in particular the publication in 2000 of the influential IOM report *To Err is Human*, and a series of highly publicised incidents of medical error and unsafe practice. The IOM's report documented the extent and financial burden of medical errors in the US, before outlining a four tiered strategy for reducing errors and improving safety (see box).

To Err is Human: Recommendations

- Establish a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety.
- Identify and learn from errors through immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be made safer for patients.
- Raise standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups.
- Create safety systems inside health care organizations through the implementation of safe practices at the delivery level. This level is the ultimate target of all the recommendations.

A number of campaigns have been launched in the US to promote the active and informed involvement of patients in patient safety. Generally, these campaigns encourage patients to 'speak up' by giving voice to their concerns and asking for clarification where they are uncertain, as well as sharing information that may be important to their care (such as allergies and current medications). A prominent example is the Joint Commission on Accreditation of Healthcare Organizations' 'Speak Up for Patient Safety' campaign, launched in the US in 2002. The campaign urges patients to:

- speak up if you have questions or concerns
- pay attention to the care you are receiving
- educate yourself about your diagnosis, tests and treatment
- ask someone you trust to be your advocate
- know what medications you take and why you take them
- use healthcare organizations that have been evaluated against established standards
- participate in decisions about your treatment.

As well as a general campaign for patient involvement, specific initiatives on wrong-site surgery, organ donation, infection control and medication mistakes have been launched. The Joint Commission's International Center for Patient Safety website (www.jcipatientsafety.org) includes the campaign materials, a facility for patients to report complaints about the quality or safety of their care, and resources to guide patients in choosing high quality healthcare services.

Within its broad mission to improve the quality and outcomes of healthcare, the US Agency for Healthcare Research and Quality (AHRQ) is supporting a raft of research and other efforts around the theme of patient safety. These include *The Patient Safety Network*, a national online resource centre (http://www.psnet.ahrq.gov/); *The Patient Safety Task Force*, coordinating the collection of data on medical errors and adverse events; and Partnerships for Implementing Patient Safety, awarding grants to support the implementation of safe practice interventions. The AHRQ has also produced a series of patient leaflets that outline issues to consider and questions to ask to improve

understanding, enhance safety and reduce the likelihood of error in various contexts; these include:

- **5 Steps to Safer Health Care**
  http://www.ahrq.gov/consumer/5steps.htm
- **20 Tips to Help Prevent Medical Errors**
  http://www.ahrq.gov/consumer/20tips.htm
- **Your Medicine – Play it Safe**
  http://www.ahrq.gov/consumer/safemeds/safemeds.htm
- **Quick Tips – When Getting a Prescription**
  http://www.ahrq.gov/consumer/quicktips/tipprescrip.htm
- **Quick Tips – When Getting Medical Tests**
  http://www.ahrq.gov/consumer/quicktips/tiptests.htm
- **Quick Tips – When Talking with Your Doctor**
  http://www.ahrq.gov/consumer/quicktips/doctalk.htm
- **Questions to Ask Your Doctor Before You Have Surgery**
  http://www.ahrq.gov/consumer/surgery.htm

The 'Five Steps to Safer Health Care' campaign, which offers patients practical advice about how to contribute to the safe delivery of their care, is supported by the American Medical Association (AMA), US Department of Health and Human Services and American Hospital Association. The AMA also played a major role in the establishing of the National Patient Safety Foundation in 1997, whose stated mission is to

> *"Improve the safety of patients through our efforts to: identify and create a core body of knowledge; identify pathways to apply the knowledge; develop and enhance the culture of receptivity to patient safety; raise public awareness and foster communications about patient safety; and improve the status of the Foundation and its ability to meet its goals."*

The Foundation has produced a statement of principle on the honest disclosure of injuries and errors, as well as a range of factsheets and other resources for patients and families (www.npsf.org). Other US organisations leading debates and efforts to involve patients in safety improvement include:

• Consumers Advancing Patient Safety	www.patientsafety.org/
• Partnerships for Patient Safety	www.p4ps.org/
• Institute for Safe Medical Practices	www.ihi.org/IHI/Topics/PatientSafety/
• The Leapfrog Group	www.leapfroggroup.org
• National Council on Patient Information and Education	www.talkaboutrx.org/index.jsp
• Veterans Association National Center for Patient Safety	www.patientsafety.gov/index.html

An assessment and critique of five leading 'speak up' campaigns, including those conducted by the AHRQ and Joint Commission, concluded that these failed to address important information needs and risked shifting responsibility for safety improvement on to patients (Entwistle et al 2005). Conducted by Entwistle and colleagues, the review found that information materials produced for patients were of limited educational value, with key issues (such as the incidence and cause of medical errors) not properly addressed. One explanation for this was the general lack of patient involvement at either the development or testing stages, which resulted in the materials having a strongly provider oriented perspective. The campaigns were felt to have a restrictive focus on

changing the attitudes and behaviours of patients, while neglecting possible cultural and systematic barriers to patient participation. Given that patients are being encouraged to check and challenge the actions of those delivering their care, the cooperation and support of health professionals is particularly important.

As in the US, focused efforts to reduce medical errors and enhance patient safety are being pursued in the UK, Australia and, more recently, in Canada. In the UK, patient safety was placed high on the NHS modernisation agenda with the publication in 2000 of *An Organisation with a Memory* (Department of Health 2000). This set out a programme to achieve major improvement in the safety of NHS care, centring on the creation of proactive systems for reporting, classifying, analysing and learning from adverse clinical events. It emphasised the need to move away from a 'blame culture' towards one that is non-punitive, encourages openness and accountability, and establishes effective channels for communication and feedback. For all its important insights, however, the report failed to address the various ways in which patients might contribute to safety improvement, nor did it consider potential barriers to patients' informed and active involvement in this area.

In *Building a Safer NHS for Patients*, published the following year, the government set out in more detail its plans for safety improvement (Department of Health 2001). Among the initiatives announced was the creation of a National Patient Safety Agency (NPSA), a special health authority with responsibility for a new national system for collecting and analysing information on adverse events and near misses. The NPSA broadly recognises that patients can make valuable contributions to safe delivery of their care (e.g. National Patient Safety Agency 2003), and has appointed a director for 'Patient Experience and Public Involvement'. A national programme for research into patient safety has also been established, supporting research into the causes of medical errors and into interventions to prevent safety failures. In 2005, the programme announced a grant for research into patient involvement in patient safety.

Alongside these government initiated reforms, the BMA and GMC have made proposals for improving patient safety, including better processes for obtaining patients' informed consent. In 2002 the BMA published a discussion paper on patient safety and clinical risk, stating that everyone involved in healthcare provision has a role and responsibility to identify and control risk. The dimensions of risk that are likely to be confronted by patients were identified as:

- their perceptions of the need for treatment. If patients' perceptions of risk are too low, diagnoses may be delayed or missed; if too high, they may result in unnecessary medical care
- the risks inherent in healthcare
- that the need for and outcomes of treatment may be affected by their personal characteristics and lifestyle choices.

Voluntary organisations are also campaigning to raise the awareness of patient safety issues and for an improvement in systems for the detection, prevention and redress of medical injury. Notable amongst these is Action Against Medical Accidents (www.amva.co.uk).

With the US, Australia has led the way in developing strategies to improve patient safety. Published in 1995, the *Quality in Australian Healthcare* study reported that adverse events were associated with 16.6% of hospital admissions, half of which were considered to be preventable. The report raised the profile of patient safety at a national level, and led directly to the convening of a National Expert Advisory Group on Safety and Quality in Australian Health Care. On the Advisory Group's recommendations, a new Australian Council for Safety and Quality in Health Care was established in 2000 to coordinate a national approach to safety and quality improvement. The stated purpose of the Council included an aim to "empower consumers to make better choices about their health and

involve them in decision-making to improve health care safety." Consequently, among its wide ranging programmes of action are initiatives intended to encourage patients to become actively involved in the safety of their care. These include the '10 Tips for Safer Healthcare' booklet, a regular consumer newsletter and a system for direct patient reporting of adverse drug events.

Beyond the national level, the WHO's 'World Alliance for Patient Safety' is working towards a coordinated global effort to address problems of patient safety. The Alliance, launched in October 2004, will promote evidence-based policies and practices, develop internationally recognised norms and standards, and reduce duplication of effort by the pooling of expertise and best practice. Importantly, the WHO is committed to making every possible effort to ensure that patients and consumers are at the centre of this international movement to improve patient safety. The mobilisation and empowerment of patients is one of the six action areas identified by the Alliance, which will be advanced under the 'Patients for Patient Safety' programme. This programme aims to:

- establish an inventory of patient safety and consumer advocacy initiatives currently being implemented (or at an advanced stage of planning) by governmental, educational or private organisations
- create routes of access for participation and information for consumers worldwide who want to contribute to the Alliance or the patient safety movement more generally
- facilitate a baseline survey of consumers and providers on patient safety matters and associated cultural issues
- support demonstration initiatives to design and evaluate programmes for active consumer participation in programmes based in hospitals or national health systems to reduce medical errors
- develop model policies and guidance for engaging consumers, patients and organisations representing them in efforts to build safer healthcare systems
- create a network of advisors from the healthcare consumer movement to be available to countries that want to apply the Patients for Patient Safety philosophy with their national or local patient safety initiatives.

Patient safety: what works?

In contrast to other areas of quality improvement, the potential contribution patients can make to promoting safer healthcare has only recently been recognised. Consequently, few patient-focused initiatives have yet been developed, and even fewer subjected to a formal evaluation. The exception to this is interventions to improve patient adherence to medical treatment, for which there is a significant and growing body of research evidence. As interest in patient partnership approaches grows, so too will our understanding of the best ways to engage patients in promoting safety and preventing adverse events. However, the relatively small number of studies outlined below reflects the current, limited, evidence base on this issue.

1. Infection-control initiatives

Around 8% of patients admitted to hospitals in the UK will contract an infection during their stay. There is widespread awareness among the public of hospital acquired infections such as MRSA, and national surveys show that hospital cleanliness is one of the leading concerns among patients. This is one of the few areas in which patients' potential contributions to safety improvement has been recognised and is being promoted. The patients' envisaged role in hospital infection initiatives is to ask healthcare professionals who they come into contact with if they have washed or sanitized their hands, usually encouraged by promotional and awareness raising materials. A number of individual studies, and one systematic review, were found reporting on the effectiveness of initiatives where patients have been involved.

McGuckin and colleagues (1999) measured the effects of patient education on staff compliance with handwashing (McGuckin et al 1999). The intervention entailed patients receiving education within 24 hours of admission to hospital about the importance of asking their healthcare workers to wash their hands. As a result of the patient education intervention, soap usage and handwashing increased by an average of 34% ($p=0.021$). This increase was consistent across all four hospitals participating in the study, regardless of initial handwashing rates. Follow up patient interviews were conducted which found that 81% of patients read the educational materials provided, and 57% asked healthcare workers whether they had washed their hands (over 80% of whom received a positive response).

Strength of evidence: Uncontrolled observational study.

Bischoff and colleagues (2000) evaluated a combined intervention intended to improve handwashing compliance among healthcare workers (Bischoff et al 2000). The intervention consisted of education/feedback for the healthcare workers (six sessions) and a patient awareness programme, followed by enhanced accessibility of alcohol disinfectant. The study was conducted across three settings: a medical intensive care unit, cardiac surgery intensive care unit and general medical ward. The main outcome measure was direct observation of handwashing over 120 hours, randomised according to day and bed locations. The first stage of the intervention (education/feedback/patient awareness) had little impact on handwashing practices, but these were significantly improved after the introduction of accessible handwashing antiseptic.

Strength of evidence: Uncontrolled observational study.

McGuckin and colleagues (2001) trialed their patient education intervention for improving hand hygiene in an acute care hospital in the UK (McGuckin et al 2001). The 35 patients who participated in the study agreed to ask healthcare workers who came into direct contact with them if they had washed their hands beforehand. The intervention

increased handwashing by 50% overall. Hand washing was more common when attending to surgical patients than medical patients ($p<0.05$). Sixty two per cent of patients felt comfortable asking healthcare workers about handwashing, and 78% received a positive response. However, while all patients asked nurses if they had washed their hands, only 35% asked doctors.

Strength of evidence: Uncontrolled observational study.

Hinkin (2002) examined the effectiveness of interventions to improve hand hygiene among health professionals (Hinkin 2002). Seven studies were identified, six of which used educational interventions. Of the three studies of single component education, only the one involving patient education found positive effects. Improved hand hygiene was observed in four studies overall, but only in two were effects sustained after the cessation of the intervention.

Strength of evidence: Systematic review – inclusion criteria not precisely defined and type of studies not pre-specified; search for studies was not extensive, no mention of quality assessment is made and study details are insufficient (CRD).

McGuckin and colleagues (2004) conducted a trial of a patient education intervention on hand hygiene compliance in a rehabilitation unit (McGuckin et al 2004). Thirty five patients were enrolled in the study, who agreed to ask all healthcare workers who came into direct contact with them "Did you wash/sanitise your hands?" Hand hygiene compliance was measured by soap/sanitiser use per resident day before and during the intervention, and at a 3-month follow up. Compliance increased by 94% during the intervention, by 34% during the 6 weeks afterwards, and by 40% at the follow up.

Strength of evidence: Uncontrolled observational study.

The National Patient Safety Agency (2004) piloted a toolkit, aimed at healthcare staff and patients, to encourage better hand hygiene and reduce levels of hospital acquired infection (National Patient Safety Agency 2004). The pilot involved increased provision of alcohol hand rub, posters targeting staff and patients, and patient information and empowerment (for example, staff were issued with badges saying "It's okay to ask"). The staff and patient-oriented components of the trial were not evaluated independently, but collectively they led to improved hand hygiene behaviour. Baseline and six month observations of staff were conducted, which found an increase in compliance from 2% to 63%. There was also a greater than two-fold increase in the use of alcohol hand rub during this period. Of the staff surveyed during the campaign, 34% had been asked about hand washing or the use of alcohol rub by a patient. Staff felt that posters displayed in wards and aprons bearing the 'its okay to ask' slogan were most effective in encouraging patients to ask about hygiene practices. It is estimated that, if the findings of the pilot studies were replicated in all hospital settings, this would save 450 lives and reduce the cost to the NHS by £140 million.

Strength of evidence: Multi-method evaluation.

Summary of known effects of hospital infection initiatives

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Not known.
Patients' experience, including communication and psychological outcomes	Not known.
Health services utilisation and cost	Increased use of antiseptic products, and potentially significant cost savings if rolled out across the NHS.
Health behaviour and health status	Improved hand hygiene among health workers and increased patient checking practices.

2. Adherence to treatment regimes

Errors in the prescribing and use of medicines are a common patient safety problem. One cause of such errors is patients failing to take their medication as prescribed. This can occur as a result of patient, provider and treatment factors. For example, it may not be clear to patients what their medicines are for or how to take them properly. Various interventions to enhance patient adherence to treatment have been developed, and we identified 20 systematic reviews of trials involving these interventions.

Ebrahim (1998) collected evidence for interventions to improve patient adherence to treatment for hypertension (Ebrahim 1998). On the basis of the 23 trials identified, there is insufficient evidence to support a specific approach to improving patient adherence. Complex interventions – involving education, easier access to care and use of protocols – may improve adherence and blood pressure control in some patients. There is some evidence that simpler drug regimens improve adherence, but simple reminder packaging is not effective. Educational interventions are unlikely to be effective on their own.

Strength of evidence: NHS Health Technology Assessment systematic review.

Roter and colleagues (1998) conducted a meta-analysis of studies evaluating interventions to improve patient adherence to treatment regimes (Roter et al 1998). They identified 153 studies, involving interventions categorised as educational, behavioural or affective. The outcome measures were health outcomes (e.g. blood pressure and hospitalisation); direct indicators (e.g. urine and blood tracers); indirect indicators (e.g. pill count and refill records); subjective reports; and utilisation (e.g. appointment making). Overall, the interventions produced significant effects, particularly when these were measured using direct and indirect indicators. Effects of a smaller magnitude were observed for health outcomes and utilisation measures. The adherence improvement strategies were most successful in patients with chronic disease (including those with diabetes and hypertension), cancer patients, and those with mental health problems.

Strength of evidence: Systematic review, no independent assessment found.

Newell and colleagues (1999) critically reviewed interventions to increase patients' adherence to medication, obtaining repeat prescriptions and attending appointments in cardiovascular disease (Newell et al 1999). Twenty studies, of reasonable methodological quality, were identified. Of four studies examining interventions to increase medication compliance, two reported positive outcomes. The interventions in these studies were reduced medication dose and a strategy combining home visits, counselling, written medical schedules, education tools and compliance-enhancing packaging. To improve patients' compliance in obtaining repeat prescriptions, reminder letters, compliance-enhancing packaging and a multi-component intervention were tested. In all three studies, significant improvements were reported. Some evidence of improvement in appointment attendance was found in the literature, although interventions targeted at physicians were consistently ineffective.

Strength of evidence: Systematic review – selection criteria were limited, an outdated scale was used to assess validity and the study may not be generalisable beyond cardiovascular disease; trials were assessed only on direction of effect (positive or negative), not size of effect (CRD).

Haddad and colleagues (2000) conducted a systematic review to determine the effectiveness of patient support and education interventions for improving adherence to

highly active antiretroviral therapy (HAART) in people living with HIV/AIDS (Haddad et al 2000). Only one study was found which met the inclusion criteria. This study randomised patients to either conventional care or an educational session and counselling/support from a pharmacist. The intervention significantly improved adherence, as measured by pill count, interview and patient self report. Successful adherence, defined as compliance with at least 90% of prescribed doses of HAART, was achieved by 76.7% of the intervention group and 52.7% of the control group.

Strength of evidence: Cochrane systematic review.

Morrison and colleagues (2000) evaluated evidence for a range of interventions to improve adherence to antihypertensive drugs (Morrison et al 2000). Twenty nine trials were identified which evaluated a range of interventions including: electronic vial caps, calendar packaging, patient cards, different dosing regimens, patient reminders, physician education, patient education, worksite care, disease management, counselling, and self-monitoring. Sackett's definition of adherence, as greater than 80% pill consumption, was used. Adherence was measured by urine sampling, pill counting, self report, electronic medication event monitoring systems and pharmacy records. The studies reported mixed findings – consistent or fairly consistent positive results were found for electronic vial caps, patient cards, physician education, worksite care and calendar packaging. Adherence was improved by reminders, but only when these were used as part of a combined intervention. Results for the remaining three interventions – self monitoring, patient education and counselling – were inconclusive.

Strength of evidence: Systematic review – the authors provided insufficient information on study selection, validity assessment, statistical methods and consideration of publication bias; only English language publications, identified via Medline, were included (CRD).

Fogarty and colleagues (2002) reviewed published articles and conference proceedings for literature on patient adherence to HIV medication (Fogarty et al 2002). Their literature search identified 20 articles and 74 conference abstracts on the subject. Adherence was most often measured by patient self report, with some use of objective methods (e.g. pill count, pharmacy refill methods) and physiological indicators (e.g. viral load, CD4 count). Based on the limited descriptions available, the interventions tested were categorised as cognitive (designed to teach, clarify or instruct), behavioural (designed to shape, reinforce of influence behaviour) or affective (designed to optimise social and emotional support). Of the five randomised trials included, only one reported a significant difference between groups (and effects were only sustained while the intervention was active). Of the remaining four, three found improvements in adherence among both control and intervention group (it is of note that, in all three cases, the control group did not just receive usual care).

Strength of evidence: Systematic review, no independent assessment found.

McDonald and colleagues (2002) systematically reviewed the evidence on interventions to enhance patient adherence to self-administered medications (McDonald et al 2002). To be included in the review, studies had to be randomised; to measure adherence and treatment outcomes; to follow up at least four fifths of the study participants; and, where initial results were positive, to perform a follow up at six months or later. Thirty nine articles, describing 33 studies, were identified. Almost half of the studies found improvements in medication adherence, but less than one fifth (17%) found improvements in treatment outcomes. Of those studies reporting beneficial outcomes, intervention effect sizes were modest. Improvements were most likely to be seen with

complex interventions, combining features such as convenient care, information, counselling, reminders, self-monitoring, reinforcement, family therapy and additional supervision or attention.

Strength of evidence: Systematic review, no independent assessment found.

Zygmunt and colleagues (2002) examined psychosocial interventions for improving medication adherence in schizophrenia (Zygmunt et al 2002). A total of 39 studies, described in 45 articles, were identified; the interventions involved were classified as individual patient, group, family, community-based or mixed modality. Significant intervention effects were found in 13 (33%) of the studies, in nine of which both adherence and clinical outcomes (e.g. psychiatric symptoms, hospitalisations, days in hospital) were improved. Unsuccessful interventions included psychosocial strategies administered to individual or families and family therapy. More effective approaches included behavioural interventions and cognitive techniques targeting patients' attitudes towards medication, and interventions specifically targeting the problems of non-adherence (rather than broad-based approaches). There was some evidence that community care improved adherence.

Strength of evidence: Systematic review – clear review question and thorough literature search, but no validity assessment or description of methods of data extraction (CRD).

Blue Cross and Blue Shield (2003) conducted a 'review of reviews' of the effectiveness of interventions to improve patient adherence to prescribed cardiovascular medications (Blue Cross Blue Shield Technology Evaluation Center 2003). Seven systematic reviews were found, providing evidence on the following type of interventions: simplified dosing schedules, behavioural interventions, educational interventions and complex interventions (involving two or more distinct modalities). Patient adherence was frequently improved through simplified dosing, in particular by changing multiple to once-daily dosing. However, findings for the other single strategy interventions were less robust and consistent. While complex interventions often produced effects of greater magnitude than single intervention approaches, these were found to be resource intensive and, therefore, may not be easily replicated in real-world settings. The authors note that there is a lack of trials targeting populations that are expected to benefit the most (i.e. those who do not adhere to medication) or which target interventions to the specific needs of patients.

Strength of evidence: Systematic review, no independent evaluation found.

Dolder and colleagues (2003) assessed interventions aimed at improving medication adherence among people with schizophrenia (Dolder et al 2003). The interventions described in the 21 studies identified were classified as behavioural (targeting, shaping or reinforcing behaviour patterns); educational (emphasis on knowledge); affective (appealing to emotions, feelings, social relationships or social support); or combined. The studies used individual and group interventions, and the number of sessions varied from one session only, to every two weeks for two years. Adherence improved in one of the four educational intervention trials, both of the behavioural intervention trials, four out of five of the affective intervention trials, and six out of ten of the combined intervention trials. Successful studies tended to be longer (mean duration of eight sessions), and have larger numbers of participants (mean sample size of 103).

Strength of evidence: Systematic review – clear review question and broad inclusion criteria; search limited to three databases and English language publications, and no

validity assessment performed; not clear whether results reported as improved were statistically significant as appropriate tests were not conducted (CRD).

Nose and Barbui (2003) described their meta-analysis of trials assessing the efficacy of interventions to reduce non-adherence (to psychotropic drugs or scheduled appointments) in people with schizophrenia (Nose & Barbui 2003). Interventions were described as one of the following: educational (14 studies); psychotherapy (3 studies); prompts (2 studies); specific service policies (five studies); or family interventions (5 studies). Overall, the interventions produced statistically significant improvements in patient adherence (odds ratio 2.59). Greater effects were reported in studies with shorter follow up periods, homogeneous patient populations and which assessed adherence to hospital discharge programmes. Most trials did not assess whether intervention effects were maintained in the long term.

Strength of evidence: Systematic review – clear review question but limited attempt to locate relevant studies; methods used to select studies, assess validity and extract data were not described (CRD).

Peterson and colleagues (2003) identified randomised trials of interventions to improve medication adherence which could be combined in a meta-analysis (Peterson et al 2003). Sixty one studies, involving 95 interventions, were included in the analysis. The studies involved various clinical populations, with hypertensive patients being the most well represented (26%). The interventions under investigation included behavioural interventions (41), educational interventions (22) and combined interventions (32). As there was substantial heterogeneity in the reported effect sizes, these had to be calculated by intervention. For behavioural interventions, there was an overall effect size of 0.07; for educational interventions, 0.11; for combined interventions 0.08. These findings indicate that strategies to improve medication adherence have a positive, but generally small effect. In real terms, adherence would be improved by only four to eleven per cent. When the combined group was analysed by intervention component, mail reminders were found to have the largest effect (0.38), followed by skill building, packaging changes and dosage changes.

Strength of evidence: Systematic review – wide-ranging review with clearly stated aims; search terms and scope were limited, and meta-analysis may not have been appropriate given statistical and clinical heterogeneity (CRD).

Vergouwen and colleagues (2003) systematically reviewed the effectiveness of interventions to improve adherence to antidepressant medication in patients with unipolar depression (Vergouwen et al 2003). Their search identified 19 appropriate studies, none of which involved depressive inpatients. The interventions tested were broadly grouped as either patient education (e.g. notifying patients of possible side effects, information leaflets or personalised information), or collaborative care (e.g. involving increased patient education, longer and more frequent visits, surveillance of adherence, primary care training and feedback or treatment recommendations). Control groups received usual care, which generally consisted of a prescription for antidepressant medication and two or three visits during the first three months of treatment. Of the six studies conducted in psychiatric outpatient units, only one which combined verbal with written information resulted in better adherence. In primary care settings, only those studies which tested collaborative care interventions significantly improved adherence. Most of these studies involved multimodal strategies, targeting both patient education and physician quality of care. The outcomes of these studies are likely to be a result of improved quality of care as well as enhanced patient adherence.

Strength of evidence: Systematic review, no independent assessment found.

Schedlbauer and colleagues (2004) examined the effectiveness of interventions designed to improve adherence to lipid lowering medication (Schedlbauer et al 2004). Eight studies, reporting data on 5,943 patients, were identified. The interventions fell into four broad categories: simplification of drug regimen; patient information/education; intensified patient care such as reminding; and complex behavioural interventions such as group sessions. Outcomes were measured on the basis of self-report, prescription refill rate and pill count; other reported events included medication side effects. Significant intervention effects were reported in three studies, which involved simplified dosing (four times daily to twice daily), pharmacist mediated patient education/information, and postal and telephone reminders. The authors note that the methods used to evaluate baseline and post-intervention adherence (refill records, patient self-report and pill count) have been shown to overestimate adherence compared to newer methods such as electronic monitoring of pill use.

Strength of evidence: Cochrane systematic review.

Schroeder and colleagues (2004) conducted a Cochrane review of interventions to improve patient adherence to antihypertensive medication (Schroeder et al 2004). Thirty eight studies, testing 58 different interventions, were found. The studies were grouped by type of intervention as: simplification of dosing regimens; patient education; patient motivation, support and reminders; and complex health and organisational interventions in combination. Outcomes were measured by self-report, direct questioning, pill counts and a computerised medication container. The most successful type of intervention was simplification of dosing, which improved adherence in seven out of nine studies. There was some evidence of improvement with patient motivation and complex interventions, but the evidence was either weak (motivation interventions) or variable (complex interventions). Patient education alone seemed largely unsuccessful.

Strength of evidence: Cochrane systematic review.

Haynes and colleagues (2005) summarised the results of RCTs assessing interventions to improve medicines adherence (Haynes et al 2005). Fifty seven trials, testing 67 interventions, were identified which measured both adherence and clinical outcomes. The majority of the studies (n=49) involved long term conditions, with the remaining eight conducted in patients with acute, short term conditions. The interventions varied in type, with the most common described as increased instruction for patients; counselling; computer and telephone assisted counselling and monitoring; manual telephone follow up; family interventions; increased convenience of care; and simplified dosing. Roughly half of the interventions led to increased adherence, although treatment outcomes for patients with long term conditions were improved with only 18 of 58 interventions. Almost all of the interventions that were effective for long term care were complex, including combinations of convenient care, information, reminders, self-monitoring, reinforcement, counselling, family therapy, psychological therapy, crisis intervention, manual telephone follow up, and supportive care. The common theme among these interventions was frequent interaction with patients, with attention to adherence. The authors note that complex and labour intensive interventions, while more successful, may not be easily replicated in non-research settings.

Strength of evidence: Cochrane systematic review.

Vermeire and colleagues (2005) assessed evidence for the effectiveness of interventions to improve adherence to treatment recommendations in type 2 diabetes (Vermeire et al 2005). They identified 21 studies, describing data for a total of 4,135 patients. The studies involved nurse interventions, home aids, diabetes education programmes, pharmacy based interventions, and interventions comparing the effect of different dosing and frequency of medication intake. Only three of the studies were considered of good methodological quality; five were rated as of poor quality. The interventions generally led to small improvements in adherence, with simplified dosing increasing appropriate medication intake. The authors note that the observed effects are unlikely to be of clinical significance.

Strength of evidence: Cochrane systematic review.

Fernandez and colleagues (2006) systematically reviewed the efficacy of educational interventions relating to psychotropic medications, for people with mental health conditions (Fernandez et al 2006). Twenty one trials were reviewed, which reported on outcomes including knowledge retention, compliance with medication, incidence of relapse and insight into illness and medications. Ten (48%) of the trials involved people being treated for schizophrenia. A range of interventions were evaluated in the studies, including medication information leaflets, educational sessions and individual treatment sessions. Of six trials measuring knowledge outcomes, four reported significant improvements associated with the intervention. There was little evidence of positive impact on compliance, relapse rates or insight into illness/medications.

Strength of evidence: Systematic review, no independent assessment found.

Heneghan and colleagues (2006) reviewed the effects of reminder packaging for improving medication adherence (Heneghan et al 2006). The primary outcome measures were adherence to medication as measured by pill count or self report. Eight RCTs met the inclusion criteria: seven conducted in the USA, one in New Zealand. The trials involved participants with hypertension (four trials), diabetes (two) and chronic mental illness (one), or who were elderly with multiple medical conditions (one) or healthy adults (one). Reminder packaging improved adherence when measured by pill count, but not by self report. The positive effects in the studies that provided data on pill count were largely accounted for by two trials where the reminder packaging was pre-packed. There was insufficient information on patient satisfaction, barriers to use, difficulties using reminder devices and costs to health services and patients.

Strength of evidence: Cochrane systematic review.

Ogedegbe and Schoenthaler (2006) conducted a systematic review to assess the effects of home blood pressure monitoring on medication adherence (Ogedegbe & Schoenthaler 2006). Of the eleven RCTs found, six reported statistically significant improvements in medication adherence. Five of these were trials involving complex interventions, which combined home blood pressure monitoring with other strategies such as patient counselling, patient education or use of timed medication reminders. The data for trials conducted in primary care settings were less favourable than that for acute or non-clinical settings.

Strength of evidence: Systematic review, no independent assessment found.

Summary of known effects of adherence interventions

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Improved with educational interventions.
Patients' experience, including communication and psychological outcomes	Not known.
Health services utilisation and cost	Most effective interventions are complex and intensive, and may not be cost-effective in real-world settings.
Health behaviour and health status	Patient education alone does not increase adherence, but is effective when combined with other strategies (e.g. counselling, reminders or self-monitoring). Adherence improved with behavioural and affective strategies.

3. Direct patient reporting of adverse drug events

Spontaneous reporting schemes, for the monitoring of adverse drug events (ADEs), have been established at both national and organisational levels. However, widespread underreporting to such schemes means that they detect only a fraction of the real incidence of ADEs. In view of this, it has been suggested that the identification of drug safety problems could be improved if patients were able to directly report suspected ADEs, and opportunities for this have already been established within some schemes (e.g. the MEDWatch programme provided by the US Food and Drug Administration). To date, there has been no systematic evaluation of direct patient reporting, although such research is currently being conducted in the UK by the MHRA.

van den Bemt (1999) investigated the relative value of reports of adverse drug events made by doctors, nurses and patients (van den Bemt et al 1999). The study took place over two months, across four wards in hospitals in the Netherlands. Spontaneous reports were collected from doctors and nurses, while patients reported events during a daily ward visit during which they were interviewed by a hospital pharmacist. While doctors reported more serious and unknown adverse drug events, patients were most likely to report adverse reactions to new drugs during the daily ward visit.

Strength of evidence: Uncontrolled observational study.

van Grootheest and colleagues (2005) reported on the first year of a direct patient reporting scheme across the Netherlands (van Grootheest et al 2005). A total of 276 reports were received from patients, most of which contained sufficient medical information to enable adequate evaluation. Patients were more likely to report serious adverse reactions than health professionals.

Strength of evidence: Uncontrolled observational study.

Summary of known effects of direct patient reporting of ADEs

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Patients willing to report ADEs and capable of providing adequate medical information.
Patients' experience, including communication and psychological outcomes	Not known.
Health services utilisation and cost	Not known.
Health behaviour and health status	Not known.

4. Equipping patients for safer healthcare

Patient safety issues are frequently technical and complex, often involving many different types of risk that may not be familiar or observable to patients. For patients to contribute to the delivery of safer healthcare, they must be informed about how and in what ways they can act to prevent or lessen the risk of harm. Practical skills may also be required, for example in self-administering medicines, using medical equipment or evaluating performance data to choose safe healthcare providers. Above all, clear, comprehensible and reliable patient safety information is essential not only to support patient involvement, but also to notify patients of the standards of care that they can reasonably expect.

Ioannidis and Lau (2001) assessed the effectiveness of interventions aimed at reducing medical errors (Ioannidis & Lau 2001). They identified 13 RCTs, three of which involved patient-focused interventions. The first trained mothers to spot serious illness in their children; the second provided patients with detailed information about their medicines; and the third involved a self-medication programme. Two of these trials (medicines information and self-medication) reported significant improvements in medical errors following the intervention. In the study of medicines information, effects were greater for easier-to-read materials. In most of the studies (nine out of 13), error rates in the control groups were high. Thus the authors note that relatively simple interventions may achieve large reductions in the incidence of medical errors.

Strength of evidence: Systematic review – a reasonable review with a clear question, thorough searching methods and a validity assessment undertaken; the authors failed to explore differences between the trials, which might have influenced the observed results (CRD).

Anthony and colleagues (2003) describe the development and implementation of an educational patient safety video at a community hospital in the USA (Anthony et al 2003). The video addresses treatment plans, medication safety, falls, surgical site identification, hand washing and discharge planning. It also identifies strategies patients may employ or observations they can make to improve patient safety. The impact of the video was measured by patient surveys, completed by 217 patients in all. Patients felt more comfortable asking questions or raising concerns after viewing the video, and rated their knowledge of patient safety higher. The video also normalised practices that were not comfortable for staff (e.g. repeatedly asking patients for personal details) or patients (e.g. inquiring about hand hygiene practices).

Strength of evidence: Multi-method evaluation.

Weingart and colleagues (2004) reported on a randomised pilot trial of an intervention to involve patients in the prevention of adverse drug events (ADEs) (Weingart et al 2004). The aim of the trial was to test the hypothesis that providing patients with personalised drug information would reduce the number and severity of ADEs. The trial also investigated whether the provision of drug safety information would improve patients' experience of care. Two hundred and nine patients admitted to a hospital in Boston were enrolled in the study, and randomly allocated to either the intervention or control group. All participants received a guide to medication safety; the intervention group additionally received a list of their current medication, with explanations of the medical terms used, which was updated every three days of their stay. Data were collected using patient/nurse questionnaires and multiple methods for the identification and classification of adverse events and near misses. There was no significant difference between the groups in the proportion, severity or preventability of ADEs or close calls. No differences in patients' experiences of their care were found. Overall, a quarter of potential

medication errors were prevented due to identification by the patient or a family member. Various factors complicated the interpretation of the findings: the small sample size; the fact that both groups received some medication information; that many patient groups which are particularly susceptible to ADEs (e.g. acute illness, cognitive impairment) were unable to enrol in the study; that the materials were not evaluated for readability; and that the intervention could have been too weak.

Strength of evidence: Single randomised controlled trial.

Summary of known effects of interventions to equip patients for safer healthcare

Outcome variables	**Current state of knowledge**
Patients' knowledge and information recall	Some evidence of improved patient safety knowledge following an educational video.
Patients' experience, including communication and psychological outcomes	Personalised medicines information has no effect on patients' experience of care. Educational video improved patients' confidence to ask questions and raise concerns.
Health services utilisation and cost	Not known.
Health behaviour and health status	Mixed evidence for impact on error rates and adverse events.

5. Preventing wrong site surgery

Wrong site surgery can include operating on the wrong person, organ or limb, or performing the wrong procedure. It is a rare event, estimated to occur only once in 113,000 cases, but can cause major injury and have devastating effects (Kwaan et al 2006). Poor communication during the preoperative assessment – between patients and doctors or among members of the surgical teams – is a key factor in the failure to properly verify the patient or surgical site. Recommendations for promoting correct site surgery emphasise the role that patients can play, by verifying that the surgical site has been correctly marked prior to the procedure (e.g. Royal College of Surgeons in England & National Patient Safety Agency 2005).

DiGiovanni and colleagues (2003) reported on a study examining patient compliance with preoperative instructions to avoid wrong-site surgery (DiGiovanni et al 2003). They asked 100 patients in a foot and ankle practice to mark 'No' on the extremity that was not to be operated on. Fifty nine per cent fully complied with the instructions given, while 37% made no mark at all (4% were partially compliant). Higher rates of non-compliance were observed in patients who had previous experience of surgery (51% compared to 29% of first-time surgery patients). The authors suggest that their findings indicate that patients expect the system to 'take care of everything', despite being asked to participate in adverse event prevention.

Strength of evidence: Uncontrolled observational study.

Summary of known effects of wrong-site surgery interventions

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Not known.
Patients' experience, including communication and psychological outcomes	Not known.
Health services utilisation and cost	Not known.
Health behaviour and health status	Evidence of variable patient compliance with requests to mark the surgical site.

Patient safety: what looks promising for future R&D?

There is clearly considerable scope for future research into patient involvement in patient safety. Far more needs to be known about the particular ways in which safety improvement can be enhanced through patient involvement and, conversely, the benefits to patients of taking a more informed and active role in the safety of their care. Given the sensitivity, seriousness and complexity of this aspect of patient care, innovative strategies are required to encourage and support both patients and healthcare professionals in partnership efforts. These will need to be subjected to formal evaluation, so that best practice can be identified and applied across settings. What follows is an outline of the main priorities for future R&D; with growing interest in and support for research into patient safety, we hope that many of these gaps in knowledge will be filled shortly.

Research should be oriented around the following objectives:

- to investigate the factors influencing patients' willingness and ability to be involved in the safety of their care; to what extent, and in what ways, do patients want to take a role in safety improvement?
- to identify the issues and settings where patient involvement is most achievable and will have the greatest impact
- to examine how patients' experience and views of medical errors/adverse events, and their potential for involvement in safety improvement, is shaped by demographic and other personal characteristics
- to evaluate the effectiveness of current patient-focused initiatives for safety improvement
- to explore barriers to the development and implementation of patient-focused patient safety initiatives, and ways of overcoming these
- to identify the organisational changes that are needed to create a patient-oriented patient safety culture
- to examine which techniques (e.g. posters, question sheets, staff badges) are most effective in encouraging and supporting patients to openly raise safety concerns with healthcare professionals
- to establish the incidence and nature of medical errors and adverse events in primary care and other non-acute settings.

Research into the above issues is needed to more fully understand the opportunities and barriers to involving patients in patient safety. However, in the meanwhile much can be done to build upon and extend existing initiatives. A strong commitment to delivering the safest possible patient care should be made at clinical, managerial and policy-making levels. Patient safety considerations should be built into decision-making across these levels. Moreover, it is crucial that patient safety is seen as a *collective responsibility*, calling for coordinated improvement efforts involving all members of the healthcare team (including patients). Broader initiatives for patient empowerment – such as the introduction of electronic medical records and use of decision aids – will help patients to become more active and informed participants in their care. Within the domain of patient safety, particular attention should be paid to improving communication with patients and listening to them on matters of safety. This may require additional training for healthcare staff on how best to explain and discuss issues such as treatment risks, correct medication use, discharge procedures and follow up care. Enhancing the availability and quality of safety information for patient and public use will also be beneficial.

References

Anthony, R. et al (2003) 'John M. Eisenberg Patient Safety Awards. The LVHHN patient safety video: patients as partners in safe care delivery'. *Jt.Comm J Qual Saf*, 29 (12): 640-645.

Barber, N. (2002) 'Should we consider non-compliance a medical error?'. *Qual Saf Health Care*, 11 (1): 81-84.

Bates, D.W. et al (1995) 'Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group'. *JAMA*, 274 (1): 29-34.

Bischoff, W.E. et al (2000) 'Handwashing compliance by health care workers: The impact of introducing an accessible, alcohol-based hand antiseptic'. *Arch.Intern Med*, 160 (7): 1017-1021.

Blue Cross Blue Shield Technology Evaluation Center (2003) 'Special report: interventions to improve patient adherence with medications for chronic cardiovascular disorders'. *TEC.Bull (Online)*, 20 (3): 30-32.

BMA (2002) *Patient safety and clinical risk*. London: BMA Publications.

BMA (2004) *Communication skills education for doctors: an update*. London: British Medical Association.

Britten, N. et al (2000) 'Misunderstandings in prescribing decisions in general practice: qualitative study'. *British Medical Journal*, 320: 484-488.

Chief Medical Officer (2003) *Making amends. A consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS*. London: Department of Health.

Consumers Association (2000) *Patient Information Leafets: sick notes?* London: Consumers Association.

Coulter, A. (2002a) 'After Bristol: putting patients at the centre'. *BMJ*, 324: 648-651.

Coulter, A. (2002b) *The Autonomous Patient*. London: Nuffield Trust.

Coulter, A. & Magee, H. (2003) *The European Patient of the Future*. Maidenhead: Open University Press.

Department of Health (2000) *An organisation with a memory: report of an expert group on learning from adverse events in the NHS*. London: Stationery Office.

Department of Health (2001) *Building a safer NHS for patients*. London: Department of Health.

Department of Health (2004) *Better information, better choices, better health. Putting information at the centre of health*. London: Department of Health.

Department of Health & Design Council (2003) *Design for patient safety*. London: Department of Health.

DiGiovanni, C.W. et al (2003) 'Patient compliance in avoiding wrong-site surgery'. *J Bone Joint Surg.Am*, 85-A (5): 815-819.

Dolder, C.R. et al (2003) 'Interventions to improve antipsychotic medication adherence: review of recent literature'. *J Clin Psychopharmacol.*, 23 (4): 389-399.

Douketis, J.D. (2001) 'Patient self-monitoring of oral anticoagulant therapy: potential benefits and implications for clinical practice'. *Am J Cardiovasc Drugs*, 1 (4): 245-251.

Drury, M. et al (2000) 'Patients with cancer holding their own records: a randomised controlled trial'. *Br J Gen Pract*, 50 (451): 105-110.

Ebrahim, S. (1998) 'Detection, adherence and control of hypertension for the prevention of stroke: a systematic review'. *Health Technol.Assess.*, 2 (1).

Egberts, T.C. et al (1996) 'Can adverse drug reactions be detected earlier? A comparison of reports by patients and professionals'. *BMJ*, 313 (7056): 530-531.

Elbourne, D. et al (1987) 'The Newbury Maternity Care Study: a randomised controlled trial to evaluate a policy of women holding their own obstetric records'. *British Journal of Obstetrics and Gynaecology*, 94: 612-619.

Entwistle, V. et al (2005) 'Advising patients about patient safety: current initiatives risk shifting responsibility'. *Journal on Quality and Patient Safety*, 31 (9): 483-494.

Fallowfield, L. & Fleissig, A. (2003) *Communication with patients in the context of medical error*. www.publichealth.bham.ac.uk/psrp/publications.htm.

Fernandez, R. et al (2006) 'Educational interventions for mental health consumers receiving psychotropic medication: a review of the evidence'. *International journal of mental health nursing*, 15 (1): 70-80.

Fogarty, L. et al (2002) 'Patient adherence to HIV medication regimens: a review of published and abstract reports'. *Patient Educ Couns*, 46 (2): 93-108.

Haddad, M. et al (2000) 'Patient support and education for promoting adherence to highly active antiretroviral therapy for HIV/AIDS'. *Cochrane Database Syst.Rev.*, (3): CD001442.

Haynes, R. et al (2005) 'Interventions to enhance medication adherence'. *Cochrane.Database.Syst.Rev.*, CD000011 (4).

Heneghan, C.J. et al (2006) 'Reminder packaging for improving adherence to self-administered long-term medications'. *Cochrane Database Syst Rev*, (1): CD005025.

Hingorani, M. et al (1999) 'Patients' and doctors' attitudes to amount of information given after unintended injury during treatment: cross sectional, questionnaire survey'. *BMJ*, 318 (7184): 640-641.

Hinkin, J. (2002) 'Hand decontamination: what interventions improve compliance?'. *EDTNA.ERCA.J*, 28 (3): 134-137.

Hobgood, C. et al (2002) 'Medical errors-what and when: what do patients want to know?'. *Acad Emerg Med*, 9 (11): 1156-1161.

Hopper, K.D. et al (1998) 'The readability of currently used surgical/procedure consent forms in the United States'. *Surgery*, 123 (5): 496-503.

Institute of Medicine (2000) *To Err is Human: building a safer health system*. Washington DC: National Academy Press.

Institute of Medicine (2004a) *Health Literacy: a prescription to end confusion*. Washington DC: The National Academies Press.

Institute of Medicine (2004b) *Patient Safety: achieving a new standard for care*. Washington DC: National Academies Press.

Ioannidis, J.P. & Lau, J. (2001) 'Evidence on interventions to reduce medical errors: an overview and recommendations for future research'. *J Gen Intern Med*, 16 (5): 325-334.

Jones, R. et al (1999) 'Randomised trial of personalised computer based information for cancer patients'. *British Medical Journal*, 319: 1241-1247.

Kaiser Family Foundation & AHRQ (2004) *National Survey on Consumers' Experiences with Patient Safety and Quality Information*. California: Kaiser Family Foundation.

Koutantji, M. et al (2005) 'The patient's role in patient safety: engaging patients, their representatives, and health professionals?'. *Clinical risk*, 11 (3): 99-104.

Kwaan, M.R. et al (2006) 'Incidence, patterns and prevention of wrong-site surgery'. *Archives of Surgery*, 141 (3): 353-357.

Leape, L.L. (1994) 'Error in medicine'. *JAMA*, 272 (23): 1851-1857.

Leape, L.L. et al (1993) 'Preventing medical injury'. *QRB Qual Rev.Bull*, 19 (5): 144-149.

Lowe, C.J. et al (1995) 'Effects of self medication programme on knowledge of drugs and compliance with treatment in elderly patients'. *British Medical Journal*, 310: 1229-1231.

Mazor, K.M. et al (2004) 'Health plan members' views about disclosure of medical errors'. *Ann Intern Med*, 140 (6): 409-418.

McDonald, H.P. et al (2002) 'Interventions to enhance patient adherence to medication prescriptions: scientific review'. *JAMA*, 288 (22): 2868-2879.

McGuckin, M. et al (2004) 'Evaluation of a patient education model for increasing hand hygiene compliance in an inpatient rehabilitation unit'. *Am J Infect.Control*, 32 (4): 235-238.

McGuckin, M. et al (1999) 'Patient education model for increasing handwashing compliance'. *Am J Infect.Control*, 27 (4): 309-314.

McGuckin, M. et al (2001) 'Evaluation of a patient-empowering hand hygiene programme in the UK'. *J Hosp.Infect.*, 48 (3): 222-227.

Morrison, A. et al (2000) 'Interventions to improve antihypertensive drug adherence: a quantitative review of trials'. *Formulary*, 35 (3): 234-236.

National Audit Office (2000) *The management and control of hospital acquired infection in acute NHS trusts in England*. London: The Stationary Office.

National Audit Office (2005) *A Safer Place for Patients: Learning to improve patient safety*. London: The Stationary Office.

National Patient Safety Agency (2003) *Seven steps to patient safety: a guide for NHS staff*. London: National Patient Safety Agency.

National Patient Safety Agency (2004) *Achieving our aims: evaluating the results of the pilot CleanyourHands campaign*. London: National Patient Safety Agency.

Newell, S.A. et al (1999) 'A critical review of interventions to increase compliance with medication-taking, obtaining medication refills, and appointment-keeping in the treatment of cardiovascular disease'. *Prev.Med*, 29 (6 Pt 1): 535-548.

Nolan, T.W. (2000) 'System changes to improve patient safety'. *BMJ*, 320 (7237): 771-773.

Nose, M. & Barbui, C. (2003) 'Systemic review of clinical interventions for reducing treatment non-adherence in psychosis'. *Epidemiol Psichiatr.Soc*, 12 (4): 272-286.

Ogedegbe, G. & Schoenthaler, A. (2006) 'A systematic review of the effects of home blood pressure monitoring on medication adherence'. *J Clin Hypertens (Greenwich)*, 8 (3): 174-180.

Peterson, A.M. et al (2003) 'Meta-analysis of trials of interventions to improve medication adherence'. *Am J Health Syst.Pharm*, 60 (7): 657-665.

Picker Institute Europe (2005) *Is the NHS getting better or worse? An in-depth look at the views of nearly one million patients between 1998 and 2004*. Oxford: Picker Institute Europe.

Pyper, C. et al (2001) *ERDIP online patient access project*. Oxford: Bury Knowle Health Centre.

Roter, D.L. et al (1998) 'Effectiveness of interventions to improve patient compliance: a meta-analysis'. *Med Care*, 36 (8): 1138-1161.

Royal College of Surgeons in England & National Patient Safety Agency (2005) *Patient safety alert: correct site surgery*. London: NPSA.

Sandars, J. & Esmail, A. (2003) 'The frequency and nature of medical error in primary care: understanding the diversity across studies'. *Fam.Pract*, 20 (3): 231-236.

Schedlbauer, A. et al (2004) 'Interventions to improve adherence to lipid lowering medication'. *The Cochrane database of systematic reviews*, CD004371 (4).

Schroeder, K. et al (2004) 'Interventions for improving adherence to treatment in patients with high blood pressure in ambulatory settings'. *Cochrane Database Syst.Rev.*, CD004804 (2).

Secretary of State for Health (2001) *Learning from Bristol: The report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-95*. London: The Stationery Office.

Shojania, K.G. et al (2001) 'Making health care safer: a critical analysis of patient safety practices'. *Evid.Rep.Technol.Assess.(Summ.)*, 43.

Thomas, E.J. et al (1999) 'Costs of medical injuries in Utah and Colorado'. *Inquiry*, 36 (3): 255-264.

VA National Center for Patient Safety (2006) *Ensuring correct surgery*. http://www.patientsafety.gov/SafetyTopics/CorrectSurg/CorrSurgPt.pdf.

van den Bemt, P.M. et al (1999) 'Adverse drug events in hospitalized patients. A comparison of doctors, nurses and patients as sources of reports'. *Eur.J.Clin.Pharmacol.*, 55 (2): 155-158.

van Grootheest, A.C. et al (2005) 'Direct reporting of side effects by the patient: favourable experience in the first year'. *Ned.Tijdschr.Geneeskd.*, 149 (10): 529-533.

van Grootheest, K. et al (2003) 'Consumer adverse drug reaction reporting: a new step in pharmacovigilance?'. *Drug Saf*, 26 (4): 211-217.

Vergouwen, A.C. et al (2003) 'Improving adherence to antidepressants: a systematic review of interventions'. *J Clin Psychiatry*, 64 (12): 1415-1420.

Vermeire, E. et al (2005) 'Interventions for improving adherence to treatment recommendations in people with type 2 diabetes mellitus'. *Cochrane Database Syst.Rev.*, (2): CD003638.

Vincent, C. & Coulter, A. (2002) 'Patient safety: what about the patient?'. *Quality and Safety in Health Care*, 11: 76-80.

Vincent, C. et al (1998) 'Framework for analysing risk and safety in clinical medicine'. *BMJ*, 316 (7138): 1154-1157.

Vincent, J.L. (1998) 'Information in the ICU: are we being honest with our patients? The results of a European questionnaire'. *Intensive Care Med*, 24 (12): 1251-1256.

Weingart, S.N. et al (2004) 'Lessons from a patient partnership intervention to prevent adverse drug events'. *International Journal for Quality in Health Care*, 16 (6): 499-507.

Weingart, S.N. et al (2000) 'Epidemiology of medical error'. *BMJ*, 320 (7237): 774-777.

Wilson, R.M. et al (1996) 'Quality in Australian Health Care Study'. *Med J Aust.*, 164 (12): 754.

Wilson, T. & Smith, F. (2001) 'What will it take to improve patient safety in primary care'. *Clinical Governance Bulletin*, 2 (5): 2-4.

Witman, A.B. et al (1996) 'How do patients want physicians to handle mistakes? A survey of internal medicine patients in an academic setting'. *Arch.Intern Med*, 156 (22): 2565-2569.

Zygmunt, A. et al (2002) 'Interventions to improve medication adherence in schizophrenia'. *Am J Psychiatry*, 159 (10): 1653-1664.

5. Improving access to health advice

Access: summary of findings

- Access refers to the availability, utilisation, relevance and acceptability, and equity of health services. As potential access is not always realised, a distinction can be made between 'having access' and 'gaining access' to health care.
- Although the NHS was established on the principle of equal availability to all on the basis of need, certain groups face difficulties accessing appropriate health care including rural dwellers, ethnic minority groups, homeless people, asylum seekers and the prison population.
- Long waiting times for hospital care is a major concern to patients and the public, and potentially increases the burden on primary and emergency services. Various initiatives are being employed to reduce patient waiting, such as targets and performance management; shifting care provision from hospital to primary care settings; and increasing capacity by widening the provider base.
- There is growing interest among patients for alternative means of accessing healthcare and health advice, and studies have found considerable enthusiasm for NHS Direct and walk-in centres. However, many patients also value continuity and integration of care, both of which could potentially be jeopardised by the proliferation of access points.
- The cost-effectiveness of new access routes depends on them complementing existing services and reducing the burden on them, rather than increasing competition and duplicating effort. Studies have found that NHS Direct and walk-in centres have an impact on immediate medical workload (e.g. GP consultations, home visits). There is some evidence, however, that these services merely delay rather than substitute for conventional GP consultation.
- Remote video consultations and outreach clinics have been shown to improve patient access and reduce travel times and out-of-pocket costs. However, studies have so far been unable to demonstrate greater overall cost-effectiveness compared with conventional approaches.
- Patient satisfaction with remote video consultations is generally high, but there is evidence of poorer quality diagnostic and management decisions. This approach may be more appropriate for certain clinical areas (e.g. psychiatry and dermatology) or types of consultation (e.g. those not involving physical examination).
- NHS walk-in centres are having little impact on inequalities of access, as users are most likely to be affluent, young and/or white. Concerns about negative effects on continuity of care are not held by centre users, who place higher value on convenience, flexibility and, in some cases, anonymity.
- Complex outreach interventions can improve clinical outcomes in certain populations, including older people with mental health problems.

Access: introduction

The National Health Service was founded on the principle of equal access to all, on the basis of need rather than the ability to pay. Since its creation, however, the NHS has been plagued by problems of access. Most significant among these is a general trend referred to as the 'inverse care law', whereby availability and utilisation of services is lowest among those with the greatest need (Hart 1971, Smith 1999). This has serious consequences for both individual and society, reducing the effectiveness and outcomes of healthcare while costs increase. Given this, there is a strong imperative to find ways of facilitating and broadening access, through enhancing the provision of existing services and the development of new ones. Of the many approaches that can be taken, this chapter considers patient-focused interventions which promote faster or more convenient access to health advice. These include walk-in centres, telephone helplines and new methods of doctor-patient communication (e.g. by telephone, email and video).

Access is a complex concept, which has multiple meanings and dimensions. One way of understanding access is in terms of service availability. On this view, access can be measured according to the extent of service provision (e.g. the number of health professionals or hospital beds) within a particular locale (Gulliford et al 2002). However, this is only part of the picture, and the issue of service *utilisation* is equally important. As potential access is not always realised, a distinction can be been made between 'having access' and 'gaining access' to healthcare (Gulliford et al 2001). In contemporary accounts of access it is not only supply and demand factors which are of interest but, crucially, the relationship between these. Good access is achieved when there is a high degree of fit between the health service and its user (Pechansky & Thomas 1981). This requires the timely provision of appropriate care to meet the health needs of the target population, and also that any individual, social, financial and organisational barriers to access are overcome. Specifically, five facets of the service-user interaction have been identified as (Pechansky & Thomas 1981):

- acceptability
- affordability
- availability
- physical accessibility
- accommodation.

Recognising its multifaceted character, Chapman and colleagues describe access in terms of four key dimensions: availability, utilisation, relevance and effectiveness, and equity (Chapman et al 2004) (see box below). Where healthcare is intended to be equally distributed as a basic right, as with the NHS, equity is the most important dimension of access, but it is also the most difficult to reliably define and measure (Gulliford et al 2002).

Chapman and colleagues: four dimensions of health care access

Availability: defined as the supply side of health services; whether resources are supplied adequately and in proportion to need. Also includes direct and indirect costs to the patient.

Utilisation: refers to the use of health services, indicating the degree of fit between user and the healthcare system. Measures the extent to which the health service accommodates the patient and community served, and includes dimensions of usability, acceptability and affordability. In addition to normative need, utilisation is affected by patients' expectations of the health service, perceptions of illness, felt needs, and the health information available to them, which in turn are influenced by social, economic and cultural variables.

Relevance and acceptability: measures whether the right service is provided to adequately address the health needs of the target population and whether it has been developed to take into account the local socio-cultural setting.

Equity: a social justice dimension indicating the extent to which resources are mobilised to reflect need in a given population. Needs-based equity is very difficult to measure as any assessment must account for variations in needs within unique geographical settings and also within different socio-cultural and economic subgroups.

Initiatives to improve access to healthcare can be broadly categorised in terms of absolute and relative strategies (Rosen et al 2001). Whereas absolute strategies seek to increase the overall availability of services, relative strategies are intended to reduce inequalities and improve fairness. The latter is achieved by specifically targeting groups or communities for whom services are inadequate, inappropriate or difficult to make use of. This might include rural populations, ethnic minority groups, children and young adults, and people with learning or physical disabilities.

Competing principles and objectives may arise in addressing problems of access, particularly when set against requirements to improve the quality and cost-effectiveness of care. For example, efficiency and effectiveness may be greatest when services are delivered centrally or by regional specialist centres. However, the increased costs and inconvenience to patients using such services may reduce accessibility, particularly for those living in rural areas. There is also a potential tension between establishing national standards and tackling variations in treatment and care, and shaping services to meet the particular needs of local populations (Gulliford et al 2002). Resource constraints mean that efforts to widen access must be balanced against the imperative to deliver affordable healthcare. While deliberations about the distribution of health resources are linked to issues of fairness and equality, ultimately the principle of social justice may not be fully reconciled with that of economic efficiency.

Access: what are main problems of access to healthcare?

Problems of access to healthcare are numerous and varied. A host of issues are raised in understanding and addressing these problems – such as the appropriate provision of services and determination of healthcare needs, geographical and physical barriers to service use, and difficulties of access arising from legal status (e.g. asylum seekers) or social exclusion (e.g. the homeless). These issues have complex organisational and political contexts, cutting across many sectors, agencies and government departments. Therefore, while healthcare systems have a lead role to play in driving improvement, this cannot be done in isolation from wider efforts to address the complex factors that influence whether and how individuals gain access to healthcare services.

Although problems of access are certainly not limited to primary care, there are two major reasons why access initiatives have strongly focused on this sector. Primary care is generally the first point of contact that a patient has with the healthcare system, accounting for 90% of all patient encounters in the NHS (Department of Health 2004). Additionally, it constitutes the entry point to many other levels of care. There is growing demand for primary care services, largely due to an increasing ageing population, rising patient expectations and efforts to shift care from hospital to community settings. In some cases, this has led to practices closing their GP lists and instituting selective registration, and to pressures on doctors to limit the length of their consultations. It is estimated that 14% of people live in areas where local practices have closed lists (Rossiter 2005), with those affected including many of the most vulnerable groups in society. Other areas of primary care affected by poor service availability include sexual health services. Recent research has found that patients face unacceptably long waits for appointments at genitourinary clinics, and some clinicians are having to turn away patients seeking treatment (Terrance Higgins Trust 2005).

The issue which has captured much of the media and public debate about primary care access is that of timeliness, and waiting times for GPs in particular (see box). Although GP access targets have brought about some improvement, they may also be distorting priorities and restricting options for patients. Most notably, the target for GPs to see patients within 48 hours has had the unintended consequence that some surgeries no longer accept advance appointments. Often coupled with the issue of timeliness is that of convenience, and these coincide in the issue of out-of-hours care. In addition to meeting needs for unscheduled care, providing services outside normal practice hours increases access for those who have difficulty attending daytime appointments. The establishment of NHS Direct, walk-in centres and commuter surgeries have increased the range and convenience of access points to primary care services. The challenge in enhancing flexibility of primary care provision is to achieve this by supporting rather than duplicating existing services, and without compromising quality. Evidence for the impact of new access arrangements is now emerging, but meanwhile concerns have been raised about the quality and safety of care, record keeping and communication with patients (Kmietowicz 2000).

Access and waiting times: findings from NHS patient surveys

Primary Care survey 2005

- 44% of respondents reported difficulties contacting their general practice or local health centre by telephone.
- 15% said they were sometimes deterred from going to their general practice because the opening times weren't convenient.
- 74% were seen within two working days of contacting their general practice. Almost half of delayed appointments were due to the lack of earlier appointment slots.
- 24% of respondents were seen on time for their appointment, and a further 47% were seen within fifteen minutes of their appointment time. Almost one in ten patients had to wait half an hour or more.
- Of the 20% of respondents who were not registered with an NHS dentist, 69% said they would like to be.

Out-patient department survey 2005

- One in five patients had to wait over three months for an appointment, and the same proportion had their appointment changed at least once.
- The majority of patients were seen within 30 minutes of their appointment time, but almost one in ten waited more than an hour.

In secondary care, the imbalance between capacity and demand is a major problem for the NHS, with long hospital waiting lists being its most visible symbol. In 2004, patients waited an average of 87 days between the date of the decision to be admitted for an operation to the actual admission (Dr Foster 2005). Any delay in admission increases the burden on primary care – which has to manage patients waiting to be assessed or admitted for treatment – and also potentially on emergency services if the need for treatment becomes urgent. Broadly, the problems of access to secondary care can be addressed either by managing existing demand or creating additional capacity, and both strategies are currently being pursued within the NHS. Hospital workload is crucially shaped by the patterns and volume of referral from primary care, and by the availability of community services to receive discharged patients who need continuing care. The role of primary care in managing demand for secondary care services is being recognised, and various incentives have been introduced to modify GP's referral behaviour (Coulter 1998). However, while growing attention is being paid to governing the entry routes into specialist services, there has been less emphasis on tackling the exit points by, for example, improving the funding and provision of community and social care.

A major problem common to both primary and secondary care is that of inequalities of access. When measured against their respective needs for healthcare, affluent groups tend to make the greatest and most efficient use of services (Dixon et al 2003). Conversely, others face major barriers accessing appropriate healthcare, including:

- ethnic minority groups
- asylum seekers and new migrants
- homeless people
- the prison population
- rural residents
- people with physical and learning disabilities
- lower socio-economic groups.

For each of the above groups, there is often a complex and dynamic interplay of factors accounting for their poor access to health services. For example, rural populations experience higher levels of geographical isolation and a lack of public transport, the effects of which are exacerbated by the increasing centralisation of services. There are

also increasing difficulties recruiting and retaining doctors in remote rural areas, in part due to concerns about social isolation and excessive out-of-hours duties (BMA 2005). Ethnic minority communities can face barriers due to language problems or lack of familiarity with services, but may also be less likely to initiate or receive healthcare if it is not sensitive to their cultural and religious needs. However, patterns of use among ethnic minority groups do not straightforwardly indicate a problem of under-utilisation; over-use of primary and emergency care services has also been documented (Gulliford et al 2001). The reasons for this are not fully understood, but possible explanations are that ethic minority patients are not always being appropriately referred to specialist care; that they are less active or effective self-carers; or that they are more demanding because of greater health needs and/or higher service expectations.

Access: what do patients and the public want?

A major theme of government policy for creating a patient-led NHS is to diversify the provider base and increase patients' capacity to choose among those providers (Secretary of State for Health 2000). This is intended to give patients faster and more convenient access to health services, by offering patients the option of quicker treatment at an alternative to their local NHS facility. Patient choice is also assumed to be a driver for quality improvement, with patients weighing up the available information to opt for the best performing hospital (Department of Health 2005). The consequences for hospitals and departments that fail to attract patients are unclear, although the possibility of closure has not been ruled out. However, the thrust of the patient choice policy is not entirely consistent with patients' own preferences for accessing healthcare. Many patients feel they should be allowed to have a choice of general practitioner, specialist doctor and hospital (Coulter & Jenkinson 2004). Even so, the leading priority among the majority of patients and the public is to have access to a good local service, which is rated as more important than being able to exercise choice of provider (Which? 2005). Although choice of provider and a good local service are not necessarily incompatible, they may become so if hospitals or departments are forced to close due to lack of business. If this does happen, there could be reduced accessibility for some patients, who will have no option but to travel further to access health services.

With regard to primary care, waiting times and appointment availability are areas of particular concern, and there is strong support among service users for easier and more convenient access. Flexibility of provision is important, and patients would like surgeries to offer both immediate and advance appointments to see a GP (National Primary Care Research and Development Centre 2005). Increasing the availability of services is also popular, particularly among those who are full-time workers. One way this can be achieved is to extend surgery hours by offering appointments at weekends and evenings. Recent research has shown some support for this option, but there is also growing interest among patients for alternative sources of healthcare and advice (Coulter 2005). For example, a national evaluation of the first wave of NHS walk-in centres found that patients valued the speed of access and convenience of the location and opening hours (Salisbury et al 2002). Almost four out of five people attending walk-in centres were very satisfied with the service they received, and 97% said they would probably or definitely use the service again. Similarly high levels of user satisfaction have been reported for the NHS Direct telephone helpline (O'Cathain et al 2000). Varying the skill mix in the primary care workforce has the potential to relieve some of the pressure on GPs, increase capacity and improve patients' access to care. While scepticism has been expressed about whether patients would accept alternatives to GP consultation, studies have shown that patients are willing to be seen and treated by nurses or other healthcare practitioners, and are generally more satisfied with the care they receive from them (Venning et al 2000).

Interpersonal aspects of medical practice are strongly valued, and most patients place high priority on having a clinician who shows commitment to their care (National Primary Care Research and Development Centre 2005). Good listening and communication skills, a supportive and sympathetic attitude, and a willingness to share decisions are consistently rated by patients as being of great importance in a clinician. Continuity of care is also valued by many patients, but is essential for people with long term conditions; as is having somebody take responsibility for coordinating and managing arrangements which can potentially involve multiple providers, organisations and even sectors (Lewis & Dixon 2005). There is a potential conflict between the emphasis on quality and continuity of care, and patients' desire for convenient and highly accessible services (Bower et al 2003). Indeed many professional organisations, the BMA and RCGP included, have suggested that initiatives to enhance flexibility of access could fragment both primary care services and patient care. Certainly, more radical solutions to access problems – such as dual registration or the abandonment of patient registration – sit uneasily with the drive to improve continuity of care. However, increasing the

availability of access routes need not threaten continuity if the personal GP system is safeguarded and clinical responsibility is clearly defined. There will also need to be improvements in communication and information-sharing between providers, and an integrated system of electronic patient records could play an important role in this.

Recent research indicates that there is considerable interest among some patients for electronic communication with health professionals, including receiving health information and advice via email. For example, a US survey found that 90% of those who are online would like to be able to communicate their doctor by email, many of whom would be willing to pay out-of-pocket to do so (Taylor & Leitman 2002). However, far fewer patients report having communicated with their health provider in this way, and it was estimated that only a fraction of US doctors offer the option of email contact (Pal 1999, Sittig 2003). A recent analysis of data from the Commonwealth Fund's international health policy surveys found considerable variation in the proportion of patients saying they could communicate with their doctor by email, ranging from 16% in the UK to 27% in New Zealand (Coulter 2006). The proportion saying they would like to be able to communicate by email ranged from 25% in Australia to 42% in the US. Among British patients, 40% expressed a desire for email communication with their doctor. Trials of email consultations in the UK have shown high levels of patient satisfaction (Neville et al 2004).

Electronic communication offers potential cost savings if short e-consultations substitute for lengthier face-to-face appointments. It is also likely to be of use in chronic disease management, as doctors could maintain regular contact with patients and conduct their routine reviews through email. Further potential applications include appointment booking, obtaining test results, ordering repeat prescriptions and delivering patient information and education.

However, concerns have been raised about issues of data privacy and protection, the possibility that doctors could become overwhelmed with inbound messages, and potentially negative effects on the doctor-patient relationship. Additionally, unless disparities in the availability of internet resources are addressed, email consultations would only benefit those patients who have online computer access (Wong 2001). Effective systems for managing and triaging email messages, and strategies for broadening access to computer technologies, are therefore needed.

Access: what strategies have been tried and by whom?

Improving the accessibility and convenience of healthcare has, and continues to be, a key objective of UK health policy. This issue was a recurring theme in the NHS Plan, which signalled the government's intention to bring services into line with patients' preferences while preserving the principle of access on the basis of need (Secretary of State for Health 2000). Many of the new initiatives set out in the Plan were intended to address access problems across care sectors, alongside which a range of strategies to foster more equitable access to services were outlined. Even prior to the publication of the Plan, the government announced two new service developments to widen accessibility to primary care services: NHS Direct and walk-in centres (see box). Steps had also already been taken to tackle the problem of inequalities of access, most notably in 1998 with the piloting of the Personal Medical Services (PMS) contract for GPs. As a locally negotiated contract, PMS gives GPs greater flexibility to tailor services to the needs of their local population (Lewis & Gillam 2002). This has led to the development or re-design of services to improve access for previously under-served groups, including ethnic minorities, the homeless and those with mental health problems.

NHS Direct
NHS Direct, is a nurse-led telephone service covering England and Wales, which gives patients 24 hour direct access to advice and information about health and self-care. A Scottish equivalent (NHS 24) has been established, and information is also now provided by alternative routes through NHS Direct Online and NHS Direct inVision. NHS Direct handles around 100,000 calls each week across its 22 sites. By the end of 2006, it is expected that it will be integrated with GP out-of-hours services and will act as a single point of contact for these (Department of Health 2003a).

Walk-in centres
As with NHS Direct, there is an expectation that walk-in centres will relieve some of the burden on local GP and emergency services. In terms of creating a more patient-led health service, the primary rationale for the centres is to provide fast and convenient access to medical advice and care. Walk-in centres offer a nurse-led drop-in service, and are open during and outside of GP surgery hours. There are currently 66 walk-in centres throughout England, with a further seven planned nearby to popular commuter train stations.

Within the broad area of healthcare access, there has been a strong focus on the problem of patient waiting times, especially for elective hospital treatment. The government has introduced a range of targets to bring down waiting times, against which hospital performance is regularly assessed. For instance, patients suspected of having cancer are expected to see a hospital specialist within two weeks of GP referral. Various initiatives have been introduced to help meet waiting list targets by increasing capacity in NHS facilities. Of these, the most contentious has been the move towards 'plurality' of providers, which in practice has largely resulted in increased private sector involvement. This includes a growing network of independently run Diagnostic and Treatment Centres, which offer a fast-track service for elective day surgery and diagnostic tests. The 'Choose and Book' e-booking system is expected to provide the mechanism by which patients can decide between alternative hospitals, with the option of receiving quicker treatment from a private facility. Moves to open up the primary healthcare market to private provider organisations are also underway.

Access has also been targeted through major workload and workforce changes. Most importantly, these include efforts to transfer work and resources from secondary to primary care, and to develop new staff roles in both the acute and community sectors.

The 'Wider Range of Services in Primary Care' programme was introduced to meet patient expectations in the following areas (Department of Health 2003b):

- greater convenience
- faster access
- more choice
- a better experience.

So far, the focus has largely been on accrediting GPs with a special interest in fields such as genetics, dermatology or neurology. By 2004, there were 1,400 such GPs delivering an extended range of services. New skills and roles for nurses were outlined in the NHS Plan, since which time there has been a sustained increase in nurse-led care management across the NHS. For example, nurse practitioners run specialist outpatient clinics in various clinical areas including diabetes, renal and respiratory care. In an effort to relieve pressure on GPs and increase access to medicines, prescribing authority has been gradually extended to nurses and pharmacists. From spring 2006, qualified nurses and pharmacists have been able to prescribe any licensed medicine to a patient, with the exception of controlled drugs (Avery & Pringle 2005).

Improving the availability of primary care and community services was a major theme in the 2006 white paper *Our Health, Our Care, Our Say* (Department of Health 2006). A number of the paper's key recommendations or initiatives are intended to improve patient access and tackle inequities in the uptake of services (see box).

Our health, our care, our say: a new direction for community services (Department of Health 2006)

Key access recommendations/initiatives include:

- Patients will have the option to register at a GP practice near their home or their work, but will register with only one practice
- Incentives to GP practices to offer longer and more convenient opening times
- A wider range of services offered closer to home through GP surgeries, health clinics and community hospitals
- Demonstration projects in six clinical specialities, to develop models of care for shifting services to community settings
- Encouraging or allowing new providers to deliver services in under-served areas
- Piloting and evaluating patient self-referral, starting with physiotherapy services
- Further development of walk-in centres, with existing centres to take booked appointments.

Professional and patient organisations in the UK have regularly contributed to debates about healthcare access, and about the implications of the government policy in this area. For example, the BMA has called on the government to improve healthcare for asylum seekers, recommending centralised funding to develop specialised services; the provision of culturally and language appropriate health service information; and the use of patient-held or duplicate medical records to ensure continuity of care (BMA 2002). To meet the needs of rural populations, the BMA has suggested an increase in mobile clinics and wider use of telemedicine for real-time 'virtual' consultations between doctors and patients (BMA 2005). Among patient groups, lobbying activities have largely focused on improving access to medical treatments, and to new medicines in particular. The National Institute for Health and Clinical Excellence, whose evaluation procedure has

been felt to delay or restrict patient access to new and potentially life-saving treatments, has been a key target for patient group campaigns.

While access to healthcare is a global concern, the nature of access problems differ according to how healthcare is organised and delivered at local and national levels. In the US, for example, debates are focused on the estimated 46 million people who do not have basic health insurance. A further 30 million are underinsured, which places limitations on their ability to access the full range of appropriate services and treatments. Major system reforms are needed to expand healthcare coverage to all uninsured and underserved populations, but a federally mandated increase in publicly funded health insurance looks unlikely. Nonetheless, there are numerous efforts within individual states to make health insurance more affordable and accessible – including raising eligibility standards to focus spending on those most in need or encouraging greater take-up of existing health insurance options. Additionally, a range of different provider organisations offer services to low-income and vulnerable populations as part of the 'health care safety net' system. Safety net services are provided across the country in acute, primary or other community settings, either at no-charge or on a sliding fee scale. The extent of their coverage is considerable; in California, for example, one in five residents receive the majority of their healthcare from safety net institutions.

Along with the USA, Canada has taken a lead in introducing new methods of delivering health services and advice. These include Canadian walk-in clinics and telemedicine initiatives in varied settings across US states (see box).

Canadian walk-in clinics
Patients have been able to receive healthcare at walk-in clinics since the late 1970s. In contrast to NHS walk-in centres which are mainly run by nurse practitioners, the Canadian version offers a doctor-led service. Various factors contributed to the emergence of the clinics, including growing patient demand for more convenient healthcare and decreases in the availability of family doctors. Since their introduction, walk-in centres have courted controversy about their impact on local services and potential duplication of care. After general practices, walk-in centres are the second most used source of routine care and health information and advice.

The National Telemedicine Initiative (USA)
Established by the National Library for Health in 1996, the National Telemedicine Initiative aimed to:

- evaluate the impact of telemedicine on cost, quality and access to health care
- assess various approaches to ensuring the confidentiality of health data transmitted via electronic networks
- test emerging health data standards.

Nineteen projects conducted in rural, inner city and suburban areas received funding from the initiative. Details of the projects and their outcomes can be accessed at http://www.nlm.nih.gov/research/telemedinit.html.

Internationally, there is a strong imperative to improve the health infrastructure in countries where there is poor, if any, access to basic healthcare services. It is estimated that 10% of the world's healthcare resources are directed towards countries that account for 90% of the global disease burden. The World Health Organization has taken a lead role in global advocacy and action, arguing that access to adequate healthcare is a basic human right. Increasing the availability of drugs and vaccines is a major priority, and the WHO has been working with other development and aid agencies to remove tariffs and

trade barriers that limit access to essential medicines, and HIV/AIDS treatments in particular. Outreach services have been widely employed in the delivery of healthcare and treatment, in order to overcome barriers to access such as social marginalisation or geographical isolation.

Access: what works?

1. New modes of professional-patient communication

The traditional model of the professional-patient consultation involved face-to-face communication in a clinical setting. However, this is not always suitable or convenient for patients, nor is it practical for clinicians working in busy practices. In addition to the telephone, the advent of new communication technologies is creating alternative means for the delivery of health information and advice. Evidence suggests that there is considerable interest among patients for communicating electronically with healthcare professionals, but benefits may be greatest for those who cannot easily attend in-person appointments due to geographical, physical or work-related constraints. Additionally, directing patients to telephone and email services may help to reduce the demand for face-to-face consultations in general practice, acute care and accident and emergency. Most of the research to date has explored the value of nurse-led telephone consultation and triage, including its potential value for delivering and/or coordinating out-of-hours care.

Lattimer and colleagues (2000) undertook a cost analysis of nurse telephone consultation out-of-hours (Lattimer et al 2000). The intervention consisted of specially trained nurses using decision support software to receive, assess and manage calls from patients or their carers. The service was added to an existing general practice cooperative, and was run from the cooperative call centre (therefore incurring no extra cost). The trial found a substantial reduction in GP workload, in the number of home visits and in emergency hospital admissions. Per year, the cost of the intervention was £81,237, but savings from reduced use of other service use totalled £94,422. The intervention therefore led to reduced general practice costs of £16,928. The main cost saving was due to reduced emergency admissions and reduced short stays (1-3 days) in hospital.

Strength of evidence: Single randomised controlled trial.

Munro and colleagues (2001) reported on their evaluation of the first wave sites of NHS Direct (Munro et al 2001). They found considerable variation between clinicians in terms of triage decision taken, including judgements about appropriate referrals to other NHS services. The study found a high level of compliance, with three-quarters of patients indicating that they had followed the advice given. Compliance appeared to differ according to the type of advice given (e.g. lower compliance with instructions to contact out-of-hours urgent care), although these findings are tentative as the study was not specifically designed to assess this issue. An economic evaluation of the service was conducted, showing an average cost per call of between £13.16 and £16.54. This average cost decreased over the duration of the study, reflecting economies of scale as service use increased. A modelling analysis of cost implications was undertaken. This showed that the potential cost-effectiveness of the service is dependent on continued reductions in call cost, and a reduction in demand for other NHS services. A complete off-setting of the costs of providing NHS Direct would take either a significant reduction in demand for GP out-of-hours, emergency and/or ambulance services, or additional impact on the uptake of other immediate care services (e.g. A&E attendances). In an earlier report, the researchers described findings of a caller satisfaction survey. Ninety seven per cent of callers were satisfied or very satisfied with the service they had received, and particularly valued getting an opinion on whether a doctor's appointment was necessary.

Strength of evidence: Multi-method evaluation including economic evaluation and modelling.

Car and Sheikh (2003) systematically reviewed evidence on the delivery of clinical care by telephone (Car & Sheikh 2003). The review primarily drew on data from RCTs and controlled before-and-after studies, but details of the search strategy and selected studies were not provided. Patients were generally positive about being able to consult with their doctor via telephone, with stated benefits including reduced travel, waiting times and costs. Telephone consultations were particularly valued by those living in rural areas whose circumstances made face-to-face appointments difficult. With regard to improving access, there is some evidence that telephone triage services can reduce use of other healthcare resources; telephone reminders significantly improve attendance and reduce the proportion of missed appointments; and there is mixed evidence for the impact on telephone-based interventions on uptake of preventive healthcare. Telephone follow-up assessments have been associated with improvements in patient satisfaction and adherence to follow-up instructions, and in reductions of emergency visits and missed appointments.

Strength of evidence: Systematic review, no independent assessment found.

Leibowitz and colleagues (2003) assessed the effect of different models of out-of-hours primary care services, including telephone triage and advice services (Leibowitz et al 2003). They were principally concerned with impact on clinical outcomes, medical work and patient and GP satisfaction. The studies provided some evidence that telephone triage and advice services may reduce immediate medical workload. Their impact on clinical outcomes is unclear, but assessments of the quality of advice given have raised concern about its variability and shortcomings. The studies showed consistent patient dissatisfaction with telephone out-of-hours consultations.

Strength of evidence: Systematic review – the authors did not provide sufficient information about the included studies to justify their conclusions; the results presented suggest that the strength of evidence in this area is weak (CRD).

Bunn and colleagues (2004) systematically reviewed evidence on telephone consultations and triage (Bunn et al 2004). They found nine studies, five of which were RCTs, that assessed interventions delivered by doctors, nurses and health assistants. Six studies were set in primary care, two in medical centres and one in A&E. The studies found that telephone consultations reduce immediate GP and home visits. However, there is evidence to suggest that telephone interventions only delay face-to-face consultations, as there was a higher re-consultation rate in some studies. Patient satisfaction was either equal to or better than face-to-face consultations. Neither adverse events, nor use of services, were increased following telephone consultations. Two RCTs compared nurse telephone consultations with normal triage by a doctor in an out-of-hours deputising service. These found that nurses could reduce GP workload without an increase in adverse events. At least 50% of the calls could be handled by telephone advice alone.

Strength of evidence: Cochrane systematic review.

Chapman and colleagues (2004) identified five studies of GP-led telephone consultations in general practice (Chapman et al 2004). There is evidence that both doctors and patients view the telephone as an appropriate method of communication, and that some patients are using phone-in services instead of arranging a face-to-face

appointment. Patients' satisfaction with telephone consultations is influenced by the ease with which they can reach their GP on the first attempt. While the availability and use of primary care may be improved, this is not the case for those who have language difficulties or communication impairments or who do not have telephone access. Four additional studies of nurse-led telephone consultations and triage were also reviewed. It was found that these interventions may lead to a reduction in GP workload, while producing similar outcomes. However, one study (Richards et al 2002) reported an increase in patient out-of-hours and A&E attendances.

Strength of evidence: Systematic review, no independent assessment found.

Pinnock and colleagues (2005) reported on a cost-effectiveness analysis of telephone asthma reviews (Pinnock et al 2005). Patients enrolled in this three month trial were randomised either to receive a face-to-face review of their asthma or a telephone review. Use of the telephone was found to substantially increase the proportion of asthma patients reviewed, with significantly shorter consultations. There was no overall difference in costs between the two groups, but more patients achieved a review in the intervention group (101 vs. 68 in the control group). Consequently, the cost per consultation was significantly lower in the intervention group (£7.19 vs. £11.11 for the control group).

Strength of evidence: Single randomised controlled trial and economic analysis.

Summary of known effects of new modes of professional-patient communication

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Not known
Patients' experience, including communication and psychological outcomes	Patient satisfaction generally improved. Increased convenience to patients and decreased waiting times and out-of-pocket costs. Improves access to healthcare, but not for those without telephone or with language difficulties.
Health services utilisation and cost	Reduction in immediate medical workload, in particular GP surgery and home visits. However, effects may only be short-term, as re-consultation rates are high. Some evidence of reduced costs with telephone consultations/reviews.
Health behaviour and health status	Impact on clinical outcomes not known, but telephone consultations do not increase adverse events. Telephone reminders increase attendance.

2. Remote teleconsultation

Among various telemedicine applications, digital imaging technology can remotely link patients and health professionals for the purpose of distance consultations. Replacing the conventional face-to-face consultation are two alternative methods of teleconsultation: asynchronous consultations using store-and-forward technology (where information is collected, stored and forwarded later for interpretation) or real-time consultations using videoconferencing facilities. There is growing interest in using teleconsultations to improve the provision of diagnostic services and potentially reduce costs, above all in the areas of dermatology, psychiatry and cardiology. Particularly for groups that are remote (e.g. rural dwellers) or hard-to-reach (e.g. prisoners), this type of telemedicine has significant potential to improve access and health outcomes.

Currell and colleagues (2000) conducted a Cochrane review of the effects of telemedicine interventions, compared with face-to-face care (Currell et al 2000). They identified seven eligible studies, two of which evaluated remote video consultations. Both studies were randomised controlled trials, and involved specialists conducting video consultations of patients at a GP practice or in an emergency department. Harrison et al (1999) reported that the time taken for consultation was significantly lower (0.5 hours vs. 2.5 hours) for patients seen by video consultation in their GP practice compared with those attending consultations at outpatient departments. In the same study, higher levels of patient satisfaction were observed, although the researchers did not indicate whether the difference with the control group reached statistical significance. Brennan et al (1999) found no significant difference in need for additional care between patients seen by video consultation and by face-to-face physician consultation.

Strength of evidence: Cochrane systematic review.

Mair and Whitten (2000) assessed patient satisfaction with teleconsultations involving real-time interactive video (Mair & Whitten 2000). Thirty two studies met their inclusion criteria, most of which were demonstration or feasibility studies rather than full scale trials. The interventions were used in a variety of clinical specialities and contexts, with psychiatry (10 studies) and dermatology (5 studies) being the most common. All the studies reported good levels of patient satisfaction, and patients positively reported increased accessibility and reductions in travel and waiting times. Some participants expressed concerns about video consultation and its effect on professional-patient communication. The authors caution against straightforward interpretation or generalisation of these results, pointing out various methodological problems in the studies (including small sample sizes, and inadequate description and measurement of satisfaction).

Strength of evidence: Systematic review – clearly stated aims and inclusion criteria, validity assessment and methodological flaws discussed; but search restricted to English language and no details given on methods of study selection and data extraction (CRD).

Whitten and colleagues (2000) attempted a meta-analysis of economic data from telemedicine evaluations (Whitten et al 2000). A comprehensive literature search identified 551 articles, only 38 of which provided usable cost data. However, a traditional meta-analysis was not possible given serious methodological flaws in the studies. The authors conclude that “it is premature for any statements to be made, positive or negative, regarding the cost-effectiveness of telemedicine in general.”

Strength of evidence: Systematic review, no independent assessment found.

Hersh and colleagues (2001) assessed telemedicine applications that substitute for face-to-face encounters specifically focusing on store-and-forward, self-monitoring and clinician-interactive services (Hersh et al 2001). The literature search identified 455 telemedicine programmes, the majority of which were based in the US. Approximately one quarter of the telemedicine applications served rural populations. Evidence for clinician-interactive telemedicine (i.e. real-time remote consultations) was mixed, and few studies measured efficacy. Several studies showed interactive teledermatology to be inferior to in-person consultation when making diagnostic and management decisions. In other specialities (e.g. cardiology, ophthalmology and pulmonary medicine), remote consultations were shown to have comparable diagnostic accuracy. One RCT in emergency medicine found comparable health outcomes, in terms of need for follow-up care and return visits. There was some evidence of improved access to care, patient and provider satisfaction and reduced costs, although methodological problems limit the reliability of these data. No studies provided conclusive data on cost-effectiveness.

In a later publication, the authors specifically examined the efficacy of telemedicine for diagnostic and management decisions (Hersh et al 2002). The majority of the studies did not support the hypothesis that diagnostic and management decisions provided by telemedicine are comparable to face-to-face consultations. The best evidence for diagnostic efficacy comes from the specialties of psychiatry and dermatology. The studies indicate that store-and-forward teledermatology provides greater diagnostic accuracy than real-time interactive teledermatology. This may be accounted for by higher quality digital imaging in store-and-forward technology. History taking and physical examinations are more difficult to conduct via teleconsultations where patient abnormalities are less visually apparent. Even within the same speciality, certain types of diagnostic investigation may be more suitable to telemedicine than others.

Strength of evidence: Systematic review, no independent assessment found.

Whitten and colleagues (2002) identified evidence for the cost-effectiveness of telemedicine interventions (Whitten et al 2002). Fifty five studies met the inclusion criteria, most (60%) of which were from the United States. They found no persuasive evidence for the cost-effectiveness of telemedicine compared to conventional consultation. Numerous problems in the design and conduct of the studies were identified, including use of inappropriate economic analytical techniques and shortness of duration.

Strength of evidence: Systematic review, no independent assessment found.

Hailey and colleagues (2003) updated earlier systematic reviews of telemedicine applications (Hailey et al 2003). Forty eight papers met their inclusion criteria, which described 46 studies (22 of which were RCTs). The majority of the studies demonstrated some advantages for telemedicine over the usual approach, and provided evidence that telemedicine was generally acceptable to patients. The findings for cost-effectiveness of telemedicine applications was mixed, although the studies did consistently show cost savings to patients. There is good evidence for the effectiveness of home-based telemedicine, supporting people self-managing their long term conditions. Telemedicine was not found to be beneficial for neurological consultations, in sleep studies, or in home care of people with epilepsy.

Strength of evidence: Systematic review, no independent assessment found.

Jacklin and colleagues (2003) reported on an economic evaluation of virtual outreach consultations, conducted with hospital specialists in London and Shrewsbury (Jacklin et al 2003). The virtual outreach intervention involved real time joint consultations between patients at a GP practice (with their GPs present) and consultants in the hospital. The study included 2,094 patients, 1,051 of whom were randomised to the intervention. The cost to the NHS of the consultation was £164 in virtual outreach and £32 in standard outpatients. The total mean costs were £724 per patient in the intervention and £625 in the control group, a difference of £99 that was statistically significant. In the virtual outreach group, patient costs and productivity losses were significant lower, and patient satisfaction was significant higher. The study findings do not support the hypothesis that the outlay costs of virtual consultation are balanced by later 'downstream' savings. Although there was a significant reduction in tests and investigations in the intervention group, the overall cost savings from this were modest. The authors suggest that the cost of virtual outreach consultations may reduce in time as volume increases, training and education drives efficient use, and once initial capital costs have been incurred.

Strength of evidence: NHS Health Technology Assessment randomised controlled trial and economic evaluation.

Jennett and colleagues (2003) assessed the socio-economic impact of telehealth (Jennett et al 2003). They found 35 studies evaluating video consultation in remote/rural health services. These were conducted in the following areas: radiology, cardiology, colposcopy, neuropyschology, minor injuries, dermatology and nutrition. Video consultation can increase access to healthcare and quality of services, and reduce travel (patient and provider) and costs. This can be achieved without an increase in the number of specialists. Economic analyses show that cost savings depend on the number of patients and distances involved. Positive economic effects are usually only shown where costs to both the healthcare system, and to patients and society, are included. The authors also report the evidence for remote video consultation in specific clinical specialities. Benefits in terms of quality of care, access, travel savings and service utilisation have been shown. Some studies report positive findings for cost-effectiveness, but the authors comment on the generally poor quality of the research in this area.

Strength of evidence: Systematic review, no independent assessment found.

Pesamaa and colleagues (2004) collected evidence for the effects of videoconferencing in child and adolescent telepsychiatry (Pesamaa et al 2004). Twenty seven trials met their inclusion criteria, eight of which evaluated videoconferencing for patient treatment or consultation. Only two of the studies were RCTs. Generally there were high levels of satisfaction among patients or family members, with technical failures being the most common reason for lack of satisfaction. The two RCTs found equal effectiveness of videoconferencing and face-to-face techniques in delivering therapy and conducting diagnosis for children with psychiatric symptoms. Three studies provided brief data for costs, with two favouring telepsychiatry. The third found a slightly higher overall expenditure for the intervention. However, the researchers in this study note that comparing average costs can be misleading given that some patients incur substantially higher costs travelling to clinics than others. For these patients, videoconferencing is likely to be the most cost-effective option.

Strength of evidence: Systematic review, no independent assessment found.

National Primary Care Research and Development Centre and Centre for Public Policy and Management (2005) collected evidence on the outcomes of remote teleconsultation (National Primary Care Research and Development Centre & Centre for

Public Policy and Management 2005). Five systematic reviews, and 29 original research papers were reviewed. Overall, the studies were of relatively poor methodological quality. The evidence for impact on health services is patchy and inconsistent; many teleconsultations do not need to be followed up with a face-to-face consultation, although follow-up rates appear to vary by speciality. One RCT found no difference between patients seen in outpatient clinics and by virtual consultation in terms of health outcomes. Generally, patients are satisfied with teleconsultations, although they do not always prefer them over the conventional face-to-face approach. Acceptability to patients is likely to be higher where existing service provision is poor or waiting times are longer. The costs of teleconsultation are highly context specific, and cost outcomes vary according to how they are calculated (e.g. including/not including costs to patients). Once the equipment has been set up, the marginal costs for teleconsultations may be lower than conventional consultations. Cost-effectiveness is more likely for rural populations, with long travelling distances to outpatient clinics.

Strength of evidence: Research review.

Summary of known effects of remote video consultation

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Not known.
Patients' experience, including communication and psychological outcomes	Satisfaction improved, and patients' out-of-pocket costs, travel and waiting times reduced. No impact on quality of life, and effect on physician-patient communication is unclear.
Health services utilisation and cost	Virtual consultations generally more costly than face-to-face equivalent; potential cost savings depend on number of patients and distances involved. No increase in need for additional care, and reduced use of tests and investigations.
Health behaviour and health status	Reduced accuracy of diagnostic and management decisions for some conditions, but impact on health status is unclear.

3. Walk-in centres

Walk-in centres are intended to improve the availability and convenience of care, while reducing patient waiting times and demand for other (e.g. GP and A&E) services. NHS walk-in centres (in England only) offer a drop-in service which is primarily managed by nurse practitioners, supported by clinical assessment software. Evidence from countries where walk-in centres are well established suggests that they are primarily used by white, affluent populations of working age. If this is also the case in England, it is possible that the walk-in centres are not only failing to address access inequalities, but may even be increasing them. Given this, a key focus of research in this area has been to identify the personal and demographic characteristics of the centre users.

Jones (2000) reviewed published literature on Canadian walk-in centres (Jones 2000). Walk-in centres have been a feature of the Canadian healthcare system for over 20 years. Nine studies were found, none of which used a controlled trial design. Patients tended to use walk-in centres because of their convenient location and longer opening hours, and because they had minor medical problems. Daytime users were more often female, but men are more likely to attend out-of-hours clinics. There were insufficient data to determine the effect of walk-in centres on demand for care, although one study found that 46% of patients attending walk-in centres later consulted their doctor for the same condition. Levels of satisfaction among those using walk-in centres is high, typically 70-80%. It is possible that walk-in centres threaten continuity of care, with one study finding that usual doctors were routinely informed of patients' attendance at a centre in under half of all cases.

Strength of evidence: Systematic review, no independent assessment found.

Horrocks and colleagues (2002) systematically reviewed the literature to assess whether nurse practitioners can provide equivalent care to doctors (Horrocks et al 2002). This review is of direct relevance to NHS walk-in centres, given that the centres are being led by nurse practitioners. Thirty five papers, reporting on 34 different studies, met the inclusion criteria. The systematic review was conducted using the eleven RCTs identified. The studies provide evidence that patients are more satisfied with their consultation when this is conducted by a nurse practitioner. There were no significant differences in health or quality-of-life outcomes between nurse and doctor-led care, although nurse practitioners undertook significantly more investigations and had longer consultations. The studies also assessed various dimensions of the quality of care. Findings from these assessments indicate that nurse practitioners may identify physical abnormalities more often; provide more self-care information and advice to patients; make more complete records than doctors; and scored more highly on communication. Two studies also found that nurses were as accurate as doctors in ordering and interpreting X-ray films.

Strength of evidence: Systematic review – clear review question and several relevant sources searched; methods for selecting studies and assessing validity not described; evidence presented supports the authors' conclusions but heterogeneity of results may limit generalisability (CRD).

Salisbury and colleagues (2002) reported on the national evaluation of the first wave of NHS walk-in centres (Salisbury et al 2002). Users were more likely to be young, male and affluent, but less likely to come from an ethnic minority group. The main reasons for using the walk-in centre was speed of access, convenience of location and opening hours. About half of those surveyed would have used a general practice if a walk-in centre had not been available, and about a quarter would have attended A&E. There were higher levels of user satisfaction with walk-in centres, compared to general practice.

While only 13% were referred to a GP, 32% intended to make an appointment to see their GP following their visit to the walk-in centre. Four weeks later, about half of those who had attended a walk-in centre had consulted their GP about the same problem. There was some confusion about the range of services available at the centre, and not all users were aware that the service was nurse-led. Most users were unconcerned about continuity of care, often viewing the centre as an alternative route to care for less serious problems. Generally the evidence for impact on other health services was mixed. Health professionals were more likely than not to be positive about walk-in centres, but concerns were raised that the centres would undermine continuity of care, were inefficient, increased public expectations and the workload of other services, and provided too limited a service. An economic evaluation found higher mean consultation costs for walk-in centres (£23.45) than general practitioner consultation (£15) and nurse practitioner consultation (£7). A modelling analysis was undertaken, and only under the most optimistic scenario was the cost of walk-in centre care similar to alternatives.

Strength of evidence: Multi-method evaluation including economic analysis and modelling.

Salisbury and Munro (2003) reviewed the international evidence for walk-in centres in primary and emergency care (Salisbury & Munro 2003). They found 244 relevant articles, from a variety of countries including North America, Australia and the UK (involving NHS walk-in centres and minor injury units). A number of studies have characterised the profile of those using walk-in centres, with higher use among younger adults, women, the relatively affluent and those in employment. Overall, the studies show high levels of user satisfaction. While continuity of care can be disrupted by walk-in centres, it appears that most patients using these services are more concerned about convenience than continuity, and value the service because it offers anonymity. The evidence for impact on other health services is conflicting, although patients self-report using walk-in centres instead of attending A&E or general practice. There was insufficient evidence to draw firm conclusions about the quality of care delivered by walk-in centres, although nurse-led minor injury clinics in the UK have been shown to deliver safe care.

Strength of evidence: Systematic review, no independent assessment found.

Chapman and colleagues (2004) reviewed evidence for interventions to improve access to primary care, including walk-in centres (Chapman et al 2004). Six studies were found, all of which reported that walk-in centres provide convenient and quick access to advice and treatment and achieve high patient satisfaction rates. They do not appear to be tackling health inequalities, as users are predominantly white and middle class. Nonetheless, they are improving access for younger and middle aged men. One study reported that while patients used walk-in centres instead of consulting their GP, up to one third of users also intended to consult their GP afterwards. There is no conclusive evidence of impact on workload in other primary care services.

Strength of evidence: Systematic review, no independent assessment found.

Summary of known effects of walk-in centres

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Not known.
Patients' experience, including communication and psychological outcomes	Improved satisfaction, convenience and – for some groups only – access. Higher satisfaction with nurse-led care. No impact

	on quality of life.
Health services utilisation and cost	Mixed evidence for costs and impact on workload of other services. High re-consultation rate indicates potential duplication of care. Increased consultation times and investigations with nurse-led care.
Health behaviour and health status	Some evidence to suggest that health outcomes at least equivalent to conventional services.

4. Outreach clinics

As with remote teleconsultations, outreach clinics aim to improve patient access to specialist services. This section is specifically concerned with the provision of outpatient care by hospital-based consultants in general practice and community-based settings. Such clinics are already well established in areas such as psychiatry, and their use is being extended to a wider range of clinical specialities. In addition to potential benefits for patients in terms of improved access and reduced waiting times and costs, specialist outreach clinics may also improve communication and integration across primary and secondary care.

Campbell and colleagues (1999) systematically reviewed published evidence for cancer treatment programmes in remote and rural areas (Campbell et al 1999). Fifteen studies were identified, involving oncology outreach programmes, teleoncology and rural hospital initiatives. The studies provided some evidence that shared care with outreach clinics is safe and can make specialist care more accessible to outlying populations. One study compared the costs of shared management/outreach patients with postulated costs had they been treated at a specialist centre. It found that direct medical costs were similar, but there were saving of $2,000 per patient in other direct costs (mostly reduced transport) and in indirect costs (e.g. loss of productivity).

Strength of evidence: Systematic review – significant heterogeneity in the included studies made it difficult to make conclusive statements about effectiveness; no attempt made to locate unpublished literature and the authors could have been more explicit about their review methodology (CRD).

Powell (2002) identified 15 studies evaluating the impact of specialist outreach clinics in primary care (Powell 2002). In surveys of patients and health professionals, the perceived advantages of specialist outreach clinics were identified as improved GP-specialist communication and improved patient experience and access. Reported disadvantages included costs (administrative and accommodation) and inefficient use of specialists' time. Patients expressed a preference for outreach over hospital-based clinics, and measures of user satisfaction and convenience were generally higher for outreach. While outreach clinics had similar health outcomes to hospital-based clinics, they did accrue additional costs.

Strength of evidence: Systematic review, no independent assessment found.

Gruen and colleagues (2003) conducted a Cochrane systematic review, to determine the effectiveness of specialist outreach clinics on access, quality, health outcomes, patient satisfaction, use of services and costs (Gruen et al 2004). Nine studies met the inclusion criteria, with the following stated aims: improving access to specialist care; improving quality of care; improving outcomes; reducing unnecessary use of services; improving collaboration between specialists and primary care; and making care more efficient. Only one study (O'Brien et al 2001) used objective measures of access, and found that outreach reduced costs to patients, distance to clinics and travel times (although absolute differences compared to standard clinic attendance were small). Studies involving remote rural populations reported significant increases in clinic attendance in outreach groups, but similar improvements were not found for urban populations. There was evidence of improved adherence to medication and reductions in attendance at hospital outpatient clinics, whereas findings for cost-effectiveness were mixed. Three studies reported improved clinical outcomes – these all involved complex interventions combining collaborative care, patient and physician education and protocol driven management. The generalisability of findings from these studies is unclear.

Strength of evidence: Cochrane systematic review.

Van Citters and Bartels (2004) systematically reviewed the evidence for mental health outreach services for older adults (Van Citters & Bartels 2004). Fourteen studies were identified, five of which were RCTs. All the intervention groups received care in residential settings, and participants were generally female and 75-85 years old. Four of the RCTs examined care management protocols, developed by multidisciplinary teams, and the fifth involved a problem-solving therapy provided by social workers. The majority of the studies, including all of the RCTs, found evidence of improvements in psychiatric symptoms.

Strength of evidence: Systematic review, no independent assessment found.

National Primary Care Research and Development Centre and Centre for Public Policy and Management (2005) collected evidence on the outcomes of outreach interventions (National Primary Care Research and Development Centre & Centre for Public Policy and Management 2005). Their review included three systematic reviews and nine empirical studies. Outreach was associated with equal or higher levels of patient satisfaction. The evidence for impact on waiting times is mixed: more rigorously controlled studies have not shown the reductions in waiting times that have been reported in survey studies. The authors also note that data from older studies showing waiting time reductions may no longer be relevant given that waits for hospital outpatient appointments have recently been shortened. Health outcomes have not been widely examined, but there is tentative evidence that these are similar for both outreach and usual care. Some studies have found higher levels of specialist referral with outreach services, although it is not clear whether this is due to a lack of resources in the outreach setting or because outreach clinics increase demand by targeting unmet need. Where economic evaluations have been conducted, these have tended to show increased service costs for outreach, although costs to patients are often reduced.

Strength of evidence: Research review.

Summary of known effects of outreach clinics

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Not known.
Patients' experience, including communication and psychological outcomes	Access to services improved (particularly in rural populations), and patient costs and travel times reduced. Evidence from surveys of improved doctor-patient communication. Higher levels of patient satisfaction.
Health services utilisation and cost	Reduced attendance at hospital outpatient clinical, but mixed evidence for cost-effectiveness.
Health behaviour and health status	Improved symptoms in older people with mental health problems. Some evidence of improved health outcomes with a complex intervention involving outreach. Improved adherence to medication.

Access: what looks promising for future R&D?

The need to improve the level and flexibility of access to healthcare is clear. Certain groups have long faced barriers to appropriate and quality healthcare, while changes in lifestyles and expectations means that traditional access routes are no longer sufficient to meet the diversity of patient needs. Digital and information technologies offer new ways of connecting patients and health professionals for the delivery of healthcare, information and advice. Access may also be improved by bringing services closer to communities and relieving pressure on acute and emergency services. This is the aim of both walk-in centres and specialist outreach clinics. Evaluation studies of these patient-focused access interventions are ongoing, and findings are still tentative in most cases. Nonetheless, what these studies have found is that patients welcome these new options for accessing healthcare services, and are generally satisfied when they make use of them.

Before we can be sure about their role in improving access, future research will need to clarify the outcomes of patient-focused access interventions and their impact on local health economies. Priorities for this research should include:

- exploring how well patient-focused interventions address access inequalities and serve groups that are most in need (e.g. ethnic minorities, socially excluded, homeless)
- further investigating the extent to which new access points either duplicate existing services (e.g. general practice and emergency services) or reduce demand for them
- consideration of the impact of distance medical technologies (e.g. remote and email consultations) on the nature of communication and trust in the doctor-patient relationship
- further analysis of the costs involved in setting up and long term delivering patient-focused interventions, considering how factors such as technological improvement and user acceptance might affect cost-effectiveness
- examining the potential applications and possible risks of electronic communication and email consultations, and the data protection issues raised by this
- identify the settings and groups for which specialist outreach services would be most beneficial and effective.

References

Avery, A. & Pringle, M. (2005) 'Extended prescribing by UK nurses and pharmacists'. *British Medical Journal*, 331: 1154-1155.

BMA (2002) *Asylum seekers: meeting their healthcare needs*. London: British Medical Association.

BMA (2005) *Healthcare in a rural setting*. London: British Medical Association.

Bower, P. et al (2003) 'Setting standards based on patients' views on access and continuity: secondary analysis of data from the general practice assessment survey'. *BMJ*, 326 (7383): 258.

Bunn, F. et al (2004) 'Telephone consultation and triage: effects on health care use and patient satisfaction'. *Cochrane.Database.Syst.Rev*, (4): CD004180.

Campbell, N.C. et al (1999) 'Systematic review of cancer treatment programmes in remote and rural areas'. *Br.J Cancer*, 80 (8): 1275-1280.

Car, J. & Sheikh, A. (2003) 'Telephone consultations'. *BMJ*, 326 (7396): 966-969.

Chapman, J.L. et al (2004) 'Systematic review of recent innovations in service provision to improve access to primary care'. *British Journal of General Practice*, 54: 374-381.

Coulter, A. (1998) 'Managing demand at the interface between primary and secondary care'. *BMJ*, 316 (7149): 1974-1976.

Coulter, A. (2005) 'What do patients and the public want from primary care?'. *BMJ*, 331 (7526): 1199-1201.

Coulter, A. (2006) *Engaging patients in their healthcare*. Oxford: Picker Institute Europe.

Coulter, A. & Jenkinson, C. (2004) 'European patients' views on the responsiveness of health systems and healthcare providers'. *European Journal of Public Health*, in press.

Currell, R. et al (2000) 'Telemedicine versus face to face patient care: effects on professional practice and health care outcomes'. *Cochrane.Database.Syst.Rev.*, CD002098 (2).

Department of Health (2003a) *Developing NHS Direct - a strategy document for the next three years*. London: Department of Health.

Department of Health (2003b) *Practitioners with special interests: bringing services closer to patients*. London: Department of Health.

Department of Health (2004) *24:7 access to primary care: your role in sustaining faster access and delivering integrated, unscheduled care*. London: Department of Health.

Department of Health (2005) *Choose and Book: Patient's choice of hospital and booked appointment - policy framework*. London: Department of Health.

Department of Health (2006) *Our health, our care, our say: a new direction for community services*. London: Department of Health.

Dixon, A. et al (2003) *Is the NHS equitable? A review of the evidence*. London: London School of Economics and Political Science.

Dr Foster (2005) 'Dr Foster's case notes: hospital waiting lists and pressures on the NHS'. *British Medical Journal*, 330: 1352.

Gruen, R.L. et al (2004) 'Specialist outreach clinics in primary care and rural hospital settings'. *Cochrane.Database.Syst.Rev*, (1): CD003798.

Gulliford, M. et al (2002) 'What does 'access to health care' mean?'. *J Health Serv Res Policy*, 7 (3): 186-188.

Gulliford, M. et al (2001) *Access to health care. Report of a scoping exercise for the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO)*. London: NCCSDO/London School of Hygiene and Tropical Medicine.

Hailey, D. et al (2003) *Recent studies on assessment of telemedicine: systematic review of study quality and evidence of benefit*. Alberta, Canada: Institute of Health Economics.

Hart, J.T. (1971) 'The inverse care law'. *Lancet*, i: 405-412.

Hersh, W. et al (2002) 'A systematic review of the efficacy of telemedicine for making diagnostic and management decisions'. *J Telemed.Telecare.*, 8 (4): 197-209.

Hersh, W.R. et al (2001) 'Telemedicine for the Medicare population'. *Evid.Rep.Technol.Assess.(Summ.)*, 24: 1-6.

Horrocks, S. et al (2002) 'Systematic review of whether nurse practitioners working in primary care can provide equivalent care to doctors'. *BMJ*, 324 (7341): 819-823.

Jacklin, P.B. et al (2003) 'Virtual outreach: economic evaluation of joint teleconsultations for patients referred by their general practitioner for a specialist opinion'. *BMJ*, 327 (7406): 84.

Jennett, P.A. et al (2003) 'The socio-economic impact of telehealth: a systematic review'. *J Telemed.Telecare.*, 9 (6): 311-320.

Jones, M. (2000) 'Walk-in primary medical care centres: lessons from Canada'. *BMJ*, 321 (7266): 928-931.

Kmietowicz, Z. (2000) 'Ombudsman slams deputising service'. *BMJ*, 320 (7251): 1689B.

Lattimer, V. et al (2000) 'Cost analysis of nurse telephone consultation in out of hours primary care: evidence from a randomised controlled trial'. *BMJ*, 320 (7241): 1053-1057.

Leibowitz, R. et al (2003) 'A systematic review of the effect of different models of after-hours primary medical care services on clinical outcome, medical workload, and patient and GP satisfaction'. *Fam.Pract.*, 20 (3): 311-317.

Lewis, R. & Dixon, J. (2005) *The Future of Primary Care - meeting the challenges of the new NHS market*. London: King's Fund.

Lewis, R. & Gillam, S. (2002) 'Personal medical services'. *BMJ*, 325 (7373): 1126-1127.

Mair, F. & Whitten, P. (2000) 'Systematic review of studies of patient satisfaction with telemedicine'. *BMJ*, 320 (7248): 1517-1520.

Munro, J. et al (2001) *Evaluation of NHS Direct first wave sites: final report of the phase 1 research*. University of Sheffield: Medical Care Research Unit.

National Primary Care Research and Development Centre (2005) *What patients want from primary care*. www.npcrdc.ac.uk.

National Primary Care Research and Development Centre & Centre for Public Policy and Management (2005) *Outpatient services and primary care*. Manchester: NPCRDC.

Neville, R.G. et al (2004) 'Email consultations in general practice'. *Inform Prim.Care*, 12 (4): 207-214.

O'Cathain, A. et al (2000) 'How helpful is NHS direct? Postal survey of callers'. *BMJ*, 320 (7241): 1035.

Pal, B. (1999) 'Email contact between doctor and patient'. *BMJ*, 318 (7195): 1428.

Pechansky, R. & Thomas, W. (1981) 'The concept of access'. *Medical Care*, 19: 127-140.

Pesamaa, L. et al (2004) 'Videoconferencing in child and adolescent telepsychiatry: a systematic review of the literature'. *J Telemed.Telecare.*, 10 (4): 187-192.

Pinnock, H. et al (2005) 'Cost-effectiveness of telephone or surgery asthma reviews: economic analysis of a randomised controlled trial'. *Br J Gen Pract*, 55 (511): 119-124.

Powell, J. (2002) 'Systematic review of outreach clinics in primary care in the UK'. *J Health Serv Res Policy*, 7 (3): 177-183.

Rosen, R. et al (2001) 'Improving access, maintaining fairness: will the NHS Plan meet the challenge?'. *Health Care UK*, Winter: 19-33.

Rossiter, A. (2005) 'Power to the patients'. *www.publicfinance.co.uk*, http://www.cipfa.org.uk/publicfinance/opinion_details.cfm?News_id=24759.

Salisbury, C. et al (2002) *The National Evaluation of NHS Walk-in Centres: final report*. Bristol: University of Bristol.

Salisbury, C. & Munro, J. (2003) 'Walk-in centres in primary care: a review of the international literature'. *Br.J Gen.Pract.*, 53 (486): 53-59.

Secretary of State for Health (2000) *The NHS Plan: a plan for investment, a plan for reform*. London: Stationery Office.

Sittig, D.F. (2003) 'Results of a content analysis of electronic messages (email) sent between patients and their physicians'. *BMC Med Inform Decis.Mak.*, 3: 11.

Smith, R. (1999) 'Medicine and the marginalised. They deserve the best, not the poorest, care'. *BMJ*, 319 (7225): 1589-1590.

Taylor, H. & Leitman, R. (2002) 'Patient/physician online communication: many patients want it, would pay for it, and it would influence their choice of doctors and health plans'. *Health Care News*, 2 (8).

Terrance Higgins Trust (2005) *Clinical trials? The third annual survey of how English HIV and sexual health clinicians and primary care trusts view their services*. London: Terrance Higgins Trust.

Van Citters, A.D. & Bartels, S.J. (2004) 'A systematic review of the effectiveness of community-based mental health outreach services for older adults'. *Psychiatr Serv*, 55 (11): 1237-1249.

Venning, P. et al (2000) 'Randomised controlled trial comparing cost effectiveness of general practitioners and nurse practitioners in primary care'. *BMJ*, 320 (7241): 1048-1053.

Which? (2005) *Which Choice? Health*. London: Which?

Whitten, P. et al (2000) 'Results of a meta-analysis of cost-benefit research: is this a question worth asking?'. *J Telemed.Telecare.*, 6 Suppl 1: S4-S6.

Whitten, P.S. et al (2002) 'Systematic review of cost effectiveness studies of telemedicine interventions'. *BMJ*, 324 (7351): 1434-1437.

Wong, G. (2001) 'Increasing email consultations may marginalise more people'. *BMJ*, 323 (7322): 1189.

6. Improving the care experience

Care experience: summary of findings

- Direct and indirect feedback from patients is seen as a means of stimulating quality improvements. The main ways in which feedback can be obtained include patient surveys, provider choice, and complaints.
- Patient surveys can be used to stimulate quality improvements. Measurement of patients' experience is a useful component of a broader quality improvement strategy.
- There is an association between poor quality experience and worse health outcomes. Poor results on patient surveys are associated with a higher rate of malpractice lawsuits.
- Having a choice of provider is popular with patients. Many patients want information about quality to inform their choices. There is some evidence that patient choice exerts downward pressure on waiting times. It may stimulate providers to improve quality in other ways, but there is little hard evidence of this.
- Public disclosure of hospital performance data stimulates providers to implement quality improvements and, if well disseminated, influences public perceptions of a hospital's reputation. There is little evidence that publishing performance information has had a direct effect on patients' choices as yet, but this may be because the information has not been well disseminated. There is a risk that publication of mortality rates could lead to cherry-picking by providers, i.e. they may refuse to treat the sickest patients.
- Patients who choose their doctor are more likely to trust them and more likely to adhere to self-care regimes. Those who choose their doctor or their hospital are also more satisfied with their subsequent care. Patients who are more satisfied with their care are less likely to want to change their healthcare provider.
- There is no evidence that giving choice and support to patients on the waiting list for elective surgery leads to inequalities in access, but there is a risk that it could do so if patients are provided with inadequate support to exercise their choices.
- Advocates can help patients in disadvantaged groups and those with low health literacy to exercise choice or seek redress. Advocates working with homeless people can improve their health-related quality of life.
- Complaints have led to some improvements, but the complaints system in England is cumbersome and difficult to use. Use of complaints records as a quality review mechanism is underdeveloped at present.

Using patient feedback to improve the care experience: introduction

> *"Health services that are truly responsive to patients will only come about if all health service leaders value feedback from patients – even when that feedback is a complaint."*
>
> Ann Abraham, Health Service Ombudsman for England, March 2005

All the topics covered in this report touch on the issue of improving patients' experience of care, but in this section we look specifically at methods for capturing and using feedback from patients with a view to encouraging healthcare providers to respond to their needs and concerns. The basic idea is that those running services need a systematic way of monitoring the quality of their services through the eyes of the patients who use them. Careful assessment of the collective experience of users can help to identify problems and determine priorities for quality improvement.

This information can be sought directly, for example by surveying patients or by organising other types of structured feedback, such as panels or focus groups, or indirectly, by monitoring complaints or responding to fluctuations in service use when patients are given a choice of provider. Incentives for improvement rely on professionalism and a desire to maintain standards, and economic goals. Aligning rates of utilisation with financial incentives and enabling patients to vote with their feet (money follows the patient) is a policy that is currently being adopted in many developed countries. The theory is that the choices patients make will send unavoidable signals to institutions offering poor quality services, giving them a strong incentive to improve.

The three topics that we look at in more depth in this chapter are as follows:

- patient surveys
- provider choice
- complaints and advocacy.

Using patient feedback to improve the care experience: what is the rationale?

Patient surveys
Patient feedback surveys are increasingly seen as a key component of healthcare quality monitoring and improvement (Cleary 1999). In recent years there has been a trend away from global satisfaction measures towards more detailed measurement of patients' experience. In the UK, USA, Canada, Australia, Denmark, Norway, and many other European countries, findings from such surveys are now widely available.

A number of different rationales have been posited for organising patient feedback surveys. The following reasons are most frequently cited:

Rationale for patient surveys

- To help healthcare staff understand the patient's perspective
- To stimulate competition between providers in relation to quality benchmarks
- To monitor patients' experience against explicit standards
- To describe and explain variations in the experience of different patient sub-groups
- To motivate providers to make quality improvements
- To identify 'the best' providers and produce rankings
- To inform patients when choosing a provider or health plan.

The main way in which patients' views on healthcare performance have traditionally been sought is through the measurement of patient satisfaction. Satisfaction is not usually recorded routinely in healthcare, so specially designed surveys have to be organised to seek the views of representative samples of patients or members of the public. There are at least five levels of aggregation at which these views may be relevant (see box).

Seeking patient feedback

- On the functioning of the health system as a whole
- On care in specific provider organisations, for example hospitals or general practices
- On care provided by particular specialties or hospital departments
- On the performance of individual clinicians
- On the outcomes of specific treatments.

Satisfaction is an ill-defined concept which has been measured in many different ways (Carr-Hill 1992, Edwards & Staniszewska 2000, Fitzpatrick & Hopkins 2000, Hall & Dornan 1988, Sitzia & Wood 1998). Generally recognised as multi-dimensional in nature, there is no consensus on which domains should be included or which are most important. Patient satisfaction is sometimes treated as an outcome measure, i.e. satisfaction with health status following treatment, and sometimes as a process measure, i.e. satisfaction with the way in which care was delivered.

Satisfaction ratings reflect three variables: the personal preferences of the patient, the patient's expectations, and the realities of the care received (Sitzia & Wood 1998, Staniszewska & Ahmed 1999, Staniszewska & Ahmed 2000). Public attitudes are influenced by many factors, including the media, commercial pressures and by patients' interaction with health professionals. Expectations may also be influenced by cultural

norms and by health status. Disentangling the effect of expectations, experience and satisfaction can be problematic when patient or public views are used to measure trends in performance. Studies have found systematic differences between the views of the public (healthy people/potential patients) and the views of current users of health services (Appleby & Rosete 2003). Patients' age and reported health status are associated with ratings of healthcare, and sex and socio-economic status can also make a difference to patients' evaluations, although the impact of these variables on hospital rankings is small (Hargraves et al 2001). Patients may be further differentiated in terms of disease severity, chronic versus acute illness, and so on and all these factors may influence their responses (Zaslavsky et al 2001). Expectations and concerns are also likely to be affected by the user's experience of healthcare and their knowledge of, or dependency on healthcare providers.

Because of these problems, there has been a recent shift towards measuring patients' experience rather than their attitudes or opinions (Cleary 1999). Following qualitative research (interviews and focus groups) to find out what patients think are the most important features of their healthcare, fixed-response questionnaires are developed focusing on specific dimensions of patients' experience (Coulter 2006b). Instead of asking patients to rate their care using general evaluation categories (e.g. excellent, very good, good, fair, poor), they are asked to report in detail about their recent experiences with a particular hospital, primary care organisation, or clinician. This type of survey asks respondents to say whether or not certain processes or events occurred during a particular visit, a specific episode of care, or over a specified period. These questions are intended to elicit reports on what occurred (experience), rather than the patient's evaluation of what occurred (satisfaction). In each case, the resulting data represent the perception of the patient, but the response task is different in the two cases. The first asks "what was your experience?" the second asks "how would you evaluate that experience?"

Questionnaires that use these report-style questions are seen as being more useful for helping providers to determine what action to take to address quality problems. Knowing that, say, 15% of patients rated their care as "fair" or "poor" doesn't give a manager or clinician a clear view of what they need to do to improve procedures and processes in their hospital. On the other hand, knowing more precise details of what went wrong, for example, the proportion of patients who said they had to wait more than 15 minutes for the call button to be answered, and monitoring trends over time in these indicators, can be more actionable. Focusing on the details of patients' experience should help to pinpoint the problems more precisely.

Provider choice

Many patients feel they should be able to choose who to consult or where and when to be treated (Coulter & Magee 2003). While provider choice has long been a feature of many health systems, until recently choice of provider was relatively constrained in the British NHS. British patients have always had the right to choose their GP, within geographical limits, but they had little say about who they were referred to for specialist advice or treatment. This changed with the publication of the NHS Plan in 2000, which included a promise to give patients more choice (Secretary of State for Health 2000). Following a number of pilot projects, choice at the point of referral was introduced from December 2005. From this date, all patients requiring referral to a specialist were guaranteed a choice of four different provider organisations. The choice on offer is essentially a choice of referral location, rather than a choice of specialist doctor.

In theory once the new activity-based funding scheme, Payment by Results, is fully implemented (Department of Health 2002), the choice system should give providers a strong financial incentive to increase throughput and drive up quality standards because funding flows will match the choices patients make. It also addresses another of the

government's priorities for the NHS, namely the reduction of waiting times. By offering patients facing a long wait for treatment the option of going to an alternative provider with shorter waiting lists, the government hoped that the incidence of long waiting times would be reduced (Dawson et al 2004).

Studies of patients offered a choice while on the waiting list for elective surgery have demonstrated that the offer of a choice of treatment location is popular (Coulter et al 2005, Le Maistre et al 2004). Patients can and do make choices, often weighing up a complex combination of factors to arrive at the decision that feels best for them. They have to consider factors such as their present health status and symptoms, impact on employment and activities of daily living, length of wait, travel arrangements, convenience for family and friends, and where they will receive the best treatment and care. Most need support in making the decision, in the form of help with practical arrangements and reliable information, especially about the quality of care in the different hospitals.

Uptake of alternative hospitals in the early British pilots was high, probably because patients wanting to take up the offer were well supported, but few participants were confident that they had sufficient information to make a truly informed decision, and insufficient effort appears to have been made to fill this gap. Some individual hospitals provided leaflets about their services, but the content of these rarely covered issues of quality and safety in any detail and it would have been difficult, if not impossible, for a patient to compare performance in different hospitals.

There are concerns about potential adverse effects of provider choice, in particular that better-off people will be better able to take advantage of choice, leaving those in disadvantaged groups with few options (Farrington-Douglas & Allen 2005). Barriers to access for these groups may include travel costs, job constraints, communication problems and low levels of health literacy (Dixon et al 2003). The government hopes that commissioners will establish arrangements to enable all eligible patients to take advantage of the opportunity to receive faster and better treatment (Secretary of State for Health 2003, Stevens 2003). The government's optimism appears to have been justified, at least as far as the London Patient Choice pilot was concerned, since there was no evidence of socio-economic inequalities in uptake (Coulter et al 2005). But the scheme that is now being rolled out across the country differs in many ways from the pilot scheme, not least in the much more limited availability of personal support and free transport for patients wanting to go to alternative providers. The risk of unequal access to, or uptake of, provider choice remains real. Furthermore, the availability of choices is likely to be constrained in some areas and in some specialties, so geographical inequities may be an unavoidable feature of the policy. Also, it is by no means clear that the provider choice scheme will lead to an improvement in quality standards and efficiency (Appleby et al 2003). There is a risk that it could have the opposite effect.

Complaints and advocacy

Patients have a right to make a complaint if they feel their healthcare was sub-standard in any respect and providers have a duty to respond to these complaints. Dealing with complaints effectively at the individual level should help to resolve problems for the individual complainants, but analysing and learning from complaints collectively could be an excellent means of identifying and ironing out common problems. Yet, according to the Health Service Ombudsman for England, *"the NHS is not using the valuable information contained in complaints to improve its services and complaint handling processes"* (The Health Service Ombudsman for England 2005).

Patients' complaints cover a wide range of issues, including errors of omission or commission in relation to specific aspects of clinical care, failure to provide information,

problems in staff attitudes and communication, and failure to diagnose a condition (see table).

Top five causes of complaint (Citizens Advice Bureau 2006)	
Aspects of clinical treatment	41%
Attitude of staff	28%
Failure to diagnose a condition	27%
Inability to access a treatment	22%
Communication or information failures	21%

In England, patients who make a complaint enter a process which can be complex and time-consuming. Prior to making a formal complaint, patients can approach the Patient Advice and Liaison Service (PALS) who might be able to resolve their concerns informally. They can also provide advice on the complaints process and help patients make a formal complaint, but PALS staff are employed by NHS trusts against whom the complaint may be being made, so many patients will prefer to seek more independent advice. This is available from the Independent Complaints Advocacy Service (ICAS) which was established in 2003 to help people decide whether or not to make a formal complaint and support them in doing so.

There are three stages to the formal complaints process: local resolution, independent review, the Health Service Ombudsman (see box).

NHS Complaints Procedure for England (Department of Health 2004)	
Stage	**What patients should do**
Local resolution	Complain orally or in writing to the primary care practitioner or NHS organisation concerned. You should receive a response from a primary care practitioner within 10 working days or from the chief executive of the NHS organisation concerned within 20 working days.
Independent review	If you are unhappy with the response to your complaint, you can ask the Healthcare Commission for an independent review of your case.
The health service ombudsman	If you remain unhappy after local resolution and independent review, you can complain to the Health Service Ombudsman, who is completely independent of the NHS and Government.

The procedure is different in Scotland and local resolution arrangements in Foundation Trusts may vary.

In her independent report to Parliament, Ann Abraham, the Health Service Ombudsman, pointed to five significant weaknesses in the system (The Health Service Ombudsman for England 2005):

Problems with the complaints system in England

- Complaints systems are fragmented within the NHS, between the NHS and private healthcare systems, and between health and social care
- The complaints system is not centred on the patient's needs
- There is a lack of capacity and competence among staff to deliver a quality service
- The right leadership, culture and governance are not in place
- Just remedies are not being secured for justified complaints.

She made a number of recommendations for improving the system, including streamlining it to make it easier for people to navigate and establishing a core set of quality standards and monitoring these.

Care experience: what do patients and the public want?

Patient surveys
Research by the Picker Institute has identified eight aspects of healthcare that patients consider most important (Coulter 2005):

What patients want

- Fast access to reliable health advice
- Effective treatment delivered by trusted professionals
- Involvement in decisions and respect for preferences
- Clear, comprehensible information and support for self-care
- Attention to physical and environmental needs
- Emotional support, empathy and respect
- Involvement of, and support for, family and carers
- Continuity of care and smooth transitions.

Surveys asking patients specific questions about each of these domains gain high response rates and show that in general most patients are very appreciative of the care they receive from NHS staff. There are also some encouraging signs that patients' experience is improving (Coulter 2006b). The results of the national patient surveys carried out in each NHS Trust in England show that improvements have been most dramatic in those areas that have been the subject of coordinated action, e.g. hospital waiting times, cancer care, coronary heart disease and mental health, although there is still room for more improvement, particularly in care of mental health patients. Standards in primary care are high on the whole, leaving less scope for improvement, but many patients want more information, especially about their medicines.

The news is not all good, however. Many patients want more involvement in decisions that affect them, and better support for self-care. Although most patients are treated with dignity and respect by NHS staff, there are signs that care is still too often delivered in a paternalistic manner, with many patients given little opportunity to express their preferences or influence decisions about their care (Coulter 2006a). Transitions between different healthcare providers, and between hospital and home, are not as well-coordinated as they should be. Pain relief is another area where care could be better. Many patients need better help with recovery and rehabilitation, including financial and employment advice and information about relevant support services. This need is especially acute for those with long term problems, such as cancer and mental illness.

Provider choice
Having the opportunity to choose a provider is undoubtedly popular with patients. A number of studies have looked at British patients' reactions to the hypothetical possibility of being given a choice of where to be treated (MORI 2003, MORI 2005, Rosen et al 2005). Most are enthusiastic about the possibility, but many are unclear about the implications of current government policy and the choices on offer. The decision about whether or not to opt for treatment at an alternative to the patient's 'home' hospital is likely to be influenced by a variety of factors. The two most obvious of these are waiting time and travelling distance. A study posing the hypothetical question about willingness to trade off these factors suggested that patients would be willing to travel further afield for their treatment if their waiting time for admission was reduced by at least 3.9 months (Ryan et al 2000). Other factors that have been identified as being of importance to patients include convenience for friends and family, concerns about continuity of care

including follow-up care, and views about, or previous experience of, their local hospital (Coulter et al 2005, Le Maistre et al 2004, MORI 2001, Rigge 2001).

Having a choice of provider is not much use unless patients have access to reliable information on which to base the selection. Studies have revealed gaps between the information patients felt was necessary to make a truly informed decision and what they actually received (Coulter et al 2005, Taylor et al 2004). When choosing providers, information about performance and clinical quality is just as important to patients as information about practical arrangements for their care:

Patients' views on information to support provider choice
London Patient Choice Project evaluation (Coulter et al 2005)

	Received sufficient information %	Did not want/need this information %	Wanted more information %
PRACTICAL INFORMATION			
Travel arrangements and how I would get there	73	12	15
The location of different hospitals	69	17	15
How long I would have to wait for my operation at the different hospitals	62	15	24
How long I would have to stay at the different hospitals	59	21	20
Arrangements for follow up care at the different hospitals	44	26	30
The visiting times at the different hospitals	30	53	17
Car parking facilities at the different hospitals	23	59	18
The size of the wards at the different hospitals	18	63	20
PERFORMANCE INFORMATION			
The hospitals' experience of treating people with my condition	45	32	23
The quality of patient care at the different hospitals	33	38	28
The qualifications and experience of the surgeons at the different hospitals	33	39	28
The success rates in the different hospitals for the operation I would have	32	40	28
The standards of hygiene at the different hospitals	30	41	29
The safety records of the different hospitals (e.g. errors, infections, etc)	24	45	32

Complaints and advocacy

A study involving interviews with users of PALS to determine patient-centred quality criteria for assessing these services, found that users and their representatives wanted PALS to be both responsive and effective (Abbott et al 2005):

Quality criteria for PALS (Abbott et al 2005)

- Responsive to the needs and wishes of individuals
- Accessible to all sections of the community, including older people, ethnic minorities and groups with special needs
- Offer clear, accurate and comprehensive information about local health and other services
- Work with their NHS organisation to create a more patient-centred service
- Collaborate effectively with other organisations
- Be adequately resourced.

Interestingly, PALS' lack of independence was not a major concern, but respondents acknowledged that people do need access to independent advocacy when 'insider' trouble-shooting fails. The authors concluded that this alternative to the adversarial approach of complaints is welcome, but PALS, like complaints procedures, may be under-used by marginalised or demoralised service users.

As we have seen, a number of bodies have been critical of the current complaints system, including several public inquiries investigating serious failings in patients' experience of systems and in standards of clinical care, for example the Bristol Inquiry (2001), the Neale Inquiry (2004), the Ayling Inquiry (2004), and the Shipman Inquiry (2005). According to the Department of Health, which commissioned a review of the complaints system, patients who have used the system have a number of criticisms:

Review of complaints system (Department of Health 2003)

- It is unclear how, and difficult to, pursue complaints and concerns
- There is often delay in responding when concerns arise
- Too often there is a negative attitude to concerns expressed
- Complaints don't seem to get a fair hearing
- Patients don't get the support they need when they want to complain
- The Independent Review stage doesn't have the credibility it needs
- The process doesn't provide the redress patients want
- There does not seem to be any systematic process for using feedback from complaints to drive improvements in services.

The Department of Health has promised a comprehensive programme of reform to address these problems.

It is also relevant to ask what patients think about the relevance and value of patient feedback and other forms of performance monitoring. There appears to be a considerable unmet demand for information about the record and experience of doctors. For example, in a UK survey nearly two thirds of patients undergoing surgery said they would like information about the surgeon's experience of treating patients with similar conditions to theirs, and nearly half said they would like information on health outcomes and patient satisfaction ratings (Coulter 2006a).

A group of general practice patients in Scotland were asked for their views on three different feedback mechanisms: patient representatives or advocates, feedback forms for complaints or suggestions, and a telephone comments line (Entwistle et al 2003). Respondents varied in their judgments about the likely effectiveness of different ways of

communicating their concerns, ideas and views. Most would prefer either to contact a patient representative, contact clinical staff (especially GPs), or write to the manager of the relevant organisation. A few would prefer to use a dedicated telephone or web-based feedback service, but over third of respondents thought these would be a waste of NHS money.

There is strong public support for public monitoring of healthcare performance, but a study conducted in England found that people were ambivalent about the value of performance indicators and hospital rankings (Magee et al 2003). They tended to distrust government information and preferred the presentational style of Dr Foster, a commercial information provider, because it gave more detailed, locally relevant information.

Using patient feedback to improve the care experience: what strategies have been tried and by whom?

Patient surveys

The most widely used surveys in the USA and the UK – the Picker surveys used in the national patient survey programme for England and the CAHPS surveys in the US – come from the same stable, since they were originally designed by researchers at Harvard University, with input and funding from other organisations, including the Picker Institute, the Commonwealth Fund, the Agency for Healthcare Research and Quality, the Rand Corporation and the National Committee for Quality Assurance.

The Picker surveys that measure patients' experience were developed by researchers at Harvard Medical School with funds from the Picker/Commonwealth Program for Patient-Centered Care, a programme established in 1987 under the auspices of the Commonwealth Fund of New York (Beatrice et al 1998). The aim was to explore patients' needs and concerns as patients themselves define them (Cleary & Edgman-Levitan 1997). This approach to measuring patients' experience has since been used in the CAHPS surveys in the USA, the WHO responsiveness surveys, and the national NHS patient survey programme in England (Carman et al 1999, Jenkinson et al 2002c, Murray et al 2001).

The first national survey using the Picker survey method involved telephone interviews with 6,000 recently hospitalized patients randomly selected from a probability sample of sixty-two hospitals in the USA, along with 2,000 of the friends or family members who served as their carers (Cleary et al 1991, Delbanco et al 1995, von Eigen et al 1999). The Picker adult inpatient questionnaire has subsequently been used with many patients in the USA and elsewhere, including Australia, Canada, and various European countries (Bruster et al 1994, Charles et al 1994, Coulter & Cleary 2001, Draper et al 2001, Gulacsi 2001). It has been found to be sensitive to changes over time and useful for setting priorities for quality improvement and monitoring the impact of subsequent changes in care delivery (Jenkinson et al 2002b, Jenkinson et al 2002a, Jenkinson et al 2003, Reeves et al 2002). A recent study compared results using this questionnaire mailed to patients after discharge from hospitals in five countries: Germany, Sweden, Switzerland, USA and UK (Coulter & Cleary 2002, Coulter & Cleary 2001). The comparative study showed that the topics covered were pertinent in each of the countries.

The Department of Health in England now requires all NHS facilities to conduct annual postal surveys of their patients' experience (Secretary of State for Health 2000). Previous national patient surveys had been organized by the Department of Health, but these covered specific patient groups – general practice patients and patients with coronary heart disease and cancer. The new survey programme was launched in January 2002 and results are incorporated in the performance assessment of NHS Trusts carried out by the Healthcare Commission. Trusts are also required to publish summaries of their results locally and to report on actions taken as a result of the survey. Special surveys have been designed for inpatients, outpatients, patients using emergency services, primary care patients, children and young people, and users of mental health and ambulance services. There are also national surveys of patients in priority groups such as cancer, heart disease, stroke, and diabetes.

The Picker questionnaires have been adopted as the standard for the NHS survey programme. Further qualitative research was carried out to adapt the instruments for this purpose and some minor modifications were made. Surveys were then designed to determine patients' top priorities. Selection of items for inclusion in the core set built on these 'importance' studies and psychometric analyses were then used to derive a standard core set of questions (Jenkinson et al 2002a).

CAHPS surveys were developed in the USA to elicit information from consumers about their healthcare experiences (Hargraves et al 2003, Hays et al 1999). CAHPS surveys have been developed for several groups of healthcare consumers, including those with commercial insurance, Medicaid recipients, and Medicare beneficiaries (Goldstein et al 2001). There are separate versions for adult and paediatric care (Homer et al 1999). The first surveys were originally developed just for health plans. Now CAHPS surveys are available or being developed for individual clinicians, behavioural health and substance abuse services, hospitals, nursing homes, and haemodialysis centres. The programme is being developed and funded by the US Agency for Healthcare Research and Quality (AHRQ).

CAHPS surveys ask for both reports of experiences and ratings. The original purpose of CAHPS was to provide information to consumers to help them make choices among health plans and now healthcare providers. This purpose led to the questionnaires and the reports of results to consumers being developed in concert and consideration being paid to how the data would be reported to the public.

CAHPS surveys are now used in the U.S. by many health plans, major employers, purchasing groups, and the Centers for Medicare and Medicaid Services (CMS). It is a component of the accreditation process for health plans administered by the National Committee for Quality Assurance (NCQA) and of NCQA's Health Plan Employers Data and Information Set (HEDIS). The Medicare Managed Care version of CAHPS (MMC-CAHPS) has been used to survey Medicare beneficiaries in managed care health plans annually since 1997 (Zaslavsky et al 2000, Zaslavsky & Cleary 2002).

International comparisons can also be useful to focus attention on problems and progress (Coulter & Cleary 2001, Coulter & Jenkinson 2004, Coulter & Magee 2003). The Commonwealth Fund of New York has organised an international series of public and patient surveys since 1998 (Blendon et al 2003, Davis et al 2004, Davis et al 2006, Donelan et al 1999, Donelan et al 2000, Schoen et al 2004). The latest of these involved patients in six countries: Australia, Canada, Germany, New Zealand, UK and USA (Coulter 2006a, Schoen et al 2005). No country excels in patient-centred care and many problems are common to all, but wide variations in some areas suggest there is much to learn from comparing approaches to quality improvement in different countries.

Surveys such as these provide an assessment of the quality of care from the patient's perspective which can be used as the first step in a programme to prioritise areas where change is needed (Cleary et al 1993, Davies & Cleary 2004, Draper et al 2001, Greco et al 2001b, Sweeney et al 2005). Comparison with national and international benchmarks can be helpful for persuading staff that better care is possible. Studying survey results over time within a general practice, clinic, or hospital can be a useful way of monitoring the effectiveness of quality improvement initiatives. Further examination of the procedures and processes used in different organizations can provide useful insights on how to improve certain aspects of care. However, gathering and disseminating the results of patient surveys may not be sufficient to prompt successful quality improvement initiatives.

Provider choice

While choice of secondary care providers is a relatively new innovation in the NHS, in other developed countries, e.g. France, Germany, Belgium, Australia, and the USA, some form of patient choice has long been the norm (Goddard & Hobden 2003). Despite this, with the exception of the US there is little evidence on the effects of patient choice in these countries (Williams & Rossiter 2004).

In the US a great deal of effort has gone into developing and making available information about the quality of care to foster informed choice. Qualitative research

revealed that American patients wanted information on health plans, what they cost, the covered benefits, the quality of care, technical competence, information and communication provided by doctors, coordination of care, access, and overall patient satisfaction. They wanted an unbiased, expert source of judgment about healthcare quality and they wanted to know how others “like them” evaluated care (Cleary et al 1991). Research into the information needs of Medicaid patients found they placed highest value on the following characteristics of health plans: access to counselling/mental healthcare; choice of doctors; communication; continuity of care; prenatal care; prescription medication; transportation; access to dental care; enrolment process (Brown et al 1999).

In the US there is evidence of a relationship between patients’ reports of their experience of care and the choices they make. (Lied et al 2003). A study that analysed the relationship between quality of care as measured by CAHPS patient surveys and data on disenrolment from health plans found that plans which were less highly favoured by patients had the highest voluntary disenrolment rates. The average disenrolment rate was four times higher for plans in the lowest 10% of patient ratings than for plans in the highest 10%. A key predictor of disenrolment was whether a plan provides all the special services needed by a patient, such as medical equipment, therapy and home care.

Interpersonal relations are a key factor in patients’ evaluations of health plans. A national survey of American healthcare consumers’ information needs found that the quality of doctors was considered the most important factor in choosing a health plan, followed by courtesy and manner of the physicians and staff, the ability to choose one’s own doctors, specialists and hospital, and the cost of the plan (Isaacs 1996). This finding was echoed in a large study of Medicare patients which confirmed that doctor-patient interactions have a major impact on patient satisfaction with health plans (Zaslavsky et al 2000). Service availability, cost and coverage are also considered very important (Booske et al 1999).

Although most of these features are measured in the CAHPS surveys and published, there is only limited research evidence that American patients currently use this type of data to make healthcare choices (Marshall et al 2000, Schneider & Lieberman 2001). However, the factors affecting health plan choice have changed dramatically in the past few years and few studies are applicable to decisions currently being made by consumers. Furthermore, few studies have evaluated the impact of new consumer assessment surveys and reports (Chernew & Scanlon 1998, Knutson et al 1998). Evaluations of the CAHPS survey suggest that some patients do attend closely to these survey results and that they can have an important influence on decisions. When state employees in the State of Washington were asked what source provided the most important information about health plan, the CAHPS report was the most frequently mentioned source. More than 70% of respondents said that the CAHPS report was helpful for deciding whether to switch health plans (Guadagnoli et al 2000). Another study in Denver and St. Louis evaluating a report including consumer ratings of plans found that 82% of respondents found the report useful in learning about quality and 66% found it useful in deciding about whether to change health plans (Fowles et al 2000).

It is interesting to note that health outcomes were rarely mentioned by patients as an important factor informing their choice of health plan. This may be because the obvious outcome measures, for example mortality rates or readmission rates, are not seen as directly relevant in choosing a health plan. They are of course more obviously relevant to choice of hospital and some health plans allow relatively free choice of hospital while others strictly limit the options. Information on process and outcome indicators in different hospitals has been a feature of the American scene for some years. Despite the fact that these indicators reveal considerable variations in performance between hospitals, very few patients are aware of the data and even fewer seem to use it (Schneider & Epstein 1998).

A number of explanations have been proposed to account for American patients' failure to use the published indicators, including the following:

Barriers against using quality report cards

- Consumers are not aware of variations in quality so don't seek information about 'the best' providers (Schneider & Lieberman 2001).
- Consumers don't believe they have a choice or prefer to leave it to their employer to choose a plan (Hoy et al 1996).
- Relevant information is not available at the time it is needed (Schneider & Epstein 1998).
- Healthcare report cards are badly designed and consumers find them hard to understand (Hibbard et al 2001, Vaiana & McGlynn 2002, Veroff et al 1998).
- Consumers don't trust the information or its source (Schneider & Lieberman 2001).

Despite the lack of evidence that report cards are being used by American patients, there is still a considerable commitment to the principle of public disclosure of information about healthcare quality (Clancy 1999, Hibbard et al 2002). Those patients who are aware of the report cards say they find them helpful and relevant even if they use them only rarely. It seems possible that public disclosure of healthcare performance information is still at an early stage in the diffusion curve and the expected impact will become apparent within the next few years.

In the meantime, the British government is committed to making information available to the public, both via the official publication of performance indicators on www.nhs.uk and by supplying information to commercial providers such as Dr Foster. A key issue will be whether greater transparency enhances or undermines public confidence in the NHS (Brownlea 2001, Mulligan 2000).

If patients are to be encouraged to make use of performance information, it will be important to engage them in the process of identifying key indicators and designing report cards and other formats for publishing and disseminating it. Research is required to fill in the wide gaps in knowledge about what British patients might want and need and what use they might make of the information.

Complaints and advocacy

Patients requiring help to resolve issues they are concerned about can turn to independent advisors or advocates for help. In addition to PALS and ICAS, a number of organisations offer this type of service. A leading charity in this field is AVMA – Action Against Medical Accidents. They have a team of medically and legally trained caseworkers who can provide free and confidential advice for people affected by a medical error or accident. A large number of smaller local groups also offer advice and advocacy. A King's Fund study found between 450 and 500 groups providing advocacy services in London alone (Heer 2004).

The Advocacy Charter defines advocacy as: *"Taking action to help people say what they want, secure their rights, represent their interests and obtain services they need. Advocates and advocacy schemes work in partnership with the people they support and take their side. Advocacy promotes social inclusion, equality and social justice."*

The King's Fund study found considerable confusion about what advocates are and what they do, with no consensus on where the boundaries of advocacy do and should lie (Heer 2004). Their report listed a range of activities covered by the term:

Advocacy

- Representing individuals' views to service providers and others, and helping them resolve issues about their health and healthcare.
- Helping to protect and support individuals who are particularly vulnerable because of illness or lack of capacity to make informed decisions.
- Providing information and advice about preventing illness and improving health, and about health services.
- Empowering individuals and groups to define their own needs, make their voices heard, and gain access to the knowledge, support and services they require.

While patient advocates are involved in a broad range of activities, these often include interpreting and expressing the views of patients and service users or helping them make their voices heard, so in this sense they constitute an important part of the feedback process. It is not an unproblematic role, however, and is potentially open to abuse. As well as concerns about the extent to which advocates can be truly independent – after all they usually need funding for their activities – questions have been raised about the reliability of their representation of the views of those for whom they are advocating. Nevertheless, there is an important role for them to play, particularly in helping patients gain their rights and, where necessary, redress.

Using patient feedback to improve the care experience: what works?

1. Patient surveys

In this section we look at the impact of surveys of patient satisfaction with, or experience of, particular organisations, i.e. hospitals or other healthcare facilities, and surveys that gain patient feedback on the performance of individual clinicians. In addition to the studies that attempted to directly evaluate the impact of patient surveys, a number of studies have examined the link between patients' experience and health outcomes. These studies are important insofar as they suggest that health benefits could be achieved from collecting and acting upon patient survey data, so we have included them below.

Impact of patient feedback surveys on the quality of care in organisations

Draper and colleagues (2001) describe the establishment and impact of surveys that measured patient satisfaction with maternity care and acute hospital care in Victoria, Australia (Draper et al 2001). The maternity survey, which was first implemented in 1983 and repeated a decade later, helped to identify problems and led to a number of policy recommendations. Regular patient surveys have been carried out in acute hospitals in Victoria since the early 1990s. Six months after the first survey, the Department of Human Services in Victoria sought feedback from individual hospitals on the extent to which the survey results had been used as a basis for implementing changes. Generally, hospitals had focused on one of three areas for quality improvement: food services, physical environment or information provision and communication (particularly at discharge and around medications). However, the study found that most hospitals had not instigated action on the basis of survey results. Respondents highlighted the difficulties of pinpointing the wards/sections where problems were arising as a barrier against making system changes. The authors make various suggestions for helping hospitals to examine the implications of their survey results and act upon them.

Strength of evidence: Case studies.

Hildenhovi and colleagues (2002) implemented a patient survey in a Finnish university hospital's outpatients departments between 1997 and 1999 (Hildenhovi et al 2002). The survey enabled the detection of strengths of the service and long term trends from the patient's perspective. Patient evaluations improved year by year, despite the fact that the questionnaire focused on issues that were rated poorest by patients. The worst ratings related to information provision and adherence to appointment times. The authors concluded that the survey instrument can be used to generate information to stimulate quality improvements.

Strength of evidence: Series of cross-sectional studies.

Crawford and colleagues (2003) conducted a systematic review of user involvement strategies, which included evidence on the impact of patient surveys (Crawford et al 2003a). This evidence is difficult to interpret, as surveys have often been used as one component in mixed-method initiatives. Nonetheless, studies show that surveys can contribute to improved service delivery and quality of care. For example, national surveys of patients with coronary heart disease led to new services (rapid access clinics) and

improvements in pain control and patient information (Airey et al 2001). Another survey, of surgical inpatients, led to revised admissions and discharge procedures/information, improved ancillary services and the establishment of a liaison group (Woods 1994).

Strength of evidence: Systematic review, no independent assessment found.

Gillies and colleagues (2003) carried out an interview study with 1,104 physician organisations across the USA to compare various quality of care indicators between California and the rest of the US and explain the differences (Gillies et al 2003). Physician organisations in California were more likely to have external incentives to improve quality and more likely to use recommended care management processes for treating patients with chronic diseases. Among other external incentives that may provide an incentive to adopt higher quality standards, physician organisations in California had a higher rate of public reporting of patient satisfaction results than those elsewhere.

Strength of evidence: Cross-sectional survey.

Reiber and colleagues (2004) assessed the impact of continuous patient feedback on diabetes outcomes (Reiber et al 2004). A total of 5,721 patients were enrolled, from Department of Veterans Affairs Medical Centres in the United States. They were randomised either to control, or to the intervention group which regularly provided feedback on clinical status, physical and mental function, and their satisfaction with organisational aspects of care. This data was summarised along with any laboratory findings, and given to healthcare professionals prior to patient consultations. Small improvement in clinical and self-care indicators were observed in the intervention group, but these did not reach statistical significance. There was no difference between the two groups in their satisfaction with their provider's interpersonal skills or the organisation of their care. The authors suggest that more favourable results could have been gained if the intervention included active patient involvement in discussing, problem solving and goal setting in addition to the use of synthesised patient data.

Strength of evidence: Single randomised controlled trial.

Jordan and colleagues (2005) conducted a cost-benefit analysis of the HCAHPS national survey, designed to collect standardised patient feedback on hospital care in Canada (Jordan et al 2005). They found insufficient information to determine whether or not the 27-item survey will lead to better choices and improved quality of care. They note that while consumers want patient ratings of care, it is unclear how these will be used in practice to choose between hospitals. The cost of collecting the HCAHPS depends on whether it can be incorporated into existing patient surveys. If conducted as a stand-alone survey, it will cost $3,300-$4,575 per hospital. If incorporated into existing surveys, it will cost $978. The nationwide cost of the survey is estimated at between $4.1 and $19.1 million per year.

Strength of evidence: Cost-benefit analysis.

Sweeney and colleagues (2005) evaluated the impact of the Patients Accelerating Change (PAC) project in England, which aims to facilitate healthcare providers' use of patient survey data to improve the quality of care (Sweeney et al 2005). They conducted interviews with 28 individuals in nine acute NHS trusts, and concluded that the PAC project had led to positive outcomes, including improved communication and information; patients feeling valued and listened to; and improved processes and procedures (e.g. discharge processes and pain management). It had also helped to focus attention on

patient and public involvement within the provider organisations. Negative effects included pressures on staff time and some resistance to change on the part of other staff not involved in the project.

Strength of evidence: Case study.

Leddy and Wolosin (2005) analysed patients' ratings of satisfaction with pain control obtained from surveys carried out in 240 hospitals across the USA involving more than 3,000,000 patients (Leddy & Wolosin 2005). The average score for all patients treated before the implementation of Joint Commission standards on pain control, which included a requirement for regular measurement and recording of patients' experience of pain, showed a small but significant improvement after implementation. Although satisfaction with pain control varied within a relatively narrow range in the two and a half years before the institution of the standards, it subsequently showed an overall upward trend. The authors concluded that clinicians should continue to obtain regular feedback on patients' satisfaction with pain control.

Strength of evidence: Series of cross-sectional surveys.

Davies and Cleary (2005) interviewed clinical and administrative staff in hospitals in Minnesota to obtain information about the use of patient survey data in quality improvement (Davies & Cleary 2004). Interviewees described a number of quality improvement initiatives that had been stimulated by survey results, including improvements in waiting times and access arrangements, better patient information and education, improved pain control and training front of house staff in customer relations. However, they identified more examples of barriers to change than success. Organisational barriers included lack of supporting values for patient-centred care, competing priorities, and lack of an effective quality improvement infrastructure. Professional barriers included clinicians and staff not being used to focusing on patient interaction as a quality issue, individuals not necessarily having been selected, trained or supported to provide patient-centred care, and scepticism, defensiveness or resistance to change following feedback. Data-related barriers included lack of expertise with survey data, lack of timely and specific results, uncertainty over the effective interventions or time frames for improvement, and consequent risk of perceived low cost-effectiveness of data collection. Factors that appeared to have promoted data use included board-led strategies to change culture and create quality improvement forums, leadership from senior physicians and managers, and the persistence of quality improvement staff over several years in demonstrating changes in other areas.

Strength of evidence: Case studies.

Coulter (2006) examined trends in patients' experience as measured in 19 English national patient surveys carried out between 1998 to 2005 (Coulter 2006b). Improvements were observed in those areas that have been the subject of coordinated action, e.g. hospital waiting times, cancer care, coronary heart disease and mental health. Most patients reported positive experiences of primary care, but many wanted more information, especially about their medicines. In secondary care, many patients wanted more involvement in treatment decisions, more help with pain relief, and better support for self-care. Although most patients said they were treated with dignity and respect by NHS staff, there were signs that care is still often delivered in a paternalistic manner, with many patients given little opportunity to express their preferences or influence decisions about their care. Transitions between different healthcare providers, and between hospital and home, were not as well-coordinated as they should be. Many patients wanted more help with recovery and rehabilitation, including financial and

employment advice and information about relevant support services. Nevertheless, the patient survey results suggest the quality of NHS care is improving, albeit slowly.

Strength of evidence: Review of cross-sectional surveys.

Impact of patient feedback surveys on the performance of clinicians

Greco and colleagues (2001) evaluated whether doctors' interpersonal skills could be improved by incorporating patient feedback into a training programme curriculum (Greco et al 2001a). The study involved a sample of 210 GP Registrars, whose patients were asked to complete an interpersonal skills questionnaire after their consultation. The GPs were randomised to one of three groups: control (no feedback); systematic patient feedback; and systematic patient feedback involving a GP supervisor as instructor. There was significant improvement in GPs interpersonal skills in both of the intervention groups, with little difference made by the addition of a GP supervisor. Improvements were greatest at the earlier stages of general practice training and diminished during the later stages. There was no significant change (either improvement or deterioration) in interpersonal skills among GPs in the control group.

Strength of evidence: Single randomised controlled trial.

Vingerhoets and colleagues (2001) assessed the effects of feeding back patients' evaluations of their care to general practitioners (Vingerhoets et al 2001). Fifty five GPs were enrolled in the RCT, with the intervention group receiving an individual written feedback report on patients' evaluation of care and guidance on interpreting and acting upon the information. Figures contained in the report related exclusively to patients of the particular GP. Impact was assessed through re-administration (one year later) of the patient questionnaire, measuring nine dimensions of care. There was no difference between control and intervention groups in seven of the nine dimensions, and for two (continuity and medical care) the intervention group scored less positively.

Strength of evidence: Single randomised controlled trial.

Leeper and colleagues (2003) organised a pilot study to determine the effectiveness of using feedback from a standardised patient to teach informed consent to surgical residents in Iowa (Leeper et al 2003). The small study involved eight surgical residents who were divided into control and experimental groups. Residents' interpersonal skills were rated by 16 standardised patients using a 14-item scale after viewing a video of an expert obtaining informed consent. There was a statistically significant improvement in the intervention group compared to the control group. The authors concluded that standardised patient feedback is effective for teaching informed consent, but they caution against over-interpretation of the results due to the small study size.

Strength of evidence: Single randomised controlled trial.

Wensing and colleagues (2003) organised a randomised controlled trial to assess the response of general practitioners to feedback from patients obtained via a patient survey (Wensing et al 2003). The trial involved 52 GPs from the Netherlands, half of whom received an individualised feedback report while the others acted as controls. GPs in the intervention group read and discussed their feedback reports and then reported on a range of actions that can be undertaken to improve the quality of care. No changes were observed in their communication behaviour after receipt of the feedback. All the practitioners were highly motivated to learn from patient views, both at baseline and after

the intervention period. Compared to the control group, GPs in the intervention group had less favourable views of the relevance of patient feedback for their practice after the receipt of such feedback. Furthermore, these practitioners felt that a patient survey required considerable time and energy and saw little reason for change.

Strength of evidence: Single randomised controlled trial.

Stelfox and colleagues (2005) looked at the relationship between complaints and malpractice lawsuits and patient feedback on care received by individual physicians (Stelfox et al 2005). Decreases in physicians' patient satisfaction survey scores from the highest to the lowest tertile were associated with increased rates of unsolicited complaints from patients and risk management episodes. Compared with physicians with the top satisfaction survey ratings, physicians in the middle tertile had malpractice lawsuit rates that were 26% higher, and physicians in the bottom tertile had malpractice lawsuit rates that were 110% higher. The authors concluded that patient satisfaction surveys may be useful quality improvement tools, but identifying physicians at high risk of complaints from patients and of malpractice lawsuits remains challenging.

Strength of evidence: Cross-sectional surveys and record linkage.

Potential health benefits of obtaining patient feedback

Fremont and colleagues (2001) reported the findings of surveys of patients treated for acute myocardial infarction at 23 hospitals in New Hampshire: three, six and twelve months after discharge (Fremont et al 2001). Patients were asked about the non-technical aspects of their care including: respect for their preferences, coordination of care, emotional support, involvement of family and friends, and continuity and transition. Patients who reported poorer experiences of care had worse health outcomes (overall health, mental health, physical health and chest pain). After adjusting for clinical and demographic factors, experience of care was still significantly related to overall health and physical health. This study indicates that long term health outcomes might be improved by obtaining and acting upon patient feedback.

Strength of evidence: Cross-sectional survey and record linkage.

Keating and colleagues (2002) examined the relationship between patients' experience of the interpersonal aspects of care and trust in their doctors (Keating et al 2001). They conducted a telephone survey with 2,052 patients, who were asked to report whether their doctor: gave them enough time to explain the reason for their visit; gave them answers to their questions that were understandable; took enough time to answer their questions; asked about how their family or living situation might affect their health; gave as much medical information as they wanted; and involved them in decisions as much as they wanted. Patients reporting the most positive experiences of care were most likely to trust their physician and least likely to have considered changing their doctor. The number of patients who considered changing their doctor increased substantially as the number of problem experiences increased. Research has shown that trust in doctors is related to various patient attitudes and behaviours, including satisfaction with care and willingness to follow medical recommendations and to reveal important personal/medical information. Given this, health outcomes may be improved by identifying and addressing factors that reduce patients' trust in health professionals.

Strength of evidence: Cross-sectional survey.

Summary of known effects of patient surveys

Outcome variables	Current state of knowledge
Patients' knowledge	No evidence found.
Patients' experience, including communication and psychological outcomes	Mixed results. Surveys can be used to stimulate quality improvements but simply publishing the survey results alone is insufficient to stimulate change.
Health services utilisation and cost	Patients who are more satisfied are less likely to want to change their healthcare provider. Poor results on patient surveys are associated with a higher rate of malpractice lawsuits.
Health behaviour and health status	There is an association between poor quality experience and worse health outcomes.

2. Provider choice

Studies to evaluate to impact of provider choice have tended to focus on three different types of outcome: rates of uptake of alternative providers and the factors influencing these; impact of information on patients' choices; and impact on patients' experience and the quality of care.

Uptake

Schur and Berk (1998) examined the effects of provider choice on patient access and satisfaction (Schur & Berk 1998). They conducted telephone interviews with approximately 2,000 low-income adults, across five states in the USA, comparing the findings of those who exercised choice of health plan and those who didn't (either because they did not have a choice or because they decided not to actively choose). Choice was positively associated with improved access to healthcare services and, especially, to patient satisfaction. However, the authors acknowledge that they failed to examine whether the improved outcomes were the result of choice per se, or because those who made choices opted for better quality health plans.

Strength of evidence: Cross-sectional survey.

Le Maistre and colleagues (2003) surveyed patients on the waiting list for heart surgery in the UK who were eligible to be offered faster treatment at an alternative hospital (Le Maistre et al 2004). Half of those who were offered a choice took up the offer of treatment at an alternative hospital. Older patients were slightly more likely to opt to remain on the waiting list at their home hospital than younger patients. The reputation of the hospital where the patient would receive their operation was the most influential factor when patients were making a decision, but speed of treatment was also very important. More than a third of patients made their own decision about which hospital to go to, but the remainder sought the advice of a Patient Care Advisor, a doctor at their home hospital, or their family and friends.

Strength of evidence: Cross-sectional survey.

Burge and colleagues (2005) used survey responses from patients prior to being offered a choice and revealed preferences after the offer to study the factors that patients consider important when deciding whether to opt for an alternative hospital (Burge et al 2005). Data on hypothetical choices were obtained using a discrete choice experiment. Respondents were asked to weigh up various factors, including hospital reputation, waiting times, travel arrangements, etc. Overall, 30% of respondents stated that they would stay at the home hospital under all circumstances; 5% said they would opt for treatment at an alternative hospital under all circumstances; and 55% switched between the options depending on circumstances. The remaining 10% opted out of all the choices. Patients were less willing to switch hospitals in order to reduce their wait if this required them to organise transport for themselves. In the event, 35% of patients chose to stay at their home hospital and 65% chose to move to an alternative provider.

Strength of evidence: Cross-sectional survey, data linkage and modelling.

Information

Marshall and colleagues (2000) reviewed the literature on the public disclosure of information on the comparative performance of healthcare providers (Marshall et al 2001). This literature describes the US experience, where report cards containing comparative quality data have been available for some time; the authors caution against any straightforward generalisability to a UK context. While patients report wanting information on quality, many did not know how to use it and felt they needed help in making sense of it. Studies have found that currently available report cards appear to have minimal impact on patient decision-making, which could be explained by poor understanding of the information, difficulties relating it to the immediate health context, or too little time to make use of the data. Nonetheless, there is some evidence of improvements in both provider behaviour and health outcomes. It is unclear, however, to what extent these effects were the result of internal use of performance data or of its public disclosure.

Strength of evidence: Research review.

Dranove and colleagues (2003) examined the impact of report cards on coronary artery bypass graft (CABG) surgical mortality rates in New York and Pennsylvania (Dranove et al 2003). The publication of the report cards led to substantial selection by providers, with a decline in the illness severity of patients receiving CABG. There was an overall reduction in the use of intensive cardiac procedures for severely ill patients. Caution in using more intensive procedures in higher-risk patients led to increased use of less effective medical therapies. These trends in admission and treatment were associated with reduced health outcomes for sicker patients, and improved health outcomes for healthier patients. Specifically, among sicker patients there were substantial increases in the rate of heart failure and recurrent heart attack and, in some cases, in mortality.

Strength of evidence: Uncontrolled observational study.

Hibbard and colleagues (2003) evaluated the impact of publicising hospital performance data on quality improvement efforts (Hibbard et al 2003). A report, comparing performance in 24 hospitals in Wisconsin, was widely disseminated among the public. These 24 hospitals constituted one intervention group; the other 98 hospitals in Wisconsin were randomly allocated to another intervention group (who received a private report of their own performance) or control (who received no report). In the public disclosure group, quality improvement efforts were strongly focused in areas where performance was low; this pattern was not found either in the privately available report or no report hospitals. The authors note that publicly disclosing performance data may improve the outcomes of quality improvement work.

Strength of evidence: Quasi-experimental study.

Hibbard and colleagues (2005) built on their earlier work, by assessing the long term impact of reporting public hospital performance data (Hibbard et al 2005). Twenty four hospitals in Wisconsin publicly reported performance data on quality and safety. They were compared with 98 hospitals that were randomly assigned to either receive a private, confidential report on their performance, or to receive no report at all. At baseline there were no significant differences among the three groups of hospitals in their characteristics, size, or baseline levels of performance. Hospitals in the 'public report' group initiated more quality improvement activities and achieved significantly greater improvement in performance than those in the 'private report' group and the 'no report' group. There were no significant changes in market share among the hospitals in the

'public report' group during the course of the study and no shifts occurred away from low-rated hospitals toward higher-rated hospitals. Consumers exposed to the public report were much more likely than other consumers to have accurate perceptions of the relative quality of local hospitals, and these perceptions persisted for at least two years after release of the report. Taken together, these findings suggest that the mechanism by which public reporting affects improvement is more likely to lie with concerns about reputation than with concerns about market share.

Strength of evidence: Controlled experimental study.

Patients' experience

Krupat and colleagues (2002) investigated the association between choice of primary care doctor and adherence to medical recommendations (Krupat et al 2002). They conducted surveys of patients with diabetes and their doctors in three medical centres in California; patients were asked to indicate what involvement, if any, they had had in the choice of doctor. They also collected data from patients' records on their behaviour and health status. Patients who chose their doctors were significantly more likely to be satisfied with their doctor, to report adherence to self-care regimens, and have been seen for four of the five recommended prevention screenings. However, the mean differences between choosing and non-choosing patients were not large. The authors conducted additional analysis to establish whether these findings could be accounted for by patient or physician characteristics, rather than being an outcome of choice per se. After controlling for several potentially confounding variables, the relationship between patient choice and positive outcomes remained strong.

Strength of evidence: Cross-sectional survey.

Hsu and colleagues (2003) assessed the impact of an intervention designed to help patients choose a new primary care provider (PCP) (Hsu et al 2003). The intervention consisted of provider-specific information to aid decision-making, delivered either by telephone or via the internet; those in the control group were randomly allocated a new doctor in the usual way. One thousand and 90 patients, whose previous PCP had retired, participated in the randomised controlled trial. Those in the intervention group were more likely to have retained their PCP one year later and to report greater satisfaction with their PCP. They also expressed higher levels of trust in their PCP, although differences with the control group did not remain statistically significant after adjustments for demographic characteristics had been made.

Strength of evidence: Single randomised controlled trial.

Krupat and colleagues (2004) evaluated the effect of matching patients and professionals based on their particular beliefs about care (Krupat et al 2004). A usual care group (randomly allocated a doctor) were compared against two intervention arms: one group (informed choice) could choose a doctor based on demographic and other characteristics, the second group (guided choice) additionally received a list of doctors whose beliefs about care most matched their own. Beliefs about care were evaluated using the 9-item short version of the Patient-Practitioner Orientation Scale, which measures the degree to which patients and practitioners hold patient-centred beliefs about the sharing of power and information. The guided choice group scored higher on satisfaction, trust and perceptions of the process. Interestingly, however, the degree of fit between patients' and physicians' beliefs about care was no better in the guided choice group than either the informed choice or usual care groups.

Strength of evidence: Single randomised controlled trial.

Dawson and colleagues (2004) evaluated the system-wide impact of the London Patient Choice pilot (Dawson et al 2004). Impact on waiting times differed by speciality, with significant reductions (relative to other trusts in the UK) in ophthalmology and orthopaedics but not in general surgery. Waiting times at trusts receiving choice patients did not significantly increase. The choice pilot coincided with investment in extra capacity for elective surgery; specifically the establishment of new treatment centres at trusts with relatively short waits. The authors note that had the new centres been established at trusts with longer waiting lists, the gap in waiting times may have been reduced or closed without the need for patient choice. There were reductions in the variations in waiting times for all three specialities included in the evaluation (ophthalmology, orthopaedics and general surgery), indicating an improvement in equity of access. Financial incentives built into the London pilot, to ensure that choice and local patients were treated equally, that will not be available in the future. Consequently, the positive impact on equity seen in the pilot may not be replicated with the national roll-out of the choice scheme.

Strength of evidence: Analysis of routine health service data.

Taylor and colleagues (2004) assessed the feasibility of offering patients choice in routine surgical referrals (Taylor et al 2004). Patients in the intervention arm of this RCT were given a choice between five local hospitals, and a booklet providing information on each of the hospitals to aid decision-making. Patients in the control group were only offered choices if this was standard for their practice, with the remainder being referred to a hospital chosen by their GP. Although consultations were longer in the intervention group, the change in consultation length in this group was not significantly greater than the change in the control group. Intervention group patients were more likely to perceive that they had been offered a choice; that they had chosen the hospital for referral; that their GP had taken their views into account; and that they received more information concerning local hospitals. There was an increase in delayed referrals as patients considered their options, from 1% to 14%, which the authors note will have administrative implications. When questioned about the factors that influenced their choices, patients were most likely to report ease of access and quality of care.

Strength of evidence: Single randomised controlled trial.

Williams and Rossiter (2004) examined the impact of choice in healthcare, drawing on evidence for GP fundholding and from recent patient choice pilots (Williams & Rossiter 2004). So far, choice has had a positive impact on patient waiting times and it does not appear that providers have selected less costly patients (even though there were direct incentives for them to do so under fundholding). There is some evidence that fundholding improved responsiveness among secondary care providers, as GPs used their purchasing authority to persuade consultants to visit practices and hold outpatient clinics. However, the transaction costs associated with fundholding are likely to have outweighed any efficiency benefits.

Strength of evidence: Research review.

Burgess and colleagues (2005) considered the economic impact of choice policies in healthcare (Burgess et al 2005). Almost all of the evidence they found is about choice was for the US health system, which may not be directly relevant to the UK context. This evidence suggests that choice increases competition between providers and can lower costs. The impact that competition has on the quality of care depends upon financial and

reimbursement incentives. Hospitals must have incentives to attract patients by improving quality, so where reimbursement rates are low or falling competition tends to have a negative effect on quality. Although US studies have found that quality is higher where markets are more competitive, evidence for the UK experience of fundholding is the opposite. Studies of patient choice behaviour indicate that choice is least likely to be exercised by people who are older, female, with lower educational attainment and who look after children. Public reporting of performance data may encourage providers to improve quality, but can also have negative consequences. For example, providers may focus efforts on improving the published criteria rather than the overall quality of care; may enhance outcomes by differentially selecting or treating patients; or may manipulate their data. The authors also report on the Dranove and colleagues study, outlined in detail above.

Strength of evidence: Research review.

Coulter and colleagues (2005) evaluated patients' perceptions of the London Patient Choice pilot (Coulter et al 2005). Two-thirds of patients offered choice accepted and were treated at an alternative to their local NHS provider. The only factor associated with uptake of alternative providers was employment status, with significantly more employed patients opting for an alternative hospital than unemployed. Patients who opted for alternatives to their 'home' hospital gave higher ratings of their overall experience of care, and were significantly more likely to say they would definitely recommend the hospital they were treated at to others. Importantly, the pilot provided patients with care advisors, free transport and agreed care pathways which may not be part of the national roll-out. The evaluation identified the important role of information in facilitating choice. Of those patients who had asked to receive information about alternative hospitals, those who chose to remain on their local waiting list were significant less likely to report receiving information on important factors.

Strength of evidence: Multi-method evaluation.

Thorlby (2006) examined the effects of patient choice for HIV/AIDS care. Interviews were conducted with clinic staff and patients, to identify the uptake of choice and its impact on the delivery and quality of care (Thorlby 2006). There is tentative evidence that the patients who opted to travel to access non-local services were more likely to be white (and relatively well educated) gay men, than people from ethnic minorities. Most patients tended to assume that clinical quality was a given, but a minority did consider clinical factors (e.g. availability of treatments) when choosing a provider. At a time when patient numbers were relatively low, clinics had made substantial attempts to improve the range and quality of their services; many had focused on the non-clinical aspects of care, such as providing complementary therapies or improving the clinic environment. However, there were fewer incentives for such improvement as the prevalence of HIV/AIDS had risen and sufficient numbers of patients could be guaranteed without the need to encourage switching from other clinics.

Strength of evidence: Cross-sectional interviews.

Summary of known effects of provider choice

Outcome variables	Current state of knowledge
Patients' knowledge	Public disclosure of hospital performance data stimulates providers to implement quality improvements and, if well

	disseminated, influences public perceptions of a hospital's reputation. There is little evidence of an effect on patients' choices, but patients say they want information about quality to inform their choices.
Patients' experience, including communication and psychological outcomes	Patients who choose their doctor or their hospital are more satisfied.
Health services utilisation and cost	No evidence that giving choice and support to patients on the waiting list for elective surgery leads to inequalities in access. Patients who choose their doctor are more likely to stay with them. Some evidence of downward pressure on waiting times.
Health behaviour and health status	Mixed results. Publication of report cards on surgical mortality led to selection by providers, with reduced health outcomes for sicker patients and improved health outcomes for healthier patients. Patients who choose their doctor are more likely to trust them and more likely to adhere to self-care regimes.

3. Complaints and advocacy

Crawford and colleagues (2003) systematically searched for evidence on user involvement strategies, including complaints services (Crawford et al 2003a). Qualitative research indicates that organisations often have negative or defensive responses to complaints or criticisms about services. However, there is also evidence to suggest that patient complaints are a major factor in bringing about changes in service provision. A survey of 17 mental health trusts in London found that eleven had made changes on the basis of complaints including improvements to ward environments, organisation of outpatient services and systems for supporting patients in crisis (Crawford et al 2003b).

Strength of evidence: Systematic review, no independent assessment found.

Graham-Jones and colleagues (2004) organised a randomised controlled trial to assess the effectiveness of a health advocate's casework with homeless people in a primary care setting in terms of improvements in health-related quality of life (Graham-Jones et al 2004). Homeless people moving into hostels or other temporary accommodation in the Liverpool area and patients registering at an inner-city health centre as temporary residents were allocated in alternating periods to health advocacy or usual care. Improvements in health-related quality of life were greatest in people recruited and supported by a health advocate early in their stay in temporary housing, in comparison with those in the control group. The authors concluded that this model of streamlined care for patients with complex psycho-social needs was effective.

Strength of evidence: Single randomised controlled trial.

Abbott and colleagues (2005) reported on an evaluation of the introduction of PALS services into London (Meyer et al 2005). They focused on six case study services – two in acute trusts, two in PCTs and two in mental health trusts. The main reasons for using PALS were: to highlight problems in the delivery of services; to seek explanation; to express dissatisfaction; to get help making sense of an issue; to obtain support; to seek practical help; and to seek guidance and information. During interview, service users generally expressed a high level of satisfaction with the service and how it addressed their individual concerns. While most users would approach PALS if they had another problem, they were doubtful about whether the service could influence trusts to prevent similar issues arising again. From the trusts' perspective, the key benefit of PALS was mediating between patients and trust services to swiftly resolve issues. Some senior managers also felt that the service was starting to bring about a more responsive culture within trusts, although PALS staff were generally less optimistic about their overall impact in this respect. The authors note that the effective function of the service depends on good, cooperative relations between PALS and all levels of trust staff.

Strength of evidence: Case studies and interviews.

Summary of known effects of complaints and advocacy

Outcome variables	Current state of knowledge
Patients' knowledge	Advocates can help patients with low health literacy.
Patients' experience, including communication and psychological outcomes	Complaints have led to improvements, but the complaints system is cumbersome and difficult to use.

Health services utilisation and cost	No evidence found.
Health behaviour and health status	Advocates working with homeless people improved health-related quality of life.

Using patient feedback to improve the care experience: what looks promising for future R&D?

It is striking that this area, which is central to health policy in the UK and in many other countries, is characterised by a particularly weak evidence base. There is a great deal we don't know about the impact of patient feedback, provider choice, or complaints and advocacy systems. More evidence is required on the following topics:

Patient surveys

- How valid and reliable are patient surveys? To what extent can they be used to discriminate between hospitals, primary care organisations and/or individual clinicians? Are they sensitive to changes over time? What could explain the oft-reported finding that younger patients, those with low income, those with poor perceived health, and those from minority ethnic groups report worse experiences than those in other groups?

- Is straightforward feedback of the results of patient surveys sufficient to stimulate quality improvement initiatives? Is there an upward trend in positive reports from patients in those institutions that have a long history of surveying their patients? If simple feedback methods are insufficient, what other means could be used to focus the attention of staff on patients' concerns?

- What is the impact of public reporting of patient survey results? How should the data be presented? What are the pros and cons of ranking or league tables? To what extent are the results trusted by patients and the public? To what extent are the results used by patients and for what purpose?

- What is the relative cost-effectiveness of this approach to gaining feedback and/or stimulating quality improvements in comparison with other approaches?

Provider choice

- What are the effects of offering patients a choice of provider at the point of referral and in primary care? To what extent do patients opt to go to alternative providers? What information do they need to inform their choices? What other support do they need?

- What are the positive and negative effects of public disclosure of performance data? What is the best way to present and disseminate such information? Does it stimulate quality improvements in all circumstances? Does it encourage cherry-picking? Do patients understand and make use of the information?

- What is the impact of provider choice on equity of access, on costs, on utilisation rates, on quality standards and on health outcomes?

Complaints and advocacy

- What are the benefits and what are the risks of encouraging patient advocates to get involved in the care of specific patient groups?

- To what extent can/should advocates be used to deal with or defuse problems before they become formal complaints?

- What is the best way to organise a complaints system? What are the pros and cons of ‘single portal’ access to the complaints process? What can be learnt from systematic analysis of complaints? How can provider organisations be encouraged to act more constructively and less defensively in respect of complaints?

References

Abbott, S. et al (2005) 'Quality criteria for patient advice and liaison services: what do patients and the public want?'. *Health Expectations*, 8 (2): 126-137.

Airey, C. et al (2001) *National survey of NHS patients: coronary heart disease 1999. Summary of key findings*. London: Department of Health.

Appleby, J. et al (2003) *What is the real cost of more patient choice?* London: King's Fund.

Appleby, J. & Rosete, A.A. (2003) 'The NHS: keeping up with public expectations?'. In Park, A. et al (eds), *British Social Attitudes: the 20th Report - Continuity and change over two decades*. London: Sage.

Beatrice, D.F. et al (1998) 'Grant making with an impact: the Picker / Commonwealth patient-centred care program'. *Health Affairs*, 17 (1): 236-244.

Blendon, R.J. et al (2003) 'Common concerns and diverse systems: health care experiences in five countries'. *Health Affairs*, 22 (3): 106-121.

Booske, B.C. et al (1999) 'Eliciting consumer preferences for health plans'. *Health Services Research*, 34 (4): 839-854.

Brown, J.A. et al (1999) 'Special issues in assessing care of Medicaid recipients'. *Medical Care*, 37 (3): MS79-MS88.

Brownlea, A. (2001) 'Earning confidence: perspectives for a modernising NHS'. *Journal of Clinical Excellence*, 3: 27-32.

Bruster, S. et al (1994) 'National survey of hospital patients'. *British Medical Journal*, 309: 1542-1546.

Burge, P. et al (2005) *London Patient Choice Project evaluation: a model of patients' choices of hospital from stated and revealed preference choice data*. Cambridge: Rand Corporation.

Burgess, S. et al (2005) *Will more choice improve outcomes in education and health care? The evidence from economic research*. The Centre for Market and Public Organisation.

Carman, K.L. et al (1999) 'Early lessons from CAHPS demonstrations and evaluations'. *Medical Care*, 37 (3): MS97-MS105.

Carr-Hill, R.A. (1992) 'The measurement of patient satisfaction'. *Journal of Public Health Medicine*, 14 (3): 236-249.

Charles, C. et al (1994) 'How was your hospital stay? Patients' reports about their care in Canadian hospitals'. *Canadian Medical Association Journal*, 150: 1813-1822.

Chernew, M. & Scanlon, D.P. (1998) 'Health plan report cards and insurance choice'. *Inquiry*, 35: 9-22.

Citizens Advice Bureau (2006) *From complaints to commitments: CAB ICAS evidence on service improvement commitments in the NHS*. London: CAB.

Clancy, C.M. (1999) 'Consumer preferences: path to improvement?'. *Health Services Research*, 34 (4): 807-811.

Cleary, P.D. (1999) 'The increasing importance of patient surveys'. *British Medical Journal*, 319: 720-721.

Cleary, P.D. & Edgman-Levitan, S. (1997) 'Health care quality: incorporating consumer perspectives'. *Journal of the American Medical Association*, 278: 1608-1612.

Cleary, P.D. et al (1991) 'Patients evaluate their hospital care: a national survey'. *Health Affairs*, 10 (4): 254-267.

Cleary, P.D. et al (1993) 'Using patient reports to improve medical care: a preliminary report from 10 hospitals'. *Quality Management in Health Care*, 2: 31-38.

Coulter, A. & Cleary, P. (2002) 'Measuring and improving patients' experiences: how can we make health care systems work for patients?'. In *Measuring up: improving health systems performance in OECD countries*. Paris: OECD.

Coulter, A. (2005) 'What do patients and the public want from primary care?'. *British Medical Journal*, 331: 1199-1201.

Coulter, A. (2006a) *Engaging patients in their healthcare*. Oxford: Picker Institute Europe.

Coulter, A. (2006b) *Trends in patients' experience of the NHS*. Oxford: Picker Institute.

Coulter, A. & Cleary, P.D. (2001) 'Patients' experiences with hospital care in five countries'. *Health Affairs*, 20 (3): 244-252.

Coulter, A. & Jenkinson, C. (2004) 'European patients' views on the responsiveness of health systems and healthcare providers'. *European Journal of Public Health*, in press.

Coulter, A. et al (2005) *Patients' experience of choosing where to undergo surgical treatment: evaluation of the London Patient Choice scheme*. Oxford: Picker Institute.

Coulter, A. & Magee, H. (2003) *The European Patient of the Future*. Maidenhead: Open University Press.

Crawford, M. et al (2003a) *User involvement in change management: a review of the literature*. London: National Co-ordinating Centre for NHS Service Delivery and Organisation R&D.

Crawford, M.J. et al (2003b) 'User involvement in the planning and delivery of mental health services: a cross-sectional survey of service users and providers'. *Acta Psychiatr.Scand*, 107 (6): 410-414.

Davies, E. & Cleary, P.D. (2004) 'Hearing the patient's voice? Factors affecting the use of patient survey data in quality improvement'. *Quality and Safety in Health Care*, 14: 428-432.

Davis, K. et al (2006) *Mirror, mirror on the wall: an update on the quality of American health care through the patient's lens*. New York: Commonwealth Fund.

Davis, K. et al (2004) *Mirror, mirror on the wall: looking at the quality of American health care through the patient's lens*. New York: Commonwealth Fund.

Dawson, D. et al (2004) *Evaluation of the London Patient Choice project: system wide impacts*. York: Centre for Health Economics, University of York.

Delbanco, T.L. et al (1995) 'Medical patients' assessments of their care during hospitalization'. *Journal of General Internal Medicine*, 10: 679-685.

Department of Health (2002) *Reforming NHS financial flows: introducing payment by results*. London: Department of Health.

Department of Health (2003) *NHS complaints reform: making things right*. London: Department of Health.

Department of Health (2004) *How to make a complaint about the NHS*. London: Department of Health.

Dixon, A. et al (2003) *Is the NHS equitable? A review of the evidence*. London: London School of Economics and Political Science.

Donelan, K. et al (1999) 'The cost of health system change: public discontent in five nations'. *Health Affairs*, 18 (3): 206-216.

Donelan, K. et al (2000) 'The elderly in five nations: the importance of universal coverage.'. *Health Affairs*, 19 (3): 226-235.

Dranove, D. et al (2003) 'Is more information better? The effects of report cards on health care providers'. *Journal of Political Economy*, 111 (3): 555-588.

Draper, M. et al (2001) 'Seeking consumer views: what use are results of hospital patient satisfaction surveys?'. *International Journal for Quality in Health Care*, 13 (6): 463-468.

Edwards, C. & Staniszewska, S. (2000) 'Accessing the user's perspective'. *Health and Social Care in the Community*, 8 (6): 417-424.

Entwistle, V.A. et al (2003) 'Public opinion on systems for feeding back views to the National Health Service'. *Quality and Safety in Health Care*, 12: 435-442.

Farrington-Douglas, J. & Allen, J. (2005) *Equitable choices for health*. London: Institute for Public Policy Research.

Fitzpatrick, R. & Hopkins, A. (2000) 'Problems in the conceptual framework of patient satisfaction research: an empirical exploration'. *Sociology of Health and Illness*, 5 (3): 297-311.

Fowles, J.B. et al (2000) 'Consumer response to health plan report cards in two markets'. *Medical Care*, 38: 469-481.

Fremont, A.M. et al (2001) 'Patient-centred processes of care and long-term outcomes of myocardial infarction'. *Journal of General Internal Medicine*, 16: 800-808.

Gillies, R.R. et al (2003) 'How different is California? A comparison of US physician organisations'. *Health Affairs*, DOI 10.1377/hlthaff.W3.492.

Goddard, M. & Hobden, C. (2003) *Patient choice: a review*. York: Centre for Health Economics, University of York.

Goldstein, E. et al (2001) 'Medicare managed care CAHPS: a tool for performance improvement'. *Healthcare Financial Review*, 22 (3): 101-107.

Graham-Jones, S. et al (2004) 'Tackling the needs of the homeless: a controlled trial of advocacy'. *Health and Social Care in the Community*, 12 (3): 221-232.

Greco, M. et al (2001a) 'Impact of patient feedback on the interpersonal skills of general practice registrars: results of a longtudinal study'. *Medical Education*, 35: 748-756.

Greco, M. et al (2001b) 'Patient assessment of interpersonal skills: a clinical governance activity for hospital doctors and nurses'. *Journal of Clinical Excellence*, 3: 117-124.

Guadagnoli, E. et al (2000) 'Providing consumers with information about quality of health plans: the consumer assessment of health plans demonstration in Washington State'. *Joint Commission Journal on Quality Improvement*, 26 (410): 420.

Gulacsi, L. (2001) 'Quality of hospital care: patient satisfaction and patients reports in Hungarian hospitals, 1992-1997'. In Gulasci, L. (ed), *Hungarian Health Care in Transition*. University of Amsterdam: Department of Social Medicine.

Hall, J.A. & Dornan, M.C. (1988) 'What patients like about their medical care and how often they are asked: a meta-analysis of the satisfaction literature'. *Social Science and Medicine*, 27 (9): 935-939.

Hargraves, J.L. et al (2003) 'Psychometric properties of the Consumer Assessment of Health Plans (CAHPS 2.0 adult core survey'. *Health Services Research*, 38 (6): 1509-1527.

Hargraves, J.L. et al (2001) 'Adjusting for patient characteristics when analyzing reports from patients about hospital care'. *Medical Care*, 39 (6): 635-641.

Hays, R.D. et al (1999) 'Psychometric properties of the CAHPS 1.0 survey measures'. *Medical Care*, 37 (3): MS22-MS31.

Heer, B. (2004) *Building bridges for health*. London: King's Fund.

Hibbard, J.H. et al (2002) 'The impact of a CAHPS report on employee knowledge, beliefs and decisions'. *Medical Care Research and Review*, 59 (1): 104-116.

Hibbard, J.H. et al (2001) 'Is the informed-choice policy approach appropriate for Medicare beneficiaries?'. *Health Affairs*, 20 (3): 199-203.

Hibbard, J.H. et al (2003) 'Does publicizing hospital performance stimulate quality improvement efforts?'. *Health Aff (Millwood.)*, 22 (2): 84-94.

Hibbard, J.H. et al (2005) 'Hospital performance reports: impact on quality, market share, and reputation'. *Health Aff (Millwood.)*, 24 (4): 1150-1160.

Hildenhovi, H. et al (2002) 'Measurement of outpatients' views of service quality in a Finnish university hospital'. *Journal of Advanced Nursing*, 38 (1): 59-67.

Homer, C.J. et al (1999) 'The Consumer Assessment of Health Plan Study (CAHPS) survey of children's health care'. *Journal on Quality Improvement*, 25 (7): 369-377.

Hoy, E.W. et al (1996) 'A guide to facilitating consumer choice'. *Health Affairs*, 15 (4): 9-30.

Hsu, J. et al (2003) 'Patient choice. A randomized controlled trial of provider selection'. *J Gen Intern.Med*, 18 (5): 319-325.

Isaacs, S.L. (1996) 'Consumers' information needs: results of a national survey'. *Health Affairs*, 15 (4): 31-41.

Jenkinson, C. et al (2002a) 'The Picker Patient Experience Questionnaire: development and validation using data from in-patient surveys in five countries'. *International Journal for Quality in Health Care*, 14 (5): 353-358.

Jenkinson, C. et al (2002b) 'Factors accounting for patients' experiences of hospital care: an analysis of the National Survey of NHS Patients - coronary heart disease'. *submitted for publication*.

Jenkinson, C. et al (2002c) 'Patients' experiences and satisfaction with health care: results of a questionnaire study of specific aspects of care'. *Quality and Safety in Health Care*`, 11: 335-339.

Jenkinson, C. et al (2003) 'Properties of the Picker Patient Experience questionnaire in a randomized controlled trial of long versus short form survey instruments'. *Journal of Public Health Medicine*, 25 (3): 197-201.

Jordan, H. et al (2005) *The costs and benefits of HCAHPS*. http://www.aamc.org/quality/hospitalalliance/hcahps_abt_execsumm.pdf.

Keating, N.L. et al (2001) 'How are patients' specific ambulatory care experiences related to trust'. *submitted for publication*.

Knutson, D.J. et al (1998) 'Impact of report cards on employees: a natural experiment'. *Health Care Financing Review*, 20: 5-27.

Krupat, E. et al (2004) 'Matching patients and practitioners based on beliefs about care: results of a randomized controlled trial'. *Am J Manag.Care*, 10 (11 Pt 1): 814-822.

Krupat, E. et al (2002) 'Choice of a primary care physician and its relationship to adherence among patients with diabetes'. *The American journal of managed care*, 8 (9): 777-784.

Le Maistre, N. et al (2004) *Patients' experience of CHD Choice*. Oxford: Picker Institute Europe.

Leddy, K.M. & Wolosin, R.J. (2005) *Patient satisfaction with pain control during hospitalization*. Oak Brook, Illinois: Joint Commission Resources.

Leeper, M.K. et al (2003) 'The effect of standardized patient feedback in teaching surgical residents informed consent: results of a pilot study'. *Current Surgery*, 60 (6): 615-622.

Lied, T.R. et al (2003) 'Beneficiary reported experience and voluntary disenrollment in Medicare managed care'. *Health Care Financ.Rev*, 25 (1): 55-66.

Magee, H. et al (2003) 'Public views on healthcare performance indicators and patient choice'. *Journal of the Royal Society of Medicine*, 96: 338-342.

Marshall, M. et al (2001) *Dying to know: public release of information about the quality of healthcare*. London: The Nuffield Trust.

Marshall, M.N. et al (2000) 'The public release of performance data: What do we expect to gain? A review of the evidence'. *Journal of the American Medical Association*, 283 (14): 1866-1874.

Meyer, J. et al (2005) *Learning the lessons from PALS: an evaluation of the London Patient Liaison and Advisory Services*. London: City University.

MORI (2001) *Patient choice in the NHS*. London: MORI.

MORI (2003) *Patient choice*. London: BUPA.

MORI (2005) *Choice in the Birmingham and the Black country SHA*. London: MORI.

Mulligan, J. (2000) 'What do the public think?'. *Health Care UK*, Winter: 12-17.

Murray, C.J.L. et al (2001) 'People's experience versus people's expectations'. *Health Affairs*, 20 (3): 21-24.

Reeves, R. et al (2002) *Development and pilot testing of questionnaire for use in the acute NHS Trust inpatient survey programme*. Oxford: Picker Institute Europe.

Reiber, G.E. et al (2004) 'Diabetes quality improvement in Department of Veterans Affairs Ambulatory Care Clinics: a group-randomized clinical trial'. *Diabetes Care*, 27 Suppl 2: B61-B68.

Rigge, M. (2001) *Headlines from qualitative and quantitative analysis of replies to College of Health telephone survey on patient choice in the NHS*. London: College of Health.

Rosen, R. et al (2005) *Public views on choices in health and health care*. London: King's Fund.

Ryan, M. et al (2000) 'Trade-offs between location and waiting times in the provision of health care: the case of elective surgery on the Isle of Wight'. *Journal of Public Health Medicine*, 22: 202-210.

Schneider, E.C. & Epstein, A.M. (1998) 'Use of public performance reports: a survey of patients undergoing cardiac surgery'. *Journal of the American Medical Association*, 279: 1638-1642.

Schneider, E.C. & Lieberman, T. (2001) 'Publicly disclosed information about the quality of health care: response of the US public'. *Quality in Health Care*, 10: 96-103.

Schoen, C. et al (2004) 'Primary care and health system performance: adults' experiences in five countries'. *Health Affairs*, W4 (DOI 10.1377): 487.

Schoen, C. et al (2005) 'Taking the pulse of health care systems: experiences of patients with health problems in six countries'. *Health Affairs - web exclusive*, W5-509 (DOI 10.1377).

Schur, C.L. & Berk, M.L. (1998) 'Choice of health plan: implications for access and satisfaction'. *Health Care Financ.Rev*, 20 (1): 29-43.

Secretary of State for Health (2000) *The NHS Plan: a plan for investment, a plan for reform*. London: Stationery Office.

Secretary of State for Health (2003) *Building on the best: choice, responsiveness and equity in the NHS*. London: Department of Health.

Sitzia, J. & Wood, N. (1998) 'Patient satisfaction: a review of issues and concepts'. *Social Science and Medicine*, 45 (12): 1829-1843.

Staniszewska, S. & Ahmed, L. (1999) 'The concepts of expectation and satisfaction: do they capture the way patients evaluate their care?'. *Journal of Advanced Nursing*, 29 (2): 364-372.

Staniszewska, S. & Ahmed, L. (2000) 'Patient involvement in the evaluation of health care: identifying key issues and considering the way forward'. *Coronary Health Care*, 4: 39-47.

Stelfox, H.T. et al (2005) 'The relation of patient satisfaction with complaints against physicians and malpractice lawsuits'. *American Journal of Medicine*, 118 (10): 1126-1133.

Stevens, S. (2003) 'Equity and choice: can the NHS offer both? A policy perspective.'. In Oliver, A. (ed), *Equity in health and healthcare*. London: Nuffield Trust.

Sweeney, G. et al (2005) 'The Patients Accelerating Change Project: does it make any difference?'. *Clinical Governance*, 10 (1): 72-83.

Taylor, R. et al (2004) *Implications of offering "patient choice" for routine adult surgical referrals*.

The Health Service Ombudsman for England (2005) *Making things better? A report on reform of the NHS complaints procedure in England*. London: The Stationery Office.

Thorlby, R. (2006) *Where the patient was king. A study of patient choice and its effect on five specialist HIV units in London*. London: Kings Fund.

Vaiana, M.E. & McGlynn, E.A. (2002) 'What cognitive science tells us about the design of reports for consumers'. *Medical Care Research and Review*, 59 (1): 3-35.

Veroff, D.R. et al (1998) 'Effective reports for health care quality data: lessons from a CAHPS demonstration in Washington State'. *International Journal of Quality in Health Care*, 10: 555-560.

Vingerhoets, E. et al (2001) 'Feedback of patients' evaluations of general practice care: a randomised trial'. *Qual Health Care*, 10 (4): 224-228.

von Eigen, K.A. et al (1999) 'Carepartner experiences with hospital care'. *Medical Care*, 37 (1): 33-38.

Wensing, M. et al (2003) 'Feedback based on patient evaluations: a tool for quality improvement?'. *Patient Education and Counseling*, 51: 149-153.

Williams, J. & Rossiter, A. (2004) *Choice: the evidence. The operation of choice systems in practice: national and international evidence*. London: The Social Market Foundation.

Woods, T. (1994) 'The use of ward forums in obtaining patient feedback'. *CCUFLINK*, 4: 7-8.

Zaslavsky, A.M. et al (2000) 'Dimensions of consumer-assessed quality of Medicare managed-care health plans'. *Medical Care*, 38 (2): 162-174.

Zaslavsky, A.M. & Cleary, P.D. (2002) 'Dimension of plan performance for sick and healthy members on the Consumer Assessments of Health Plans Study 2.0 survey'. *Medical Care*, 40 (10): 951-964.

Zaslavsky, A.M. et al (2001) 'Adjusting performance measures to ensure equitable plan comparisons'. *Health Care Financing Review*, 22 (3): 109-126.

7. Improving service development

Service development: summary of findings

- Public involvement refers to the ways in which lay individuals can participate in decisions about the development, planning and provision of health services. Although there is overlap, this differs from patient involvement which is concerned with the contributions that people can make to decisions about their own treatment and care.
- There are a wide range of methods for public involvement: from information-giving, through consultation, to full user control. These methods can be distinguished in various ways, but most importantly in the extent to which they seek to empower people and democratise the decision-making process.
- Many different purposes are given as a rationale for public involvement in the health service, including potential benefits to the NHS (e.g. restoration of public confidence); to people (e.g. more responsive services); to public health (e.g. improved health); and to society as whole (e.g. building social capital).
- Public involvement has been a key feature of patient-centred health service reforms in recent years. Since 2001, there has been a statutory obligation for NHS organisations (acute trusts, PCTs and strategic health authorities) to involve and consult patients and the public about health service planning.
- Barriers to involving the public include: lack of clarity about aims and objectives; resource limitations and organisational constraints; professional or managerial resistance; problematic relationships between stakeholders; and concerns about representativeness.
- There is very little reliable evidence about the effectiveness of public involvement methods, for which the lack of an agreed evaluation framework is a major factor. Before developing a coherent framework for the assessment of outcomes, the intended aims of public involvement must be specified and defined.
- While the existing literature provides some successful examples of public involvement, many studies reported that involvement strategies had little overall impact on the decisions that were taken about service development. Health managers and professionals are often reluctant to cede any control of agendas or decision-making authority.
- Participants in citizens' juries generally enjoy their experience and feel more knowledgeable as a result of it. The jury method may have greater impact, as individuals are given support and information in order to make *informed* contributions to policy decisions. However, it is resource intensive and cost-effectiveness has not yet been demonstrated.
- There is some evidence that organisational actors rate the impact of public involvement more highly that that of the lay participants. Reasons for this include a potential difference in the expectations of these groups, or that participants are not given clear a clear sense of their role or potential for influencing the decision-making process.

Service development: introduction

There is increasing recognition that a high quality health service is one which is both organised around and responsive to the needs of the people who use it. To this end, patients and the public must have genuine opportunities for involvement in decisions about their own care and the way that services are delivered. Previous chapters have documented many such opportunities, for example in sharing treatment decisions, choosing appropriate providers or giving feedback on individual experiences of care. The focus of this chapter is lay involvement in organisational decision-making: to shape the development, planning and provision of health services. A wide and often complex range of activities can be considered under this topic. Nonetheless, as we discuss below, what unites these activities is that they principally focus on engaging individuals as citizens or members of the general public. This is not to say that patients or service users are excluded, quite the opposite, but that their participation is expected to collective rather than individualistic in character. Given this, and following many other recent commentaries (e.g. Florin & Dixon 2004), the term 'public involvement' shall be used to describe this topic.

There is substantial overlap between public involvement and other lay participation strategies, which can be confused rather than clarified by the definitions and concepts that are available. In the UK, the term patient and public involvement (PPI) is often used as shorthand to describe the processes by which members of the public can shape service development. However, a useful distinction between these two types of involvement can and should be made, with patient involvement describing *"the involvement of individual patients, together with health professionals, in making decisions about their own care"* (Florin & Dixon 2004). Public involvement differs from this both its methods and objectives. By involving the public in *strategic* decision-making, improvements at an organisational level are hoped for (Crawford et al 2003a). Public involvement is also different from community development, insofar as the latter (at least in its ideal form) focuses on enabling communities to themselves define and resolve problems in their local areas rather than engaging them in dialogue within organisational structures (Anderson et al 2002).

Related to the development of health services, two issues where public involvement might usefully be sought are priority setting and local needs assessment. As priority setting involves making *value* judgements about the allocation of limited resources, there is a legitimate role for the public (Dicker & Armstrong 1995). Mullen identifies the following six areas for public involvement in priority setting:

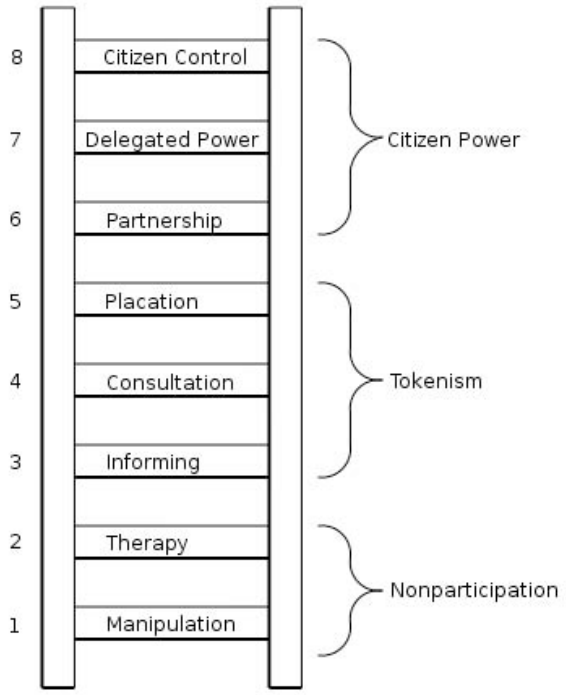
- rights to healthcare
- scope of health service
- which groups should receive priority
- local health service provision
- non-medical aspects (e.g. appointment systems, food, décor)
- choice of treatment for individual patient.

The needs assessment process is an additional opportunity to ensure that resource allocation decisions reflect community/user values and expectations. However, public involvement has the potential to increase inequity in service provision if local participation is *de facto* restricted to articulate, middle class individuals. Given this, the contribution of minority and previously excluded groups is essential to equitable needs assessment (Jordan et al 1998).

There are a spectrum of activities and techniques by which public involvement can be achieved. These exist along a 'continuum of participation', from information-giving to full user control (Hickey & Kipping 1998). Using a ladder-style framework Arnstein identifies eight levels of citizen participation (Arnstein 1969). Using this, she argues that

information giving, consultation and placation are tokenistic forms of involvement. These offer citizens little opportunity to genuinely influence and shape decisions, thereby failing to shift the balance of power towards lay interests. Partnership, delegated power and, especially, citizen control have the greatest potential for empowering citizens and democratising the decision-making process.

Arnstein's ladder of citizen participation



Drawing on Arnstein's approach, a more recent typology recognises five levels of public participation, each with increasing degrees of impact (see box).

Five levels of public participation (Involve & togetherwecan 2006)

Level 1: Inform
Public participation goal: to provide the public with balanced and objective information to assist them in understanding the problems, alternative opportunities and/or solutions.

Level 2: Consult
Public participation goal: To obtain public feedback on analysis, alternatives and/or decisions.

Level 3: Involve
Public participation goal: To work directly with the public throughout the process to ensure that public concerns and aspirations are consistently understood and considered.

Five levels of public participation (cont)

Level 4: Collaborate
Public participation goal: To partner with the public in each aspect of the decision, including the development of alternatives and the identification of the preferred solution.

Level 5: Empower
Public participation goal: To place final decision-making in the hands of the public.

In another model, approaches are defined by the capacities in which the individual's participation is sought (Audit Commission 1999). These are:

- **consumers of services**: asked for their views on particular services
- **taxpayers**: when decisions focus on the balance between level of services and cost
- **citizens**: when people's opinions of policy questions are being sought.

Similarly, a distinction has been made between 'consumerist' and 'democratic' approaches to public participation. The former focuses on individuals as the users of products or services, and employs consultation and market research techniques to gather opinion of those products/services. The second situates participation within a broader political context, aiming to enhance democratic accountability within the public sector. Compared to the rather passive forms of participation in the consumerist model, the democratic approach is strongly associated with public empowerment and active citizenship. It assumes that, as citizens, individuals have a right to shape decisions that affect their own lives and that of their communities.

Service development: what is the rationale?

As accounts of public involvement differ, so too do the reasons that are given for why such involvement should be sought. Some argue that public involvement is a good in itself, while others emphasise that taxpayers have a right to influence decisions about a service that they pay for (Farrell 2004). There is a strong rationale to involve the public where decentralisation and devolved decision-making are sought. Indeed, public involvement is often seen as an important strategy in tackling the democratic deficit in the health services. This links public involvement to the democratic values of openness, transparency and trust (Anderson et al 2002), and to the broader process of public sector renewal. Health improvements may also be sought, particularly where public involvement involves partnership working between health professionals and patients, carers and local communities (Anderson et al 2002). However, stakeholders may hold very different ideas about what 'partnership' means in practice, and the contexts in which it is appropriate. These diverse meanings have important implications for what participants see public involvement as both ideally and realistically achieving. Driving the consumerist model, described in the previous section, is a concern about responsiveness and choice. In this model, public involvement is principally conceived as a means of enhancing the process of service development, by more closely aligning this with the views and preferences of those who use and need health services.

Public involvement is sometimes explained or justified in terms of the benefits it can deliver for lay participants, but its impact is in no way limited to this group. A strategy document to support public involvement in the NHS presented a rationale encompassing outcomes for the health service, its users, public health and local communities (see box).

In the public interest: developing a strategy for public participation in the NHS (Department of Health 1998)

Benefits to the NHS

- Restoration of public confidence
- Improved outcomes for individual patients
- More appropriate use of health services
- Potential for greater cost-effectiveness
- Contribution to problem resolution
- Sharing responsibilities for healthcare with the public

Benefits to people

- Better outcomes of treatment and care
- An enhanced sense of self-esteem and capacity to control their own lives
- A more satisfying experience of using health services
- More accessible, sensitive and responsive health services
- Improved health
- A greater sense of ownership of the NHS

Benefits to public health

- Reduction in health inequalities
- Improved health
- Greater sense of understanding of the links between health and the circumstances in which people live their lives
- More healthy environmental, economic and social policies

Benefits to communities and to society as a whole

- Improved social cohesion
- A healthier democracy – reducing the democratic deficit
- A health service better able to meet the needs of its citizens
- More attention to cross-cutting policy issues and closer co-operation between agencies with a role to play in health improvement

Across public policy in general, similarly broad-reaching aims of public involvement can be identified as (Involve & togetherwecan 2006):

- **governance**: e.g. promoting active citizenship
- **social cohesion and social justice**: e.g. building social capital and empowerment
- **improved quality of services**: e.g. encouraging appropriate and effective use of public services
- **capacity building and learning**: e.g. as a basis for future growth and development.

Service development: what does the public want?

Unsurprisingly, the notion of having a say in how health services are planned, developed and delivered is popular among the general public. Particularly as users of health services, lay individuals often feel that they can make valuable and unique contributions to decisions about service provision. In a recent British survey the overwhelming majority of respondents were generally supportive of the overall concept, as well as indicating an interest in getting personally involved in decisions about local GP and hospital services (Developing Patient Partnerships & NHS Alliance & National Association for Patient Participation 2006). It found that:

- 90% of the public agree that local people ought to have a say in how local health services are run
- 74% would like to have a say in how their GP surgery is run
- 74% would like to have a say in how their local hospital is run.

While people like the idea of sharing decisions about local services, they appear to be less keen on getting involved when actual opportunities arise. Indeed, many public involvement initiatives have reported difficulties recruiting or retaining sufficient numbers. This does not necessarily reflect public apathy, and could be equally attributable to the ineffectiveness of organisations' recruitment strategies. Nonetheless, there is an apparent disparity between interest in the principle and practice of shaping service development among the general public.

Qualitative reports of public involvement point to a number of factors that may account for this disparity, and which should be taken into account when developing new initiatives. These include:

- **scepticism about the impact of participation**: the 2006 Power Inquiry commented on the widespread sense among the British public that their views and interests are not taken into account in political decision-making (The Power Inquiry 2006). This can lead to disaffection and disengagement, not only in the realm of formal politics but also in wider processes of public participation.
- **low levels of organisational commitment**: members of the public are less likely to engage with public involvement initiatives where they know or suspect there to be a lack of support from managers or health professionals (Farrell 2004).
- **perceived lack of expertise**: for example, Nancarrow and colleagues reported the difficulties experienced by a podiatry service in Sheffield in trying to recruit onto a user panel (Nancarrow et al 2004). When individuals were asked directly about the initiative, many indicated that they had not volunteered because they were 'ordinary people' who felt 'unqualified' to participate.
- **unsuitable choice of methods**: local communities generally welcome the opportunity to comment on issues affecting them, but consultation is not sufficient if people want to be more actively engaged in defining problems and shaping solutions. If stakeholders are not asked in advance about how they want to be involved, methods may be chosen which are deemed inappropriate or insufficient by the very groups they are expected to target.
- **too much consultation**: there is risk of 'consultation fatigue' among local communities or service users if their involvement is sought too frequently and becomes burdensome, or if organisations have made no attempt to avoid duplication or coordinate their efforts (Anderson & Florin 2000).

Service development: what are the barriers to public involvement?

As the following section outlines, since 1997 the government has pursued an agenda of public involvement in the health service. Various opportunities have been created for lay participation in strategic decision-making, and all NHS trusts have a statutory duty to involve and consult patients and members of the public. However, there is considerable evidence to indicate that the scope and impact of public involvement is significantly limited. For example, questions about public involvement have been asked in the National Tracker Survey, a longitudinal survey of PCGs/PCTs (Alborz et al 2002). In 2001/2002 only 31% of PCG/PCT chairs felt that they were effective at consulting local communities, with the majority struggling to develop effective methods for this. Representatives of community health councils were also surveyed, and many reported that they were rarely consulted in the areas of commissioning, service development or clinical governance. More recently, a British population survey found that 76% of people had never been asked about what they would like from their local NHS services and 50% felt they had no power to influence service development in their area (Developing Patient Partnerships & NHS Alliance & National Association for Patient Participation 2006).

Case study and anecdotal reports indicate a sense among many lay participants that their involvement is more tokenistic than genuine, with little apparent impact on decision-making processes. One possible explanation for this relates to the methods that are employed for public involvement. Certainly, as Anderson and colleagues (2002) point out, *"It is better to do a good consultation than offer partnership and fail to deliver."* Nonetheless, consultation is a provider-led approach in which the agenda and decision-making role firmly remains with health managers and/or professionals. Despite the common use of the rhetoric of partnership, the reporting of public involvement initiatives indicates that these often fail to move beyond consultation to give the public a more active and direct role in shaping service development.

There are several, well-documented factors that promote or inhibit public involvement in the health service and which also account for the problems described above. Outlined in detail below, these factors can broadly be described as:

- lack of clarity about aims and objectives
- resource limitations and organisational constraints
- professional or managerial resistance
- problematic relationships between stakeholders
- concerns about representativeness.

Lack of clarity about aims and objectives

Different groups may have different ideas about what public involvement should entail and achieve. A major problem for many public involvement initiatives is a lack of clarity about aims. These may have been poorly defined, not well linked to specific goals, subject to dispute or not have been discussed at all (Anderson et al 2002). If it is not clear what the initiative is intended to achieve and how, it may be difficult to secure public interest and commitment, gather momentum, produce a coherent strategy of action or maintain direction. Once an initiative is underway there is also the danger that lay individuals become disheartened as their efforts fail to lead to expected outcomes, and end up feeling disappointed and distrustful (Crawford et al 2003a). Furthermore, participants need to know how and in what ways they can make a difference, but case study accounts indicate that they are often uncertain about their role (e.g. Brodie 2003). This can also contribute to a sense that their involvement is merely tokenism or, at best, indicates that it has not been thought through carefully.

Resource limitations and organisational constraints

In a survey of primary care groups, conducted by the Kings Fund in 1999, 76% of chief executives reported that developing public involvement was a high priority (Anderson et al 2002). However, when compared to other key priorities for PCGs, this was ranked relatively low in importance. Chief executives placed public involvement ninth out of 13 key issues, with establishing infrastructure, developing primary care and financial management rated as their leading priorities. While healthcare organisations often express a commitment to listening and learning from service users and local communities, in practice this has to compete with other concerns which by comparison may appear to be more pressing or important. One consequence of this is that money is often channelled into one-off projects, instead of being used to build and maintain the infrastructure necessary for sustained public participation in governance (Anderson et al 2002). Without adequate resources – including funding, staff time and training - public involvement initiatives are likely to fail, or will have limited impact on service development. Successful public participation also crucially depends on a receptive and supportive organisational culture. Integration into formal institutional practices is essential, but many organisations see public involvement as something that is separate from their routine planning activities and decision-making processes. To be seen as more than a tick-box exercise, the values of the participatory approach must not only be recognised by organisations but also embedded into mainstream practice at all levels.

Professional or managerial resistance

Having one or more individuals within organisations who are committed to involving stakeholders can mean the difference between merely 'doing' public participation and bringing about lasting changes in the way that decisions about service planning and delivery are made. Yet, organisational and/or professional resistance to moves towards greater public involvement are commonly documented (Crawford et al 2003a). Health professionals may see such moves as a threat or challenge to their professional judgement, and attempt to preserve areas of decision-making autonomy. This can reduce public involvement to a power struggle, and undermine efforts to build open and trusting relationships between those involved. Staff may hold ambivalent or negative attitudes towards public involvement, where their own views about services are not sought by managers. This was documented, for example, in two case studies of user involvement in adult mental health services (Rutter et al 2004). In both cases, it was expected that nursing staff would empower and involve patients in their own practice, but the nurses themselves had little access to decision-making processes or influence with senior managers.

Problematic relationships between stakeholders

Public involvement brings together wide ranging experiences, values and opinions. It is about *"understanding differences, finding common ground and negotiating mutually agreeable solutions…valuing alternative perspectives and thinking about things in new ways"* (Anderson et al 2002). New voices in the decision-making process need to be supported and encouraged, and their views taken seriously even when they are not shared by managers or professionals. This process requires ongoing dialogue and communication which, in turn, is dependent on the building and maintaining of good relationships between lay individuals and staff. However, accounts of involvement indicate that managers and health professionals often strive to retain control of agendas and resources, with lay participants feeling that their role is merely to rubberstamp decisions that have already been made. Genuine partnerships are particularly difficult to achieve where there are significant differentials of power and authority. For example, service users may be reluctant to voice criticisms in front of those who are responsible for their treatment (Linhorst et al 2001). A further potential concern for those involved is to maintain their independence and the distinctiveness of their contributions. In particular, participants in longer-term initiatives may gradually come to adopt a more official

perspective and lose their capacity to advocate for public interests. A study of health service committees found that lay members fell into one of three categories: representing dominant (professional) interests; representing challenging (managerial) interests; or representing repressed (patients) interests (Hogg & Williamson 2001).

Concerns about representativeness

Concerns about the representativeness of those who contribute to public involvement initiatives are well-documented. For example, a 2003 survey of mental health trusts and user groups found that a lack of representativeness was seen by both service providers and users to be the main barrier to successful public involvement (Crawford et al 2003b). The issue of representativeness is a complex one, and is crucially shaped by the context in and methods by which public involvement is sought. Crawford identified three forms of representativeness: democratic, statistical and typical (Crawford et al 2003a). For democratic representativeness, the participant must represent the views and interests of those who elected them; for statistical, they must be characteristic of the general population; for typical, they must have a shared set of experiences with a particular group of people (e.g. users of a particular health service). Where lay participants are felt to represent only a select group or to be pursuing strong personal agendas, the legitimacy and creditability of the initiative may be called into question. In some instances, lay participants have suspected organisations of raising representativeness issues to intentionally downplay or discredit their contributions.

Others have questioned the importance of representativeness and suggested instead that public involvement should be committed to the values of inclusiveness and diversity. This in itself poses a considerable challenge, especially to reach and include those who are underserved by or excluded from mainstream services (Lockey & Hart 2004). Further obstacles to inclusion are presented by language difficulties, cultural differences, learning and physical disabilities, caring responsibilities and poor mobility. There are also disincentives to involvement that may disproportionately affect marginalised groups, including lack of reward, unrealistic expectations and workloads, fear of disparagement, and inaccessibility of management discourse and practice (Rutter et al 2004).

Service development: what strategies have been tried and by whom?

Patient and public involvement (PPI) has been a strong theme in health policy since Labour to power in 1997, although efforts to improve lay participation in service development certainly predate this time. For example, Community Health Councils were formed in 1974 as independent bodies representing the interests of the general public in the NHS. The first patient participation groups within GP surgeries were set up in 1972, and since 1978 these groups have been supported by the umbrella organisation National Association for Patient Participation (www.napp.org.uk). The introduction of the internal NHS market in the early 1990s led to a renewed focus on participation, in particular driven by the guidance in *Listening to Local Voices*. While this was primarily concerned with local needs assessment, it also called for public involvement in establishing priorities, developing service specifications and monitoring services (McIver & Brocklehurst 1999).

In 1999, the government set out the benefits of greater inclusiveness in decision-making processes in *Patient and Public Involvement in the New NHS*, with particular emphasis on how this could rebuild public confidence in the health service (Department of Health 1999). Soon afterwards, the case for PPI was more strongly made in the wake of a number of high profile service failures. The Kennedy Inquiry into the deaths of babies undergoing heart surgery at the Bristol Royal Infirmary stated that (Secretary of State for Health 2001):

> "*the involvement of the public in the NHS must be embedded in its structures: the perspectives of patients and the public must be heard and taken into account wherever decisions affecting the provision of healthcare are made*."

The role of lay participation was formalised in the Health and Social Care Act, published in 2001. Section 11 of the Act placed a statutory duty on all NHS Trusts, PCTs and strategic health authorities to involve and consult patients and the public in relation to:

- the planning and provision of local services
- the development and consideration of proposals for changes to the way services are provided
- decisions that will affect the operation of services.

A new infrastructure to support PPI was initially set out in the *NHS Plan*, including various mechanisms intended to enhance the level of input into strategic decision-making by service users and local communities (see box). The changes needed to achieve this vision of a more patient-centred service were subsequently outlined in *Shifting the Balance of Power* (Department of Health 2001).

NHS Plan: changes for patients

Patients' views
10.24 A patients' forum will be established in every NHS Trust and Primary Care Trust to provide direct input from patients into how local NHS services are run. For the first time patients will have direct representation on every NHS Trust board – elected by the Patients' Forum. […] The Forum will be supported by the new Patient Advocate and Liaison Service, and will have the right to inspect and visit any aspect of the Trust's care at any time.

NHS Plan: changes for patients (cont.)

Patients represented throughout the NHS
10.28 Patients and citizens have had too little influence at every level of the NHS. As a result of this plan, each health authority area will be required to establish an independent local advisory forum, chosen from residents of the area, to provide a sounding board for determining health priorities and policies, including the health improvement programme

10.29 There will be major increases in the citizen and lay membership of all the professional regulatory bodies, including the General Medical Council

10.30 One third of the members of the new NHS Modernisation Board will be citizen and patient representatives

10.31 Citizens and patient representatives will make up one third of the new independent Reconfiguration Panel on contested major service changes

10.32 The Commission for Health Improvement will include citizen and lay inspectors on all its review teams.

10.33 Older people will be represented on Commission for Health Improvement inspection teams to ensure older people's dignity and interests are fully taken into account in all inspections.

10.34 A new Citizens Council will be established to advise the National Institute for Clinical Excellence on its clinical assessments. It will complement the work of the NICE Partners Council which provides a forum for the health service and industry to comment on the work of NICE.

Of the above, the establishment of a Citizen's Council to advise NICE on the value judgements that underpin its decisions was perhaps the most ambitious. Broadly based on the citizens' jury model, the 30 member council has been active since 2002. According to NICE, its role is to:

- keep them in touch with public opinion
- tell them their views on issues that could challenge the independent groups that advise them
- provide a perspective on technical issues such as the levels of evidence they should consider
- and be there to give them non-technical common-sense advice.

Earlier uses of citizens' juries in healthcare include a series of pilots in 1996-7 funded by the Institute for Public Policy Research and Kings Fund. Both these, and the NICE Citizens' Council, have been formally evaluated and the findings are described in the following 'What works?' section.

In order to oversee the new PPI arrangements, a statutory body – the Commission for Patient and Public Involvement in Health (CPPIH) – was set up in 2003. The CPPIH had a wide remit, and was broadly charged with *"promoting public involvement in health service decision-making and policies affecting health."* It was also responsible for monitoring the activities of PPI forums, and contracting organisations to provide administrative and knowledge support to forum members. However the CPPIH almost immediately ran into problems, in part due to under-funding but also because it had failed to sufficiently raise its profile and build grassroots support (Baggott 2005). Only 18

months after it was established, the decision was taken to abolish it (with closure expected by Summer 2007). Following a review of PPI arrangements, it was announced in May 2006 that PPI forums would be replaced with 'local improvement networks'. Rather than being associated with a specific organisations (as forums were), the networks will cover geographic primary care trust areas.

Two further mechanisms for enhancing community involvement in health service planning are Overview and Scrutiny Committees (OSCs) and the new governance arrangements in Foundation Trusts. Intended to replace some of the function of the Community Health Councils, OSCs are made up of local councillors whose role it is to review and scrutinise how health services are developed and provided for their constituents. By April 2006, there were 32 Foundation Trusts (FTs) in England. As autonomous organisations, free of central government control, FTs are expected to give local communities a genuine say in how they are run (Department of Health 2002). The key mechanism for this is the new governance arrangements, whereby individuals can become 'members' of their local hospital and stand in elections for the Board of Governors. The majority of Governors are required to be patients or the public, with staff members and representatives from PCTs and other local organisations constituting the remainder. However, while the government suggests that these arrangements represent a new form of 'social ownership', others have challenged the notion of enhanced public accountability. Moreover, early research findings indicate that the influence of Governors over strategic decision-making has so far been fairly limited (Lewis & Hinton 2005). Finally in the UK, there are increasing moves to involve patients and the public in clinical governance activities and the development of clinical guidelines, although neither of these are legislated requirements (e.g. Crawford et al 2003a).

Increasing public participation in healthcare has also been a goal in Canada, where it has been strongly related to discussions about modernising governance (Simces and Associates 2003). A national health forum was established in 1994 to involve and inform Canadians, with early activities including 71 deliberative dialogue sessions intended to gain a better understanding of the public's view on key health issues. A variety of research, consultation and other deliberative activities were subsequently conducted to determine priorities for action. Service users also routinely act as consultants in service and program planning, and sit as members on priority setting committees and on hospital, health centre and health authority boards. There have also been longstanding efforts to involve service users and the public in healthcare planning in the USA. One notable initiative is the Oregon experiment, which was the first major attempt to systematically involve the public in decisions about the rationing of healthcare (see box).

The Oregon Health Plan

In attempting to define a basic package of care that would achieve universal coverage, Oregon combined evidence about the effectiveness of interventions with the findings of an exercise in which state residents were asked to rank the importance of a list of healthcare services. Various criticisms of the Oregon approach have been raised including (Crawford et al 2003a):

- poor response to phone surveys and local meetings intended to elicit public preferences
- instances of political climb-down in face of publicly sensitive cases
- politicians ignoring public views
- under-representation of Medicaid service users and over-representation of health professionals.

Nonetheless, the Plan has achieved some successes, in particular in increasing the number of residents enrolled in Medicaid by over 100,000 and contributing to a reduction in the proportion who are uninsured by 18% in 1993 to 11% in 1996 (Ham 1998).

In addition to the above largely government-led initiatives, voluntary and community groups have been central to efforts to improve the responsiveness of health services through public participation in policy, planning and provision. For example, the Engaging Communities Learning Network helps PCTs work more closely with local communities and front-line staff. The Long Term Medical Conditions Alliance (LMCA), and many of its individual members, seek to involve users and carers in the running of their organisations and some have lay representation in their governing bodies. In some cases, ex-patients directly act as providers of services by running self-help or support groups. This includes the self-management programmes organised by a number of voluntary sector organisations which are community-based and led by lay tutors. The LMCA also has produced three guides to help organisations in working towards user/carer involvement, which are available on its website (www.lmca.org):

- How to develop a strategy
- A good practice guide
- Sharing our experience

Alongside the activities of health-related organisations, there are a number of groups that are more generally promoting public involvement and active citizenship. These include:

• The Scarman Trust	http://www.thescarmantrust.org
• Involve	http://www.involving.org/home
• Together We Can	http://www.togetherwecan.info
• Shared Practice	http://www.sharedpractice.org.uk

Service development: what works?

Having extensively reviewed the literature on this topic, our general impression is that the evidence base for public involvement is relatively weak. There are many published accounts of public involvement initiatives, but few report on benefits or costs, and almost none involved a formal assessment of outcomes. In part, this is a reflection of the difficulty of evaluating public involvement projects, and the lack of an agreed framework for such evaluation. Reliable information on impact is required, and research must be informed by a much needed debate about how outcomes should be defined and measured. Importantly, the aims of public involvement, against which initiatives will be measured, need to be understood both from the perspective of participants as well as those of managers and/or professionals. Where the existing literature is most instructive is in identifying a number of factors which promote or hinder public involvement. This is a useful starting point for future projects, and should guide the development of more effective strategies for devolved governance in the health sector.

1. Evidence from systematic and research reviews

Most of the evidence for public involvement has been summarised in seven published systematic or qualitative research reviews. These reviews cover a wide range of approaches, and many of their authors comment on the paucity of reliable and detailed evidence of effectiveness. Given this, they tend only to assess the overall impact of public involvement, rather than describe outcomes by method used. Individual studies that have not been included in these reviews are outlined in the following three sections covering: consultation and deliberative methods; participation groups and forums; and lay representation.

Rose and colleagues (2002) reviewed user and carer involvement in change management in a mental health context (Rose et al 2003). The topic under consideration was defined as user/carer consultation or involvement in “planning or implementing changes at the level of procedures, organisational structures, service design or delivery.” The researchers identified 112 papers, reports or books which covered a range of user involvement strategies. They note that the outcomes described in the studies are usually ones that are not readily amenable to measurement. The majority of studies (n=58) reported that outcomes of user involvement are unclear or unknown; 52 studies mentioned positive outcomes, and 14 found negative ones. The studies show that a facilitative organisational culture is the most important factor in involving users in change management, followed by a strategy for providing information and the provision of resources.

Strength of evidence: Systematic review, no independent assessment found.

Simpson and House (2002) examined the impact of involving users in the planning, delivery and evaluation of mental health services (Simpson & House 2002). An extensive literature search was unable to find any comparative studies of user involvement in service planning, but they did identify twelve studies involving users either as service providers or as trainers of service providers. In the majority of studies, users acted in or alongside case management services for clients with mental illness. These found that there was no detrimental impact in terms of symptoms or functioning, and there was some evidence of improved quality of life, life problems and social functioning. Positive effects on service use were also reported in terms of longer time between hospital visits, reduced need for hospital admission and shorter hospital stays.

Strength of evidence: Systematic review – clear inclusion/exclusion criteria, systematic approach used for data extraction and validity assessment conducted; while the possibility of publication bias was not investigated, the authors' conclusions appear to follow from the results presented (CRD).

Crawford and colleagues (2003) updated and extended an earlier systematic review (Crawford et al 2002) on the effects of involving patients in the planning and development of healthcare (Crawford et al 2003a). They identified papers which described a wide range of involvement methods, often combined within the same study; these included patient forums and participation groups, citizens' juries, public meetings and user representation at meetings. These show that user involvement can positively contribute to changes in services: for example, by making services more accessible through simplification of appointment procedures, longer opening hours, improvements in transport and targeting access problems for people with disabilities. There is also evidence that involvement can lead to new services being commissioned and the provision of new or improved sources of patient information. In most studies, users welcomed the opportunity for involvement and benefited from improved self-confidence. However, there were also some negative findings, including concerns that user involvement was employed to 'rubberstamp' decisions that had already been taken. Decision-making may also be slowed down when users are involved and there are many examples where involvement has not made an impact on the organisation and delivery of services. The authors note that the evidence-base for the benefits of user involvement is not strong, and that studies have tended to focus on qualitative process evaluation or surveys of service users and/or providers. Consequently, impact on service use, patient satisfaction, health outcomes or quality of life is not known. The literature review indicated that some staff felt resentment towards patients in being given a voice to shape service development, when they themselves had none.

Strength of evidence: Systematic review, no independent assessment found.

Simces and colleagues (2003) were commissioned by Health Canada to review evidence for the link between public involvement/citizen engagement (PI/CE) and quality healthcare (Simces and Associates 2003). They identified studies which explored PI/CE across various areas including planning and development of healthcare; healthcare governance; and community development/collaborative practices. The study authors allege a range of benefits in relation to healthcare or health outcomes. However, in practice there is limited empirical evidence to demonstrate that PI/CE contributes to better quality healthcare. The authors note that few studies undertook any systematic evaluation of PI/CE using specific criteria or outcome measures.

Strength of evidence: Research review.

Carr (2004) collected literature on user participation in social care services (Carr 2004). Although there is much interest in this issue, there is a paucity of research monitoring and evaluating the outcomes of service user involvement. The author outlines the problems of measuring cultural and organisational change, and its sustainability. Studies have indicated the benefits of user involvement for those personally involved, including increased social contact, knowledge and skills, opportunities for learning and self-esteem. However, it is not clear whether it has an impact at a collective level – for example, in the instigation of change or improvement of services. The review found that much attention has been given by service providers to the process of user consultation, but not to its aims and outcomes.

Strength of evidence: Research review.

Farrell (2004) reported the findings of twelve projects to improve patient and public involvement in healthcare, five of which specifically examined user involvement in the development and/or evaluation of services (Farrell 2004). These projects were evaluated using stakeholder surveys or interviews, or a combination of these methods. The studies provide some evidence that user involvement can have a number of beneficial outcomes, including: increases in people's confidence, understanding and skills; influence on policies, plans and services; and sharing of learning, resources and expertise across local health economies. Potential barriers to user involvement include a differences of opinion about what constitutes an appropriate level of involvement; a perception among the public that health service managers do not welcome their involvement; a failure to create working partnerships with the voluntary and community sector; and insufficient efforts to raise awareness of user involvement or publicise specific opportunities.

One of the studies investigated the involvement of physically disabled or chronically ill children and young people in local health service development (Sloper & Lightfoot 2003). Ninety nine health authorities and 410 NHS trusts were surveyed, with response rates of 66% and 59% respectively. Twenty seven respondents described initiatives involving chronically ill or disabled children, with 17 of these resulting in service changes. However, the extent to which such changes were driven by the involvement of young service users is questionable given that initiatives generally did not go beyond consultation to involve children directly in decision-making processes.

Strength of evidence: Research review.

Involve and togetherwecan (2005) assessed the costs and benefits of public participation initiatives, including those in the area of health (Involve & togetherwecan 2005). They conducted an extensive literature review, and carried out interviews with individuals involved in 15 partnership projects across England and Wales. Claimed benefits of participation include: increased governance, greater social cohesion, improved quality of services, and greater capacity building and learning. However, the authors found very little reliable data on costs and benefits, which may in part be accounted for by a lack of common understanding about what the potential outcomes of public participation might be. Existing studies rarely examine costs and benefits from the perspective of participants, and there appears to be an unwillingness to invest in assessing participation. Staffing was generally the largest single expenditure, but project managers were generally unable to give a firm estimate of costs, often because projects were funded from a number of different budgets.

Strength of evidence: Research review and cross-sectional interviews.

Summary of known effects from systematic reviews

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Public involvement provides opportunities for learning, and can lead to improved knowledge of health services.
Patients' experience, including communication and psychological outcomes	People welcome opportunities for involvement, and these can increase participants' self-confidence, self-esteem and levels of social contact. Some evidence that employing mental health service users as case workers (or trainers of case workers) improves quality of life

	and social functioning among clients. Mixed evidence for impact of planning and delivery of services.
Health services utilisation and cost	Some evidence that decision-making is slowed down. Staffing is generally the largest expenditure, but insufficient data to indicate cost-effectiveness. User involvement in the delivery of mental health services found to reduce hospital admissions, increase time between hospital visits and shorten duration of hospital stays.
Health behaviour and health status	Not known.

2. Consultation and deliberative methods

Consultation and deliberative methods are broad ranging, but they are united in their aim to identify the views of the public (or a specific group) on the quality of services or a policy proposal. Consultation methods include consultation documents, public meetings, public inquiries and community visioning approaches. More complex decisions are not so readily amenable to public consultation, but rather require participants to become informed about an issue before they comment on it. Deliberative methods generally involve a smaller number of participants, who are given the time and resources to discuss pertinent issues before reaching a consensus opinion. Citizens' juries, for example, usually take place over a period of three to four days, during which time jurors hear evidence from and cross-examine expert witnesses. Other deliberative approaches include consensus conferences, deliberative polling, deliberative mapping and community workshops.

McIver (1998) reported on an evaluation of six citizens' juries set up as NHS pilot schemes between 1996 and 1997 (McIver 1998). This sought to: assess the extent to which citizens' juries were effective in enabling local people to contribute to debates about local health services; to assess the benefits and drawbacks of citizens' juries; and to consider citizens' juries in the context of other public involvement methods. Through the citizens' juries, people were able to formulate practical recommendations about courses of action and these recommendations did have some influence on decisions made by health authorities. Other benefits included: allowing health authorities access to a wider range of views than they normally would; facilitating the development of informed public views, which were felt by health authorities to be particularly useful; increased knowledgeability among participants about the NHS; and providing members of the public with a route into further participation in NHS practices. The drawbacks of this approach were: the time and effort needed to plan the jury; the associated costs (approximately £16,000 plus staff time); and that only a small number of people could participate who may not be representative of the broader local community. The author notes that the citizens' jury pilots addressed may of the shortcomings of other public involvement methods because: they were clear about the role the public would play; they had built-in mechanisms to ensure views would have an influence on services; and they addressed practical issues (e.g. physical access, transport, information) that contribute to good public involvement.

Strength of evidence: Multi-method evaluation.

Strobl and Bruce (2000) assessed a consultation process carried out in Liverpool, which was intended to contribute to the development of a city health plan (Strobl & Bruce 2000). Fifty eight meetings were held in the community as well as with statutory sector groups, with facilitators providing background information on the plan to encourage discussion and generate ideas. Information on the consultation was collected using questionnaires and semi-structured interviews with people involved in the process. While participants thought it was worthwhile to raise important health issues, many were sceptical or unsure about whether their contributions would be included in the subsequent health plan. Those who were most negative about the potential for influence referred to past experiences of not being listened to or a lack of commitment in the draft plan to act on their contributions. Problems were encountered in translating the individual ideas into a coherent strategy, and the absence of a process for quantifying or prioritising responses was identified as a major reason for this. Participants were generally satisfied with the way that the meetings were run, but both participants and facilitators identified lack of time as a main shortcoming. Among the factors identified as promoting or acting as a barrier to successful participation were establishing clarity about the aims of the process, and open two-way communication at all stages (including during the post-consultation phase).

Strength of evidence: Multi-method evaluation.

Maxwell and colleagues (2003) described the role and impact of a public dialogue exercise, to inform the Romanow Commission on the Future of Health Care in Canada (Maxwell et al 2003). The 'ChoiceWork dialogue' method employed gives participants time to work through and consider difficult issues in order to reach judgements. Twelve dialogue sessions were organised, each involving approximately 40 participants chosen to be broadly representative of the Canadian population. The cost of the exercise was high at 1.3 million Canadian dollars, but the results did have a marked influence on the commission's report that was subsequently published. Participants were enthusiastic about their involvement and in general were able to digest, discuss and apply complex knowledge to make difficult choices.

Strength of evidence: Uncontrolled observational study.

Nancarrow and colleagues (2004) evaluated a user consultation group, established to support developments in a podiatry service in Sheffield (Nancarrow et al 2004). They document the difficulties of recruiting people to the panel, noting that the eventual membership was not strongly representative of typical service users. The panel itself determined its own direction and agenda, received a detailed introduction programme in advance of its first meeting, and members were reimbursed for all expenses and given a small gift at the end of the year. The panel's discussions and activities led directly to innovations in service delivery including the introduction of a freephone contact number and changes to patient information materials. When asked about their experiences, all of the panel members felt that they had made a difference to the service.

Strength of evidence: Case studies with interviews.

Rowe and colleagues (2004) evaluated a two-day deliberative conference on the topic of radiation dose assessment in food (Rowe et al 2004). They propose a set of criteria for evaluating the outcomes of public participation initiatives, including: representativeness, independence, early involvement, influence, transparency, resource accessibility, task definition, structured decision-making and cost-effectiveness. The conference was held on behalf of the UK Food Standards Agency, in order to make its views on dose assessment transparent and hold a debate with key stakeholders to inform future policy. The evaluation was conducted by a questionnaire survey and telephone interviews with participants. Participants were generally positive about the deliberative conference, scoring it most highly in terms of independence, transparency, resources and cost-effectiveness. The only criteria which scored particularly poorly was representativeness, with a number of respondents concerned that some groups who would be affected by future decisions were not adequately represented. Overall, respondents were unsure about the impact of the conference on decision-making, and this may reflect the fact that the evaluation was conducted soon after the conference had been held.

Strength of evidence: Multi-method evaluation.

Stevenson and colleagues (2004) outlined the findings of research, commissioned by the Scottish Executive Development Department, into the use of people's juries and people's panels in Social Inclusion Partnerships (Stevenson et al 2004). The research was specifically concerned to assess how useful these approaches are for increasing community involvement and input into local decision-making. The research found that these methods had limited impact on specific plans or strategies in Social Improvement

Partnership areas. In some cases, juries and panels were integrated into wider structures and systems but in others they were viewed as 'stand-alone' initiatives. Both methods are resource intensive, and the research found that effectiveness was limited because insufficient time and resources had been devoted to them. Additionally, they are likely to be more effective when addressing a specific topic or issue, when linked to existing planning or budgetary cycles and when their recommendations fell within the responsibility of a single organisation.

Strength of evidence: Multi-method evaluation.

Davies and colleagues (2005) conducted an evaluation of the NICE Citizens' Council (Davies et al 2005). They used a variety of research methods, including a before-and-after analysis of participants' perceptions and a direct observation of Council sessions. The cost to set up and support the Council for its first two years in operation was £469,717. This is a per meeting cost of over £100,000. The costs of additional meetings (with all the infrastructure in place) are estimated at between £80,000 and £90,000. The authors note that studies of local juries have found far lower costs (averaging around £25,000 per meeting). Members consistently reported enthusiasm for the project, and many were planning to find other forms of participation and involvement after they had served their time on the Council. However, the evaluation also found that very little actual deliberation took place during Council meetings. The researchers identify three factors that improved the likelihood of constructive deliberation: giving members clarity around the positions in the debate and choices; encouraging Council members to have some personal engagement with a particular line of argument; and the use of facilitators who are able to recognise the need for different facilitation styles and move easily between them.

Strength of evidence: Multi-method evaluation.

Summary of known effects of consultation initiatives

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	The process of hearing evidence and cross-examining witnesses in the citizens' jury method increases knowledge about health services.
Patients' experience, including communication and psychological outcomes	Lay public values consultation and/or participation in deliberative approaches. Evidence that citizens' juries can influence decisions taken about local services, but some participants concerned about representativeness of jury members.
Health services utilisation and cost	Citizens' juries are a relatively expensive method of public involvement, and the impact is dependent on sufficient investment of time and resources.
Health behaviour and health status	Not known.

3. Participation groups and forums

These final two sections describe methods of involvement that are based on ongoing relationships between stakeholders. In the first of these, individuals establish or are recruited onto small groups which are associated with a particular service provider or organisation. This includes patient participation groups, which have existed in the NHS since the early 1970s. These groups bring together service users and health professionals (typically in general practice) to discuss the way in which services are provided and ways of improving this. In 2005, one in four general practices in England had a patient participation group (National Association for Patient Participation 2006). More recently, these have been joined by Patient and Public Involvement (PPI) Forums, which are connected to every primary, acute, mental health and ambulance trust in England. PPI forums are statutory bodies, whose functions are to monitor and review services; provide advice, reports and information to the trust; obtain the views of patients and carers; and assist patients, families and carers in particular circumstances (Baggott 2005).

Linhorst and colleagues (2001) evaluated a consumer council, set up in a public psychiatric hospital in Missouri (Linhorst et al 2001). The consumer council was intended to encourage user participation in organisational decision-making within an inpatient setting. Twelve users sat on the council, equally representing the four clinical programmes of the hospital. Staffing was provided to support the functioning of the council and to act as liaison between the council and the hospital's executive committee. The authors list a number of changes made in which the council played a significant role. However, when service users were interviewed, many could not name any of the council's accomplishments. The council had not been successful in achieving major policy changes, and staff perceived that the council had greater influence than did the service users. The authors detail a number of barriers to user participation in organisational decision-making, in particular the strong power imbalance between users and staff in inpatient psychiatric services.

Strength of evidence: Case study with interviews.

Rutter and colleagues (2004) described two case studies (both in London-based NHS Trusts) of user involvement in the planning and delivery of adult mental health services (Rutter et al 2004). User groups were the most commonly employed method of involvement, with other activities including user forums, user/professional forums, users on management recruitment panels and user development workers. In both examples, the conditions of user involvement were controlled by Trust management, who were able to choose whether or not they took users' views into account. There were also a number of key practice and policy areas where user involvement was not sought, which lead to dissatisfaction and distrust among participants. A small number of examples where user involvement had led to positive outcomes were identified, but there was an overall sense that impact had been limited. Reasons given for this included restricted scope for local decision making; failure to clarify limits to users' influence and autonomy; lack of staff expertise, training and confidence; absence of policy to support involvement; and failure to respect user autonomy. The authors note that, in commenting on the activities, managers tended to focus on the processes of user involvement, whereas users themselves were more concerned with the outcomes.

Strength of evidence: Case studies with interviews.

Sitzia and colleagues (2004) reported on an evaluation of the Cancer Partnership Project, which aimed to create a more integrated and supportive approach to user

involvement in cancer services (Sitzia et al 2004). The CPP (funded by McMillan Cancer Relief and the Department of Health) supported user involvement in a number of different ways, in particular by establishing partnership groups (i.e. committees of NHS patients, managers and health professionals) in local communities or at the level of cancer networks. While service users were generally enthusiastic about working in partnership with health professionals, there were some tensions between these groups. For example, some health professionals were felt to lack commitment to the groups, while participants wanted to share personal experiences which was discouraged by NHS members. It was acknowledged that a change in both culture and systems was needed for service users to influence service policy and delivery. Many of the groups had made significant progress in their projects and in terms of their visibility. Factors associated with effective influencing were successful functioning of the group, strategic thinking and working, and the support of senior professionals and managers.

Strength of evidence: Case studies with interviews.

Summary of known effects of patient participation groups and forums

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Not known.
Patients' experience, including communication and psychological outcomes	Participants often enthusiastic, but can become disillusioned if they feel managers/professionals are not taking their views into account.
Health services utilisation and cost	Limited impact on organisational decision-making, partly because control over decisions retained by managerial staff.
Health behaviour and health status	Not known.

4. Lay representation

The final method for involving members of the public in strategic decision-making is through lay membership of advisory, regulatory and executive bodies. For example, lay individuals have been asked to join professional regulatory groups such as the General Medical Council and patient liaison groups have been established for many of the medical royal colleges. Lay members also contribute to primary care trust boards, clinical ethics committees and medical education and training boards. This can be a challenging role, as individuals may have to work hard to carry authority with other members, while simultaneously ensuring that they bear in mind the interests of the lay constituency that they are expected to represent. There is a risk that, as lay members develop the expertise and understanding to contribute to strategic decision-making, that they assume a more official perspective which inhibits their capacity to talk on behalf of patients and the public.

Pickard and colleagues (2002) investigated the involvement of users in clinical governance activities within Primary Care Groups (PCGs) and Trusts (PCTs) (Pickard et al 2002). They collected data from key stakeholders in twelve PCGs or PCTs, using semi-structured interviews. Despite an organisational commitment to lay involvement in clinical governance, in practice little has been done towards this. Lay members of PCG/PCT boards rated their influence on decision-making as low, and the authors question whether the public can realistically shape professional viewpoints. Lay board members were also found to be relatively unthreatening, as they were largely drawn from the professional strata.

Strength of evidence: Cross-sectional interviews.

Lewis and Hinton (2005) reported on the implementation of new governance arrangements at Homerton University Hospital NHS Foundation Trust (Lewis & Hinton 2005). With the transition to foundation status, the trust elected a council of governors, half of whom were from public or patient constituencies. Among Trust board directors, there was a feeling that decision-making power would remain with them, although they acknowledged the right of governors to be consulted and listened to. Over the first year, there were few examples of the governors' council influencing management decisions, and many governors expressed disappointment about their apparent lack of power. However, the first year may not be representative of future outcomes, as this was a time during which governors were gaining necessary knowledge and experience. A number of factors restricting the effectiveness of the council of governors were identified, including: the infrequency of formal meetings; the fact that (aside from expenses) governors were not remunerated for their participation; the large number of attendees at meetings of the council of governors; and that council activities increased the workload of some Trust directors.

Strength of evidence: Case study with interviews.

Summary of known effects of lay representation

Outcome variables	Current state of knowledge
Patients' knowledge and information recall	Lay board members expected to gain knowledge of health service and organisational structure.
Patients' experience, including communication and psychological outcomes	Participants commonly report lack of influence over decisions, and no evidence of devolved power to lay representatives.

Health services utilisation and cost	Some evidence of increased workloads for NHS managers.
Health behaviour and health status	Not known.

Service development: what looks promising for future R&D?

All NHS organisations have a statutory duty to involve the public in service planning and operation, and some are developing creative approaches to achieve this. However, very few initiatives are being subjected to formal evaluation and, consequently, there is a paucity of data on whether the various approaches fulfil their goal of increasing levels and the quality of public involvement in the health service. Without such data, commissioners will be unable to confidently compare public involvement methods and consider which may be most appropriate for their particular circumstances. But evaluations are not only important to healthcare organisations. Patients and the public have a right to know how their participation is making a difference, and especially whether it has a genuine impact on decisions that affect local services.

Above all, this problem rests with the lack of a coherent and agreed upon framework for assessing the effectiveness of public involvement methods. In working towards such a framework, the first step is to establish a consensus about what it is public involvement should achieve. The following aims are among those that might be considered important:

- to empower local communities
- to devolve decision-making
- to strengthen accountability
- to improve responsiveness
- to improve the quality of care
- to improve health outcomes
- to reduce complaints and litigation
- to build partnerships
- to ensure the legitimacy of policy decisions
- to determine priorities
- to tackle the democratic deficit.

The challenge of developing an evaluation strategy is not only to identify the criteria against which projects will be judged, but also define them in such a way that they can be reasonably measured. It is also essential that funding for monitoring and evaluation is built into the commissioning, planning and implementation of public involvement initiatives.

References

Alborz, A. et al (2002) 'Are primary care groups and trusts consulting local communities?'. *Health & social care in the community*, 10 (1): 20-28.

Anderson, W. & Florin, D. (2000) 'Consulting the public about the NHS'. *BMJ*, 320 (7249): 1553-1554.

Anderson, W. et al (2002) *Every voice counts: primary care organisations and public involvement*. London: King's Fund.

Arnstein, S. (1969) 'A ladder of citizen participation'. *Journal of the American Planning Association*, 35 (4): 216-224.

Audit Commission (1999) *Listen up! Effective community consultation*. London: Audit Commission.

Baggott, R. (2005) 'A funny thing happened on the way to the forum: reforming patient and public involvement in the NHS in England'. *Public Administration*, 83 (3): 533-551.

Brodie, D. (2003) 'Partnership working: a service user perspective'. In Glasby, J. & Peck, E. (eds), *Partnership working in action*. Oxford: Radcliffe Medical Press.

Carr, S. (2004) *Has service user participation made a difference to social care services?* London: Social Care Institute for Excellence.

Crawford, M. et al (2003a) *User involvement in change management: a review of the literature*. London: National Co-ordinating Centre for NHS Service Delivery and Organisation R&D.

Crawford, M.J. et al (2003b) 'User involvement in the planning and delivery of mental health services: a cross-sectional survey of service users and providers'. *Acta Psychiatr.Scand*, 107 (6): 410-414.

Crawford, M.J. et al (2002) 'Systematic review of involving patients in the planning and development of health care'. *British Medical Journal*, 325: 1263.

Davies, C. et al (2005) *Opening the box: evaluating the citizens council of NICE*. Milton Keynes: The Open University.

Department of Health (1998) *In the public interest: developing a strategy for public participation in the NHS*. London: Department of Health.

Department of Health (1999) *Patient and public involvement in the new NHS*. London: Department of Health.

Department of Health (2001) *Shifting the Balance of Power with the NHS*. London: Department of Health.

Department of Health (2002) *A Guide to NHS Foundation Trusts*. London: Department of Health.

Developing Patient Partnerships & NHS Alliance & National Association for Patient Participation (2006) *Effective practice-based commissioning: engaging with local people*. London: DPP.

Dicker, A. & Armstrong, D. (1995) 'Patients' views of priority setting in health care: an interview survey in one practice'. *BMJ*, 311 (7013): 1137-1139.

Farrell, C. (2004) *Public and patient involvement in health: the evidence for policy implementation*. London: Department of Health.

Florin, D. & Dixon, J. (2004) 'Public involvement in health care'. *BMJ*, 328 (7432): 159-161.

Ham, C. (1998) 'Retracing the Oregon trail: the experience of rationing and the Oregon health plan'. *BMJ*, 316 (7149): 1965-1969.

Hickey, G. & Kipping, C. (1998) 'Exploring the concept of user involvement in mental health through a participation continuum'. *J Clin Nurs*, 7 (1): 83-88.

Hogg, C. & Williamson, C. (2001) 'Whose interests do lay people represent? Towards an understanding of the role of lay people as members of committees'. *Health Expectations*, 4: 2-9.

Involve & togetherwecan (2005) *The true cost of public participation*. London: Involve.

Involve & togetherwecan (2006) *People and participation*. London: Involve.

Jordan, J. et al (1998) 'Health needs assessment. Whose priorities? Listening to users and the public'. *BMJ*, 316 (7145): 1668-1670.

Lewis, R. & Hinton, L. (2005) *Putting health in local hands: early experiences of Homerton University Hospital NHS Foundation Trust*. London: Kings Fund.

Linhorst, D.M. et al (2001) 'The involvement of a consumer council in organizational decision making in a public psychiatric hospital'. *J Behav Health Serv Res*, 28 (4): 427-438.

Lockey, R. & Hart, A. (2004) 'Improving consultation with disadvantaged service users'. *British Journal of Midwifery*, 12 (12): 784-789.

Maxwell, J. et al (2003) 'Giving citizens a voice in healthcare policy in Canada'. *BMJ*, 326 (7397): 1031-1033.

McIver, S. (1998) *Healthy debate? An independent evaluation of citizen's juries in health settings*. London: King's Fund.

McIver, S. & Brocklehurst, N. (1999) 'Public involvement: working for better health'. *Nurs Stand.*, 14 (1): 46-52.

Nancarrow, S. et al (2004) ''The squeaky wheel gets the grease': a case study of service user engagement in service development'. *Journal of Integrated Care*, 12 (6): 14-21.

National Association for Patient Participation (2006) *Ten minute guide to patient participation*. http://www.napp.org.uk/Patient%20Participation%20Groups.pdf.

Pickard, S. et al (2002) 'User involvement in clinical governance'. *Health Expectations*, 5: 187-198.

Rose, D. et al (2003) *User and carer involvement in change management in a mental health context: review of the literature*. London: National Co-ordinating Centre for NHS Service Delivery and Organisation R&D.

Rowe, G. et al (2004) 'Evaluation of a deliberative conference'. *Science, Technology and Human Values*, 29 (1): 88-121.

Rutter, D. et al (2004) 'Patients or partners? Case studies of user involvement in the planning and delivery of adult mental health services in London'. *Soc Sci Med*, 58 (10): 1973-1984.

Secretary of State for Health (2001) *Learning from Bristol: The report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984-95*. London: The Stationery Office.

Simces and Associates (2003) *Exploring the link between public involvement/citizen engagement and quality health care*. http://www.hc-sc.gc.ca/hcs-sss/alt_formats/hpb-dgps/pdf/pubs/2003-qual-simces/2003-qual-simces_e.pdf.

Simpson, E.L. & House, A.O. (2002) 'Involving users in the delivery and evaluation of mental health services: systematic review'. *BMJ*, 325 (7375): 1265.

Sitzia, J. et al (2004) *Formative evaluation of the Cancer Partnership Project*. London: McMillan Cancer Relief.

Sloper, P. & Lightfoot, J. (2003) 'Involving disabled and chronically ill children and young people in health service development'. *Child Care Health Dev.*, 29 (1): 15-20.

Stevenson, R. et al (2004) *Evaluation of people's panels and people's juries in social inclusion partnerships*. Edinburgh: Scottish Executive Social Research.

Strobl, J. & Bruce, N. (2000) 'Achieving wider participation in strategic health planning: experience from the consultation phase of Liverpool's 'City Health Plan''. *Health Promotion International*, 15 (3): 215-225.

The Power Inquiry (2006) *Power: in independent inquiry into Britain's democracy*. www.powerinquiry.org.