

## Towards efficient guidelines: how to monitor guideline use in primary care

A Hutchinson

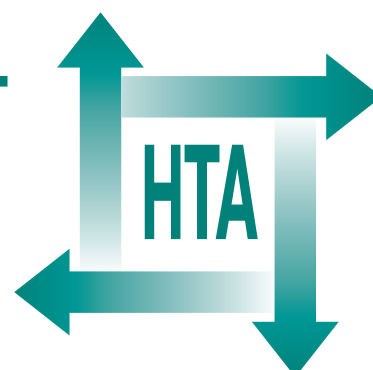
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Health Technology Assessment  
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**Declared competing interests of authors:** none

Published August 2003

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This report should be referenced as follows:

Hutchinson A, McIntosh A, Cox S, Gilbert C. Towards efficient guidelines: how to monitor guideline use in primary care. *Health Technol Assess* 2003; **7**(18).

*Health Technology Assessment* is indexed in *Index Medicus/MEDLINE* and *Excerpta Medica/EMBASE*.

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The research reported in this monograph was identified as a priority by the HTA Programme's Methodology Panel and was funded as project number 94/08/10.

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ISSN 1366-5278

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Published by Gray Publishing, Tunbridge Wells, Kent, on behalf of NCCHTA.

Printed on acid-free paper in the UK by St Edmundsbury Press Ltd, Bury St Edmunds, Suffolk.



## Abstract

### Towards efficient guidelines: how to monitor guideline use in primary care

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**Objectives:** To develop a model for using routine data monitoring in the evaluation of clinical guideline usage in primary healthcare settings.

**Design:** A monitoring framework was developed following a number of semistructured interviews with potential users. These data informed a postal survey among a random sample of primary healthcare professionals. Then to test out the framework, a further semistructured interview study was used to explore the practical issues relating to monitoring guideline use. Case studies were then undertaken to investigate the use of evidence-based review criteria and patient-centred outcome measures as methods for providing monitoring information. A case study in one general practice used interviews to examine the possible costs associated with guideline-use monitoring.

**Setting and participants:** Interviews were undertaken with primary care professionals from one local health community. The postal survey was undertaken among staff from a purposive sample of Health Authorities in England and a random sample of general practitioners and practice nurses from the selected Health Authority areas. The second phase involved interviews with Health Authority, Primary Care Group and general practice staff from three Health Authority areas. Case studies were undertaken in volunteer general practices and among patients who consented to provide confidential health outcome information.

**Results:** Interviewees recognised some value in guideline-use monitoring, however they were concerned about the practicalities from two

perspectives. First, although primary care computing systems were to be found in most general practices, the technology for monitoring was absent in many practices. Training in these skills would be required before monitoring of guideline use could be a practical reality. Second, there were clear signals of a more general lack of interest or awareness in the subject of continuous review of care. This, together with a feeling of being overloaded with new initiatives, meant that implementation of a monitoring framework could be problematic and might need considerable support in order to make progress.

**Conclusions:** Effective methods can be developed for monitoring guideline use in primary care. However there is a need to address the degree of understanding that many primary healthcare professionals have of the concepts and practical issues in the area of guideline-use monitoring, and of expectations of this within the NHS. In addition there are a number of technical issues concerned with efficient capture of clinical information and its evaluation. Further research is recommended in the following areas: the extent to which patient concordance with the guideline recommendations be taken into account in the assessment of clinician conformance with guideline recommendations; the costs and benefits to patient care of guideline-use monitoring; the most efficient methods of developing valid and reliable review criteria which are policy and evidence (guidelines) based; whether review criteria are more useful than guidelines in improving quality of care; what additional benefits to patient care can be offered by monitoring patient-centred health outcomes in addition to process of care, and at what cost?





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## List of abbreviations

AHCPR	Agency for Health Care Policy and Research	NSF	National Service Framework
CHD	coronary heart disease	PCAG	Primary Care Audit Group
DF	degrees of freedom	PCG	Primary Care Group
HA	Health Authority	PCT	Primary Care Trust
IM&T	information management and telecommunications	RCGP	Royal College of General Practitioners
IT	information technology	SAQ	Seattle Angina Questionnaire
MAAG	medical audit advisory groups	SPSS	Statistical Package for Social Sciences
MDS	minimum data sets	SD	standard deviation
NICE	National Institute for Clinical Excellence	TARPC	Tayside Audit Resource for Primary Care

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.





## Executive summary

### Background

The elements of interest in this study relate to the overall drive to improve quality in primary care. The use of national evidence-based clinical practice guidelines is becoming a normal (if not always an accepted) feature of primary care, and National Service Frameworks (NSFs) are the context in which guideline use will take place. Clinical governance and clinical audit requirements mean that primary care teams must give consideration to achieving explicit standards of care, such as those proposed by national evidence-based guidelines. NSFs and performance monitoring will require Primary Care Trusts (PCTs) to monitor the effectiveness of care given by teams to provide, among other things, a global picture of care across the trust. This process is likely to include information collected through the use of clinical audit review criteria, based on guidelines.

There is limited research evidence with which to base decisions on the methods of monitoring guideline use that may be appropriate to the requirements of the wide range of potential users. There has been little evaluation of the types of information that can be used to provide the information that clinical teams need to review their conformance with clinical guideline recommendations.

### Objectives

The study aimed to develop a guideline-use monitoring framework in primary healthcare settings. There were five objectives:

- to develop a conceptual framework for guideline-use monitoring in primary care
- to identify the principles that users require for using routine data monitoring of guidelines
- to use survey techniques to review guideline monitoring issues of significance to users, including acceptability, practical applicability and cost in routine practice
- to develop a framework for monitoring the use of both consensus-based and evidence-based guidelines

- to test the model in a limited manner; to determine usefulness in terms of acceptability, practicality, cost and effort required by those using the framework.

### Methods

Both qualitative and quantitative methods were used in the study. In Phase 1 a series of semistructured interviews was used to gain an understanding of the issues for potential users, to develop the monitoring framework. These data informed a postal survey among a random sample of primary healthcare professionals. In Phase 2, to test out the framework, a further semistructured interview study was used to explore the practical issues relating to monitoring guideline use. Case studies were then undertaken to investigate the use of evidence-based review criteria and patient-centred outcome measures as methods for providing monitoring information. A case study in one general practice used interviews to examine the possible costs associated with guideline-use monitoring.

In Phase 1 of the study, the interviews were undertaken with primary care professionals from one local health community. The survey was undertaken among staff from a purposive sample of Health Authorities in England and a random sample of general practitioners and practice nurses from the selected Health Authority areas.

In Phase 2, interviews were undertaken among Health Authorities, Primary Care Group (PCG) and general practice staff from three Health Authority areas. Case studies were undertaken in volunteer general practices and among patients who consented to provide confidential health outcome information.

### Results

A conceptual framework to support guideline-use monitoring in primary care has been developed, through an amalgam of quality improvement principles from the international literature and an exploration of the requirements of practitioners at

three levels in the NHS: general practice, PCGs and Health Authorities. Clinicians see benefits in having systems that can be used to evaluate how well clinical teams are performing against evidence-based clinical standards. However, few have much experience of using guidelines and then assessing conformance with the recommendations. More importantly, many clinicians have concerns about the demands that such systems would place on them in terms of time and cost. Many also have concerns about the confidentiality of information transfer outside the clinical unit. In particular, clinicians had problems with the notion that someone in, for example, a PCT might be 'monitoring' the quality of their care, although many respondents recognised that clinical governance required conformance with standards and that some form of internal and external assessment was required.

Demands on time and the variation in practice computing systems meant that it was only possible in this study to capture review criteria information onto paper-based records, although most of these data were actually held on computer systems. There was a very high level of conformance of the practice teams with guideline recommendations for the management of asthma and stable angina, although the nature of the retrospective data capture meant that the clinical teams had not had prior sight of the guideline recommendations. It appears to be more problematic to capture outcome data from patients, perhaps because of the need to capture new information and to seek informed consent in a study (which would not be required in routine clinical practice).

A costs framework has been developed that can be used to explore the potential costs of guideline-use monitoring and may be of assistance in exploring the wider cost implications of clinical audit at the general practice level.

## Conclusions

Methods have been demonstrated that would enable primary care teams and PCTs to monitor clinical guideline conformance while understanding the problems of both the practical and the human issues in establishing the systems.

Effective methods can be developed for monitoring guideline use in primary care. The practical difficulties relate to two main issues. The first is the technical issues concerned with efficient capture of clinical information and its evaluation; in particular, the existing variation in expertise in computerised information, and the need for training of teams in the use and meaning of process and outcome information related to guideline recommendations. The second, and more problematic, issue is the limited degree of understanding that many primary healthcare professionals have of the concepts and practical issues in the area of guideline-use monitoring, and of expectations of this within the NHS.

## Recommendations for research

- To what extent should patient concordance with the guideline recommendations be taken into account in the assessment of clinician conformance with guideline recommendations?
- What are the costs and benefits to patient care of guideline-use monitoring?
- What are the most efficient methods of developing valid and reliable review criteria which are policy (NSFs) and evidence (guidelines) based?
- Are review criteria more useful than guidelines in improving quality of care?
- What additional benefits to patient care can be offered by monitoring patient-centred health outcomes in addition to process of care, and at what cost?

# Chapter I

## Background to the study

### Introduction

This introductory chapter has two objectives. The first is to set the context for the research in terms of the many structural and policy changes made in the NHS during the course of the study, especially in primary care. The second is to explore the research literature relevant to methods for monitoring guideline use. In the context of this study, the term primary care is limited to the activities of general practice.

In 1994 the NHS Health Technology Assessment R&D programme identified a need to “develop a framework and methods for deciding when it is appropriate (cost-effective) to develop (and implement) a guideline, as they can be costly to produce and may be ineffective”. Subsequently, a suite of three projects were commissioned. These projects were:

- to study the cost-effectiveness of guideline development
- to explore methods for undertaking cost-effectiveness studies within guideline development<sup>1</sup>
- to examine the requirements and methods for monitoring guideline use in primary care.

This report presents the results of the third project, which set out to explore approaches for monitoring clinical guideline use in general practice, where possible through the routine collection of clinical data, at three levels:

- individual general practices
- local primary care organisations
- at the wider population (Health Authority) level.

The project focused on assessing means of monitoring the use of clinical practice guidelines in general practice. As some of the results later showed, the term ‘monitoring’ often requires some explanation (even reassurance) within the NHS. Here, the term means to maintain regular surveillance, with implications for a continuous process rather than an *ad hoc* examination of guideline use. Both theoretically and practically, the process is linked with quality improvement and also with performance management. The project

was not, however, specifically concerned with the technology of data-capture systems (such as general practice computing systems), although the conclusions of the study are set in the context of the NHS Information Strategy.<sup>2</sup>

The research does not consider issues about guideline implementation. There is a considerable research literature about the methods that might be used to implement guidelines, that is, to get them into practice. This study is concerned about activities once implementation has taken place and guidelines are in use. Hence, the literature reviewed in this chapter, and the methods used in the study, relate to monitoring the use of guidelines rather than reflecting on the opportunities and difficulties of implementation of guidelines.

The project was undertaken from 1997 to 2000, a period that saw considerable changes in NHS primary care. Many of these changes had considerable implications for the process of the study and the pertinence of the results.

### Study aim and objectives

The study aimed “to develop a model for using routine data monitoring in the evaluation of clinical guideline usage in primary healthcare settings”.

There were five objectives for the study as set out in the initial proposal in 1996. These were:

- to develop a conceptual framework for the use of guideline monitoring in primary care
- to identify, from a limited number of users (clinicians, managers and clinical audit staff), the principles they require for using routine data monitoring of guidelines, using a focus group approach
- to use survey techniques among a wider audience to review issues of significance to users, including acceptability, practical applicability and cost in routine practice
- to develop a model for monitoring the implementation of both consensus-based and evidence-based guidelines, based on these concepts and user requirements, which functions in a variety of primary care settings

- to test the model in a limited manner, to determine usefulness in terms of acceptability, practicality, cost and effort required by those using the model, and so to develop a 'prototype' system.

The design of monitoring systems for such purposes requires three principal components: the development of a conceptual framework; an understanding of user requirements; and an understanding of the state of the technologies to support information capture.

This study explores the first two of these components. It does not examine the technology aspects of primary care data capture in guideline implementation monitoring and the remaining challenges, although the project conclusions do take account of developments in this field.

In the initial proposal (before a number of important changes to UK general practice had been initiated), it was suggested that the introduction of the effective monitoring of guideline usage should provide support for three separate functions in the context of primary care fundholding. At that point, the term fundholding described a policy of individual general practices holding contracts to purchase secondary care from hospitals or other healthcare institutions. These functions were:

- contract monitoring (within the fund, or through contracts between hospital trusts and Health Authorities/Health Boards on behalf of the general practice)
- guideline-use review
- guideline-based clinical audit.

The study proposed to determine the practicality of monitoring systems that could address all three purposes, seeking eventually to develop a prototype or framework based on user requirements.

To retain a pragmatic approach to the research and to its implications, the study sought to use existing or planned monitoring mechanisms, rather than propose, for example, the introduction of new and separate information systems. In addition, it was proposed to seek to explore the costs and the benefits of such a system to clinicians and managers, so allowing policy-makers, whose brief it is to improve clinical effectiveness, to consider how guideline monitoring might best be used to enhance patient care.

In particular, it was anticipated that the monitoring framework would inform the work of

local primary care quality organisations and would provide local clinical groups with efficient methods of assessing the impact of using guidelines.

Many changes have occurred in the structure and context of NHS primary care since the project was accepted in outline in 1995, commissioned in 1998 and reported in 2002. These are considered in the next section, so that the changes to the original methodology and the results of the empirical studies may be seen in the context of both current NHS structures and preceding changes.

## The changing context of the study

To ensure the relevance of the project amid fast moving changes in the NHS, some aspects of the original proposal were modified, although the overall design remained as proposed (these modifications are discussed in Chapter 2).

During the time spanned by the initial commissioning, commencement and completion of the study, the setting in which NHS primary care was provided changed radically. The NHS policy of fundholding (in existence in 1996 when the study outline was first accepted) was changed to one of a reorganised primary care service based on groups of general practices called, in England, Primary Care Groups (PCGs). These organisations were required to develop common purpose in standards of quality of care (the process of clinical governance). Subsequently, PCGs have become Primary Care Trusts (PCTs), with greater responsibility for NHS budgets,<sup>3</sup> and Health Authorities have been disestablished in England and Wales, with new Strategic Health Authorities established in England in 2002.

In these new contexts, the monitoring of clinical guideline use might provide support, among other things, for:

- assessment of guideline use in the context of the Health Improvement Programme (now the Health Improvement Modernisation Plan) at the Strategic Health Authority or PCT level
- monitoring, across the PCT, of the impact of components of National Service Frameworks (NSFs) within the context of the local Health Improvement Programme
- guideline-use review at the general practice level and review of the impact of guideline use
- guideline-based clinical audit
- outcome evaluation of guideline-based care.

Devolution of responsibility from the Health Authorities to the PCTs means increased accountability in primary care for clinical performance and the setting of national standards. The move towards greater accountability within the wider NHS means a drive for increased efficiency and quality. This drive for quality links to two main objectives: to ensure fair access to effective, prompt, high-quality care and to ensure that clear national standards for services and these objectives are being supported by consistent, evidence-based guidance to raise quality. NSFs<sup>3</sup> are designed to prescribe how services can best be organised for patients with particular conditions. NSFs include a definition of the scope of the framework, the evidence base, national standards and a timescale for delivery. At the same time the development (and expected use) of clinical guidelines has increased in prominence with the establishment of the National Institute for Clinical Excellence (NICE)<sup>4</sup> and its twin programmes of technology appraisal and guideline production. All guidelines produced by NICE for the NHS in England and Wales have accompanying clinical audit tools, using review criteria that are based on recommendations in the guideline.

Concurrently, the pressures to self-evaluate the quality of a health professional's care have increased with the advent of clinical governance and there is an increased expectation that health professionals should demonstrate that their care is effective.

Although providing methodological challenges to the study, these changes in philosophy, structures and process actually enhanced its potential value. For example, the requirements of clinical governance on PCTs demand methods of routinely monitoring guideline use and of NSF and guideline implementation. So while the process of primary care contract monitoring is no longer relevant within health communities (i.e. the high-level monitoring process discussed in the original proposal in the context of fundholding), high-level monitoring of guideline use will be increasingly required by PCTs of their clinical teams. Furthermore, Health Authorities and Health Boards have a statutory role in monitoring primary care organisations,<sup>3</sup> including the use of health service clinical guidelines.

In the following sections the concepts, roles and methods of monitoring guideline use are explored. As indicated earlier, the literature review is concerned with the use of quality indicators and monitoring the use and effect of guidelines, rather

than being concerned with the actual implementation of clinical guidelines in primary care.

## The drive for quality in primary care: setting the scene for guideline monitoring

Approaches and methods for monitoring guideline use are important components of the much broader drive for quality improvement in primary care. This professional movement has a long history, but it is one that gained increasing momentum in the years leading up to the new contract for British general practitioners (GPs) in 1989. Calls from the Royal College of General Practitioners (RCGP) for an increased focus on quality in the early 1980s<sup>5,6</sup> were followed by discussion papers from the government that specifically began to consider the quality of primary care in the UK.<sup>7</sup> Following hard on the introduction of the new general practice contract came the formal introduction of medical audit, described in *Working for patients*<sup>8</sup> as:

“The systematic, critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources, and the resulting outcome and quality of life for patients.”

In the context of an increasingly active national health policy, and following the introduction of medical (subsequently clinical) audit in the NHS, came further initiatives to formulate advice on quality of care for individuals, including first proposals for national clinical guidelines in England.<sup>9</sup> This was not welcomed unanimously. At the same time, professional interest was increasing in both the potential value and the limitations of clinical guidelines, particularly in primary care, which was seen as the likely recipient of much of the advice provided through national clinical guidelines.<sup>10</sup>

Arguably, however, the most important NHS quality initiative, and one that will have a great impact on guideline use, has been the recent advent of clinical governance, described as:<sup>11</sup>

“a framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.”

In this context, national evidence-based clinical practice guidelines are becoming a normal (if not always an accepted) feature of primary care and

NSFs the setting in which guideline use will take place. Clinical governance and clinical audit requirements mean that primary care teams must give consideration to achieving explicit standards of care, such as those proposed by national evidence-based guidelines. National Assessment Frameworks and the associated performance monitoring procedures<sup>3</sup> will require PCTs to monitor the effectiveness of care of individual teams, so as to provide, among other things, a complete picture of care across the trust. This is likely to include information collected through the use of guideline-based clinical audit review criteria. The Commission for Health Improvement may use these data, among others, to monitor the effectiveness of care in each Trust.<sup>11</sup>

All of these initiatives have special relevance to both the setting and the results of the study. The methods set out in Chapter 2 demonstrate how the study design altered as the structural changes in the NHS put different emphasis on the objectives of guideline monitoring. With increasing investment in the NHS has come increasing performance monitoring and increased focus on 'doing the right things right' for patients. Monitoring guideline use is therefore now more likely to be a routine requirement for quality assessment in primary care than it was when the study was commissioned. The following section explores the place of monitoring in a quality improvement framework and discusses the use of review criteria as the primary monitoring tool.

## Monitoring the use of clinical guidelines: role, concepts and methods

During the early 1990s in the UK there was increasing professional and policy interest in clinical guidelines as a means of promoting clinically effective and cost-effective clinical care.<sup>9,10</sup> That interest could be linked to three separate issues: first, the increasing demand for professional and managerial accountability in healthcare (much of which arose initially from policy-makers); second, the rapidly expanding knowledge base in medicine that made it difficult for clinicians to keep abreast of primary research;<sup>12</sup> and third, the pressure to use limited resources more effectively.

These pressures were underscored by the recognition of unexplained variations in clinical practice, with the continuance of obsolescent clinical practice and with the considerable lag between the publication of research evidence and

its introduction in practice.<sup>13</sup> In addition, and importantly when healthcare budgets are under severe pressure, it is likely that some clinical practice variation represents opportunity costs for healthcare systems (i.e. possible missed opportunities for undertaking more work for the same amount of resources already in the system).<sup>14</sup>

Thus, one of the principal means of enabling improvements in healthcare has been seen to be the development and use of clinical practice guidelines relevant to primary care that are evidence based, contain up-to-date information and have practical recommendations for action.<sup>10</sup>

While the research literature continues to demonstrate the difficulty in implementing clinical guidelines,<sup>15</sup> it also suggests that monitoring guideline use is a process valuable to healthcare practitioners and policy-makers. A substantial review by the the Agency for Health Care Policy and Research (AHCPR) (now known as Agency for Healthcare Research and Quality)<sup>16,17</sup> of the means by which guidelines could be used to monitor quality of care suggested that:

“purchasers and providers need to agree upon criteria for the review of practice based upon guidelines. These standards should be monitored through the commissioning process to ensure that the guidelines achieve a quality of care consistent with the evidence upon which they are based.”

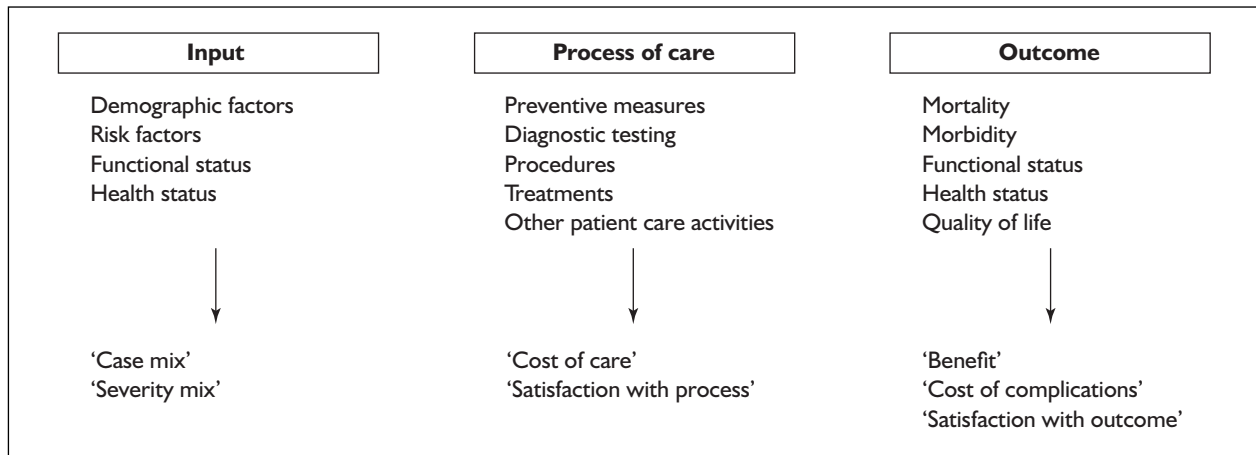
This research background is particularly informative since the authors drew on models of performance review that related both to individuals and to organisations such as health maintenance organisations, which may now in some ways be seen as analogous to PCTs.

The Agency used as the basis for their proposals an overarching input/process of care/output model of quality of care, in which most of the process of care components could be encapsulated in a clinical practice guideline (*Figure 1*).

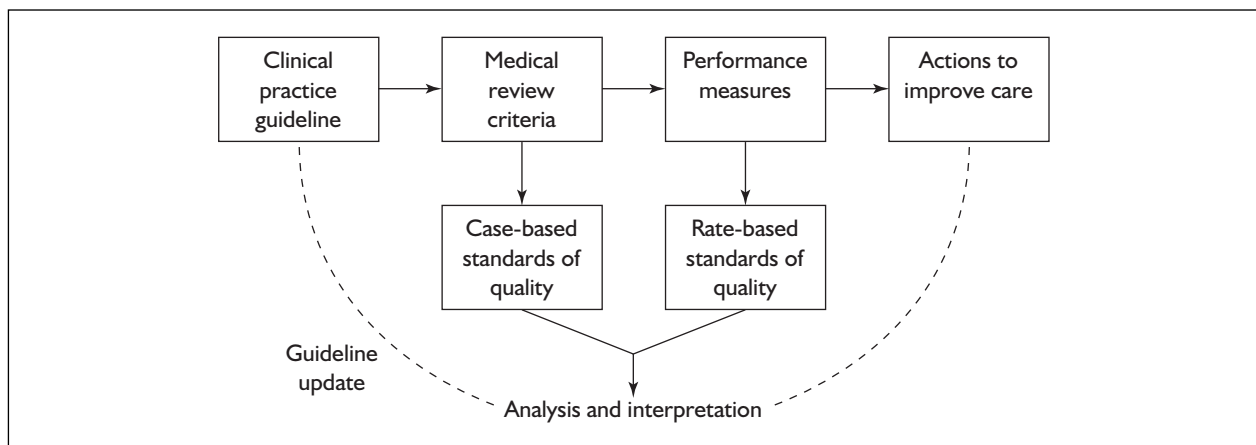
Extending the proposal of the evaluation model, AHCPR identified and defined three types of evaluation tool that might be developed around clinical guidelines and used to assess quality of care. These were:

- medical review criteria: systematically developed statements that can be used to assess specific healthcare decisions, services and outcomes (review criteria in this circumstance are a type of quality indicator<sup>18,19</sup>)





**FIGURE 1** A model of care as a basis for quality evaluation<sup>17</sup>



**FIGURE 2** Relationship between clinical practice guidelines and evaluation tools<sup>17</sup>

- performance measures: methods or instruments to estimate or monitor the extent to which the actions of a healthcare practitioner or provider conform to the clinical practice guideline
- standards of quality: authoritative statements of (i) minimum levels of acceptable performance or results, (ii) excellent levels of performance or results, or (iii) the range of acceptable performance or results.

Figure 2 demonstrates the inter-relation between these evaluation tools, set in the context of a quality management cycle consisting of four key elements: planning, doing, checking and acting.

The Agency working group responsible for the report saw the clinical guideline as the health planning element of care in this context. The 'checking' element of the guidelines-based quality management cycle was referred to as 'measuring guideline conformance', an equivalent assessment process to monitoring guideline use and assessing

the closeness or otherwise of the care with guideline recommendations. Just as might be appropriate in the NHS, the evaluation tools were derived for different levels of organisation in the health service.

In this guidelines-based quality cycle, the aim of the monitoring process is primarily to examine the effect of providing particular aspects of care to individuals or groups of individuals for whom the guideline is pertinent (and after 'checking' to take appropriate action).

Medical review criteria were considered by Palmer and Banks<sup>20</sup> to be most effective when directly derived from clinical practice guidelines and to be of use in the clinical performance review of either individual clinicians or groups of clinicians.

Subsequent to the completion of the study the use of review criteria as quality indicators in primary care has been examined from two perspectives. First, exploring the desiderata for review criteria

development based on consensus methods<sup>19</sup> and, second, considering their place within the pallet of the available types of indicator that may be useful for quality assessment in primary care.<sup>18</sup> While both of these reviews are useful in terms of understanding the place of review criteria in quality assessment, they do not specifically address the task of guideline-use monitoring. However, the AHCPR reviews<sup>16,17,20</sup> do make a cogent argument for using review criteria and performance measures as the instruments of choice for guideline monitoring. The role of review criteria in monitoring guideline use at the three levels of health service organisation – general practice, Primary Care Organisation and Health Authority – is considered in the next section.

## Review criteria as the basis for guideline-use monitoring

Review criteria can be used to monitor quality of care (and guideline use) at a number of levels in a health service and in a number of configurations. For example, a cluster of medical review criteria from the same guideline would, in the framework detailed in *Figure 2*, form the basis of an evaluation tool described (above) as a performance measure. Such a measure may relate to a predetermined group of people with a similar clinical condition to whom a guideline applied, perhaps in one institution such as a general practice, or in a larger institution such as a PCT.

Depending on the purpose of the review process, the performance measure may, for example, be a proportion of those people whose care met the criteria. Furthermore, depending on the purpose of the guideline monitoring process and the organisation undertaking the monitoring, the level of aggregation of the results may vary. Thus for an individual practice interested in monitoring its ‘conformance’ to the recommendations of a guideline, the performance measure may contain a sizeable number of review criteria, especially since there will be subgroups of patients to whom branches of the guideline refer. For the PCT, a more aggregated measure may be more appropriate.

Different levels of monitoring guideline use may require different types of evaluation tools. For example, the PCT may be monitoring the care provided by a practice within the scope of an NSF. It may want less detail than would the practice, and a commissioning or monitoring Health Authority may want more detail. Review criteria may not always be the correct type of quality

indicator: this will depend on the level and purpose of monitoring. By the time the level of monitoring has reached that required in the NHS Performance Assessment Framework<sup>21</sup> (in which high-level indicators are to be used at Health Authority and PCT level), the monitoring tools may be based on epidemiological data, rather than on medical care review criteria.

For example, McColl and colleagues<sup>22</sup> explored how primary care activity, including a variety of dimensions of care, might be monitored using existing data, routinely collected by the NHS from such sources as hospital episode statistics. Subsequently, they investigated how Health Authority staff perceived the value of these criteria and found “many barriers to overcome at individual, practice and Primary Care Group levels”.<sup>23</sup> Although these methods do not have the guideline specificity required by Palmer and Banks,<sup>20</sup> the approach may be appropriate for developing performance measures for a Strategic Health Authority monitoring a PCT.

Several studies have taken an approach similar to that suggested by the AHCPR<sup>17</sup> in the development of guideline-based review criteria for primary care, while others have suggested methods not so closely linked to individual guidelines.

Hadorn and colleagues<sup>24</sup> demonstrated many of the techniques for developing guideline-based review criteria, including methods for developing criteria that are usable in routine data capture, when they derived criteria for evaluating the treatment of heart failure based on a national clinical practice guideline.

There is significant experience in the UK of developing and using review criteria to monitor standards of care, and there is also evidence of their value in monitoring conformance with guideline recommendations in primary care. In translating the review criteria approach to general practice in the UK, Baker and Fraser<sup>25</sup> set out desiderata for medical care review criteria. They considered that review criteria should be:

- measurable
- clear and precise
- appropriate to the clinical setting.

Research on standards of care in British general practice<sup>26</sup> in the 1980s used explicit review criteria, derived from consensus-based clinical standards, to assess the degree of change resulting from educational interventions.

**BOX 1** Linkage between guideline recommendation and related review criterion**Guideline recommendation**

All patients who require regular symptomatic treatment should be treated with a  $\beta$ -blocker

**Review criterion**

The percentage of patients with stable angina who require regular symptomatic treatment who have been treated with a  $\beta$ -blocker, unless contraindicated

Campbell and colleagues<sup>27</sup> took a rather different approach to the development of clinical review criteria, using an adaptation of the RAND appropriateness method to determine criteria based on the necessity and appropriateness of the monitoring criteria and the proportion of criteria recorded in the medical record. Validity and reliability were subsequently established for criteria for three common conditions: asthma, diabetes and depression.<sup>28</sup>

A limited number of guideline-based review criteria have been used to assess the implementation of guideline-driven practice initiatives in primary care in over 50 general practices in the north of England.<sup>29</sup> Although only three guideline-derived review criteria were used as the monitoring tools for each of three conditions commonly found in primary care (angina of effort, asthma and leg ulcer), the use of only 30 cases per doctor proved to be a sufficient number from which to judge conformance with guideline recommendations in each condition.

NICE has now begun to publish evidence-based review criteria alongside national guidelines as a means of providing clinicians and organisations with guideline monitoring tools.<sup>30</sup> For England and Wales this will be the usual method of producing review criteria for use by the NHS (although there is some doubt about whether the methods are standardised across the range of guidelines).

Hutchinson and colleagues explored how practical review criteria can be derived from more than one guideline for asthma, coronary heart disease (CHD) and depression, and also have used these techniques to derive criteria from national NICE guidelines for type 2 diabetes.<sup>30</sup> Using the two AHCPR categories of evaluation tools, review criteria and performance measures, these UK review criteria each represent a direct translation of a guideline recommendation. But, in measuring the proportion of cases meeting the criterion in an organisation, UK versions of review criteria fall somewhere between the AHCPR definitions of a medical review criterion and a performance measure (see, for example, *Box 1*).

In addition to measuring the process of care in the evaluation of guideline use, the AHCPR<sup>16</sup> proposed the use of specific outcome measures that also related closely to the recommendations of the guideline. This inter-relation may be demonstrated as in *Figure 3*, as adapted by the Clinical Practice Evaluation Programme of the RCGP<sup>31</sup> from the work of Palmer and Banks.<sup>17</sup>

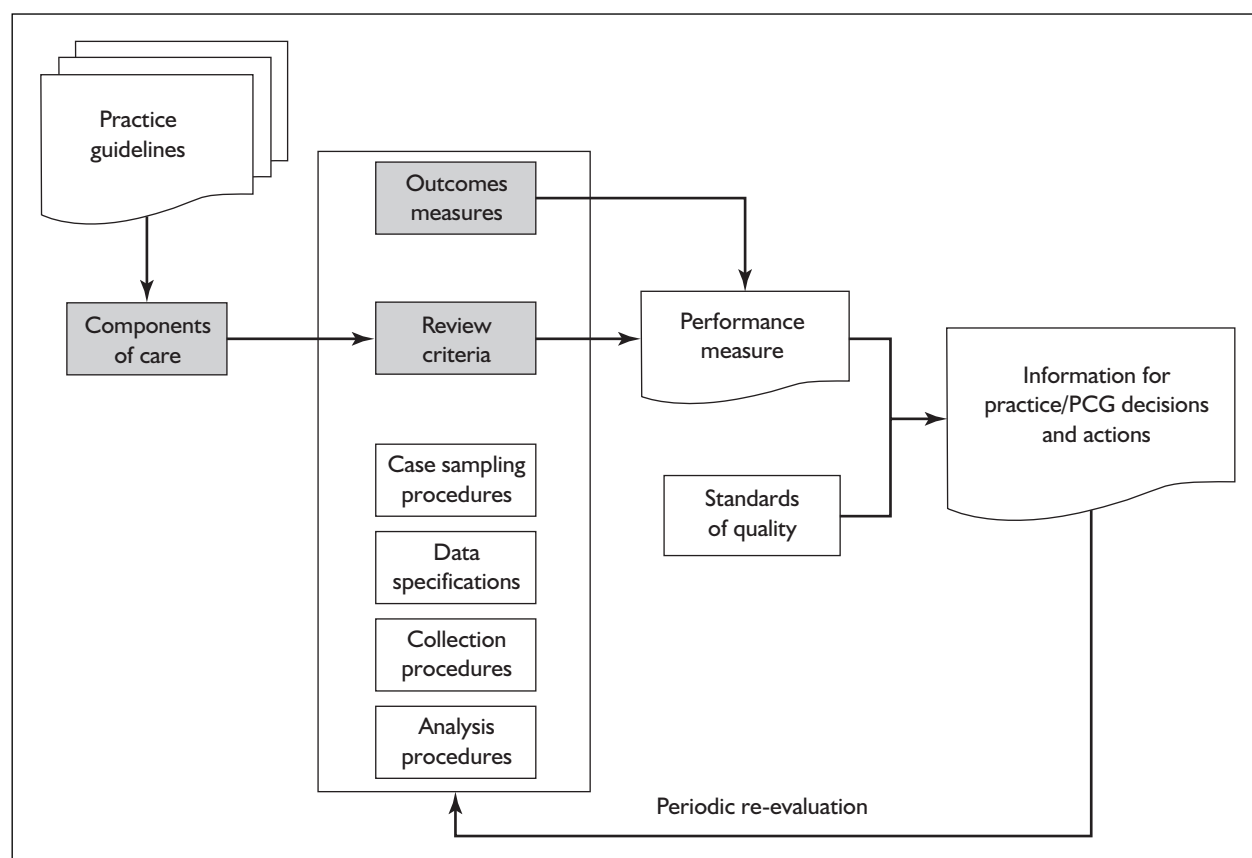
Using methodologies previously described for the development and use of primary care outcome measures in assessing quality of care,<sup>32,33</sup> it has recently been demonstrated how condition-specific measures can be used (and found to be responsive to change) in conjunction with associated evidence-based review criteria.<sup>29,34,35</sup> However, since considerable effort and costs are incurred in developing valid and reliable condition-specific outcome measures, it is likely that in routine practice a 'nearest best' choice of an existing accompanying outcome measure will be made, rather than specific outcome measures being developed to monitor the impact of each guideline.

Overall, therefore, there is a fairly strong research base to support methods of developing guideline- or evidence-based review criteria and there is a strong conceptual basis for drawing together review criteria, performance measures and outcome measures as a means of monitoring guideline use. There is less evidence on how such methods might become part of routine practice. One of the limiting factors is the lack of frameworks to bring together the information derived from the monitoring exercise.

## Information requirements to support guideline-use monitoring

The purpose of this section is to consider the conceptual information framework in which guideline-use monitoring may be located, so informing the overall monitoring framework.

One of the challenges of monitoring guideline use in primary care is the difficulty in capturing and managing complex demographic and clinical information. For each patient there may be a



**FIGURE 3** A framework for monitoring guideline use<sup>17</sup>

considerable data set, sometimes held on paper, sometimes mainly electronically, often a mixture of both. Although progress has been made in the electronic management of information in UK primary care and there is now a real policy drive<sup>2</sup> to underpin the information management and telecommunications (IM&T) structure of the NHS, using the information that is currently available is often problematic.

The basic building block of all of the methods of quality evaluation discussed above is demographic and clinical data relating to the clinical recommendations of the guideline (its process and/or its impact). Different levels of monitoring of guideline use will be required according to the purposes for which the information is required<sup>36</sup> and different levels of detail will be needed to support these functions. Furthermore, in the development of a guideline-use monitoring framework, monitoring may be undertaken in relation to various stages in the care pathway:

- input of care
- process of care
- outcome of care

and at the levels of organisation:

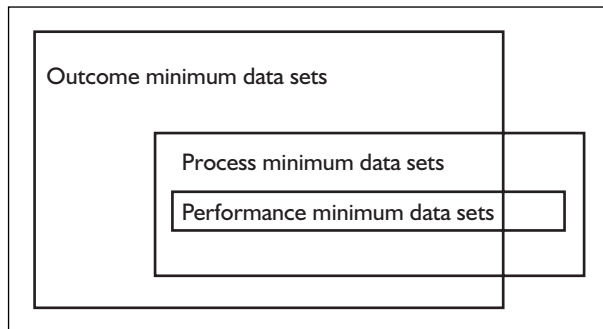
- general practice
- PCG/PCT
- health authority/board

and for different purposes, e.g.

- clinical audit
- target setting
- performance monitoring (e.g. of NSF implementation).

These levels of monitoring can also be used to construct a hierarchy of information, in terms of the number of data items to be collected and the required and actual complexity of the data. Thus, the (high-level) performance monitoring of guideline-based care of a PCT by a Health Authority would (sensibly) require a small minimum data set. Rather more extensive guideline-specific minimum data sets (perhaps based on review criteria) would be required to monitor a guideline-based process of care at this level.

Routinely collected data from the NHS would not be specific enough to provide reliable outcome data for specific clinical problems. For the assessment of the outcome of care for a general



**FIGURE 4** Potential data information flow

practice population of patients with a specific clinical problem, an additional data set would be required (perhaps provided by each patient rather than from medical records) to enable monitoring of overall changes consequent on guideline use.

Any guideline-use monitoring framework that derives from a conceptualisation should also be practical and, if possible, it should not require extensive further systems development. It should also require a minimum amount of new data capture, having where possible common components of the minimum data sets.

One model of the overlapping information requirements is shown in *Figure 4*.

Establishing user requirements of the monitoring framework is likely to be a key issue in developing and using any framework. It is axiomatic that monitoring can be conducted by different people, by different means, for different purposes. McColl and colleagues<sup>22</sup> showed, for example, that health service professionals are well able to make judgements about the type of quality improvement tools they require for particular purposes. So, before developing a system for guideline-use monitoring in primary care, it is necessary to develop a conceptual model (or range of model options) that would provide a framework to identify the why, when, what and who questions of monitoring and, broadly, how it would be undertaken.

Without such a prior conceptual framework, experience of similar work<sup>37</sup> has demonstrated that healthcare professionals have difficulty focusing on user requirements and there is then a potential for important aspects to be omitted from the monitoring system.

Different groups may decide to monitor (or be required to monitor) for different reasons. The basis of monitoring may be different for policy-makers, managers and clinicians, and this can affect how they decide to monitor. Different 'monitors' may have differing requirements for the different elements to be monitored. For example, the 'marker' elements in a set of monitoring data may differ between doctors and nurses. Doctors and nurses may require more detail on most elements of guideline usage data so as to follow their progress in changing clinical behaviour, and have a particular interest in markers concerned with clinical effectiveness, while PCTs or Health Authorities have less detailed requirements. Because these bodies have a corporate responsibility for quality of care and clinical governance, they may not require much clinical detail but may be interested in markers concerned with cost-effectiveness and with quality and equity of care.

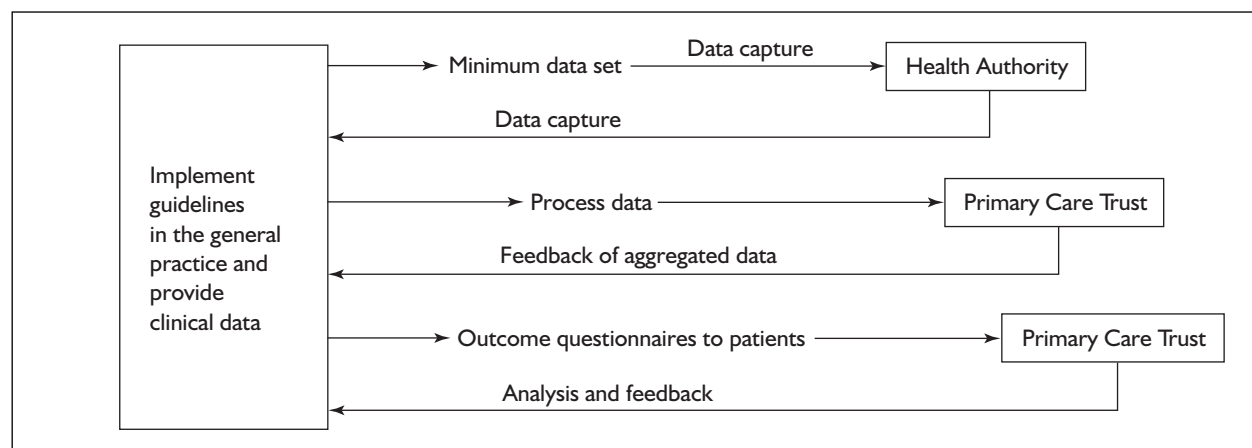
An information flow to take account of these requirements and the different levels of aggregation and feedback might be conceived as in *Figure 5*, in which the PCT acts as both a monitor and a centre where data may be analysed on behalf of the individual practices.

A conceptual framework on which to base the information needs to support guideline-use monitoring in *Figure 5*, and which might guide the development of the framework, can be exemplified as in *Figure 6*. This sets out in hierarchical form the development of specific minimum data sets (MDS), taking into account user requirements and the sources of the required information, including review criteria and associated outcome measures.

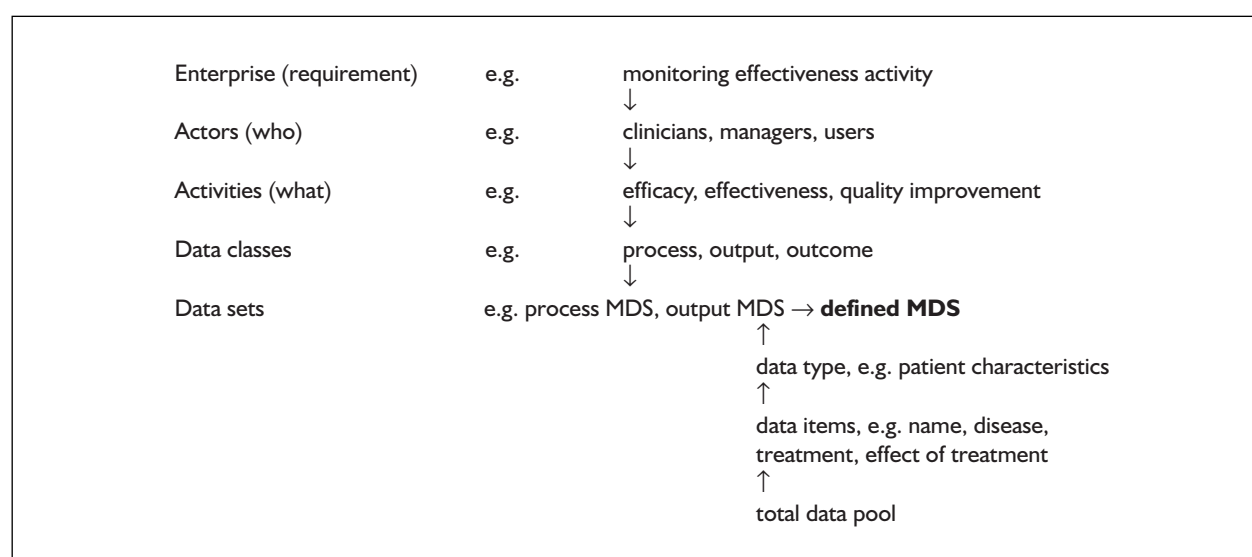
In summary, this discussion indicates the need for clarity of purpose to be achieved before specific monitoring-use tools are created and the IM&T frameworks and specific MDSs are created. With the ability to create software templates in general practice computing systems, the probability increases that an efficient guideline-use monitoring framework can be developed to work effectively.

## Costs of monitoring guideline use

A consideration of costs in monitoring guideline use is concerned here with the best use of resources once the decision has been made to monitor, rather than, for example, with the cost-effectiveness of one monitoring system compared



**FIGURE 5** Model of information requirements



**FIGURE 6** Minimum data sets (MDS) development

to another, for there are insufficient primary data on which to make such an assessment.

Any model that is developed to monitor (and hopefully assist) guideline use must formulate a system that is both effective (it does what it is designed to do well) and efficient (it does it at least cost for equal effectiveness). Costs in this case include both financial costs and human resource costs, while efficiency includes a need to place a minimal additional burden on staff (ideally, reducing the burden).

### Developing a cost framework

The provision of good quality care is not simply about increasing patient benefit, but must also reflect the realities of limited NHS resources.<sup>11</sup> Any quality-assurance initiatives should promote care that it is likely to be cost-effective in terms of

time, money and effort invested.<sup>38</sup> In order to assess this reasonably accurately, it is necessary to know the level of investment required in the process of reviewing care, as an integral part of quality assurance. So must it be with the mechanisms that support the assessment of quality, such as guideline-use monitoring.

Costs have been shown to be a significant barrier to the implementation of guidelines.<sup>39</sup> It seems reasonable to extend this idea and consider costs as a potential influence to the uptake of other elements of the quality-assessment cycle, such as monitoring the use of clinical guidelines. Some understanding of costs, or at least the elements of costs, would be required by general practices and PCGs (PCTs) in any decision on whether to monitor guidelines (is it cost-effective?) and how to monitor guideline use (what is the most cost-efficient method to use?).

Considering the amount of audit activity being undertaken in the NHS, the lack of relevant papers on the costs of primary care guideline use and monitoring is a little surprising. However, discussions with those working within the field confirmed this gap in research and knowledge, which has also been acknowledged in the literature.<sup>40</sup> The situation also pertains in secondary care. For example, a survey of 21 UK hospital trusts revealed that there is no consistent approach to funding clinical audit<sup>41</sup> and therefore little understanding of the real costs involved.

Some research has been undertaken to identify the costs of implementing guidelines in terms of providing the care to the level recommended in the guideline. Hu and colleagues<sup>42</sup> considered the impact of the pressure ulcer guidelines developed in the USA by the AHCPR,<sup>43</sup> analysing the costs of the direct services and supplies that were required. Recommended care was broken down into the tasks involved and the time taken by various staff to perform these was estimated. As this was an American study, patient and institution bills were also used to evaluate the costs of the services. No analysis was done on the costs of monitoring this care.

A number of investigators highlighted several areas where there would be potential costs for a general practice using review criteria to monitor clinical practice or, more specifically, the use of guidelines.

The Tayside Audit Resource for Primary Care (TARPC)<sup>44</sup> was set up in 1990 to promote and develop all aspects of primary care audit within Tayside in Scotland. The project was designed to address the reasons why primary healthcare teams find it difficult to carry out audit. The three key reasons given for this difficulty by primary healthcare teams were:

- lack of time
- lack of funds to buy the necessary staff time
- lack of audit skills among clinicians and ancillary staff.

TARPC offered facilitation, audit education, information technology (IT) training and reimbursement for time spent on audit (4 hours per week: £1000 throughout the project) to selected general practices in Tayside. However, the decision to reimburse for 4 hours was taken on judgement, with no analysis published to identify how much time was actually spent on the audit.

Earnshaw<sup>45</sup> described a rolling half-day surgical audit programme in a hospital and discussed the costs involved in terms of time taken in meetings, equating the number of days lost per year for each consultant involved to the opportunity costs of number of operating lists or outpatient clinics lost. The author emphasised that the costs involved were complex and included costs of the audit department, clinicians' salaries and loss of earnings caused by reduced clinical activity.

In a similar analysis to Earnshaw,<sup>45</sup> Johnson and Faux<sup>46</sup> considered the indirect costs of medical audit. Resources required for audit are especially considered in relation to audit support staff and they point out that another area with a potentially large impact of resources is the time required to perform projects and attend medical audit meetings. The authors focused on the costs of medical audit meetings and assessed the cost impact on the running of one hospital trust. The authors then inferred the potential cost impact for the NHS. They assessed the cost of holding medical audit meetings during 1994/5 in three ways:

- cost of medical and nursing staff time to hold the rolling programme of 12 half-day meetings a year
- potential income that could have been generated by the trust had the half-day clinic and theatre activities not been cancelled
- reduction in cost that could be attained if the length of the audit meetings were changed to 2 hour sessions (which could be held at an extended lunchtime break), with no cancellation of clinical activities.

Robinson and colleagues<sup>47</sup> sought to measure the cost-effectiveness of audit of thrombolysis in some district general hospitals by analysing the cost of audit per extra patient treated with thrombolysis (the incremental cost-effectiveness ratio). Their cost estimations included data collection, a series of four audit meetings and subsequent actions. They aimed to identify, measure and value the resources consumed as a result of the audits that would otherwise have been available for other activities.

The types of cost identified were:

- **labour:** staff time needed to set up audit programme; preparation and attendance at audit meetings; time needed to adhere to audit intervention (forms, history, examination, etc.)
- **supplies:** paper and projection materials for analysing and presenting observations and implementing agreed changes
- **overheads:** additional heat and lighting, physical space occupied (lecture room, desk, etc.)

- **equipment:** faster wear and tear on photocopiers, medical records and computers.

The study focused most on the labour costs since it was estimated that these were likely to be the largest. Equipment costs were excluded as they were considered to be negligible, as were projection material costs, being seen as likely to be a fairly small and constant proportion of hospital expenditure.

A log of time spent by the research team on audit was kept and time spent by medical staff (e.g. attendance at meetings) was also noted. Other time that could not be directly measured, for example, time spent on discussion about standards and adhering to interventions, was estimated after questioning the staff. The value of labour was calculated from basic annual salaries. Estimated overall costs in each hospital ranged from £3700 to £5200 for data collection, a series of four audit meetings and subsequent clinical actions.

Emberton and co-workers<sup>48</sup> conducted a study estimating the feasibility and cost of an audit of process and outcome in prostatectomy. Costs were analysed per patient and they concluded that the large multicentre comparative audits increased the costs of care by no more than a few per cent. They also estimated costs in terms of the time taken by various staff in collecting data and organising the audit and analysis, and the cost of consumables such as printing and posting. However, the audit was based on physician and patient questionnaires rather than medical record review.

Tunbridge and colleagues<sup>49</sup> tested the feasibility of continuous audit of process and outcome in diabetes care in four general practices with organised diabetes care, to determine whether data already collected by general practice teams could be the basis of a useful continuing audit of diabetes care.

The data items collected for audit included:

- patient characteristics (gender and age), relevant diabetes history (duration of diabetes and type of treatment) and measurements derived from regular annual review assessments
- measurements of metabolic outcome and risk factors, including smoking status, body mass index, glycosylated haemoglobin levels and serum cholesterol and triglyceride levels
- measurement of markers of adverse health, including blood pressure, foot pulses, proteinuria, creatinine levels, retinopathy and cataracts

- measures of outcome of patient health, including visual acuity, prevalence of foot ulceration and amputation below the knee, and drug therapy.

These data were taken from the record card and entered into a computer database, and the time taken to do so was recorded. The data collected were required by the protocols being followed by the practices, so no extra consultation time was judged to be needed. Extra time taken was recorded for data transfer from the record card to the summary sheet, and data entry onto the computer. This was estimated per patient from the number of records processed on sample occasions. Recording time was found to be considerably increased if the record card data were incomplete. Time taken for data checking and analysis per practice depended on practice size. The time taken in writing an edited and critical report of tables produced per practice was also recorded. However, no formal cost analysis was undertaken.

## Overview

Evidence on the costs of monitoring guideline use must so far rely on an extrapolation from the limited evidence base of the costs of clinical audit. Cost model development from a theoretical perspective must draw on the data modelling methods identified in the literature review, together with the requirements of users (of guideline-use monitoring) and their experience, and the requirements of the NHS information strategy.<sup>2</sup> In the case of this study it does not, however, consider the relative costs and benefits of the many hardware and software systems available to UK primary care.

An initial theoretical cost framework was derived from the literature to act as a guide for developing a study framework (see *Box 2*).

### BOX 2 Main cost areas in guideline-use monitoring

1. IM&T systems:
  - (a) software/systems costs
  - (b) training costs
    - human resources
    - external training costs
2. Data collection:
  - (a) in-practice costs
    - GP/practice nurse time
    - data entry clerk costs
  - (b) external costs
    - IT consultant costs
3. Data analysis:
  - (a) in-practice costs
  - (b) costs of outside agencies



## **Implications of the literature for the design of the study**

The theoretical framework for this study on guideline-use monitoring draws on concepts from a number of fields.

Although there is a limited literature on monitoring use, in contrast to the rapidly expanding literature on guideline implementation, the detailed consideration given to the topic by the AHCPR in the USA provides a valuable framework on which to base an exploration. While there are still many differences between the US healthcare system and that in the UK, the models proposed are relatively context free.

To be successful, the design of data monitoring systems for purposes such as quality improvement requires both a conceptual framework and an understanding of user requirements. Detailed design of MDS for guideline-use monitoring is beyond the scope of the project reported here, but efficient monitoring systems will require consideration of the 'who, what and why' questions, with data capture and transfer limited to the provision of primary information. Monitoring methods require minimum, not maximum, data sets.

This fusion of conceptual approaches forms the basis for the development of the guideline-use monitoring framework described in Chapters 3 and 4, and the field testing of methods described in Chapter 5.



## Chapter 2

# Study methods: guideline monitoring

### Choice of overall study design

This chapter sets out the rationale of the study design that comprised two phases:

1. initial development of the framework through the conceptual development of the guideline monitoring framework, interviews and a survey seeking the requirements and views of potential users
2. exploration and testing of methods for monitoring guideline use through interviews with users and case studies.

This study is concerned with the reasons for, and potential methods of, monitoring the use of clinical practice guidelines in British primary care. When the options for study design were considered, choices of research design were made on methodological, contextual and practical grounds, the requirements set out by the research commissioners and the resources available for the study.

When the study proposal was first accepted in 1996, the number of primary care teams using explicit clinical practice guidelines in routine practice was thought to be small. The choice of methodological approach therefore principally lay along two main lines: either an exploratory study to understand the issues of guideline monitoring (who would want to undertake guideline-use monitoring, why and for what purposes, and a consideration of how this might be done) or an intervention trial to examine which monitoring method(s) might be most effective.

The possibility of undertaking a two-way experimental design intervention trial was considered; for example, comparing the effect on care of using consensus guidelines against the effect of the evidence-based guidelines, measured through monitoring information. However, the considerably larger numbers of practices required in such an experimental design would have greatly increased the cost of the study (beyond the available resources) and provided potential problems in recruitment. Most importantly, though, it was not clear from the literature that the issues raised by the concept of monitoring

guideline use had been explored in the NHS to the extent that they had in, for example, the USA.<sup>17</sup>

There was, therefore, only a limited research literature base on which to build an experimental hypothesis and there was no exploratory work available from the UK that would provide a base for the work. Furthermore, because of the complex inter-relations and possible confounding variables, it might have proved difficult to study the relationships between the monitoring process and outcomes.<sup>50</sup> Practical constraints, such as the availability of good quality data from clinical record systems, might also have constrained the value of an experimental study.

An exploratory study design was therefore chosen, based on observational and descriptive methods, using both qualitative and quantitative approaches. The adoption of an investigative/exploratory study design that uses both qualitative and quantitative methods allows an understanding of the requirements of potential users of a framework designed to monitor the use of evidence-based guidelines. It also allows the exploration of potential methods of monitoring in different NHS primary care settings.

The study design therefore allows exploration of:

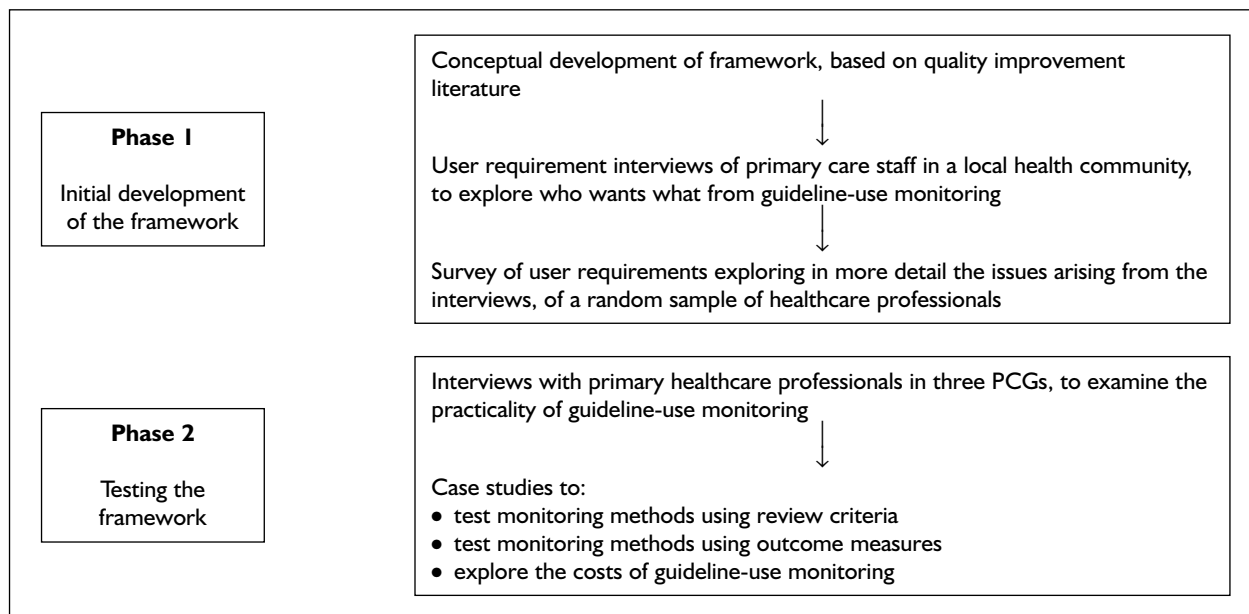
- user requirements (identifying the actual and potential needs of professionals who may use any proposed guideline-use monitoring system)
- potential monitoring methods at three levels of information (general practice, PCG and Health Authority)
- monitoring methods in a limited number of settings.

The study was undertaken in two main phases and *Box 3* sets out the linkages between the components of the study.

### Guidelines and assessment instruments used in the study

#### Clinical practice guidelines

The choice of tracer conditions (and guidelines) for use in the study was based on the likely impact

**BOX 3** Schema of the project plan

of the guidelines in primary care, relative frequency of conditions, need for multidisciplinary input to ensure good quality care and the potential for variation in clinical practice. These criteria were similar to those used in choosing clinical guidelines for development, principally focusing on chronic diseases. The choice of tracer conditions was also partly driven by the availability of good quality guidelines at the time of the study.

When the proposal was initially accepted in 1996 there were two types of good quality guidelines, consensus based and evidence based, available to the project. The consensus guidelines were the British Thoracic Society's Guidelines for Asthma<sup>51</sup> and the Clinical Standards Advisory Committee report on back pain,<sup>52</sup> which refers to evidence but does not have an evidence-based structure. The evidence-based guidelines were, the guideline on stable angina,<sup>53</sup> the guideline on asthma in adults<sup>54</sup> and the guideline on acute low back pain<sup>55,56</sup> produced by the RCGP.

However, following an agreement to reduce project costs and to respond to the referees' comments after the acceptance of the initial proposal, only the evidence-based guidelines for asthma and stable angina were used in the project. Thus, the study tracer conditions chosen were asthma in adults and stable angina.

### Assessment instruments

The feasibility case studies were chosen as a means of demonstrating the framework (rather than

engaging in a substantial data capture exercise) when the resources available to the project were reduced before commissioning the project. The studies explored the extent to which outcome and process measures could be used to capture data from patients with the two illnesses, as a means of monitoring guideline use and conformance with guideline recommendations. In each case the purpose of using the measures was to explore the opportunities and values of using these approaches to monitor guideline use, rather than, at this stage, to gather data sets of sufficient size to monitor care reliably.

### Evidence-based review criteria for CHD and asthma

Developed in the RCGP Clinical Practice Evaluation Programme,<sup>31</sup> these measures (see Appendix 4) are derived principally from the clinical guidelines used in the study, are based on development methods described by AHCPR<sup>16</sup> and Hadorn,<sup>24</sup> and are designed for use in British general practice. Only a limited number of criteria for each condition were used, since experience in other studies<sup>29</sup> suggested that the usefulness of the data capture approach could be assessed by using only a limited set of review criteria for each condition.

### Patient-centred outcome measures used in the study

Initially, the study proposal suggested that the implementation of the guidelines could be assessed using information from both population-based health outcome indicators<sup>22</sup> and

multidimensional health outcome assessment tools.<sup>32,57</sup> However, because the study resources were subsequently limited in discussions with the funding body and also because the study approach was designed to be exploratory rather than experimental, it was not possible to collect sufficient data using population-based outcome indicators for any valid methodological conclusions to be drawn. Instead, the study used two patient-centred, condition-specific outcome measures, one for asthma and one for stable angina.

These patient-completed questionnaires (see Appendix 5) were either derived directly from the Asthma Outcome Measure for Ambulatory Care<sup>35,57</sup> (developed for use in general practice and outpatient care) or derived and revalidated from the Seattle Angina Questionnaire (SAQ)<sup>34</sup> within another project in British general practice. Thus, both measures were known to be valid and reliable in the settings in which they would be used in the study. They were used in this study to investigate whether general practice teams are able to use evidence-based measures of outcome as indicators of guideline use and conformance.

Methods of analysis are described in more detail, together with the findings, in the section 'How can review criteria and outcomes measures be used to monitor guideline use?' in Chapter 5.

## Initial development of the guideline-use monitoring framework

### Conceptual development of the framework

The objective of this stage was to consider literature and pre-existing models of guideline-use monitoring, assess what may be appropriate for UK use and derive a framework. The literature and pre-existing models were considered in the light of UK contexts, resources and circumstances. The research team then brought to bear experience and views to derive features of a potential framework, refined these ideas and then took them to potential users to test assumptions and gather further requirement details.

### User-requirement interviews

The main objective of this stage of the project was to explore and identify the opportunities and barriers arising from the routine monitoring of guideline use, through semistructured interviews of a limited number of potential users in primary

#### BOX 4 The interview sample

- One medical practitioner of a PCG with a special interest in quality
- Three non-medical members of a PCAG
- Two medical practitioners of a total purchasing project
- One GP at a research practice
- One GP concerned with quality of care issues in their region
- One GP with a special interest in quality
- Two members of their local RCGP faculty

care. These were undertaken at the three levels of service provision of concern to the project: general practice, PCG and Health Authority. For practical reasons the interviews were undertaken in a local health community area, in general practice, a local Primary Care Audit Group (PCAG), a PCG, and a Health Authority.

A convenience sample identified 14 people for semistructured interviews. One person declined to be interviewed and two did not respond to the requests for interview within the required timeframe, so 11 people were actually interviewed. The final sample is described in *Box 4*.

In the project proposal it was initially suggested that one multidisciplinary focus group would meet on one occasion to generate issues and concerns relevant to guideline monitoring in primary care, from which semistructured interview schedules could be developed. However, the pressure on primary care staff generated by the move to a 'primary care led NHS' was such that it proved impossible to establish a broadly based focus group within a reasonable timescale. The structure for the interview schedule was therefore developed from issues identified in the research literature and on the initial conceptual development of the framework (see above). Interviews were recorded and a subsequent rolling thematic analysis carried out,<sup>58</sup> from which themes were also derived for the survey (see 'Postal survey of user requirements', p. 18). The interview schedule is presented in Appendix 1.

#### Focus of the interviews

The interviews set out to explore the views and experience of the participants concerning aspects of guideline use, including:

- what guideline-use activities people wished to monitor
- views or concerns that NHS professionals might have about the use, value and approaches in monitoring guideline usage

- views or concerns that the potential users might have about the usability of the identified information
- experience of routinely monitoring guideline use
- information and data requirements needed to support monitoring
- current practice regarding the use of clinical guidelines.

### **Analysis**

The interviews were analysed using explicit, structured methods of qualitative data analysis.<sup>59</sup> This method, called 'FRAMEWORK', uses a number of distinct but interconnected stages in a systematic process. The five key stages are: familiarisation; identifying a thematic framework; indexing; charting; mapping and interpretation. The familiarisation stage involves listening to the interview tapes, reading the transcripts and studying any observational notes. The main objective here is to obtain an overview of the body of material gathered, through immersion in the data. Following this preliminary review of the data, the analyst returns to these research notes and attempts to identify the key issues, concepts and themes present in the data. From this, a thematic framework is constructed within which the data can be examined and referenced. Once the thematic framework has been constructed, the data are reorganised according to the appropriate thematic reference. Finally, the analyst pulls together the key characteristics of the data, and begins the interpretation of the data set as a whole.

All of the interviews were tape-recorded and the interviewer kept a written record of key points. The tapes were subsequently transcribed. The interviewer then identified main themes and subthemes through reviewing the content of the tapes and the transcriptions. Once the first draft of themes had been completed, two other members of the research team independently reviewed the structure and content of the themes. The views of the three researchers were then drawn together in a number of meetings until a consensus was achieved on the main themes of the analysis.

### **Postal survey of user requirements**

Following the user-requirement interviews, the issues that were identified were explored further with a wider constituency of users, by means of a postal survey. The purposes of the survey were two-fold. First, to seek and to use information from a wider constituency of health professionals to develop further both the conceptual framework

and the principles of routine guideline-use monitoring. Secondly, to map out current progress among respondents in the field of guideline use, identifying both problems and successes with special reference to monitoring use and impact.

In order to construct the survey sample, a 10% purposive sample was first drawn of the Health Authorities in England, the sample numbering nine authorities in total. The selection criteria were that the sample would include a range of settings, in five NHS regions: Northern and Yorkshire, North West, West Midlands, Eastern and Trent. To preserve confidentiality, the Health Authorities are not named in the report.

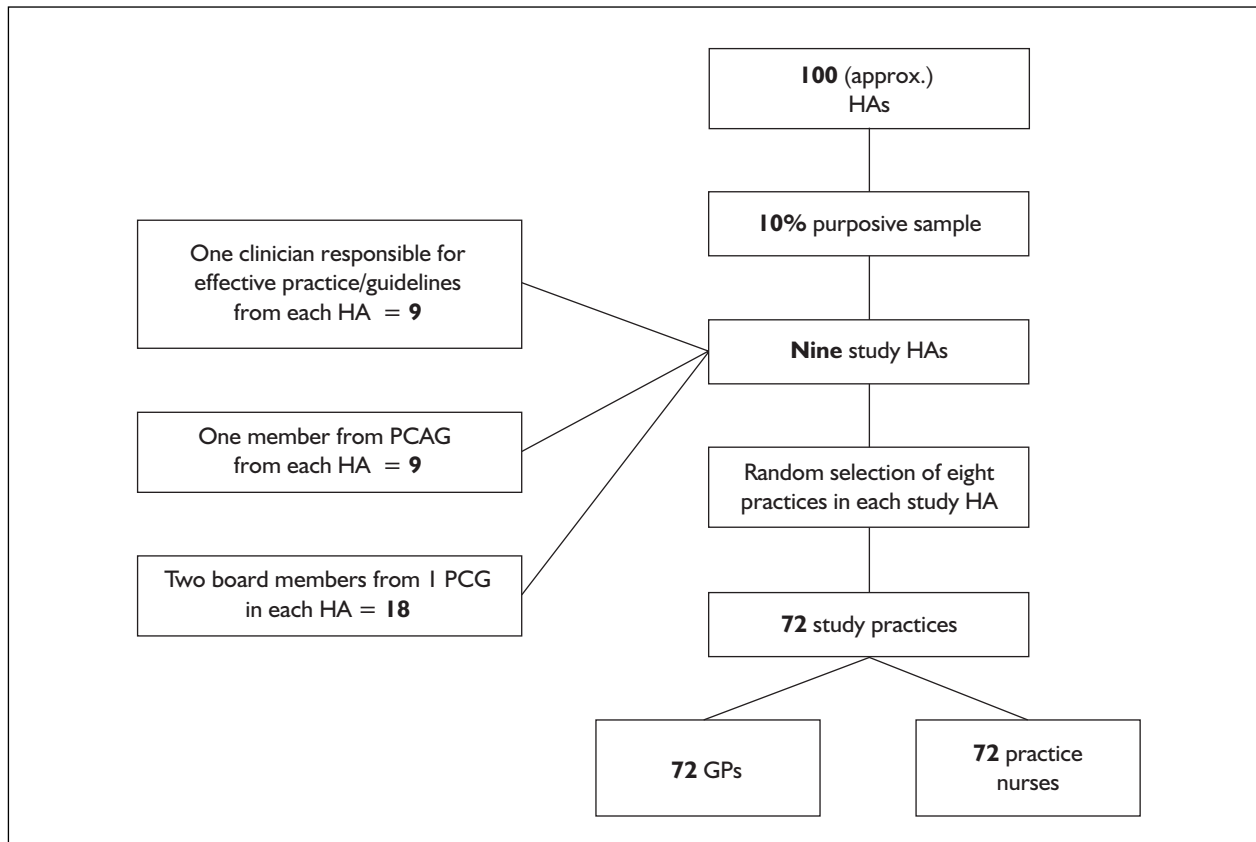
A decision was made not to include Health Authorities in Wales and Health Boards in Scotland, partly because of limited resources and partly because of the emerging different structures for primary care in those two countries.

### **Survey subjects**

The constituency for the survey comprised five professional groups: GPs, practice nurses, PCG leads, PCAG chairs and 'health commissioners' who were likely to be involved in guideline implementation, principally clinicians in Health Authorities. *Figure 7* sets out the approach to the recruitment framework of the sample for the survey. The proposed total number of cases for the survey was 180. This number was larger than the original proposal as a result of a subsequent decision to send a questionnaire to pairs of professionals in each of the 72 practices in an attempt to achieve a greater number of responses.

Once the nine Health Authorities had been selected, eight general practices were randomly selected from each area using Health Authority general practice lists. In each of the practices from each Health Authority, a doctor and a practice nurse were approached (the latter through writing to a doctor in the practice, for it was not possible to identify the name of a practice nurse independently). In addition, each Authority was asked to identify two PCG board members and a PCAG staff member, together with one member of staff involved with guideline development or use. The sample of 180 individuals comprised nine people from the Health Authorities, nine PCAG chairs, 18 PCG board members, 72 GPs and 72 practice nurses (*Figure 7*).

The purposive sampling of Health Authorities, rather than taking a random sample, was a change from the original proposal, aimed at conserving



**FIGURE 7** Survey recruitment

study resources. Existing knowledge and links were used to identify the Health Authorities from which the random samples of staff were selected.

#### **Issues covered in the survey**

These included:

- opinions of respondents on the purpose and value of monitoring clinical guideline use from three perspectives: performance/contract monitoring, process of care (guideline use) and outcome of care (patient care monitoring)
- current and predicted guideline activity in primary care and at the interface between primary and secondary care in the respondents' area/practice, to determine the scope and scale of guideline use and to determine who was taking what responsibilities, why and/or why not
- achievements and difficulties in guideline use and in any attempts at monitoring of guideline implementation, for example through Health Authority contracts with PCGs
- views on the structure and process of ideal and practical systems for guideline-use monitoring.

The survey instrument is available in Appendix 2.

#### **Analysis**

Survey data were analysed using standard methods<sup>60</sup> using the Statistical Package for Social Sciences (SPSS version 9). The results were then triangulated with the components of the conceptual framework (see 'Conceptual development of the framework', p. 17) and the user-requirement interviews (see 'Postal survey of user requirements', p. 18), to enable review and refinement of the framework. Following revision of the framework, it was tested in the second phase of the study.

#### **Testing the monitoring framework methods**

There were four components to this phase of the study. First, an interview study was conducted to explore practical aspects guideline-use monitoring at the three levels of interest to the study: general practice, PCG and Health Authorities. The interview schedules were developed from the information generated in Phase 1 of the study.

This was followed by a series of exploratory case studies:

- to test guideline-use monitoring methods using review criteria
- to test methods of collecting outcome data
- to investigate the potential costs of guideline-use monitoring.

These fieldwork components were undertaken in three locations in the NHS in England, centred on Health Authorities in two NHS regions: Trent and West Midlands. This geographical spread was a pragmatic choice based on access from the study centre and overall resources available to the project. Given the demands of the research on already busy NHS staff, the decision on location was also driven by the willingness of staff to become involved with the project. The settings were three Health Authorities and three associated PCGs.

### **Experience and practical aspects of monitoring: interview study**

Since the guideline-use monitoring framework is designed to be multilayered and to address the needs of users from different sectors, including managers and clinicians, and also to address different levels of sophistication (detail) and different reasons for monitoring, three groupings of NHS professionals were included in this component of the study:

- at the general practice level: GPs and practice nurses (19 individuals in total)
- at the PCG level: clinical governance leads and staff involved in clinical audit (six individuals)
- at the Health Authority level: clinicians and managers involved with primary care quality management (three individuals).

Initially, the options for this component of data collection included undertaking a second, more focused, survey. However, the recognition that response rates might be small, together with the expectation that interviews would give more richly textured information, determined the decision to undertake an interview study. A semistructured interview schedule was developed which drew upon the analysis of the semistructured interviews and the survey in the earlier phase of the study.

The interviews explored practical aspects of implementing guideline monitoring, and sought views on the perceived opportunities, benefits and barriers of monitoring. Information was sought on:

- who is (or might be) involved in guideline monitoring
- current practice of guideline use and guideline-use monitoring

- technology issues
- possible constraints and practical barriers for overcoming these.

Although the data were collected from three types of institution, the roles of the PCGs and the Health Authorities appeared so similar in the analysis of the earlier survey (see 'Postal survey of user requirements', p. 18) that the interview schedules were the same for these two types of institution. The interviews were recorded on paper and on tape by the interviewer. Information from the interviews was subsequently analysed by three members of the project research team into points and themes using the FRAMEWORK method (see 'User-requirement interviews', p. 17).

### **Testing monitoring methods using review criteria**

The aim of this case study was to test the feasibility of using evidence-based review criteria to monitor guideline use. GPs who had agreed to be interviewed (see previous subsection) were invited to take part in testing monitoring methods. Not all of the doctors who were interviewed were able to take part in these exploratory studies because of the perceived workload involved and the potential cost (see also 'A costs framework for guideline-use monitoring', Chapter 5), although direct costs of the work were met by the study.

Each doctor in each practice was asked to identify up to 30 adult patients with either asthma or stable angina, this number having previously been found to give a satisfactory process and outcome profile in other studies.<sup>29,34,35</sup> The choice of condition was left to the participating GPs. Participants were asked to collect information about the care given to each patient over a 12-month period on a paper-based data collection sheet, the data set being based on guideline-derived review criteria (see 'Guidelines and assessment instruments used in the study', p. 15) (Appendix 4). Each doctor was given a source document including the evidence-based guidelines so that the doctor could determine the basis for the review criteria. Review criteria data were not collected directly from the participating practices' computing systems because the systems varied and the data required for the review criteria were not always available in the computerised records.

In the analysis, comparisons are made of the extent to which the process data match the review criteria requirements (see 'How can review criteria and outcomes measures be used to monitor guideline use?' in Chapter 5 for further details).



### Monitoring guideline use using patient-centred outcome measures

For each patient for whom process data were gathered, the doctor was asked to offer a relevant outcome data collection form to the patient who, provided they felt able to give informed consent, was asked to complete the form anonymously and return it to the research team. Individual named patient data were not required since the exploratory studies examined the care of groups of patients in each participating practice. Outcome data were collected using previously validated measures: the Newcastle Asthma Outcomes Measure<sup>35,57</sup> and the UK version of the SAQ.<sup>34</sup> Further details of the methods are provided in Chapter 5.

### Costs of monitoring case study

The aim of this case study was to explore with a practice team whether the framework provided the basis for a tool that could be used by a practice or a PCG to assess the cost impact of guideline monitoring. In particular, the study was concerned with the costs of collecting information against review criteria from clinical records and health outcomes data from patients.

Exploration of the literature and discussions with professional bodies and researchers in the field provided little information on which to base a formal cost model. A review of literature from both the UK and the USA was undertaken (using the search terms listed in Appendix 6). This yielded only a few relevant papers, suggesting that, overall, limited work had been done, or was being done, in the analysis of costs incurred in clinical audit.

Once an initial cost framework had been developed from the literature and exploratory

discussions, it was sent to a number of experts for comment. This process was, first, to ensure that the framework was comprehensive and, second, to gain an informed opinion about whether the costs might be considered to be reasonably stable across a guideline-use monitoring programme or whether costs may fluctuate across differing stages.

Since real data on costs were not available, this objective was investigated through an in-depth qualitative analysis in a single large general practice, rather than through a formal cost audit approach.

Staff from one of the practices that had been involved in the process and outcome data collection (see 'How can review criteria and outcomes measures be used to monitor guideline use?' in Chapter 5) were then interviewed to explore their views on the costs involved in the data collection process, using the costs framework as a basis for the interviews. The objectives of the interviews were:

- to investigate the potential costs involved and barriers faced when monitoring guideline usage using review criteria in primary care
- to explore one practice's experience of using review criteria and obtain their views on how the process and consequent costs may differ with varying levels of experience and resources
- to explore the costs of accessing process data and the possible costs of linkage to outcomes data.

This information was then used to refine the guideline-use monitoring cost framework in Chapter 5.



## Chapter 3

# Conceptualising a guideline-use monitoring framework

### Introduction

The starting point for the development of this guideline-use framework was an existing model that the US AHCPR had developed in the context of using clinical guidelines to evaluate quality of care. This AHCPR model addressed a number of key issues relevant to this guideline monitoring project, although any resultant framework that was applicable, relevant and usable in a UK setting would clearly be different. Here, relevant issues, concepts and definitions are considered as the first stage of framework development.

Clinical guidelines, although an important tool in quality improvement, cannot by themselves be assumed to deliver improved quality of care. Clinical guidelines have been defined as:<sup>17</sup>

“systematically developed statements to assist practitioners’ and patients’ decisions about health care to be provided for specific clinical circumstances.”

Although guidelines *per se* cannot be used for evaluation, they can be used to derive both medical review criteria and performance measures, which can be considered as core elements in any guideline-use monitoring framework. Medical review criteria have been defined as:<sup>17</sup>

“systematically developed statements that can be used to assess specific health care decisions, services, and outcomes.”

It has also been argued that medical review criteria can be used “to determine how the process of care relates to guidelines”.<sup>17</sup> The differences between guidelines and review criteria are highlighted in *Box 5*.

However, even more than review criteria, the definition of performance measures given in the AHCPR model appeared to provide the type of approach that is at the centre of the framework required in this project. These performance measures have been defined as:<sup>17</sup>

“methods or instruments to estimate or monitor the extent to which the actions of a health care practitioner or provider conform to the clinical practice guideline.”

The technical relationship between clinical guidelines and medical review criteria and performance measures was outlined by AHCPR,<sup>17</sup> using the example of postoperative pain control (*Box 6*).

In exploring the elements or building blocks to be incorporated into a framework for monitoring the use of guidelines, it became clear that the different contexts between the UK and the USA would have an impact at the level of both definitions and operating features in a UK context. In particular, the definite distinction and separation of review criteria and performance measures may not be so clear in the NHS. For example, as the literature review has already indicated, review criteria being developed for the NHS may be considered an amalgam of the US definitions of medical review criteria and performance measures. This reflects the manner in which clinical audit has developed in the NHS. It also takes into account the professional sensitivities associated with the terms ‘performance measurement’ and ‘monitoring’, both of which tend to have negative connotations and to meet considerable professional resistance among NHS clinicians.

#### **BOX 5** Differences between guidelines and medical review criteria

	<b>Clinical practice guidelines</b>	<b>Medical review criteria</b>
<b>Purpose</b>	Guide care to be given	Evaluate decisions already made
<b>Data</b>	Data obtained as required	Use data documenting care given
<b>Care sequence covered</b>	Cover all pathways	Cover main pathways
<b>Role of clinical judgements</b>	Complement clinical judgement	Allow for clinical judgement

**BOX 6** Example of a clinical practice guideline-derived evaluation tool for determining quality of care for postoperative pain control

<b>Clinical practice guideline</b>	Pain should be assessed and documented at regular intervals postoperatively, as determined by the operation and the severity of pain (e.g. every 2 h while awake for 24 h after surgery)
<b>Medical review criterion</b>	For the patient recovering from surgery, pain was assessed and documented every 2 h while awake for the first 24 h following surgery
<b>Performance measure</b>	Calculate the following for consecutive surgical patients seen over a 6-month period: the number of patients whose pain was assessed and documented every 2 hours while awake  The performance measure is: $\frac{\text{No. of cases with criterion met}}{\text{No. of surgery cases}} \times 100\%$
<b>Standard of quality</b>	A performance rate of $\leq 95\%$ triggers a review to determine how to improve the assessment and documentation of the patient's pain status every 2 h while awake for the first 24 h postoperatively

**BOX 7** Stages in development and implementation: guideline-derived evaluation instruments

<b>Stage</b>	<ol style="list-style-type: none"> <li>1. Clarify the purpose of the performance measure</li> <li>2. Identify a relevant clinical practice guideline</li> <li>3. Identify populations covered by the guideline</li> <li>4. Identify guideline recommendations and draft medical review criteria</li> <li>5. Identify clinicians and sites of care</li> <li>6. Define case samples and case sampling period</li> <li>7. Identify data source</li> <li>8. Write medical review criteria, specifying acceptable alternatives and time window</li> <li>9. Specify data items and data rules</li> </ol>	} Purpose and development of measurement tools
	<ol style="list-style-type: none"> <li>10. Draft data collection forms and procedures</li> <li>11. Devise analysis procedures</li> <li>12. Pilot test and revise criteria, forms and procedures</li> </ol>	
	<ol style="list-style-type: none"> <li>13. Conduct review and assign criteria status</li> <li>14. Report review findings</li> <li>15. Interpret findings, apply standards of quality</li> <li>16. Investigate review findings</li> <li>17. Act on review findings</li> <li>18. Conduct review again to re-evaluate performance</li> </ol>	} Stages beyond the remit of the guideline-use monitoring project

In producing this amalgam of definitions, NHS review criteria resemble a performance measure more closely than do AHCPR medical review criteria. For example, a typical NHS review criterion might be: 'the percentage of patients whose pain was assessed and documented every 2 hours while awake'.

This is an amalgamation of the AHCPR medical review criterion and the accompanying performance measure illustrated in *Box 6*.

## Translating the AHCPR framework into an NHS context

In interpreting the work from the AHCPR, consideration was given at all stages to the context of NHS policies, structures and working practices.

The 18 individual stages outlined by AHCPR<sup>16</sup> in their methodology for assessment tools is set out in *Box 7*. These stages are used as a basis for considering the elements comprising a guideline-use monitoring framework.

## **Purpose and development of measurement tools**

### **Stage 1: Clarify the purpose of the performance measure**

Clarification of purpose is obviously a crucial component of any monitoring process. Yet, in the guideline-use monitoring project as with many others, it was not always possible to keep this stage as 'pure' as may be methodologically desirable. Ideally, each use of a performance measure would be considered and made explicit for each monitoring occasion. In reality, this is not feasible, not least because different people (stakeholders) will have different reasons for using the measure. Moreover, it would not be easy to accommodate a stakeholder-specific process measure for each reason and decision. Thus, a framework should be able to accommodate multiple users and their attendant multiple reasons for use. A flexible framework that allows different users to use the same data for different purposes is difficult to develop, and the integrity difficult to attain. In part this is because, according to the AHCPR report authors,<sup>17</sup>

“it should not be assumed that a guideline will yield a single unique set of medical review criteria that will meet the needs of all users who have the common purpose of improving quality.”

Since the monitoring framework may have to accommodate multiple users and have to be used at multiple levels to meet all needs, one set of performance measures may not be enough. The framework development difficulties associated with these multiple-user and multiple-use issues will be revisited in the discussion of several later stages.

### **Stage 2: Identify a relevant clinical practice guideline**

In some ways it could be argued that this stage is becoming increasingly redundant in the NHS. With the advent of NICE in England and Wales,<sup>3</sup> a clinical guideline developed by NICE is expected to be the NHS guideline chosen for that condition. Thus, only if a NICE guideline does not exist will this stage be required. In addition, the emphasis on centrally derived priorities for the NHS will increasingly be reflected in the areas in which NICE has developed guidelines, so the need for choice will be diminished. The requirement of any framework to address in detail the criteria for choosing guidelines therefore becomes redundant.

### **Stage 3: Identify populations covered by the guideline**

NHS policy on guideline development is also pertinent here, with a push for most relevant populations to be covered by NICE or other national guidelines. Although local considerations on populations will come into play, they need to be addressed at that local level. The key issue for the framework is that it identifies the need for this stage to take place at the local level in any guideline-use monitoring project, rather than it giving details about how it is addressed locally.

### **Stage 4: Identify guideline recommendations and draft medical review criteria**

Since NICE guidelines will be accompanied by audit tools that include review criteria, it might be anticipated that this stage of the use-monitoring framework should increasingly be redundant in terms of giving detailed information about criteria development. However, it is already clear that one set of criteria per guideline is unlikely to satisfy all potential users. Furthermore, even if a common purpose were agreed, different stakeholders might think that different criteria and measures reflect the information needed for the common purpose. For example, service users on the one hand and clinicians on the other might think different items should be considered in the assessment of delivery and outcomes of care. If only a limited set of recommendations (and hence review criteria) are to be used, for example because of resource issues, then the difficulties of identification of appropriate measures may be increased.

### **Stage 5: Identify clinicians and sites of care**

This stage should allow some of the earlier concerns to be addressed. Applicability to clinicians and site involved will allow a refinement of the criteria to be selected.

### **Stage 6: Define case samples and case sampling period**

Stages 5 and 6 are the practical steps needed for local adaptation and implementation of guideline-use monitoring. AHCPR<sup>16</sup> also recognised the importance of limiting what was considered:

“Although a practice guideline is written broadly to include many manifestations of a condition, measuring conformance to a guideline must be narrowly focused in order to reduce error and thus enhance the validity of measurement.”

Thus, in the guideline-use monitoring framework a small number of criteria will be used, possibly as a subset of all the possible criteria, balancing the requirements of multiple stakeholders, purposes and uses.

### **Stage 7: Identify data source**

One of the key requirements for the framework must be that the data required to evaluate criteria conformance should easily be obtained.<sup>16</sup> In the NHS, many, but by no means all, general practices are computerised. However, many different systems are used and different systems sometimes mean that data acquisition and sharing are problematic. This can be an issue, for example, when attempting to share data between general practice and PCTs. The ability of many of the systems to extract data items automatically is also limited. Indeed, under some current circumstances a more feasible framework may be one that takes a paper-based data collection as its starting point. So, although a flexible framework is required,<sup>17</sup>

“Different users will have or seek access to different types of data, depending on the specific purpose for the evaluation tool. It may also not yet be realistic to make specific data capture systems a prerequisite of the framework.”

In general practice, the source of many data will be patient records; computerised or otherwise. The ability to aggregate these data is also a desirable aspect of any framework, especially in populating review criteria or performance. However, some information for a performance measure, such as outcome of care, may have to be provided directly by the patient.

### **Stage 8: Write medical review criteria, specifying acceptable alternatives and time window**

Since national bodies in the NHS are now developing review criteria, the scope for writing local criteria is increasingly limited. Nevertheless, the realities of data collection and local requirements such as local Health Improvement Plans means that any framework needs to be able to allow flexibility both in data items collected and in the periods of data capture.

### **Stage 9: Specify data items and data rules**

Approaches already established in the NHS,<sup>30,31</sup> by combining review criteria and performance measures in one, could be considered as having started this process, meeting the AHCPR requirements for data item inclusion. That is, the

data fulfil at least one of the following requirements; they:

- help to assess the criterion
- help to follow decision rules for evaluating criteria compliance
- define exclusions or acceptable alternatives
- identify gaps in knowledge referring to the clinical practice guideline.

In essence, data items should earn their place to avoid the pitfall of collecting data for collection's sake. While this is more difficult in a framework that may aim to be of use to different people for different purposes, it becomes more important to avoid a large number of data items, because of the impact that this may have on the ability and willingness to gather data. It is important to ensure that the minimum data set is specified, rather than (almost) a maximum data set.

## **Data collection and analysis**

### **Stage 10: Draft data collection forms and procedures**

### **Stage 11: Devise analysis procedures**

### **Stage 12: Pilot test and revise criteria, forms and procedures**

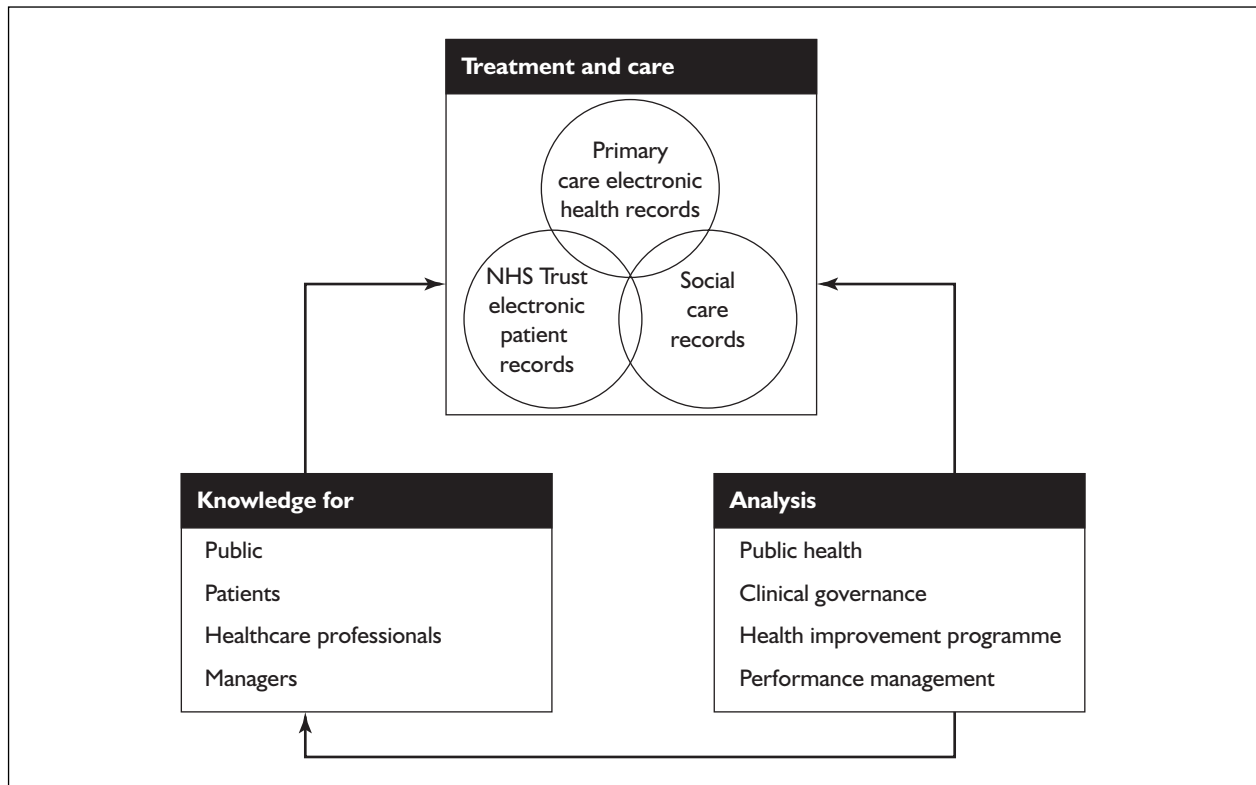
These three stages outlined by AHCPR are practically important but need to be derived at project level rather than at general-principle level. Some of the practicalities are addressed in the feasibility studies described in Chapter 5.

## **Principles for a guideline-use monitoring framework in primary care**

The need for a guideline-use monitoring framework sits very easily and centrally in the notion of information needed for clinical practice, as argued in the NHS Information for Health strategy.<sup>2</sup> This sets out the principles of information systems and approaches, specifying that healthcare professionals need information:

- to support the evaluation of the care they give
- to underpin clinical governance, planning and research
- to help with continuing professional development.

Any guideline-use monitoring framework therefore would ideally supply some of that information. It would also incorporate, as far as



**FIGURE 8** NHS information strategy: local implementation

possible, issues identified by the NHS Information Strategy<sup>2</sup> as being important. For example:

- it should be person based
- systems will be integrated
- management information will be derived from operational systems
- information will be shared across the NHS.

The potential multiple users and uses of information are outlined in a diagram from the NHS strategy document (*Figure 8*).

### **A guideline-use monitoring framework**

By a process of working through the various stages of the AHCPR model and incorporating requirements for a UK context, several general and specific issues emerged. The framework should:

- allow multiple users for different purposes
- have the smallest possible number of data items

- use a combined review criteria/performance measure approach
- allow professional quality improvement agendas and managerial requirements to be met
- principally be condition specific, but could be aggregated with other similar datasets
- allow data at practice level to be useful, but also allow aggregation
- allow the use of both process data and outcomes data, including patient-reported outcomes; that is, making use of data that can actually be collected.

In the next stage of the project these assumptions were reaffirmed through interviews that investigated the experiences and expressed requirements of concerned individuals (Chapter 4). Further verification was sought through a survey of health professionals (Chapter 4). Results of subsequent testing methods are reported in Chapter 5.





## Chapter 4

# Initial development of a framework for monitoring guideline use in primary care

### Introduction

Two sets of findings are presented in this chapter. First, results are reported from interviews with 11 healthcare professionals, where the issues and concepts relating to a guideline-use monitoring framework were explored. These are presented in a manner that reflects the AHCPR-based<sup>16,17,20</sup> framework conceptualisation process discussed in Chapter 3, and similar section headings are used. The implications for framework development are also discussed. Secondly, the results of a survey of health professionals are presented, in which further elucidation of the interview findings is sought.

Finally, the findings of the two studies are brought together in a short overview.

### Developing the framework through semistructured interviews

#### Clarify the purpose of the (performance) measure

It was clear that this stage was problematic to almost all of those interviewed, and various concerns and issues were raised. There was concern over the term 'monitoring', which was used in the project proposal (and hence in the interviews). In many instances the term was perceived in a negative manner, in terms of policing by external bodies, and as a way of identifying and then 'weeding out' bad practice. The term also suggested compulsion, according to one interviewee. While there was overall support for the principle of trying to improve standards and clinical practice through a quality cycle, the use of terms such as monitoring tended to have more negative connotations, rather than conveying that it was about quality improvement.

The terms associated with quality improvement found more favour. Views were expressed that suggested keeping an eye on things, checking what was done and ensuring that things do not go wrong were worthwhile activities that could have a

role in service improvement at individual and other levels.

There was also a concern that any framework had to be clear and explicit about its function, otherwise barriers to acceptance and use of any framework could be reinforced. For example, one respondent was not clear about why monitoring of guidelines would be undertaken. Thus, the implication is that any framework should be accompanied by a rationale for using it, to as specific a level as required for potential users.

#### Identify a relevant clinical practice guideline

At the time the project fieldwork was undertaken there were few national evidence-based guidelines in England and Wales so there existed a need to identify relevant guidelines and then to evaluate usage and conformance. Interviewees did not see as straightforward the process of selecting guidelines that could be used in conjunction with any monitoring framework. For instance, the nature of guidelines themselves was discussed by several of the respondents. There was a feeling that while evidence-based guidelines may be preferable as an ideal to consensus guidelines, the nature and amount of evidence, particularly for primary care, were often problematic and scarce. These issues obviously affect the reliance people feel able to place on evidence-based guidelines. There were also concerns raised over the guideline development processes themselves, both in the nature of the evidence base and in the consultation processes employed. Other areas of concern included how up to date the guidelines were and how relevant they were for everyday clinical practice (again related in part to the nature of the evidence base).

In terms of framework development any reservations about guidelines in general (and also the particular guidelines used with any framework) are potentially problematic. Reservations about development processes, from evidence base through to making them accessible and easy to use, have an impact on any framework that must try to accommodate a range of guidelines.

## Develop the mechanisms for guideline-use monitoring

Many of the next stages identified in the AHCPR<sup>16,17</sup> model can be considered as stages in the development of measurement tools in the process of monitoring guideline use. These stages, outlined in *Box 8*, are familiar to anyone undertaking clinical audit.

There were very few issues raised in the interviews that could be viewed as particularly pertinent to these stages, except for the vexing issue of computerisation and computing systems. One individual thought that only computerised systems could be used for data collection in any framework, and that this would involve data collected during the consultation. However, while the attraction of this is obvious, it is perhaps also currently unrealistic given the apparent level and nature of computer usage in many areas of UK primary care. Frameworks developed should also be able to accommodate other means of data collection to reflect the variation in current practice, whether or not the variation is desirable.

There are other practical reasons why any model should have multiple approaches to data collection, including the diversity of computing systems in use and the very real difficulty of non-compatibility of systems. This diversity was an issue for many of those interviewed, in terms of both systems and the degree of competency and use of systems. The quality of systems and the familiarity and competence of those using them were said to be poor by a few interviewees. To design a framework based only around computerised data collection may not therefore seem the best thing to do, despite its attractions.

Although the final phase of the AHCPR<sup>16</sup> model was beyond the scope of this project (*Box 9*), many of the issues raised during interviews were primarily to do with these topics.

### Protected time for clinicians

An important issue raised was that of finding protected time for clinicians, which many of those interviewed linked to the need to see a culture change in respect of both clinical guidelines and quality improvement activities as a whole. In part, this was a response to the idea that increasing amounts of activity were required because of policy, structural and system changes that resulted in clinical governance, health improvement plans and other initiatives. These, in addition to the changing requirements for healthcare professionals in the realm of continuing professional development

### BOX 8 Steps in the development of measurement tools

1. Identify populations covered by the guidelines
2. Identify guideline recommendations and draft the medical review criteria
3. Identify clinicians and sites of care
4. Define case samples and case sampling period
5. Identify data source
6. Write medical review criteria, specifying acceptable alternatives and time window
7. Specify data items and data rules
8. Draft data collection forms and procedures
9. Devise analysis procedures
10. Pilot test and revise criteria, forms and procedures

### BOX 9 Implementation of performance review

1. Conduct review and assign criteria status
2. Report review findings
3. Interpret findings, apply standards of quality
4. Investigate review findings
5. Act on review findings
6. Conduct review again to re-evaluate performance

(including revalidation), required more and more resources to fulfil requirements. While these issues apply to the implementation phases, they are in many ways the key issues in considering how any framework would be accepted and used.

## Implement a framework for guideline-use monitoring

One of the key issues raised was that of relevance: any undertaking that used resources had to be seen as relevant. There was a strong feeling that the reason for collecting data had to have resonance with clinicians and their daily practice. This idea of relevance, as well as having validity in its own right, is important because of its relationship to other important issues, for example the issues of ownership and participation in the work required. Several interviewees argued that it was important for all members of practices, especially the clinical teams, to be signed up to the tasks in hand. This was also the case at the more pragmatic end of the spectrum, such as staff involvement to help to ensure that activities such as audit (monitoring) could be carried out. This, it was suggested, was easier to achieve if agreement about purpose and worth was achieved among team members. 'Signing up' would appear to be enhanced if relevance to all of those involved could also be demonstrated. While leadership and allocation of responsibilities were other facilitating factors, relevance was again seen as improving the likelihood of success, although it was by no means guaranteed.

The requirements of protected time and cultural changes were also mentioned by several respondents, both in terms of specific requirements for monitoring activities and in the wider continuing professional development sense.

### **Frameworks for guideline monitoring**

The interviews also attempted to seek views about what ideal frameworks for guideline monitoring may look like. For many interviewees there were no definitive ideas or opinions about what may constitute an ideal framework. The 'traditional audit cycle' was thought by one respondent to represent the ideal. There were differing views about the data that should be collected: some respondents thought data should be collected prospectively, while others thought that retrospective data collection was more feasible. Thus, even when discussing ideal frameworks, feasibility was a crucial element. This issue also came through when some of the interviewees stated that "you had to monitor that which could be monitored". These considerations no doubt contribute to the thoughts of some respondents that process information (rather than outcomes) was more likely to be collected, and that a sample of patients rather than all patients would provide the data collected.

One respondent raised an important concern related to the sensitivity and flexibility of any framework, arguing that any framework needed the ability to evolve, to keep up with changes in the guidelines used as well as the nature of the data concerned. Respondents returned to the factors of relevance, interest and (ownership) participation while discussing ideal frameworks, highlighting again the importance associated with the people and personnel elements of both designing and using any monitoring frameworks. These issues relating to the human involvement in frameworks were also evident in discussions around the introduction and implementation of any framework, at least in part owing to the workload issues associated with this type of work. Some of the concerns expressed were related to the quantity of information (e.g. the number of data items) that individuals or practices might be required to provide.

### **Practicalities of guideline-use monitoring**

There was a view that any monitoring framework should perhaps be introduced in a stepwise manner, building in terms of both capacity and complexity as it went. The elements of relevance and 'doability' came into this. In particular, the number of data items was one aspect that might

require a stepwise approach to increasing the number of parameters. Also raised were ideas about the suitability of different professions to undertake these functions. This was concerned with efficient and accurate identification and collection of data. Several respondents posited the idea that nurses may be suited to this type of activity. Nurses, they suggested, were often more familiar with note sets than were administrative staff. The changing nursing role, especially in chronic disease management, was also discussed as an issue to consider when looking at quality improvement including audit, monitoring and use of frameworks.

The nature of guidelines themselves was a topic addressed by the interviews, as was the role of guidelines in assisting the delivery of care and in improving the quality of care. While the view about increasing acceptability and use through a local adaptation process was repeated, the view that many guidelines are in effect ignored was also a clear message. The idea was also suggested that guideline use could create more work for practices on top of all the other current requirements, which has considerable implications for uptake and monitoring of guidelines.

### **Overview of the interview findings**

In many ways the issues raised in the interviews were those that might be expected in relation to developing frameworks for monitoring guideline use. The specific concerns expressed included the role of guidelines in primary care, the workload issues associated with new and ever-increasing changes such as clinical governance, and the role of monitoring. The more general concerns voiced were those often associated with change management issues such as ownership, relevance, purpose and 'people issues'. Most of these issues could have been predicted from the discussion of models such as that of the AHCPR.<sup>16,17</sup>

One of the important considerations raised by the interviews was the need for any framework to be flexible, to accommodate change and growth. This area was not especially well covered in previous thinking. By its very nature it would therefore require a more sophisticated framework.

Respondents in this study are likely to be at the enthusiastic, advanced end of the spectrum of professional users of a guideline monitoring framework. This is an important indicator as it allows an estimation to be made about whether the majority of those in primary care are as 'sophisticated' or not, and the implications for

how likely it is to be able to deliver a framework that people would recognise, understand and use. Any framework seems likely to require a substantial amount of work and professional development before it could be routinely used in primary care. Any framework that did not have substantial elements of the familiar, such as the audit cycle, would have an uphill struggle for ready and rapid acceptance or use.

In terms of the use-monitoring framework, it may be helpful to manage concerns about guidelines by using guideline-based review criteria (performance measures) that have first been field-tested in primary care. There are difficulties in this. Given the complex nature of primary care in terms of both the disease or condition and the personnel involved, the guidelines that may be considered useful may reflect these patterns and thus themselves be wide ranging and complex. This degree of complexity is not easily handled by review criteria, which have to be quite narrow and straightforward in manner to allow data collection. Appropriate review criteria/performance measure construction should allow two AHCPR model stages to be covered:

- Stage 3: Identify populations covered by the guidelines.
- Stage 4: Identify guideline recommendations and draft the medical review criteria.

These stages can be seen as part of processes that allow issues of relevance and prioritisation to be addressed. Although local populations and priorities will impact on the number and nature of resulting review criteria, it should be possible to use the framework to identify and accommodate what is important and to exclude the unimportant or irrelevant.

The issues raised by the initial 11 interviews were then used as a basis for the survey questionnaire to see whether a wider constituency shared these concerns. The results are reported below.

## Exploring the framework content through a survey of health professionals

The purpose of this stage of the research was two-fold. The first aim was to develop further the conceptual framework and the principles of routine data monitoring with a wider constituency of primary care health professionals and with staff from Health Authorities. The second was to map

out current progress among respondents in the field of guideline use, identifying both problems and successes with special reference to monitoring use and impact.

The constituency for the survey comprised five groups: GPs, practice nurses, PCG leads, PCAG facilitators and Health Authority staff who were involved in guideline implementation, principally clinicians.

The content of the survey was guided by the analysis of the semistructured interviews (see previous section). The main themes for the survey included:

- opinions of respondents on the purpose and value of monitoring clinical guideline use from the three perspectives: contract monitoring, process of care (clinical audit) and outcome of care (patient care monitoring)
- current and predicted guideline activity in primary care and at the interface between primary and secondary care in the respondents' area/practice, to determine the scope and scale of guideline use as well as who is taking what responsibilities, why and/or why not
- achievements and difficulties in any attempts at monitoring of guideline implementation.

(See Appendix 2 for the full questionnaire.)

### Response rates

Of the 180 questionnaires that were sent out, 48 responses were received, giving an overall response rate of 27%. Twenty-eight of the respondents were clinicians from a variety of medical and nursing specialities. Two of the nine Health Authority areas provided almost half (46%) of the responses, responses ranging in number from one to 11 per area. Overall, this was a rather disappointing result in terms of response rate, although not in the richness of the data that the 48 responses provided. A number of factors may have accounted for this. For example, the number of questionnaires being received by primary care and Health Authority staff is considerable and it is likely that response rates for most studies in primary care are not achieving high response rates as a result of 'questionnaire fatigue'. Furthermore, it was clear from the original interviews reported in the previous section that many staff had given little thought to guideline-use monitoring. The content of the survey may have therefore held little of apparent interest to recipients. The roles of the respondents to the survey are given in *Table 1*.

**TABLE 1** Roles of respondents

GP	13
Practice nurse	15
PCAG chair (also GPs)	5
PCG lead (also GPs)	9
Health Authority effective healthcare lead	6
Total number of respondents	48

### Collection of data used for quality improvement: role of practice staff

Twenty-eight general practice staff responded to this set of questions. Clinical data were mainly reported as being collected by the clinical members of the practice team (GP, practice nurse and health visitor), although half of the practices responded that administrative staff also undertook some level of collection of clinical data.

Audit data were also mainly collected by clinical staff, although this less commonly included the health visitor. Again, these data were sometimes collected by administrative staff. Prescribing data were usually collected by the GP.

Unsurprisingly, collection of administrative data was usually carried out by staff with administrative roles, while some clinicians indicated that they also contributed.

Although 40 of the 48 respondents indicated that clinical and audit data were mainly collected using computerised methods, 19 respondents said that some of the audit data was collected using paper-based methods.

### What type of quality improvement information is collected?

Respondents were asked about their current experience of capturing three types of data relevant to quality improvement and (by implication) monitoring of guideline use. The three information types were: process of care data, outcome of care data and referral data. Because

this section of the study was concerned with the development of a conceptual framework, respondents were asked to answer these questions from an ideal viewpoint if they were not currently collecting data personally. Most of the 38 respondents who were in general practice, in at least one of their roles, answered that process of care data were collected in the consultation (as might be expected), with fewer (29) reporting that some form of care outcome data was collected during the consultation.

The respondents were asked what influenced the selection process for the data items collected within these three different types of information; that is, personal interest, practice policy, local policies or national priorities. There was a fairly uniform response (*Table 2*), except for the suggestion that referral data might be collected for personal professional interest.

### What impact does the information have?

Respondents were asked what impacts these data collection activities had on the practice teams in terms of changes to the respondent's own practice, stimulation of discussion within the general practice team and changes made to practice protocols. Of the 48 respondents, a minority used referral data to make changes to clinical practice (*Table 3*).

Respondents considered that the NHS changes at the time of the survey (particularly the introduction of PCTs, establishment of NICE and the Commission for Health Improvement) were likely to impact on general practice data collection by:

- leading to an increase in overall data to be collected and an increase in different types of data
- leading to an increase in the types of people becoming involved in data capture and in different systems being used.

**TABLE 2** Factors influencing type of information collected

	Process data	Outcome data	Referral data
Personal interest	26	27	18
Practice policy	33	32	27
Local priorities	31	32	31
National priorities	28	32	26
<i>n</i> = 38.			

**TABLE 3** Impact of information

	Process of care data	Outcome data	Referral data
Changes made to own personal practice	40	38	26
Discussion within practice team	41	40	32
Changes made to practice protocols	38	36	26
<i>n</i> = 48.			

Over half of the respondents had concerns about the uncertain benefits to practice of these increases in activity, and more than one-quarter had concerns about both the financial implications and whether the information systems would be able to handle the increased demands. More than half (26) were concerned about the increased time pressures that these changes in information capture would bring.

### Using clinical guidelines

In relation to the use of clinical practice guidelines in their work, most respondents were using a range of types of guidelines:

- guidelines and protocols developed in the practice (37 respondents)
- local adaptations of national guidelines (35)
- national guidelines (29); this figure may be lower because there were fewer national guidelines to access.

Over half of the respondents identified local and national policies as a basis for selecting guidelines, as well as having a practice policy for selection. Most of the respondents (36) identified the GP and the practice nurse(s) as being the clinicians most likely to be active in selection. However, health visitors were also said to be involved in less than half of the cases and administrative staff were also said to play a part.

There was a very positive response from those who replied to the questionnaire in relation to the value of guidelines. Almost all agreed that guidelines might benefit patient care, aid teamwork and decision-making, that they were a good basis for clinical audit and that a potential benefit was a reduction in inappropriate variation in clinical care. Rather fewer saw guidelines as useful summaries of evidence and as producing cost-effective benefits for care, and only one respondent saw no benefits from guidelines.

Respondents also had a number of concerns about guidelines. More than half of the respondents (26)

thought there were too many and they were not applicable to individuals (30), and a substantial minority had concerns that guidelines were:

- not updated often enough
- too prescriptive
- not accessible
- too long.

Other concerns were that some guidelines were not applicable to primary care and were not relevant to everyday practice.

When asked how guidelines were adapted and used in practices, respondents specified a range of approaches, including:

- developing a practice protocol based on the guideline recommendations (34)
- developing an audit protocol and developing disease-specific reminders (29)
- using the guidelines as a clinical support tool (41)
- using disease-specific reminders (17).

### Facilitating quality improvement

Respondents were asked about a range of issues (derived from the semistructured interviews; see previous section) concerned with the facilitation of quality improvement through the monitoring of routinely collected guideline data. Perceptions of the issues from both PCG and practice level were sought. In order to avoid leading questions, participants were asked whether they agreed with a number of statements about guideline monitoring (*Box 10*). The results are reported at three levels: practice, PCG and Health Authority, and by type of respondent.

### Views on monitoring at a practice level

The statements in *Box 10* were only rated by the 28 clinicians in the sample who answered specifically about their role. Monitoring guideline use at a practice level was received positively by both GPs and practice nurses. For example, all 28 respondents agreed that practice monitoring

**BOX 10** Benefits and costs of monitoring guideline use

## Monitoring guideline use could ...

- inform your own practice about care provided
- improve patient care
- be seen as having no benefit to practice
- create too much work
- improve consistency of care across the practice team
- help practice meet the demands of clinical governance
- be seen as a policy exercise
- improve performance across the practice team
- be seen as a 'stick to beat' practice and PCGs
- be viewed as low priority
- create uncertainty over who should have access to the results

would improve consistency of care. Almost all agreed that clinical governance would be supported by the process of monitoring and that performance across teams would be enhanced.

There was little disagreement between the GPs and the practice nurses in their responses to any of the questions. Monitoring was not perceived by the clinicians as something that might be used to performance-manage the practice, and only about half considered monitoring as a function that would create too much work. One-third of the practice nurses felt there was some uncertainty over who would have access to the results, while less than one-fifth of GPs had such concerns.

**Views on monitoring at a PCG level**

Overall, monitoring at a PCG level was assessed positively by all five groups of respondents (GPs, practice nurses, PCG chairs, PCAG chairs and Health Authority clinicians). However, when asked whether monitoring at this level was perceived as having no value to practice, the PCG members and the Health Authority members of the sample showed low to moderate levels of agreement, compared with negligible levels of agreement from the other three groups. That is, the two clinical groups felt strongly that there would be a value in monitoring guideline use at the PCG level, while some of those with a management role felt less certain.

Questions relating to whether monitoring results were perceived as a 'stick to beat' the PCG received only low to moderate levels of agreement from all five groups, particularly practice nurses, only one of whom agreed. This may be surprising given the strong reactions to monitoring that came out of the interviews in relation to monitoring at the practice level (see previous section).

There was some concern among about half of the nurses and GPs that the PCG might use the guideline monitoring information to examine care provided by the practice. Only the practice nurses expressed concerns about whether PCG monitoring might benefit patient care, with about half disagreeing with the proposal. Even the extra workload at the PCG was not seen as a barrier by most of the respondents. About half of the practice clinical staff thought that PCG monitoring might increase consistency of care, while most of the people with other roles thought it would. Similar levels of response were obtained in relation to the perceived benefit of PCGs using guideline monitoring data to meet the demands of clinical governance.

There was some acceptance that PCG guideline monitoring was merely a policy exercise, particularly from PCAG chairs, although less than half of the GPs and practice nurses thought so. Those with clinical management roles felt that there was an opportunity for PCG guideline-use monitoring to improve performance across the team, although the GPs and practice nurses took a different view, showing only low to moderate levels of agreement with the statement. While some respondents felt that PCG level monitoring might create uncertainty over access to results, they comprised less than half of respondents in each of the five groups.

**Views on monitoring at the Health Authority level**

These statements about the Health Authority were only rated by those in the sample with a clinician-management role. All felt that guideline-use monitoring was of benefit to practice and it was not viewed as a 'stick to beat the practices' or as a low priority. There was, however, a range of opinion regarding whether guideline-use monitoring helped to meet the demands of clinical governance, whether it improved patient care and consistency of care, whether it was seen as a policy exercise and who should have access to the results. Surprisingly, given the response to monitoring in the interviews, the response of the five PCAG chairs in the majority of cases was more positive than that of the PCG members or the Health Authority members of the sample. However, the responses were more positive in all those areas in which PCAG chairs might be expected to take a particular interest, such as reducing practice variation, improving patient care and informing practices about the care provided through guideline-use monitoring.

**TABLE 4** Design principles for a monitoring system

Salient features	Sum of scores	No. of valid responses	Mean score
Explicit aims	123	33	3.73
Small number of items	100	32	3.12
Specific to primary care	101	33	3.06
Set developed by users	88	33	2.67
Flexible system	82	32	2.56

5: most important; 1: least important.

**TABLE 5** Data collection principles for a monitoring system

Salient features	Sum of scores	No. of valid responses	Mean score
Time efficient	89	40	2.22
Rely on good records	77	40	1.92
No duplicate entry	44	23	1.91
Unobtrusive	31	18	1.72

3: most important; 1: least important.

### Design requirements for a guideline-use monitoring system

Two questions were asked of respondents in respect of the design criteria for a guideline-use monitoring system. In the first question, respondents were asked to rank five items in order of priority, giving each a score of 1–5, seeking to identify the priorities for the system design features. The five items are ranked by mean score. The need to have explicit aims for the system ranked highest (*Table 4*). Respondents were then asked to rank three priorities for the data collection system. Here, the ranked mean scores showed less divergence (*Table 5*).

Respondents were asked to what extent they had concerns over confidentiality of data collection from the perspective of guideline-use monitoring, despite the presence of Caldicott (data protection) guardians.

Only four respondents had no concerns. The most frequent concerns were about clarity of the purpose of the data; for instance, who would have access to it, the PCG or the Health Authority or both (25 responses), inappropriate use of the data (26 responses) and that the data would be used for performance monitoring (16) or resource decisions (12).

### Difficulties caused by guideline-use monitoring

Finally, respondents were asked a series of questions (*Box 11*) relating to the potential difficulties they foresaw in the use of a guideline

### BOX 11 Difficulties with guideline-use monitoring

What do you foresee to be the difficulties with a guideline monitoring data collection system ...?

- state of the records in general practice
- accuracy of data entry on to practice computing systems
- diversity of practice computing systems
- identifying the data items to collect
- relevance to everyday practice
- time demands
- fear of policing by external agencies
- motivation of practice staff
- rate of introduction of a monitoring system
- involvement of stakeholders
- intrusion into patient/doctor consultation
- lack of adequate funding
- degree of training required

monitoring system. The results are reported at three levels: general practice, PCG and Health Authority, and by type of respondent. Again, these questions were derived from issues arising from the interviews reported in the first section of this chapter.

### Difficulties with monitoring at a practice level

These statements were only rated by the clinicians in the sample. On the whole, there was little disagreement between the GPs and the practice nurses in response to any of the statements. The statements that received the highest levels of agreement were those that difficulties with monitoring were related to:

- the state of GP records (22 of 28 respondents)



- the accuracy of data entry (22 of 28 respondents)
- the diversity of systems (about half had concerns)
- time demands (mentioned by almost all)
- the rate of introduction of monitoring processes (about half had concerns)
- lack of funding (22 of 28 respondents)
- the degree of training required (more than half).

That is, the concerns were mainly about the resource issues and somewhat less about the professional concerns over intrusion into the consultation (nearly a half of respondents) and concerns about 'policing' by outside agencies (expressed by about one-third of respondents). However, concerns about motivation were mentioned by almost half of respondents, rather more by the practice nurses than by the GPs.

#### **Difficulties with monitoring at a PCG level**

Overall, there was a clinician/clinician-manager split on the majority of items in this section. In particular, there were high levels of agreement from clinician-managers that the difficulties of monitoring lay in the state of GP records, the accuracy of data entry, the diversity of systems, time demands and the motivation of staff. By contrast, these statements received rather lower levels of agreement from the clinicians, with only half of the GPs agreeing with these points. Diversity of computer systems might be expected to be seen as less of a problem from the individual practice level than from those (such as PCG chairs) who might be charged with aggregating data. Apart from the practice nurses, there was a general view that the rate of introduction of guidelines was potentially problematic.

Clinicians showed the highest level of concordance with other respondents over the perceived problem of lack of funding; more than half of all of the respondents highlighted this as a problem. Clinicians did not perceive intrusion into consultation, or the relevance of the role, as difficulties with monitoring at a PCG level, although almost half of the GPs (6) expressed concerns about the problem of external policing.

#### **Difficulties with monitoring at the Health Authority level**

This section was only completed by the clinician-managers in the sample. Although only computed on small numbers, there was a definite split in responses between the PCAG members of the sample and the PCG and Health Authority

members of the sample. PCAG members displayed high levels of agreement with the majority of the statements in this section of the questionnaire, expressing concern about the difficulties on all of the issues in *Box 11* in relation to monitoring primary care guideline use at the Health Authority level – both resource problems and professional problems. The two exceptions to this were motivation of staff and intrusion into consultation. The PCG members and the Health Authority members of the sample felt that there were very few difficulties with monitoring at the Health Authority level.

## **Overview**

Taken together, the results from the interviews and from the survey present a picture of some unreadiness for guideline-use monitoring in the NHS. Although these results were gathered in 1998/9 and significant developments in guideline development and use in the NHS have occurred since then (see also Chapter 6), there have also been a number of changes in the way in which primary care is managed, with consequent impact on strategic development. Thus, some of the key questions raised by respondents about the underlying principles for guideline-use monitoring (quality improvement rather than quality assurance) and the practicalities (MDS and relevance to everyday practice) remain pertinent and also fit with the components of the AHCPR model.

The next stage of guideline-use monitoring framework development called for some practical testing of approaches that fitted the requirements of primary care users. One element of this work required some further exploration of users about the practical aspects of setting up monitoring systems: how could it be done, who could do it, what roles would be filled by the different types of NHS primary care organisation.

Another aspect of the framework that required case studies was the capture of linked types of guideline-use monitoring information, particularly on the process of care through review criteria and on the outcome of care through accessing data that are not routinely recorded. Finally, some understanding of the practical impact of setting up these monitoring systems was needed to ensure that the final monitoring was both conceptually acceptable to NHS professionals and pragmatic. Results of the case studies are presented in Chapter 5.



## Chapter 5

# Testing the monitoring framework: findings

### Health professionals' views and experience of guidelines and guideline-use monitoring

#### Introduction

This section reports the results of the interviews undertaken with a range of NHS staff working in, or with an interest in, primary care. Respondents discussed issues arising from the results reported in Chapter 4, particularly relating to the use of guidelines and to views on, and experience of, guidelines monitoring. The interview schedule is available in Appendix 3.

Twenty-eight interviews were completed. Although this number was not as great as had originally been planned for in the study proposal, it became clear during the research that NHS staff were under great pressure, both from policy initiatives and from daily workload. The professional time needed to take part in an interview, and possibly in subsequent data collection, was a rare commodity and it proved difficult to recruit to this interview study.

Nevertheless, the interviews that were undertaken were spread across a range of staff from all three levels in the study – general practice, PCG and Health Authority – in three Health Authority areas (Table 6).

Initial analysis of the interview data indicated that at each level there were three main thematic areas relating to primary care guidelines monitoring:

- policy
- process (including technology use)
- people.

**TABLE 6** Workplace or type of respondent

Type of staff	No. of interviewees
Health Authority	3
PCG	5
GP	11
Practice nurse	8
GP/PCG member	1

Analysis later showed that all three issues were interlinked and that 'people issues' were the main common factor. The results are presented through these three themes, at each level of organisation:

- general practice
- PCG
- Health Authority.

#### Results

##### General practice: policy

Practice nurses and GPs provided this information.

External expectations and demand, expressed through guideline monitoring and as an expression of national and local policy, were key concerns of respondents. Their impression was of an ever-changing nature of 'who demands what', which was policy driven and could come from national, regional or local (usually Health Authority) sources. In particular, respondents felt that policy-makers had unrealistic expectations of the quantity and the quality of information demanded of them in monitoring quality of care.

Many respondents acknowledged that PCGs had so far made little demand on their time in specifically monitoring guideline use. Nevertheless, they were able to draw on experience of guideline-based clinical audit and of payment processes linked to the implementation of local disease management protocols, to reflect on PCG policy-driven requirements.

Within-PCG variation in the use of guidelines was apparent from responses to questions on local policies on protocol or guideline monitoring. Some practice nurses, for instance, were not using clinical guidelines and said so explicitly, but they were collecting data based on local non-standard protocols and were thus adopting and monitoring local policy.

Overall, it was difficult to obtain a coherent view from any practice regarding what types of guideline/protocol monitoring data they were required to collect, for whom and for what external purposes.

Furthermore, there did not seem to be local policies driving the collection of common data sets related to guideline monitoring, other than those related to annual reports or disease register payments. Within practices, decisions (policies) on clinical audit tended to be the drivers. Some respondents expressed the hope that the introduction of PCGs and PCTs would lead to an increase in capturing information of clinical (rather than contractual) interest.

Lack of clarity on what to capture, and why, appeared to be linked to a lack of experience in using guidelines, or even a lack of awareness of guidelines, with a very low level of interest in incorporating guidelines and their use into practice policies. Perhaps this is a reflection of some of the negative views of guideline use identified in the survey reported in the second section of Chapter 4. If there is limited understanding of how evidence-based guidelines influence practice policy, then there will be little to monitor. Nevertheless some practices had developed guideline-based computer templates for use in the doctor's consultation, and these could clearly form the basis for a guideline-use monitoring process.

#### **General practice: process and technology**

The structure of the practice teams, in terms of their different mixes of staff and differing views across teams and within teams of quality, together with (variable) experience of guideline use and monitoring, had an impact on the processes relevant to this field and to the use of appropriate technology. Even where some of the practice teams were using guidelines such as the British Thoracic Society Asthma guideline,<sup>51</sup> often in a clinic setting that was practice nurse led, information was mainly being collected on paper records.

However, it was also clear that some practices were spending considerable effort in deriving templates for computer screens, investing in IT and moving towards 'paperless' records. In these practices there was already an element of data monitoring for clinical audit purposes. At the practice level this was working well in some instances, although it was system dependent. However, few practices in this sample were designing data collection systems that were in common with other practices, apparently because there was a lack of compatibility between them. Within a PCG or PCT, practices are at differing levels of sophistication and experience in monitoring their care or conformance with guidelines.

Three different IT systems were used among the practices represented by the respondents. Some systems did not provide standard templates while others did, but sometimes the respondents did not appear to be satisfied with them and had derived their own (by definition non-standard) templates.

Practice policy decisions often drove choice and use of the practice IT systems. Both the decisions to collect information in a certain way, and the use of the systems, were influenced by the attitudes of the practice teams towards technology. In some cases the whole practice team was working together towards a fully computerised operation as the ideal. More often, however, there would be a mix of attitudes, with certain members of the team using computers and moving towards the 'ideal', while others still dealt mainly with paper records. It was often the case in these practices that information was subsequently entered onto the practice system by another member of staff, a duplication of effort that was recognised by interviewees. Nevertheless, if data are actually entered, then an IT-supported guideline-use monitoring system is an option.

Some respondents commented that systems could also drive policy and practice, both in what is currently done and in what can be done. Time taken to ensure that the information on the systems was entered correctly and quality assured was a recurring theme, as it was in the survey reported in Chapter 4.

Furthermore, it was clear from respondents that there was often a lack of clarity within teams about what services were being provided in which a guideline might be implemented. Taking asthma and stable angina as examples, there was great variability in how the service for chronic diseases was structured (e.g. as specific clinics) and some practices had continued to experiment to find the best way of providing the service. Thus, any technology on which to base an unintrusive monitoring system (see second section of Chapter 4) would need to be flexible in operation, although the data captured would be similar.

#### **General practice: people**

Perspectives of guideline-use monitoring and the personal and professional relationships that might enable the process varied considerably between respondents.

The term monitoring, as defined in quality-assurance terms in Chapter 1, was alien to many of the respondents and no consensus emerged

during the interviews on the meaning of the term. Following an explanation by the interviewer, many of the respondents came to recognise the usefulness of the term, while clearly preferring some other word that did not have an implication of external management (“it’s all such a daunting task”, said one).

In the running of the chronic disease management services for which guideline monitoring might be most commonly appropriate, the degree of involvement of either the practice nurse or the doctor was dependent on the degree of autonomy and trust that existed within the practice team. The extremes of the situations described by respondents were considerable. They ranged from the clinic run solely by the nurse, with little day-to-day involvement from other clinical staff but with clear policy involvement, to services or clinics with GP involvement but which lacked the trust to allow the practice nurse to work autonomously. These variations impacted on the choice of design of services and information systems, and have implications for guideline use, monitoring and use of the monitoring information.

Respondents felt strongly that the composition of the team and the attitude of the team towards quality were important in the design of any framework for using clinical guidelines and monitoring their use. It was thought important that the whole team should be signed up to the initiative and that the clinicians had to see it as relevant to their everyday work.

Although there seemed to be no coherent view across the respondents about the specific policies and processes for using guidelines and monitoring their use, many had clearly thought about the issues and begun to move forwards on designing templates for data capture or following protocols of care. Again, time was identified as a key resource issue.

#### **PCGs: policy**

National health policy initiatives, particularly NSFs, were seen by the PCG respondents as the most likely drivers for stimulating the use of evidence-based guidelines across the PCG practices, although none had a policy for promoting a particular national guideline across the group. However, local guidelines that had been constructed using evidence-based appraisal methods and adapted for local priorities and local influencing factors seemed to be a popular approach in all five PCGs. At the time of the interviews, project approaches were more common than an overall policy approach.

At this level of organisation, though, some were trying to establish quality monitoring systems across primary and secondary care interfaces, based on common data sets to be collected in general practice and hospital practice. In at least one PCG, the local protocol for care was very close to the British Thoracic Society guideline<sup>51</sup> on asthma, with the aim of capturing a similar data set across the 22 practices in the PCG. Other new policy initiatives were recognised by PCG leads as having a potential impact on guideline use and monitoring, particularly the regular clinical performance review that may arise from the establishment of the Commission for Health Improvement.<sup>11</sup>

More mundanely, one aspect of guideline monitoring that may become part of routine practice was seen to be the link between guideline recommendations and the prescribing and monitoring of drugs.

#### **PCGs: process and technology**

Views of PCG senior staff were very similar to those of Health Authority staff in regard to the process of monitoring guideline use. Information management was seen as being at a very varied level of development within the PCGs, with some practices being virtually paperless and some almost completely paper based. While it was acknowledged that it is possible to monitor quality in a paper-based system, the additional demands on time were seen as a significant barrier; so, there was a recognition that any monitoring system would be IT based. Three challenges were identified:

- a need to get the relevant health professionals to a baseline level of skill and familiarity with using practice computer systems
- a need to work towards some standardisation of the systems used in the PCG, to support comparative data analysis
- the requirement for a standardised data capture approach so that guideline monitoring (and other quality initiatives) could be uniform across the locality.

There was a general view from respondents that the IT issues would be easier to address than the ‘people issues’.

#### **PCGs: people**

Respondents were concerned that monitoring the use of guidelines was just one task among many for the young organisations of PCGs (and PCTs). Although there was some experience of working

with chronic disease management systems for such conditions as asthma and diabetes, the balancing of national and local priorities was seen as a challenge. Health Improvement Plans and NSFs appeared to offer opportunities to stimulate local interest, but the development of local protocols from NSFs required time, a commodity in short supply.

The different care priorities between different groups of professionals and different general practices was also seen as a complicating factor, but one that was recognised by the PCGs. The ability to monitor and share information about quality of care was seen as being partly dependent on the levels of trust between professionals, although this was viewed positively in the main, as teams were generally seen as wishing to work together.

#### **Health Authority: policy**

Staff had considerable experience in managing local policies, based on national initiatives, for chronic disease management, which required a minimum of protocol-based data to be collected. With the introduction of Health Improvement Plans and the establishment of PCGs, respondents were responsible for translating national policy (e.g. as NSFs) into local policies and protocols in partnership with the PCGs. However, recognising the changing balance of the NHS, staff saw much of their role, in assisting with the introduction of guidelines and closely monitoring their use, subsequently moving to the PCGs.

#### **Health Authority: process and technology**

Respondents were engaged in a number of projects, all aimed at developing an equitable level of care across the Health Authority and the PCGs. Much of this activity was related to developing local guidelines and protocols for specific areas of work, such as the development in one PCG of the primary care evidence-based anticoagulant service.

Local monitoring processes were mainly concerned with the high-level monitoring of the local Health Improvement Plan, rather than monitoring the specific use of a local guideline or a protocol. Some of this activity is now on a commissioning basis, such as the commissioning of a local clinical audit programme and its subsequent monitoring through clinical governance leads, rather than the process being undertaken through the Health Authority. So far, the process is one of target setting for processes, rather than monitoring of clinical process or outcome.

Local IT strategy and implementation were of considerable concern to these respondents. Activities ranged from developing benchmarking clubs to improve data quality to fire-fighting and providing logistical support to individual practices. There was a general concern over the quality of general practice data as it related to patients and services: most of the data were thought to be of poor quality and therefore unreliable. In one Health Authority, clinical templates were being designed so that all general practices across all of the PCGs could capture similar data.

#### **Health Authority: people**

Although Health Authority staff clearly recognised the need to engage with primary care staff in quality management and in monitoring guideline use, their role was also required to be one of performance managers. There was a tension here between trying, on the one hand, to win the hearts and minds of (at least the leaders of) general practice and, on the other, to performance-manage or commission work that had a national policy drive. Some respondents saw the PCGs and emerging PCTs as playing an increasing role in the performance-management of individual practices, particularly on clinical issues. This may require the monitoring of guideline use as one element of the process.

#### **Overview**

Although this study dealt much more with the detail of data capture to support guideline-use monitoring than did the earlier interviews and survey, many of the concerns overlapped with earlier findings. Thus, even though the interviewees recognised some value in guideline-use monitoring, they were concerned about the practicalities from two perspectives. First, although primary care computing systems were to be found in most general practices, the technology for monitoring was absent in many (probably the majority) of practices. Training in these skills would be required before monitoring of guideline use could be a practical reality.

Secondly, and possibly more fundamentally, there were clear signals of a more general lack of interest or awareness in the subject of continuous review of care. This, together with a feeling of being overloaded with new initiatives, meant that implementation of a monitoring framework could be problematic and might need considerable support in order to make progress. That support would have to come from PCGs (now PCTs), against a background of many other priorities.

**TABLE 7** Number of cases meeting each criterion for asthma

Review criterion	All (n = 57)			
	Yes	No	CI/NA	Missing
1. Has this patient been treated with short-acting $\beta_2$ -agonists on an 'as required' basis?	56	1	0	0
2. Has this patient required inhaled short-acting $\beta_2$ -agonists for more than 2–3 doses a day?	51	6	0	0
3. If yes, has this patient also been treated with inhaled corticosteroids?	47	7	0	3
4. Has this patient had an exacerbation of their asthma?	20	36	0	1
5. If yes, has this patient been treated with oral corticosteroids?	17	18	0	22
6. Has this patient been advised to stop smoking?	11	3	42	1
7. Has this patient been offered education about their condition and its management?	56	1	0	0
8. Has this patient had their inhaler technique checked?	49	8	0	0

CI/NA: contraindicated or not applicable.

## How can review criteria and outcomes measures be used to monitor guideline use?

### Introduction

Earlier sections of this report have been concerned with developing an overall framework for monitoring guideline use, through a conceptual development and through seeking the views of potential NHS users. In exploring guideline monitoring methods that might be useful in assessing conformance of clinical practice (or, more correctly, recording of clinical practice), two complementary approaches have been considered, both of which arise from the conceptual work initially undertaken by the US AHCPR:<sup>17</sup>

- capturing information using review criteria, based on information available from the clinical record
- using standardised outcome measures, in this case based on information provided by patients.

Doctors who were interviewed and provided information discussed in the previous section were asked whether they would take part in a study to explore these methods of collecting process and outcome information. Eight GPs agreed to take part.

### Overall results on data capture

Doctors in Health Authority no. 1 were the only ones to choose to collect information on both angina and asthma. Angina review criteria data were collected on 148 patients by six doctors (range 19–30 cases) and asthma review criteria information on 57 patients was provided by two doctors. Fifty-nine angina outcomes questionnaires and 24 asthma outcomes questionnaires were

returned. Overall, the patient outcomes questionnaires returned for angina amounted to about 40% of the number of process data forms completed (not quite one-quarter in Health Authority no. 1 and nearly half in Health Authority no. 2). For asthma only 42% of outcome questionnaires were returned (one-third in Health Authority no. 1 and just over half in Health Authority no. 3).

### Review criteria data collection

#### Asthma

Asthma-specific process data collection sheets were provided to the study practices in Health Authorities nos 1 and 3 (Appendix 4). The practices were asked to record the relevant data for patients who were diagnosed with asthma.

In total, 57 completed forms were received, with one doctor collecting information in each Health Authority. The information was analysed using SPSS version 9. Of the 57 cases, 33 were male and 24 were female. Their mean age was 46.3 years (range 18–78 years) and the mean length of time since diagnosis was 13.3 years (range 1–65 years).

Table 7 shows the number of cases that met each review criterion, including those where a criterion was not applicable or was contraindicated.

#### Angina

Angina-specific process data collection sheets (Appendix 4) were provided to the study practices in Health Authorities nos 1 and 2. The practices were asked to record the relevant data for patients who were diagnosed with stable angina.

In total, 148 completed forms were received; 100 from Health Authority no. 2 and 48 from Health Authority no. 3. The information was analysed

**TABLE 8** Number of cases meeting each criterion for angina

Review criterion	All (n = 148)			
	Yes	No	CI/NA	Missing
1. Has this patient had their blood pressure measured?	144	4	0	0
2. Has this patient had their serum lipids measured?	125	21	0	2
3. Has this patient had an exercise test?	58	74	14	2
4. Has this patient been treated with aspirin 75 mg daily?	108	21 (other dose 4)	14	1
5. Has this patient been treated with short-acting nitrates?	109	34	1	4
6. Has this patient been treated with $\beta$ -blockers?	80	36	28	4
7. Has this patient been advised to stop smoking?	33	4	107	4

CI/NA: contraindicated or not applicable.

**TABLE 9** Recoding to score the Newcastle Asthma Symptoms Questionnaire<sup>57</sup>

Descriptive answer	Scale on questionnaire	Recoded score
Never	1	0
On one or a few days/nights	2	1
On several days/nights	3	2
On most days/nights	4	3
Every day/night	5	4

using SPSS version 9. The numbers of cases meeting each review criterion are given in *Table 8*. Of the 148 cases, 71 were male and 77 were female. Their mean age overall was 67 years (range 40–89 years) and the mean length of time since diagnosis was 6.5 years (range 1–26 years).

*Table 8* shows the number of cases that met each review criterion, including those where a criterion was not applicable or was contraindicated.

## Outcomes data collection

### Asthma

Patients with asthma whose process data were collected in general practices in Health Authorities nos 1 and 3 were also asked to complete the Newcastle Asthma Symptoms Questionnaire, a nine-item self-report measure (see Appendix 5).

In total, 24 completed forms were received from the patients; 14 from Health Authority no. 3 and ten from Health Authority no. 1. The information was analysed using SPSS version 9. There were no missing answers on any of the forms. The raw data were used to compute a total symptoms score through recoding the answers, as shown in *Table 9*.

The sum of the scores was calculated to form the raw total score. This score was divided by 36, and then multiplied by 100 to form the transformed

total score (a high transformed total score indicates a poor level of functioning).

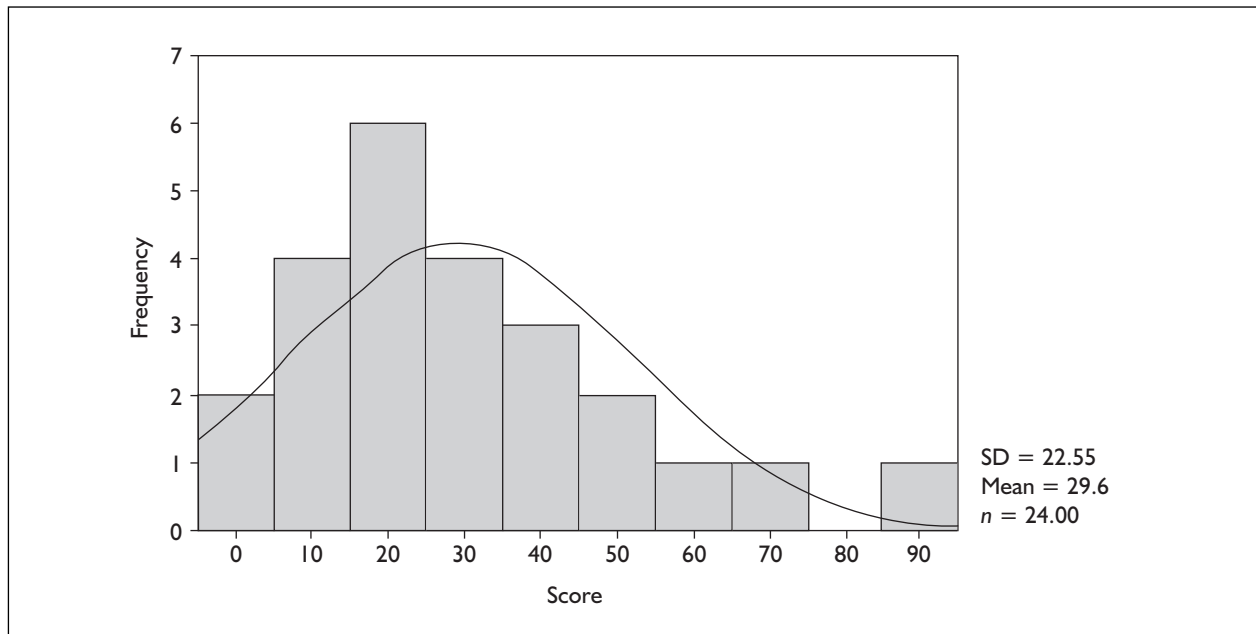
The mean score for the 24 questionnaires was 29.6 (range 0–91.7). The distribution of the scores obtained overall is shown in *Figure 9*. The scores were plotted against a normal distribution curve (*Figure 9*) and a one-sample Kolmogorov–Smirnov test demonstrated that they were not significantly different from a normal distribution ( $Z = 0.807$ ,  $SD = 22.55$ ,  $p = 0.533$ ). The results were then analysed using an independent  $t$ -test to investigate any differences in the asthma outcomes of patients from the different health authorities. No significant differences were found ( $t = 0.283$ ,  $df = 22$ ,  $p = 0.780$ ). Overall, the results showed that a range of severity of cases might be expected in a general practice population. Although the Newcastle Asthma Symptom Questionnaire is responsive at the individual patient level,<sup>35</sup> the low numbers of cases mean that the results must be treated with caution. However, the information provided could form a baseline for examining change in health status (i.e. outcomes of care) over time in a practice or a PCG population.

### Angina

Patients with stable angina whose process data were collected in general practices in Health Authorities nos 1 and 2 were asked also to complete the UK version of the SAQ,<sup>35</sup> a 14-item self-report measure (Appendix 5).

In total, 59 completed forms were received from patients; 48 from Health Authority no. 2 and 11 from Health Authority no. 1. The information was analysed using SPSS version 9. The raw data were used to compute the total scores for three scales assessing physical limitations, angina frequency and perception, and treatment satisfaction. Each of these represent a specific dimension of stable angina and so no summary scale is created. Each





**FIGURE 9** Distribution of asthma questionnaire scores, plotted against a normal distribution curve

scale results in a score from 0 to 100, with lower scores indicating a low level of functioning.

Total scale scores are computed by assigning to each response an ordinal value from 1 to 5 or 1 to 6 as appropriate for the item response choice, with 1 always indicating the lowest level of functioning. These values are summed across each of the scales. The lowest possible score on each scale is then subtracted from this value: this is then divided by the range of the scale and multiplied by 100.

Questions 1a–g form the physical limitations scale; questions 2, 3, 7 and 8 form the angina frequency and perception scale; and questions 4, 5 and 6 form the treatment satisfaction scale. In relation to the physical limitations scale (questions 1a–g), the response option ‘Limited, or did not do, for other reasons’, coded as 6 in the raw data, was not included in computing the score as the response is interpreted to be not applicable in the UK version of the SAQ. Total scale scores were not computed if there were any missing data for the items comprising the scale, and these cases were excluded from analyses of the scale.

The mean scores for the three subscales were:

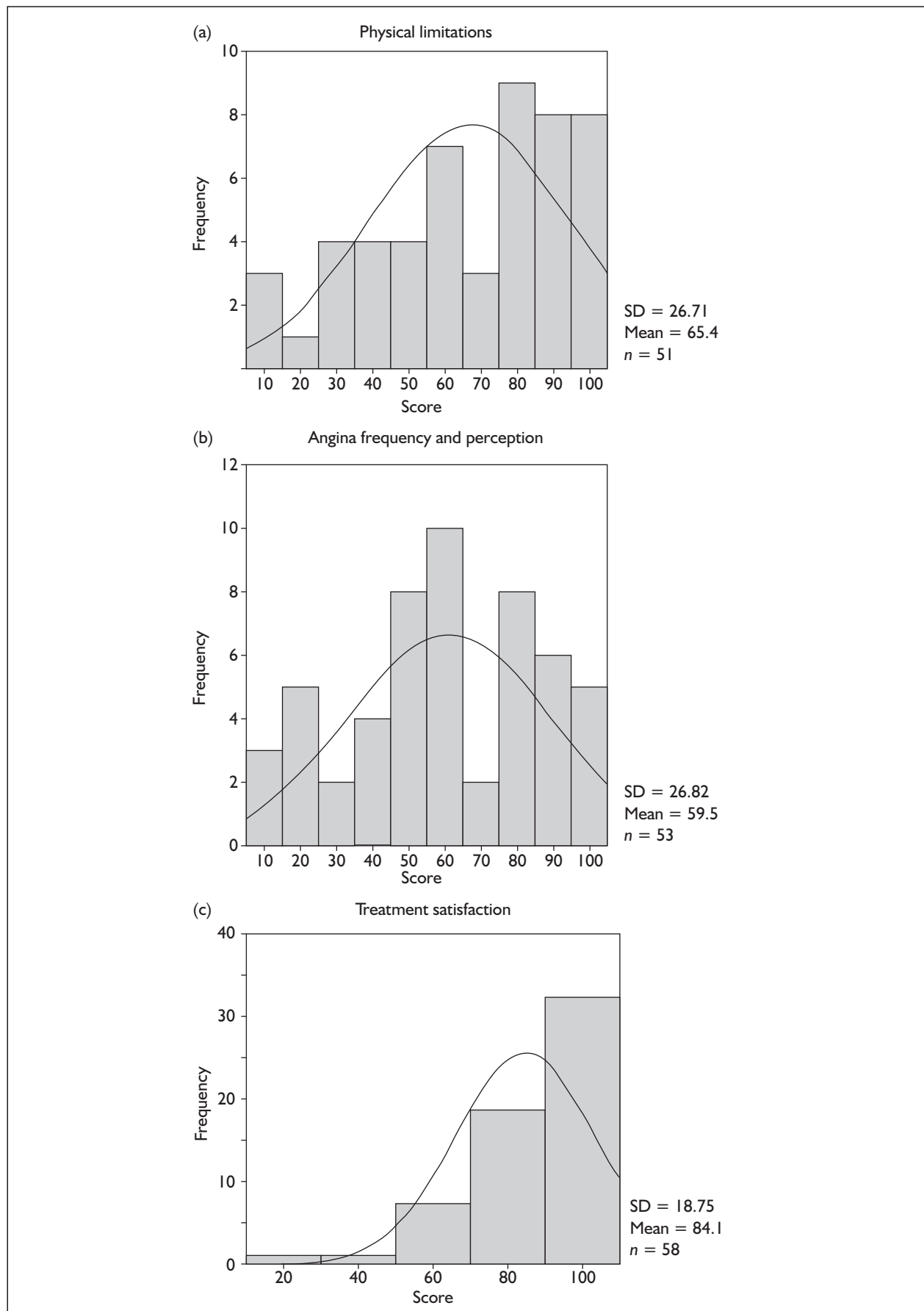
- physical limitations 65.4 (range 7.1–100)
- frequency and perceptions 59.5 (range 5.9–100)
- treatment satisfaction 84 (range 25–100).

The distributions of these scores are presented in *Figure 10*. The scores were plotted against normal

distribution curves (*Figure 10*) and a one-sample Kolmogorov–Smirnov test indicated that treatment satisfaction was not normally distributed ( $Z = 1.647$ ,  $SD = 18.75$ ,  $p = 0.009$ ). The other two scales were not significantly different from a normal distribution (physical limitations:  $Z = 1.045$ ,  $SD = 26.71$ ,  $p = 0.225$ ; angina frequency and perception:  $Z = 0.693$ ,  $SD = 18.75$ ,  $p = 0.723$ ).

As the data were not normally distributed for all of the three scales, both parametric and non-parametric tests were used to investigate any correlation between the scales. Pearson’s product moment correlation, a parametric test, was used to analyse the normally distributed data from the physical limitations scale and angina frequency and perception scale. The non-parametric Spearman’s rho was used in analyses involving the treatment satisfaction scale, as this was not normally distributed. These analyses showed significant correlation between physical limitations and treatment satisfaction ( $\rho = 0.345$ ,  $n = 50$ ,  $p = 0.007$ ).

The results were further analysed, using both parametric and non-parametric analyses, to investigate whether there were any differences between the health outcomes of the patients from the different Health Authorities. This showed a small significant difference between the scores obtained on the angina frequency and perception scale ( $t = 2.604$ ,  $df = 50$ ,  $p = 0.012$ ), but no significant difference on the other two scales (physical limitations:  $t = 1.542$ ,  $df = 48$ ,  $p = 0.130$ ;



**FIGURES 10** Distribution of angina questionnaire scores, plotted against a normal distribution curve: (a) physical limitations; (b) angina frequency and perception; (c) treatment satisfaction

treatment satisfaction:  $U = 148$ ,  $p = 0.56$ ). As with the measures of outcome for asthma, the results showed a range of health status that might be expected in a general practice population and one that could form the basis of an assessment of improvements in outcome as a result of changes in process of care.

### Overview of process and outcomes data collection

In the context of monitoring guideline use in primary care, these exploratory results show that review criteria can be used to assess conformance with guideline recommendations. Similarly, patient-completed health outcome measurement can also provide useful information in routine practice.

However, there are several practical and technical challenges. Even collection of a limited additional number of process data items is time consuming and requires additional resources, so whatever is collected must be valuable in the care of patients and captured at least cost. Some general practices may be able to do this electronically, but paper systems are likely to feature for some time to come. Experience with using review criteria will certainly increase with the publication of each new clinical guideline from NICE, and this is clearly going to become a routine technology in the future. Assessment of conformance with the guideline recommendations is a relatively straightforward computation.

Outcome measurement probably offers a greater challenge. Some of the impact of low response rates may be a result of the project nature of the study, rather than being seen by both patients and NHS staff as being part of routine clinical practice. However, the computation of scores and the production of information that is useful to clinical teams are much more difficult for this form of outcome data than for process data. The information may be useful, but it is likely that either the task of producing it will fall to PCT staff or investment in practice-based electronic scanning and analysis systems will be required to provide the information.

## A costs framework for guideline-use monitoring

### Identifying cost areas for the framework

The exploratory studies of methods of capturing guideline-use monitoring data, and investigation of the requirements of users, have both shown that

the cost of monitoring is a potential barrier to implementation. Several studies in the UK and North America, reported in Chapter 1, have identified areas of activity in the wider quality improvement field where costs may accrue. Although guideline-use monitoring (based on routine data where possible) may not have quite such a range of cost impacts, the monitoring framework requires cost considerations to be included for the overall framework to be considered a practical tool. In particular, the balance between costs and benefits may be the key to the successful establishment of guideline-use monitoring.

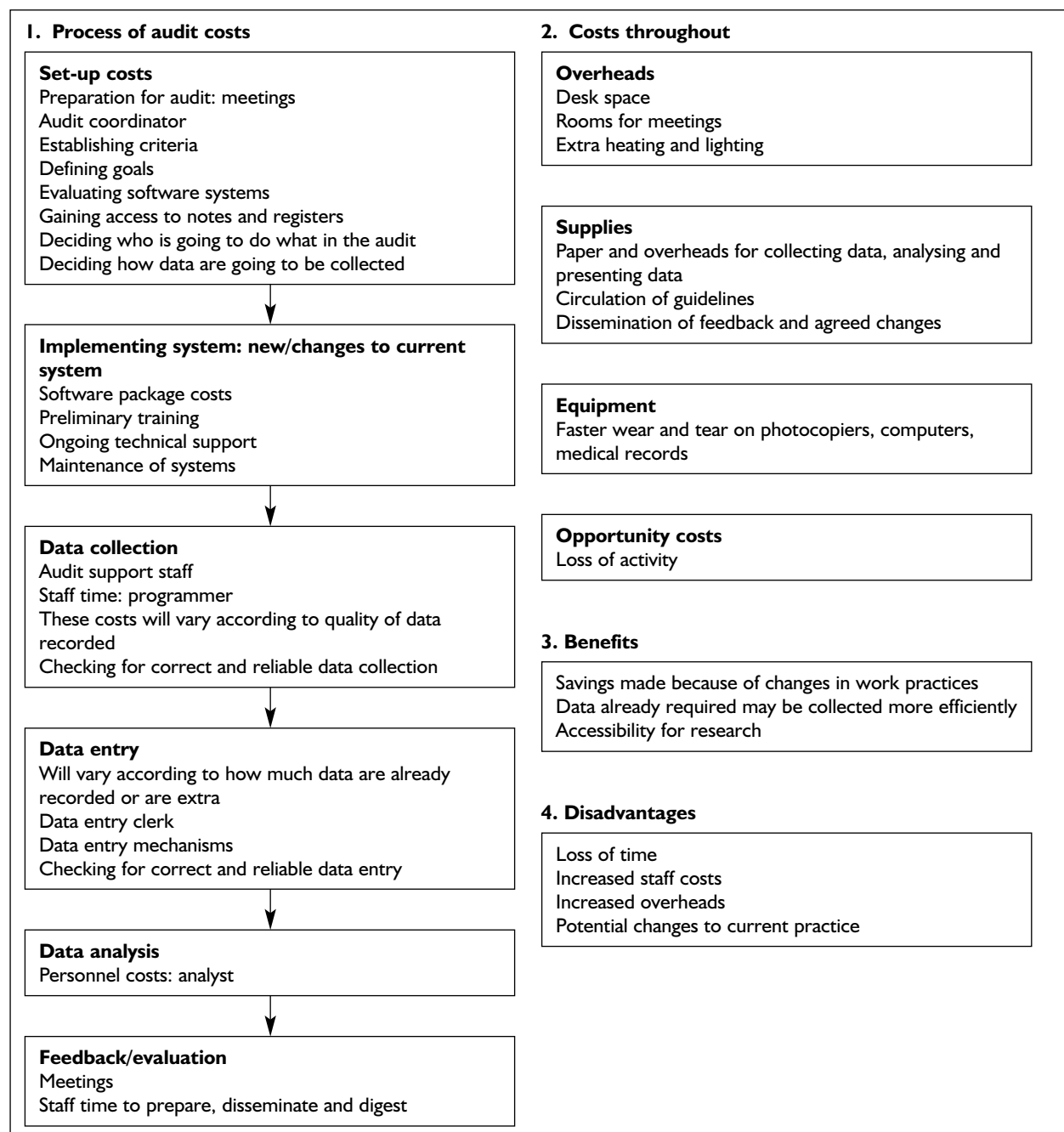
Although the published literature is not very extensive on this subject, it is possible to identify a number of aspects that would have relevance to guideline-use monitoring. These may be characterised as:

- establishment of monitoring systems
  - policy development
  - data collection process
  - data collection systems
  - human resources
- data capture and analysis
  - materials
  - processes
  - human resources
- information processing
  - materials
  - human resources:

A framework of the areas where costs may potentially lie was produced by systematically mapping out the cost criteria in the relevant literature (Appendix 6). These were categorised according to the part of the audit process to which they related, creating a comprehensive list of areas of cost that may be incurred through audit (of which guideline monitoring may be one component), and are set out in *Box 12*.

In developing the guideline monitoring cost framework, it was predicted that the precise level of costs associated with each stage of the process would vary from practice to practice according to a number of factors, such as size of practice, patient group, healthcare professional experience in the area and access to resources. For example, it has been shown that the costs of collecting data for audit purposes can vary considerably depending on which staff perform the task.<sup>61</sup> There is also no current consensus on how many of the cost areas should be derived in primary healthcare.<sup>62</sup> Therefore, no attempt was made to translate this

**BOX 12** Potential areas of guideline monitoring costs identified from the literature



framework into equivalent monetary cost, although there are some exploratory studies in this area that could potentially be of use in this process.<sup>62,63</sup>

### Initial exploration of the costs framework: a case study

During the progress of the study it became clear that any formal validation of the costs framework would be a substantial study in itself. Instead of validation, an extended interview was held with

one of the general practice teams involved in data collection to explore the practical issues related to the cost framework developed in the previous section. In the context of this case study, costs were considered as effort expended for benefit gained in being able to monitor guideline use, rather than as costs recorded in monetary value.

The tape-recorded and written notes from the practice group interview were analysed and coded within four main themes:

- **outcomes:** incentives, availability and type of data, use of data, collecting data
- **recording data:** current practice, templates, process
- **data retrieval**
- **costs:** set-up costs, opportunity costs, data entry.

## Outcomes

### *Incentives*

The main incentive for using outcome data is that they are a good measure of how well the practice is doing. Participants felt it to be more important to use outcome data on their own rather than to link outcome data to the process of care. To meet the performance monitoring objective, it is necessary for the outcome measures to be short term, focused and concerned with areas of care where the effects of any changes implemented in practice could be witnessed by those who are making the changes.

### *Availability and type of data*

Some routine outcome data are recorded; for example, blood pressure and glycosylated haemoglobin in diabetes. It was thought that some types of outcomes may be important to the patient, while others would be important to the clinical team. For example, following myocardial infarction, the concern of the doctor would be secondary prevention, but the patient tends to be more focused on minimising current symptoms and disruption to daily life. Participants considered that customer satisfaction is a short-term outcome measure that is seen to be as important as longer term clinical outcomes, such as amputation in diabetes. There would be additional costs in capturing these types of data.

### *Use of data*

Outcome data are presently used to monitor care, but more attention is needed in using this to highlight areas where change is required. Symptom scores could be used as quantitative measures for regular comparisons. As some variation in outcomes could be the result of environmental or other factors that are not under the control of the practices, information should also be gained at a population level. Analysis of these data would require additional monetary and skills resources.

### *Collecting data*

Some data can be difficult to collect reliably if they are externally produced, as the laboratories do not routinely provide them to practices. The most useful way of collecting these data is to incorporate them into computer templates. Although this takes considerable time and effort to

set up, often using clinical time, once this is done the data collection can be incorporated into everyday practice and requires little extra time. Patient-centred information is also useful as this can be sent to, and completed by, the patient before they attend for review.

## Recording data

### *Current practice*

Many of the data required in the project review criteria are those that are recorded as standard practice. The interviewees therefore thought it unlikely that these data would be regularly recorded. Variation across practices in the way these data were collected could prove problematic and set-up costs in some practices could be considerable in practices that had not already invested in appropriate information systems.

### *Templates*

In the study practice, for most of the routine condition-specific clinics, many templates are used. These have been designed to serve as reminders for the care offered in clinics; for example, for asthma and diabetes. All of the asthma review criteria could be recorded on a template, requiring minimal effort once the template had been written. In current practice, the templates are designed by the practice and therefore tailored to individual practice needs. A future ideal would be the use of standard templates offered nationally across practices by computer companies, allowing a core of information and small local adaptations, thus reducing costs. Such a template would need to be user friendly and ask only for information that is the responsibility of the practice.

### *Process*

The information on chronic disease management is usually recorded during consultation, and should therefore not be an additional cost.

### *Data retrieval*

Retrieving data can often be more of a struggle than the recording. It seems especially difficult to obtain data at a population level from general practice computing systems, since the systems operate on an individual patient basis.

## Costs

### *Set-up costs*

The main expense of recording data is setting up the initial template, which takes about 6 hours to do, often of clinical time. Much of this time is spent on coding issues, either searching for relevant codes or creating new ones.

### **Opportunity costs**

The opportunity costs involved in monitoring care are mainly not seeing the patients or spending longer in the practice. A locum doctor is employed to cover the practice doctors when they are engaged in audit-related work. This equates to 1 day of template production, or approximately £600–£700.

### **Data entry**

If data are entered into a computer template this takes little time. However, in a paper-based practice time has to be allowed for someone to collect the data, type them in and then analyse them using a computer.

### **Overview of findings from the cost framework case study**

The discussion served to highlight various areas where costs may lie and proposed several ways in which these could be minimised. In general, these confirmed the cost areas in *Box 12*. Beyond the set-up phase for guideline-use monitoring, a practice with efficient systems may be able to record or capture relevant information relatively cheaply. Conversion of data to information, however, would still require investment in skills, particularly for analysis if undertaken at the practice level.

### **Testing the framework: a brief overview**

The interviews and three case studies allowed the framework to be further developed and tested in a number of ways, albeit with limited numbers of NHS staff and patients. The concerns and experiences gleaned from the interviews highlighted issues discussed earlier both from the literature and from earlier project phases. Thus, the framework appeared to be addressing and recognising issues pertinent to users, including doubts and difficulties. These reservations may account for some of the difficulties that presented themselves in the feasibility studies, in particular the difficulties associated with asking already busy individuals to take on yet another task. However, the feasibility studies showed that it is possible to use both process and outcome data to look at the issue of guideline conformance. It is also possible to identify associated costs, although a formal study will be required to explore the whole range of costs across a sample of general practices and PCTs.

Further implications of these findings are discussed in Chapter 6.

## Chapter 6

# Monitoring guideline use in primary care: what are the implications for the NHS?

### Policy matters: the current NHS context on monitoring quality in primary care

Three recent NHS initiatives, in particular, set the policy context for understanding the results of this study. First, clinical governance is of increasing importance as the policy initiative on which all other NHS-led quality initiatives are based. Although there is much in the sentiment of clinical governance that resonates with professionally led primary care quality initiatives of the past, the targeting of responsibilities on NHS managers places an emphasis of performance management alongside that of quality improvement. Both responsibilities are likely to be drivers in any systems to monitor guideline use in primary care.

Secondly, organisational levels at which monitoring of guideline use may take place in the future are highlighted by recent (2001) changes in the structure and responsibilities of NHS organisations in England and Wales. The disestablishment of Health Authorities, the establishment of Strategic Health Authorities with performance monitoring roles in England and the consequent changes in responsibilities of PCTs (acting as 'mini-health authorities') mean that performance monitoring requirements of NHS healthcare initiatives are likely to increase.

Thirdly, the national guidelines programme in England and Wales is now fully established through NICE. Guidelines have been published by NICE, accompanied by review criteria that clinical teams and trusts are expected to use to monitor the quality of their care. National clinical audit tools incorporating these audit criteria are also being developed by NICE and the Commission for Health Improvement to enable the assessment of the process of care in comparison with NSFs and national clinical guidelines.

The requirements for a guideline-use monitoring scenario that was anticipated by the project proposal in the mid-1990s could not have foreseen these considerable changes in NHS policy and practices. Yet, the structure of the project has

enabled an exploration of the practical issues of guideline monitoring that is grounded in up-to-date NHS practice. The challenges of monitoring the use of clinical guidelines for quality-improvement and performance-monitoring purposes are now very real.

### Who would monitor guideline use – and why?

Findings from the project concern three organisational levels in which healthcare professionals may wish or need to monitor guideline use in primary care.

In the context of this study, primary care means general practice and it is general practice teams that will most commonly use clinical practice guidelines (or their recommendations). These teams are also most likely to seek to monitor how effective their care has been. It can be argued that the respondents to both the survey reported in Chapter 4 and the interviews reported in Chapter 5, were more likely to be enthusiastic towards quality initiatives because they took the time to complete the questionnaires and interviews. Nevertheless, many of these respondents certainly had a positive view towards the use of guidelines and the value of monitoring to assess the impact of care. These positive views often extended beyond the practice of their own teams to the overall impact of the care provided by the PCG or PCT. The results of the study arise from two sets of interviews and from a relatively small national survey sample. Although the results are triangulated and the themes brought together in these conclusions, the methodological limitations must be taken into account in determining the strength of the results.

There seemed to be little dissent among respondents to the notion that guideline-use monitoring may be part of a general practice- or PCG-based quality improvement programme. Perhaps more surprisingly, there was no great resistance either to the principle of general practices or PCGs being performance monitored –

either practices by PCGs or PCGs by Health Authorities. Most respondents recognised the need to be able to demonstrate that general practice and primary care are providing good and improving quality of care. For some respondents their view was very much centred on their own clinical team. Others had a broader view and these respondents often also had responsibilities outside a general practice; for instance, in a PCG or a Health Authority. These different levels of purpose would need to be recognised in a guideline-use monitoring framework. It may be that the experience of providing information on which certain types of target payments were made to general practice had normalised the process of performance monitoring.

Respondents who had a clinical management role in PCAGs, PCGs or Health Authorities all recognised the performance management role as important, particularly in managing new initiatives such as NSFs where they were expected by central NHS functions to demonstrate progress. Most, however, tended to take a quality-improvement approach to the topic of guideline use and guideline-use monitoring.

Despite the relative enthusiasm in their views, most respondents saw problems in the detail of monitoring for both quality-improvement and performance-monitoring purposes.

## What are the barriers to implementing monitoring?

Several principles to guide the development of a monitoring framework arise from a consideration of barriers to implementation. First, a framework needs to be perceived (and promoted) as a tool that is relevant to everyday practice and to be of demonstrable use. Current NHS initiatives do not suggest that more resources will be available to use the review criteria and audit tools currently being produced by NICE. So, any framework needs to be efficient in its requirements for data, using a minimum data set approach that (preferably) meets the requirements of more than one user. Concerns about data confidentiality and data protection were also quite frequent, which means that any guideline-use monitoring framework would need to incorporate methods for assuring that information about individuals remained within the general practice.

Most respondents in the general practices and from PCGs had limited experience of using

clinical guidelines, and rather more of using local clinical protocols. This may partly be a feature of the time when the study was undertaken, with fieldwork in 1999 and early 2000, but it may also be a pointer to a relative lack of experience in this group of professionals. If they are, as a group, more enthusiastic than others (and there are no data from the study to be able to assess this), then this may suggest that many general practice teams have limited experience of using guidelines and assessing conformance with the guideline recommendations. Respondents from Health Authorities and PCGs indicated that this was an issue for them, with considerable variability across local health communities in the extent to which guidelines were used.

Some of the other perceived barriers to monitoring were related to the availability of usable information and to technology use. Concerns were expressed over the state of general practice record systems, the accuracy of data entry, the diversity of computer systems, and the need to fund technology and training. In principle, none of these potential barriers is insurmountable, and training approaches such as PRIMIS,<sup>3,64</sup> may already be having a positive effect here. However, guideline-use monitoring systems will need to take such problems into account, perhaps by having layers of complexity as well as layers of information for different types of organisational user. Thus, for example, a general practice that is at an early stage of developing guideline-use monitoring may use a very limited number of review criteria, whereas a practice with more experience may be routinely capturing and using more detailed information from an extended set of review criteria and associated measures of health outcome.

Nevertheless, in looking to the future, there could be real opportunities for a useful, non-intrusive monitoring process offered by the implementation of the NHS Information Strategy. Although the data are difficult to come by, there is an increasing use of electronic information in primary care and this is likely to be the key to accessing the information required for guideline-use monitoring.

The costs of monitoring, and indeed of other quality initiatives, were frequently referred to in the interviews and the survey. It is surprisingly difficult to identify studies looking at the real costs of clinical audit, and there is even less research looking at the costs and benefits of a quality process, as did Robinson and colleagues<sup>47</sup> in using thrombolysis after suspected myocardial infarction



as a model. By developing a cost framework from the literature, which could be applied to guideline-use monitoring, it was possible to identify the main areas of cost impact when establishing and using a monitoring system.

What is more difficult to assess is the impact of adding a new task such as monitoring to other quality improvement tasks in the organisation. It may be that there is limited impact in a practice that has efficient information systems already in place (requiring additional marginal costs only) and where resource-intensive tasks such as deriving review criteria and developing computer templates are managed at a national or at a PCG level. However, analysis and the provision of information will require training and human resources, either available within the practice or from outside, as many PCAGs already do.

Perspectives varied on what were the most difficult barriers to implementing guideline-use monitoring, but all of these could be classed under the theme of 'people issues'. Both GPs and practice nurses saw lack of time as a principal barrier to implementing monitoring (and to new quality improvement initiatives in general). Even the most enthusiastic respondents gave an impression of a hard-pressed service where new initiatives rarely came with new resources. Whatever the facts of the case, implementation of guideline-use monitoring (and perhaps guideline use) faces a barrier if the perception of front-line staff is that the process would increase the effort required to provide benefits.

Possibly the most important theme to arise from the findings in relation to barriers to the implementation of guideline-use monitoring relates to interpersonal or 'people issues'. For those who had management responsibilities, the kernel of the issue was often described as "winning hearts and minds". Respondents from general practice also made the point that it was about the philosophy of the practice team and the recognition of the relevance of reviewing quality of care through such mechanisms as guideline-use monitoring. At the general practice level the driver for implementing monitoring is the relevance that the subsequent information has to the everyday business of providing good quality of care for patients. Since it is from this basis of information that any performance monitoring information will come, the primary focus of monitoring should be to provide clinical teams with useful information in the most efficient manner to serve their needs.

## Is guideline-use monitoring feasible in the NHS?

Although the case studies on using review criteria and outcome measure were limited because of the available resources and demands on clinician time, there were some important findings relating to the feasibility of guideline-use monitoring.

While the literature shows that evidence-based review criteria can be developed in a number of ways, less information is available about how these can be used to monitor care in conformance with guideline recommendations. In a study in the north of England,<sup>29</sup> considerable support was provided to enable practice teams to collect information on just three review criteria on asthma and on stable angina, together with associated health outcome measures, showing quite variable conformance with the guideline recommendation.

In the case studies in this project most of the eight doctors were able to collect review criteria data for up to 30 patients without additional external support. Capturing patient-provided outcome data proved more problematic. Reasons for this are unclear but may be due to a lack of systems (the questionnaires had to be dispensed by busy clinicians). Alternatively, patients may have felt unwilling to take part in a research project. Informed consent was needed for the research team to be able to use the anonymous information and this potential barrier would not be present when a practice is monitoring the quality of the care it provides.

Despite these difficulties, the use of review criteria as a guideline monitoring tool provided good evidence that practices were conforming with the recommendations of the guidelines, using eight criteria reflecting the key recommendations of the chosen guidelines. Furthermore, there was enough variance within the results to demonstrate that differences in the process of recording care could be identified. For example, there was considerable, but not full, conformance with all of the criteria and appropriate use of the 'contraindicated' or 'not applicable' headings.

Furthermore, since the process data were retrospective over the previous 12 months, the clinical teams had not had a chance to go through a formal process of adopting the guideline. It could be argued that the guideline was not a necessary tool in this process, providing only the background information to support the review

criteria, which actually closely reflected their current practice. If guideline-use monitoring is going to use guideline-based review criteria for common conditions, perhaps it is primarily agreement with the criteria that is required among and within the clinical teams, rather than a more formal and extensive process of agreeing the implementation of a full clinical guideline. Where new guidelines are being disseminated, however, the establishment of a monitoring process may be best delayed until the completion of an implementation process, when a baseline measure can be taken on which to assess any future change in conformance with the recommendations.

Using patient-centred outcome measures in the eight case study sites was more difficult. Although the data showed enough variance to be able to demonstrate a range of health status, the information was more difficult to capture. It was also more difficult to analyse, and any routine process of outcome data capture of this sort would require training in analysis and interpretation of the data. Assessing patient outcomes is likely to be a later stage of any guideline-use monitoring initiative in the NHS. Yet this should not be ignored, for good process of care may not always mean good outcomes for patients, or clinicians and patients may have differing views about what may constitute a good outcome.

## What does a guideline-use monitoring framework for primary care look like?

Set in the context of the current NHS, it seems as though guideline-use monitoring will become a routine practice. Policy demands for evidence that national initiatives, such as NSFs or Health Improvement Programmes (now called Health Improvement Modernisation Plans), are being adhered to will increase demands for performance monitoring data related to patient care. Added to this, the proliferation of national clinical guidelines with associated review criteria brings with it the policy imperative to use these to drive good-quality patient care, from both a national policy perspective and a professional perspective.

Some of what might be called the freedoms of the framework proposed by the AHCP, such as choosing guidelines and developing criteria, are increasingly being lost under these NHS policy drives. However, it might be argued that the effort freed up by not having to develop techniques can be refocused locally to develop and use practical

monitoring systems based, where possible, on routine data.

## The principles of a monitoring framework

A limited number of general principles apply to the framework for monitoring local guideline use. It should:

- serve (and be seen to serve) the purposes of the users
- contain the minimum amount of information needed to serve the purposes
- be capable, where possible, of serving the needs of more than one group of users, perhaps using subsets of data
- be capable of being used at different levels by the same type of user, to accommodate different levels of skills and need
- where possible, use data already collected for other purposes, but be capable of accommodating other types of information (e.g. directly from patients).

## A model guideline-use monitoring framework

Review of the evidence, the participant studies and the case studies suggests that the establishment and running of a framework within a general practice as part of a PCT may comprise the steps set out in *Box 13*.

## What is the future of guideline-use monitoring in primary care?

There is much in the process of guideline-use monitoring that will draw on the techniques and strengths of clinical audit and, in “an organisation with a memory”,<sup>65</sup> these approaches and skills will be available to primary care teams and to PCTs. There are, perhaps, three main differences from the way in which clinical audit has been undertaken in primary care, all of them recognised by respondents in both the survey and the interviews.

First, the term monitoring implies a routine, in which a regular (although not necessarily frequent) review is undertaken of conformance with the recommendations and expectations (outcomes) of clinical guidelines. Not only does this require data capture systems to be set in place in the general practice and the PCT, but it also implies an obligation to review regularly the results of care.

Second, the NHS changes<sup>4</sup> mean that more demands for monitoring will be made rather than

**BOX 13** A model guideline-use monitoring framework

- Prioritise and choose the purpose(s) for which monitoring is to be undertaken, recognising the requirements, rights and concerns of users, and the implications of increased workload
- Determine which available guidelines and performance measures (including review criteria) most closely approximate to the purpose. Since predetermined guideline recommendations and externally derived review criteria will almost certainly be used, it is unlikely that these tools will exactly fit local requirements
- Access or develop locally sensitive performance measures where appropriate (for example, to accommodate different levels of experience between practices)
- Identify the sources of information needed to populate the proposed performance measures
- Determine the frequency of the data capture, consistent with minimising workload
- Determine the acceptable methods of data capture (which may include paper-based methods) and methods of sharing data between institutions where appropriate
- Identify the appropriate resources, including training, needed to capture the data and turn them into the type of information required by users
- Review the planned process with data providers and users (who may be different people or groups of people) to identify and resolve any perceived problems
- Pilot the process and review to make required changes
- Regularly evaluate the process of monitoring to ensure that it efficiently meets (possibly changing) user needs

less, and that there will be an increasing focus on PCT-wide programmes that are similar in nature to the programmes undertaken by other trusts.

Third, performance monitoring of conformance with guidelines by PCTs of general practices and of PCTs by Strategic Health Authorities will increase and will use data that were previously only used for clinical audit purposes.

Although the techniques and processes for guideline-use monitoring are at an early stage, and there is much to do in improving information systems and resourcing the process before monitoring works in everyday practice, it is a developing field to which the findings of this report can contribute. Implementing guideline-use monitoring, and making the most of the results to improve patient care and outcomes, will require the type of cultural change and quality improvement that are at the heart of the “organisation with a memory”<sup>65</sup> initiative.

## Recommendations for research

The following research questions arise from the project:

- To what extent should patient concordance with the guideline recommendations be taken into account in the assessment of clinician conformance with guideline recommendations?
- What are the costs and benefits to patient care of guideline-use monitoring?
- What are the most efficient methods of developing valid and reliable review criteria which are policy (NSFs) and evidence (guidelines) based?
- Are review criteria more useful than guidelines in improving quality of care?
- What additional benefits to patient care can be offered by monitoring patient-centred health outcome in addition to process of care, and at what cost?





## Acknowledgements

This study was supported by the NHS Research and Development Health Technology Assessment Programme.

We are grateful to Professor Martin Eccles, Professor Jeremy Grimshaw and Professor James

Mason for their contributions to the early development of the study. In particular, we would like to thank the many health professionals who gave up valuable time to make the study possible. Our thanks also go to Oona Hunt and Karen Beck who assisted with the production of this report.





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## Introduction

Good morning/afternoon, as you are already aware, the aim of this interview is to identify your views regarding the monitoring of guideline use in primary care. This interview is being conducted as part of a Health Technology Assessment project to develop a prototype system for monitoring clinical guideline implementation in general practice through routine data collection. We are interested in identifying, from potential users of any monitoring model, the issues involved in the implementation of guidelines in general practice

and the monitoring of guideline use. The interview should last about 1 hour. It will take a semistructured format. We are trying to gather what you think is important with regard to monitoring. The interview is entirely private and confidential and your name will not be linked to anything you say here. Do you have any objections to my taping our conversation? Thank you.

- (1) I'd like to begin by clarifying your job title.
- (2) Where are you located?
- (3) What number of GPs does your MAAG cover?
- (4) Could you tell me a bit about your work?

## I. Experience of monitoring

Could we start by discussing your own experiences of monitoring?

<p>(1) How would you define monitoring – what do you understand by monitoring?</p>	
<p>(2) What involvement, if any, do you have with monitoring?</p>	
<p>(3) Could you tell me a bit more about this:</p> <p>What information is collected?</p> <p>Who else is involved?</p> <p>How is this collected?</p>	
<p>(4) Can you think of one example of a monitoring project that has gone well and one example of one that has gone wrong?</p> <p>Positive</p> <p>Negative</p>	

(5) Is there anything else that you'd like to tell me about these?	
(6) What do you think are the important issues about monitoring for general practice?	
(7) How would you say your views/involvement in monitoring relate to the experience of others, e.g. GPs, PCG members?	

## II. Experience of guidelines

I'd now like to move on to talk about guidelines and your experience of them.

(1) Could you map out the different types of guidelines that are used in this area?	
(2) What are the positives and negatives of different types of guidelines?	
(3) What experience of different types of guidelines have you had in your work?	
(4) What tend to be the problems/advantages of using guidelines in practice?	
(5) What seems to work well in terms of using guidelines in general practice?	
(6) Which other people work with guidelines in your organisation/area? Do you work with them?  Tell me a bit about it.	

(7) How do they relate to evidence-based medicine and clinical effectiveness in general?	
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### III. Views on monitoring of guidelines

I'd like to now move on to talk about your views on monitoring of guidelines.

(1) Would you say that it is a good thing to monitor guideline usage?	
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(2) What do you think are the potential gains of monitoring guidelines?	
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Level of the clinician

Practice level

PCG level

(3) Do you think that monitoring necessarily leads to improved quality of care?	
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(4) How do you think monitoring links to proposed NHS changes, e.g. clinical governance/clinical effectiveness?	
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### IV. Ideal model of monitoring

We've talked about your actual experiences of monitoring and guidelines, what would you think might be the ideal?

(1) What sort of information would you want to collect to see if the guideline was being used?	
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(2) Who would be involved with this?	
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(3) What would be the time demands of an ideal model?	
(4) What do you think the cost issues involved in this process may be? What would be the costs of an ideal model?	
(5) Do you have any views on what type of system might be best to use (e.g. opinions on computer versus pen & paper)?	
(6) When would you collect the data (e.g. retrospectively or prospectively)?	

## V. Practical model of monitoring

Having discussed what would be ideal, what would you say is actually practical?

(1) What sort of information could you collect to see if the guideline was being used?	
(2) Who would be involved in the routine collection of data?	
(3) How much time do you think this would involve?	
(4) What would be the cost of this?	
(5) How might these data be collected and incorporated routinely into practice; i.e. when would you collect the data?	
(6) What do you think might be the problems with this?	

(7) Are there any other issues regarding monitoring guideline implementation in general practice which you feel we haven't covered?	
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## VI. Use of data

Finally, in discussing the collection of information, it is important to consider what will be done with that information once it has been collected.

(1) What would you say would be the best use of the data?	
(2) Who do you think should have access to the data that have been collected?	
(3) How should findings be disseminated?	
(4) Who should be responsible for the dissemination of findings?	
I've covered the specific areas I wanted to ask you about – is there anything else about those areas that we might have left out?	
Is there anything else, in more general terms, that you want to add?	
Thank you very much for your help.	



**Appendix 2**  
**Survey instrument**

**Questionnaire**

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# **How to Monitor Guideline Use in Primary Care**

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*A specialised survey of general practitioners, practice nurses,  
Primary Care Group leads,  
Medical Audit Advisory Group facilitators (and similar organisations)  
and health commissioners to determine the important issues regarding  
monitoring guidelines in Primary Care*

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We have sent this to you as .....  
If this is incorrect please amend.

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**Section of Public Health**

*July 1999*



The University of Sheffield

We are interested in identifying your views regarding the use of clinical guidelines in general practice and the monitoring of clinical guideline use. This questionnaire is intended to cover the views of both practitioners and commissioners of health care services.

When answering the following questions, we would ask you to answer in the role in which you were recruited to the study (see front cover).

The questionnaire is divided into six sections. These will cover:

1. Your current level of involvement in the collection of data for quality improvement (if any);
2. The impact of new NHS changes on current practice;
3. Your views regarding clinical guidelines and the use of clinical guidelines;
4. Your views regarding issues surrounding the monitoring of clinical guideline use as part of quality improvement;
5. Your thoughts concerning appropriate systems for this and;
6. Any concerns you may have regarding the collection of data.

<b>Collection of Data to be used for Quality Improvement and Clinical Audit</b>													
<p>1. We are interested in developing a picture of the different types of information that are currently collected routinely in your everyday practice. If you are not directly involved in the collection of data but members of your team are, then we would also like to know about this. Please indicate, for each type of data listed below, if this is collected and if so, by whom, using what method.</p>													For Office Use Only
	<b>GP</b>	<b>Nurses</b>	<b>Health visitor</b>	<b>Other clinical staff</b>	<b>Practice manager</b>	<b>Other administration staff</b>	<b>Other</b>	<b>Not Applicable</b>	<b>Computer</b>	<b>Pen &amp; paper</b>	<b>Other</b>	<b>Not collected</b>	<b>Not applicable</b>
<b>Clinical data</b>													
<b>Audit data</b>													
<b>Prescribing data</b>													
<b>Administrative data</b>													
<b>Other</b>													
Other data ..... ..... Other personnel ..... ..... Other systems ..... .....													

The following questions are designed to establish a clearer picture of the collection of clinical data with which you may be involved. Please answer these questions in regards to your own current involvement in the collection of clinical data or that of your team members/colleagues. If you are not currently involved in the collection of clinical data please answer the following questions as you think would indicate an ideal method of clinical data collection.

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**Recent NHS Changes**

Recent NHS changes have included Primary Care Groups (PCGs), clinical governance, the launch of the National Institute for Clinical Excellence (NICE), and the forthcoming National Service Frameworks (NSFs).

<p>6. What changes, if any, have already been made by you in terms of data collection relevant to general practice?</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>	
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<p>7. Do you think these recent NHS changes, as a whole, will have an impact on the way that your practice collect data?</p> <p><b>Yes</b> – <input type="checkbox"/></p> <p>These changes will be to .....</p> <p style="text-align: center;"><i>[please tick all applicable answers]</i></p> <table border="0"> <tr> <td>collect more data</td> <td><input type="checkbox"/></td> <td>collect different types of data</td> <td><input type="checkbox"/></td> </tr> <tr> <td>use different systems for data collection</td> <td><input type="checkbox"/></td> <td>involve different people in data collection</td> <td><input type="checkbox"/></td> </tr> <tr> <td>other – please specify .....</td> <td></td> <td></td> <td><input type="checkbox"/></td> </tr> </table> <p><b>No</b> – please give reasons .....</p> <p><b>Don't know</b> – please give reasons .....</p> <p>Any further comments.....</p>	collect more data	<input type="checkbox"/>	collect different types of data	<input type="checkbox"/>	use different systems for data collection	<input type="checkbox"/>	involve different people in data collection	<input type="checkbox"/>	other – please specify .....			<input type="checkbox"/>	<p>For Office Use Only</p>				
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<p>8. What general concerns, if any, do you have regarding the effect of current changes on your everyday practice?</p> <p style="text-align: center;"><i>[please tick all applicable answers]</i></p> <table border="0"> <tr> <td>More data collection</td> <td><input type="checkbox"/></td> <td>Uncertain benefits to practice</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Financial implications</td> <td><input type="checkbox"/></td> <td>Inability of current systems to handle demand</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Increased time pressures</td> <td><input type="checkbox"/></td> <td></td> <td></td> </tr> <tr> <td>Other – please specify .....</td> <td></td> <td></td> <td><input type="checkbox"/></td> </tr> </table>	More data collection	<input type="checkbox"/>	Uncertain benefits to practice	<input type="checkbox"/>	Financial implications	<input type="checkbox"/>	Inability of current systems to handle demand	<input type="checkbox"/>	Increased time pressures	<input type="checkbox"/>			Other – please specify .....			<input type="checkbox"/>	
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**Guidelines**

Over the last few years there has been increasing professional and policy interest in clinical guidelines to promote effective and cost-effective clinical care. One of the principal means of enabling improvement in health care is seen to be the development and use of primary care relevant clinical practice guidelines. We are interested in knowing your current practice with regards clinical guidelines and your views of clinical guidelines

<p>9. Do you use/have used clinical guidelines in your work and if so which type(s)?</p> <p><b>Yes</b> – <input type="checkbox"/></p> <p>These guidelines are .....</p> <p style="text-align: center;"><i>[please tick all applicable answers]</i></p> <table border="0"> <tr> <td>local adaptations of national guidelines</td> <td><input type="checkbox"/></td> <td>guidelines/protocols developed in the practice</td> <td><input type="checkbox"/></td> </tr> <tr> <td>national guidelines</td> <td><input type="checkbox"/></td> <td>locally developed guidelines e.g. by Health Authority, MAAG</td> <td><input type="checkbox"/></td> </tr> </table> <p><b>No</b> – please explain why .....</p>	local adaptations of national guidelines	<input type="checkbox"/>	guidelines/protocols developed in the practice	<input type="checkbox"/>	national guidelines	<input type="checkbox"/>	locally developed guidelines e.g. by Health Authority, MAAG	<input type="checkbox"/>					
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<p>10a. Do you work with other people in your organisation who use clinical guidelines?</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>													
<p>10b. The guidelines used are .....</p> <p style="text-align: center;"><i>[please tick all applicable answers]</i></p> <table border="0"> <tr> <td>guidelines/protocols developed in the practice</td> <td><input type="checkbox"/></td> <td>local adaptations of national guidelines</td> <td><input type="checkbox"/></td> </tr> <tr> <td>national guidelines</td> <td><input type="checkbox"/></td> <td></td> <td></td> </tr> <tr> <td>other – please specify .....</td> <td></td> <td></td> <td><input type="checkbox"/></td> </tr> </table>	guidelines/protocols developed in the practice	<input type="checkbox"/>	local adaptations of national guidelines	<input type="checkbox"/>	national guidelines	<input type="checkbox"/>			other – please specify .....			<input type="checkbox"/>	
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other – please specify .....			<input type="checkbox"/>										

<p>10c. These guidelines are used by .....</p> <p>.....</p> <p>.....</p>	<p>For Office Use Only</p>
<p>11. How do you think that guidelines for use in practice should be selected?</p> <p><i>[please tick all applicable answers]</i></p> <p>Personal interest <input type="checkbox"/> Practice policy <input type="checkbox"/></p> <p>Local priorities <input type="checkbox"/> National priorities <input type="checkbox"/></p> <p>Other – please specify..... <input type="checkbox"/></p>	
<p>12. Who do you think should be involved in the selection process?</p> <p><i>[please tick all applicable answers]</i></p> <p>GP <input type="checkbox"/> Nurse <input type="checkbox"/></p> <p>Health visitor <input type="checkbox"/> Other clinical staff <input type="checkbox"/></p> <p>Practice manager <input type="checkbox"/> Other administrative staff <input type="checkbox"/></p> <p>Other – please specify..... <input type="checkbox"/></p>	
<p>13. Do you see any of the following as the benefits of guideline use in practice?</p> <p><i>[please tick all applicable answers]</i></p> <p>Improve patient care <input type="checkbox"/> Aid teamwork/shared care <input type="checkbox"/></p> <p>Aids decision making <input type="checkbox"/> No benefits <input type="checkbox"/></p> <p>Good basis for audit <input type="checkbox"/> Cost-effective <input type="checkbox"/></p> <p>Reduce inappropriate variation in care <input type="checkbox"/> Guidelines provide useful summaries of evidence <input type="checkbox"/></p> <p>Other – please specify ..... <input type="checkbox"/></p>	
<p>14. Do you consider any of the following to be the difficulties in using guidelines?</p> <p><i>[please tick all applicable answers]</i></p> <p>Too many guidelines <input type="checkbox"/> Lack of confidence in the evidence-base <input type="checkbox"/></p> <p>Not up-dated often enough <input type="checkbox"/> Too prescriptive/inflexible <input type="checkbox"/></p> <p>Guidelines are not provided in an accessible format <input type="checkbox"/> Not applicable to primary care setting <input type="checkbox"/></p> <p>Not always possible to apply to individual patients <input type="checkbox"/> Not always relevant to everyday practice <input type="checkbox"/></p> <p>Too long <input type="checkbox"/> No difficulties <input type="checkbox"/></p> <p>Other – please specify ..... <input type="checkbox"/></p>	
<p>15. How do you think recommendations/evidence from guidelines should be put into practice?</p> <p><i>[please tick all applicable answers]</i></p> <p>Develop a protocol <input type="checkbox"/> Use as a support tool <input type="checkbox"/></p> <p>Don't implement guidelines <input type="checkbox"/> Use to develop an audit protocol <input type="checkbox"/></p> <p>Develop disease specific reminders: <input type="checkbox"/></p> <p>Is this specifically ..... <input type="checkbox"/></p> <p>on screen <input type="checkbox"/> paper <input type="checkbox"/></p> <p>Other – please specify..... <input type="checkbox"/></p>	

**Quality Improvement**

One element of the process of facilitating quality improvement through guideline use is through the monitoring of routinely collected data. This can be done in a variety of ways, at different levels.

16. Please indicate whether you agree with any of the following statements regarding monitoring:	For Office Use Only
Monitoring guidelines use could .....	PCG level      Health Authority level
provide information about care provided	<input type="checkbox"/> <input type="checkbox"/>
improve patient care	<input type="checkbox"/> <input type="checkbox"/>
be seen to have no benefit to practice	<input type="checkbox"/> <input type="checkbox"/>
create too much work	<input type="checkbox"/> <input type="checkbox"/>
improve consistency of care across practice team	<input type="checkbox"/> <input type="checkbox"/>
help practice meet the demands of clinical governance	<input type="checkbox"/> <input type="checkbox"/>
be seen as a policy exercise	<input type="checkbox"/> <input type="checkbox"/>
improve performance across practice team	<input type="checkbox"/> <input type="checkbox"/>
be seen as a possible 'stick to beat'	<input type="checkbox"/> <input type="checkbox"/>
not be viewed as a low priority	<input type="checkbox"/> <input type="checkbox"/>
create uncertainty over who should have access to results	<input type="checkbox"/> <input type="checkbox"/>
other – please specify .....	<input type="checkbox"/> <input type="checkbox"/>

#### Developing a Useful System for Guideline Use

To be able to monitor clinical guideline use, data systems need to be in place to support this process. The following questions are concerned with the salient features that any system would need to be comprised of.

17. Please rank the following items, in order of importance, with 5 being the most important and 1 being the least important:	
An ideal system would .....	
have a small number of items <input type="checkbox"/>	have explicit aims <input type="checkbox"/>
be specific to primary care <input type="checkbox"/>	be a flexible system <input type="checkbox"/>
have had the data set developed by the users <input type="checkbox"/>	
18. Please rank the following items, in order of importance, with 3 being the most important and 1 being the least important:	
The data collection process would .....	
have to be unobtrusive <input type="checkbox"/>	rely on good records <input type="checkbox"/>
have to be time efficient <input type="checkbox"/>	
19. Do you foresee any difficulties which might prevent the effective use of such guideline monitoring systems?	
<i>[please tick all applicable answers]</i>	PCG level      Health Authority level
State of records in general practice	<input type="checkbox"/> <input type="checkbox"/>
Accuracy of data entry on to practice computer systems	<input type="checkbox"/> <input type="checkbox"/>
Diversity of practice computing systems	<input type="checkbox"/> <input type="checkbox"/>
Identifying the items of data to collect	<input type="checkbox"/> <input type="checkbox"/>
Relevance	<input type="checkbox"/> <input type="checkbox"/>
Time demands	<input type="checkbox"/> <input type="checkbox"/>
Fear of policing by external agencies	<input type="checkbox"/> <input type="checkbox"/>
Motivation of practice staff	<input type="checkbox"/> <input type="checkbox"/>
Rate of introduction	<input type="checkbox"/> <input type="checkbox"/>

	PCG level	Health Authority level	For Office Use Only
Involvement of stakeholders	<input type="checkbox"/>	<input type="checkbox"/>	
Intrusion into patient/doctor consultation	<input type="checkbox"/>	<input type="checkbox"/>	
Lack of adequate funding	<input type="checkbox"/>	<input type="checkbox"/>	
Degree of training required	<input type="checkbox"/>	<input type="checkbox"/>	
Other – please specify .....	<input type="checkbox"/>	<input type="checkbox"/>	

**Concerns Regarding Data Collection**

There are systems in place to ensure confidentiality, e.g. Caldicott Guardians. We recognise, however, that you may have some concerns regarding issues of confidentiality and data collection systems. The following question is designed to address any concern you may have.

20. What concerns, if any, do you have about the uses of any collected data?			
Inappropriate use of the data	<input type="checkbox"/>	None	<input type="checkbox"/>
Resource decisions	<input type="checkbox"/>	Performance monitoring	<input type="checkbox"/>
Confidentiality – is this specifically .....	<input type="checkbox"/>	Lack of clarity of purpose (e.g. by the Health Authority or PCG)	<input type="checkbox"/>
Patient confidentiality	<input type="checkbox"/>		
Practitioner confidentiality	<input type="checkbox"/>		
Other – please specify .....			<input type="checkbox"/>

**Thank you**

If you have any additional comments, please add them onto the attached sheet

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## Questionnaire

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# How to Monitor Guideline Use in Primary Care

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*A specialised survey of general practitioners, practice nurses,  
Primary Care Group leads,  
Medical Audit Advisory Group facilitators (and similar organisations)  
and health commissioners to determine the important issues regarding  
monitoring guidelines in Primary Care*

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We have sent this to you as .....  
If this is incorrect please amend.

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The University of Sheffield

Section of Public Health

July 1999





This questionnaire is part of a project aimed at evaluating a system for monitoring clinical guideline use in general practice through routine data collection. We are interested in identifying your views regarding the use of clinical guidelines in general practice and ways in which usage might be monitored.

When answering the following questions, we would ask you to answer in the role in which you were recruited to the survey (see front cover).

The questionnaire is divided into six sections. These will cover:

1. Your current level of involvement in the collection of data for quality improvement (if any);
2. The impact of new NHS changes on aspects of your current practice;
3. Your views regarding clinical guidelines and the use of clinical guidelines;
4. Your views regarding issues surrounding the monitoring of clinical guideline use as part of quality improvement;
5. Your thoughts concerning appropriate systems for this and;
6. Any concerns you may have regarding the collection of data.

Collection of Data to be used for Quality Improvement and Clinical Audit																																																																																					
<p>1. We are interested in developing a picture of the different types of information that are currently collected routinely in your practice. As part of this, we would also like to know how these items are collected and the current responsibilities of members of your practice with regards data collection. Please indicate, for each type of data listed below, if this is collected in your practice and if so, by whom, using what method.</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="width: 20%;"></th> <th style="width: 5%;">GP</th> <th style="width: 5%;">Nurses</th> <th style="width: 5%;">Health visitor</th> <th style="width: 5%;">Other clinical staff</th> <th style="width: 5%;">Practice manager</th> <th style="width: 5%;">Other administration staff</th> <th style="width: 5%;">Other</th> <th style="width: 5%;">Not Applicable</th> <th style="width: 5%;">Computer</th> <th style="width: 5%;">Pen &amp; paper</th> <th style="width: 5%;">Other</th> <th style="width: 5%;">Not collected</th> <th style="width: 5%;">Not applicable</th> </tr> </thead> <tbody> <tr> <td><b>Clinical data</b></td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td><b>Audit data</b></td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td><b>Prescribing data</b></td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td><b>Administrative data</b></td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td><b>Other</b></td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> </tbody> </table> <p style="margin-left: 20px;">Other data .....</p> <p style="margin-left: 20px;">Other personnel .....</p> <p style="margin-left: 20px;">Other systems .....</p>		GP	Nurses	Health visitor	Other clinical staff	Practice manager	Other administration staff	Other	Not Applicable	Computer	Pen & paper	Other	Not collected	Not applicable	<b>Clinical data</b>														<b>Audit data</b>														<b>Prescribing data</b>														<b>Administrative data</b>														<b>Other</b>														<p>For Office Use Only</p>
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The following questions are designed to establish a clearer picture of the collection of clinical data with which you may be involved. Please answer these questions in regards to your own current involvement in the collection of clinical data.

If you are not currently involved in the collection of clinical data please answer the following questions as you think would indicate an ideal method of clinical data collection.

<p>2. What types of data are usually collected?</p> <p style="text-align: center;"><i>[please tick all applicable answers]</i></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;"></th> <th colspan="2" style="text-align: center; border-bottom: 1px solid black;">During consultation</th> <th colspan="2" style="text-align: center; border-bottom: 1px solid black;">Outside of consultation</th> </tr> <tr> <th></th> <th style="text-align: center; border-bottom: 1px solid black;">Actual</th> <th style="text-align: center; border-bottom: 1px solid black;">Ideal</th> <th style="text-align: center; border-bottom: 1px solid black;">Actual</th> <th style="text-align: center; border-bottom: 1px solid black;">Ideal</th> </tr> </thead> <tbody> <tr> <td>Process of care data</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Outcome of care data</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Referral data</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Other – please specify .....</td> <td colspan="4"></td> </tr> </tbody> </table>		During consultation		Outside of consultation			Actual	Ideal	Actual	Ideal	Process of care data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Outcome of care data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Referral data	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other – please specify .....					<p>For Office Use Only</p>
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<p>3. What do you think should be the purpose of this data collection – either actual or ideal?</p> <p>Process of care data .....</p> <p>.....</p> <p>Outcome of care data .....</p> <p>.....</p> <p>Referral data .....</p> <p>.....</p> <p>Other .....</p> <p>.....</p>																															
<p>4. What influences the selection process of these types of data – either actual or ideal?</p> <p style="text-align: center;"><i>[please tick all applicable answers]</i></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;"></th> <th style="text-align: center; border-bottom: 1px solid black;">Process of care data</th> <th style="text-align: center; border-bottom: 1px solid black;">Outcome of care data</th> <th style="text-align: center; border-bottom: 1px solid black;">Referral data</th> <th style="text-align: center; border-bottom: 1px solid black;">Other</th> </tr> </thead> <tbody> <tr> <td>Personal interest</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Practice policy</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Local priorities</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>National priorities</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Other – please specify .....</td> <td colspan="4"></td> </tr> </tbody> </table>		Process of care data	Outcome of care data	Referral data	Other	Personal interest	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Practice policy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Local priorities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	National priorities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other – please specify .....					
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<p>5. What is usually done with these data – either actual or ideal?</p> <p style="text-align: center;"><i>[please tick all applicable answers]</i></p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;"></th> <th style="text-align: center; border-bottom: 1px solid black;">Process of care data</th> <th style="text-align: center; border-bottom: 1px solid black;">Outcome of care data</th> <th style="text-align: center; border-bottom: 1px solid black;">Referral data</th> <th style="text-align: center; border-bottom: 1px solid black;">Other</th> </tr> </thead> <tbody> <tr> <td>Changes made to own personal practice</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Discussion within practice team</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Changes made to practice protocols</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td>Other – please specify</td> <td colspan="4"></td> </tr> </tbody> </table>		Process of care data	Outcome of care data	Referral data	Other	Changes made to own personal practice	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Discussion within practice team	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Changes made to practice protocols	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other – please specify										
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**Recent NHS Changes**

Recent NHS changes have included Primary Care Groups (PCGs), clinical governance, the launch of the National Institute for Clinical Excellence (NICE), and the forthcoming National Service Frameworks (NSFs).

<p>6. What changes, if any, have already been made within your practice in terms of data collection, in response to these changes?</p> <p>.....</p> <p>.....</p> <p>.....</p> <p>.....</p>	
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<p>7. Do you think these recent NHS changes, as a whole, will have an impact on the way that you collect data relevant to general practice?</p> <p><b>Yes</b> – <input type="checkbox"/></p> <p>These changes will be to .....</p> <p style="text-align: center;"><i>[please tick all applicable answers]</i></p> <table border="0"> <tr> <td>collect more data</td> <td><input type="checkbox"/></td> <td>collect different types of data</td> <td><input type="checkbox"/></td> </tr> <tr> <td>use different systems for data collection</td> <td><input type="checkbox"/></td> <td>involve different people in data collection</td> <td><input type="checkbox"/></td> </tr> <tr> <td>other – please specify .....</td> <td></td> <td></td> <td><input type="checkbox"/></td> </tr> <tr> <td><b>No</b> – please give reasons .....</td> <td></td> <td></td> <td><input type="checkbox"/></td> </tr> <tr> <td><b>Don't know</b> – please give reasons .....</td> <td></td> <td></td> <td><input type="checkbox"/></td> </tr> <tr> <td>Any further comments .....</td> <td></td> <td></td> <td></td> </tr> </table>	collect more data	<input type="checkbox"/>	collect different types of data	<input type="checkbox"/>	use different systems for data collection	<input type="checkbox"/>	involve different people in data collection	<input type="checkbox"/>	other – please specify .....			<input type="checkbox"/>	<b>No</b> – please give reasons .....			<input type="checkbox"/>	<b>Don't know</b> – please give reasons .....			<input type="checkbox"/>	Any further comments .....				<p>For Office Use Only</p>
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<p>8. What general concerns, if any, do you have regarding the effect of current changes on practice?</p> <p style="text-align: center;"><i>[please tick all applicable answers]</i></p> <table border="0"> <tr> <td>More data collection</td> <td><input type="checkbox"/></td> <td>Increased time pressures</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Financial implications</td> <td><input type="checkbox"/></td> <td>Inability of practice information systems to handle demand</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Uncertain benefits to practice</td> <td><input type="checkbox"/></td> <td></td> <td></td> </tr> <tr> <td>Other – please specify .....</td> <td></td> <td></td> <td><input type="checkbox"/></td> </tr> </table>	More data collection	<input type="checkbox"/>	Increased time pressures	<input type="checkbox"/>	Financial implications	<input type="checkbox"/>	Inability of practice information systems to handle demand	<input type="checkbox"/>	Uncertain benefits to practice	<input type="checkbox"/>			Other – please specify .....			<input type="checkbox"/>									
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**Guidelines**

Over the last few years there has been increasing professional and policy interest in clinical guidelines to promote effective and cost-effective clinical care. One method of helping bring about improvements in health care is seen to be the development and use of primary care relevant clinical practice guidelines. We are interested in knowing your current practice with regards clinical guidelines and your views of clinical guidelines

<p>9. What types of clinical guidelines do you currently use in your every day management of patients?</p> <p style="text-align: center;"><i>[please tick all applicable answers]</i></p> <table border="0"> <tr> <td>Local adaptations of national guidelines</td> <td><input type="checkbox"/></td> <td>Guidelines/protocols developed in the practice</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Locally developed guidelines e.g. by Health Authority, MAAG</td> <td><input type="checkbox"/></td> <td>None – please go to question 11</td> <td><input type="checkbox"/></td> </tr> <tr> <td>National guidelines</td> <td><input type="checkbox"/></td> <td></td> <td></td> </tr> </table>	Local adaptations of national guidelines	<input type="checkbox"/>	Guidelines/protocols developed in the practice	<input type="checkbox"/>	Locally developed guidelines e.g. by Health Authority, MAAG	<input type="checkbox"/>	None – please go to question 11	<input type="checkbox"/>	National guidelines	<input type="checkbox"/>			
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<p>10a. Do you have a practice policy regarding the selection of guidelines?</p> <p style="text-align: center;"><i>[please tick all applicable answers]</i></p> <p><b>Yes</b></p> <table border="0"> <tr> <td>Personal interest</td> <td><input type="checkbox"/></td> <td>Practice policy</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Local priorities</td> <td><input type="checkbox"/></td> <td>National priorities</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other – please specify .....</td> <td></td> <td></td> <td><input type="checkbox"/></td> </tr> </table> <p><b>No</b></p>	Personal interest	<input type="checkbox"/>	Practice policy	<input type="checkbox"/>	Local priorities	<input type="checkbox"/>	National priorities	<input type="checkbox"/>	Other – please specify .....			<input type="checkbox"/>	
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<p>10b. If yes, who is involved in this selection process?</p> <p style="text-align: center;"><i>[please tick all applicable answers]</i></p> <table border="0"> <tr> <td>GP</td> <td><input type="checkbox"/></td> <td>Nurse</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Health visitor</td> <td><input type="checkbox"/></td> <td>Other clinical staff</td> <td><input type="checkbox"/></td> </tr> </table>	GP	<input type="checkbox"/>	Nurse	<input type="checkbox"/>	Health visitor	<input type="checkbox"/>	Other clinical staff	<input type="checkbox"/>					
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Practice manager <input type="checkbox"/>	Other administration staff <input type="checkbox"/>	For Office Use Only
Other – please specify .....	<input type="checkbox"/>	

The next two questions consider the potential benefits and the potential problems associated with the use of guidelines.

<p>11. Do you see any of the following as the benefits of guideline use in practice? <i>[please tick all applicable answers]</i></p> <table border="0" style="width: 100%;"> <tr> <td style="width: 45%;">Improve patient care <input type="checkbox"/></td> <td style="width: 10%;"></td> <td style="width: 45%;">Good basis for audit <input type="checkbox"/></td> </tr> <tr> <td>Aid teamwork/shared care <input type="checkbox"/></td> <td></td> <td>Cost-effective <input type="checkbox"/></td> </tr> <tr> <td>Reduce inappropriate variation in care <input type="checkbox"/></td> <td></td> <td>Guidelines provide useful summaries of evidence <input type="checkbox"/></td> </tr> <tr> <td>Aids decision making <input type="checkbox"/></td> <td></td> <td></td> </tr> <tr> <td>Other – please specify .....</td> <td></td> <td><input type="checkbox"/></td> </tr> </table>	Improve patient care <input type="checkbox"/>		Good basis for audit <input type="checkbox"/>	Aid teamwork/shared care <input type="checkbox"/>		Cost-effective <input type="checkbox"/>	Reduce inappropriate variation in care <input type="checkbox"/>		Guidelines provide useful summaries of evidence <input type="checkbox"/>	Aids decision making <input type="checkbox"/>			Other – please specify .....		<input type="checkbox"/>				
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Other – please specify .....		<input type="checkbox"/>																	
<p>12. Do you consider any of the following to be the difficulties in using guidelines? <i>[please tick all applicable answers]</i></p> <table border="0" style="width: 100%;"> <tr> <td style="width: 45%;">Too many guidelines <input type="checkbox"/></td> <td style="width: 10%;"></td> <td style="width: 45%;">Not up-dated often enough <input type="checkbox"/></td> </tr> <tr> <td>Lack of confidence in the evidence-base <input type="checkbox"/></td> <td></td> <td>Guidelines are not provided in an accessible format <input type="checkbox"/></td> </tr> <tr> <td>Too prescriptive/inflexible <input type="checkbox"/></td> <td></td> <td>Too long <input type="checkbox"/></td> </tr> <tr> <td>Not specific enough <input type="checkbox"/></td> <td></td> <td>Not always possible to apply to individual patients <input type="checkbox"/></td> </tr> <tr> <td>Not applicable to primary care setting/relevant to everyday practice <input type="checkbox"/></td> <td></td> <td></td> </tr> <tr> <td>Other – please specify .....</td> <td></td> <td><input type="checkbox"/></td> </tr> </table>	Too many guidelines <input type="checkbox"/>		Not up-dated often enough <input type="checkbox"/>	Lack of confidence in the evidence-base <input type="checkbox"/>		Guidelines are not provided in an accessible format <input type="checkbox"/>	Too prescriptive/inflexible <input type="checkbox"/>		Too long <input type="checkbox"/>	Not specific enough <input type="checkbox"/>		Not always possible to apply to individual patients <input type="checkbox"/>	Not applicable to primary care setting/relevant to everyday practice <input type="checkbox"/>			Other – please specify .....		<input type="checkbox"/>	
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<p>13. How do you adapt guidelines for use in practice? <i>[please tick all applicable answers]</i></p> <table border="0" style="width: 100%;"> <tr> <td style="width: 45%;">Develop a protocol <input type="checkbox"/></td> <td style="width: 10%;"></td> <td style="width: 45%;">Develop an audit protocol <input type="checkbox"/></td> </tr> <tr> <td>Develop disease specific reminders: <input type="checkbox"/></td> <td></td> <td></td> </tr> <tr> <td>Is this specifically ..... on screen <input type="checkbox"/></td> <td></td> <td>paper <input type="checkbox"/></td> </tr> <tr> <td>Other – please specify .....</td> <td></td> <td><input type="checkbox"/></td> </tr> </table>	Develop a protocol <input type="checkbox"/>		Develop an audit protocol <input type="checkbox"/>	Develop disease specific reminders: <input type="checkbox"/>			Is this specifically ..... on screen <input type="checkbox"/>		paper <input type="checkbox"/>	Other – please specify .....		<input type="checkbox"/>							
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<p>14. How are guidelines used in practice?</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 45%;">Used as a support tool <input type="checkbox"/></td> <td style="width: 10%;"></td> <td style="width: 45%;">Don't use guidelines <input type="checkbox"/></td> </tr> <tr> <td>Used as disease specific reminders <input type="checkbox"/></td> <td></td> <td></td> </tr> <tr> <td>Is this specifically ..... on screen <input type="checkbox"/></td> <td></td> <td>paper <input type="checkbox"/></td> </tr> <tr> <td>Other – please specify.....</td> <td></td> <td><input type="checkbox"/></td> </tr> </table>	Used as a support tool <input type="checkbox"/>		Don't use guidelines <input type="checkbox"/>	Used as disease specific reminders <input type="checkbox"/>			Is this specifically ..... on screen <input type="checkbox"/>		paper <input type="checkbox"/>	Other – please specify.....		<input type="checkbox"/>							
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**Quality Improvement**

One element of the process of facilitating quality improvement through guideline use is through the monitoring of routinely collected data. This can be done in a variety of ways, at different levels.

<p>15. Please tick to indicate whether you agree with any of the following statements regarding monitoring:</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Monitoring guidelines use could .....</td> <td style="width: 10%;"></td> <td style="width: 15%;">PCG level</td> <td style="width: 10%;"></td> <td style="width: 15%;">Practice level</td> </tr> <tr> <td>inform own practice about care provided</td> <td><input type="checkbox"/></td> <td></td> <td><input type="checkbox"/></td> <td></td> </tr> <tr> <td>improve patient care</td> <td><input type="checkbox"/></td> <td></td> <td><input type="checkbox"/></td> <td></td> </tr> </table>	Monitoring guidelines use could .....		PCG level		Practice level	inform own practice about care provided	<input type="checkbox"/>		<input type="checkbox"/>		improve patient care	<input type="checkbox"/>		<input type="checkbox"/>		
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	PCG level	Practice level	For Office Use Only
Monitoring guidelines use could .....			
be seen to have no benefit to practice	<input type="checkbox"/>	<input type="checkbox"/>	
create too much work	<input type="checkbox"/>	<input type="checkbox"/>	
improve consistency of care across practice team	<input type="checkbox"/>	<input type="checkbox"/>	
help practice meet the demands of clinical governance	<input type="checkbox"/>	<input type="checkbox"/>	
be seen as a policy exercise	<input type="checkbox"/>	<input type="checkbox"/>	
improve performance across practice team	<input type="checkbox"/>	<input type="checkbox"/>	
be seen as a possible 'stick to beat'	<input type="checkbox"/>	<input type="checkbox"/>	
be viewed as a low priority	<input type="checkbox"/>	<input type="checkbox"/>	
create uncertainty over who should have access to results	<input type="checkbox"/>	<input type="checkbox"/>	
other – please specify	<input type="checkbox"/>	<input type="checkbox"/>	

**Developing a Useful System for Guideline Use**

Data collection systems need to be in place to support guideline monitoring. The following questions are concerned with the salient features that any system would need to be comprised of.

<p>16. Please rank the following items, in order of importance, with 5 being the most important and 1 being the least important:</p> <p>An ideal system would .....</p> <p>have a small number of items <input type="checkbox"/> be specific to primary care <input type="checkbox"/></p> <p>have explicit aims <input type="checkbox"/> be a flexible system <input type="checkbox"/></p> <p>have had the data set developed by the users <input type="checkbox"/></p>																																														
<p>17. Please rank the following items, in order of importance, with 3 being the most important and 1 being the least important:</p> <p>The ideal data collection system would .....</p> <p>rely on good records <input type="checkbox"/> have to be time efficient <input type="checkbox"/></p> <p>keep duplicate entry to a minimum <input type="checkbox"/></p>																																														
<p>18. Do you foresee any difficulties which might prevent the effective use of such guideline monitoring systems?</p> <p style="text-align: center;"><i>[please tick all applicable answers]</i></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>PCG level</th> <th>Practice level</th> </tr> </thead> <tbody> <tr><td>State of records in general practice</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr><td>Accuracy of data entry on to practice computer systems</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr><td>Diversity of practice computing systems</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr><td>Identifying the items of data to collect</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr><td>Relevance to everyday practice</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr><td>Time demands</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr><td>Fear of policing by external agencies</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr><td>Motivation of practice staff</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr><td>Rate of introduction</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr><td>Involvement of stakeholders</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr><td>Intrusion into patient/doctor consultation</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr><td>Lack of adequate funding</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr><td>Degree of training required</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> <tr><td>Other – please specify .....</td><td><input type="checkbox"/></td><td><input type="checkbox"/></td></tr> </tbody> </table>		PCG level	Practice level	State of records in general practice	<input type="checkbox"/>	<input type="checkbox"/>	Accuracy of data entry on to practice computer systems	<input type="checkbox"/>	<input type="checkbox"/>	Diversity of practice computing systems	<input type="checkbox"/>	<input type="checkbox"/>	Identifying the items of data to collect	<input type="checkbox"/>	<input type="checkbox"/>	Relevance to everyday practice	<input type="checkbox"/>	<input type="checkbox"/>	Time demands	<input type="checkbox"/>	<input type="checkbox"/>	Fear of policing by external agencies	<input type="checkbox"/>	<input type="checkbox"/>	Motivation of practice staff	<input type="checkbox"/>	<input type="checkbox"/>	Rate of introduction	<input type="checkbox"/>	<input type="checkbox"/>	Involvement of stakeholders	<input type="checkbox"/>	<input type="checkbox"/>	Intrusion into patient/doctor consultation	<input type="checkbox"/>	<input type="checkbox"/>	Lack of adequate funding	<input type="checkbox"/>	<input type="checkbox"/>	Degree of training required	<input type="checkbox"/>	<input type="checkbox"/>	Other – please specify .....	<input type="checkbox"/>	<input type="checkbox"/>	
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Other – please specify .....	<input type="checkbox"/>	<input type="checkbox"/>																																												

---

**Concerns Regarding Data Collection**

There are systems in place to ensure confidentiality e.g. Caldicott Guardians. We recognise, however, that you may have some concerns regarding issues of confidentiality and data collection systems. The following question is designed to address any concern you may have.

19.	What concerns, if any, do you have about the uses of any collected data?		
	Inappropriate use of the data	<input type="checkbox"/> Resource decisions	<input type="checkbox"/>
	Performance monitoring	<input type="checkbox"/> None	<input type="checkbox"/>
	Confidentiality –	<input type="checkbox"/> Lack of clarity of purpose (e.g.	<input type="checkbox"/>
	is this specifically .....	by the Health Authority or PCG)	
	Patient confidentiality	<input type="checkbox"/>	
	Practitioner confidentiality	<input type="checkbox"/>	
	Other – please specify .....		<input type="checkbox"/>

**Thank you**

If you have any additional comments, please add them onto the attached sheet

---



## **Introduction**

Good morning/afternoon, thank you for agreeing to see me. This interview is being conducted as part of a Health Technology Assessment project to develop a prototype system for monitoring (clinical) guideline implementation in general practice through routine data collection. We are interested in identifying the issues involved in the implementation of guidelines in general practice and the monitoring of guideline use and data transfer between general practice, the PCGs and the Health Authority. The interview should last about 1 hour. It will take a semistructured format. The interview is entirely private and confidential and your name will not be linked to anything you say here. Do you have any objections to my taping our conversation? Thank you.

---

## **Practice background**

I'd like to start by asking you some background information about your practice.

Could I ask you to tell me a bit about your role within the practice?

Could you tell me a bit about your practice, e.g.  
(if needed) Would you say it was an urban, inner city, rural, mixed practice?

How many partners are there?

What other staff do you have here?

What is your list size?

---

## **Asthma/stable angina patients:**

How many patients with asthma/stable angina are on the practice list?

How many/what proportion (approx.) do you think you see?

How often do you see, on average, patients with asthma/stable angina?

What is the average age of these patients?

---



What is the average time since diagnosis of these patients?

---

**Services for asthma/stable angina patients**

Do you have established services for these patients, e.g. asthma clinics?

If so, could you tell me a bit more about this please? e.g.

What are the aims of this?

Who is involved with these?

What happens during an average session?

What type of information is recorded during these sessions?

Clinical

Non-clinical

**How is this information recorded?**

Manual

Computer (which system?)

What, if anything, is done with this information once it is recorded?

---

**During consultation:**

Moving on to discuss consultations:

Are these different from the times you see patients in the special clinics/services?

How long is an average consultation with patients with asthma/stable angina?

Could you walk me through an average consultation for a patient with asthma/stable angina? e.g.

Regarding process of care, what items of information would you collect?

Do these differ as treatment progresses?

If so, how?

Do you record the information during consultation or after the patient has left the room?

How do you record this information?

What is done with this information once it has been recorded?

Who is involved in this process?

How are these data retrieved?

Do you collect any other type of information?

And if so, does this follow the process we have just discussed?

If not, how does this differ?

---

**Sources of support/reference:**

What information/material informs your treatment of patients with asthma/stable angina?

Could you tell me a bit more about this?

Do you currently use any guidelines for asthma/stable angina?

If so, which guidelines do you currently use?

Has the use of these guidelines informed your data collection for asthma/stable angina?

Are there any other sources of support that you use which we have not discussed?

If so, could you tell me a bit more about this please?

---

Local priorities:

Moving on to discuss how your current practice relates to local priorities and quality initiatives, e.g. clinical effectiveness, clinical governance.  
Could you tell me a bit about local priorities?

How does your current practice fit with local priorities?

What requirements, if any, are there on you to collect data from the PCG or Health Authority?

Could you tell me a bit more about this please? e.g.  
What types of information?

How are these data transferred to the PCG/Health Authority?

What is done with the data once transferred?

Which quality improvement initiative does this fit into, if any?

I've covered the specific areas I wanted to ask you about – is there anything else about those areas that we might have left out?

Is there anything else, in more general terms, that you want to add?

---

Thank you very much for your help

---

# Appendix 4

## Process data collection form for asthma and angina

### Asthma Data Collection Sheet

Health Authority .....

Doctor Name ..... (will be kept in confidence, but is essential for return of information)

Please place tick  in the box to indicate a positive response. If you make an error, please fill in the box with a cross

#### Patient details:

Sex: Male  Female

Age: .....

Postcode: .....

Patient Visit (e.g. first visit): .....

Length of time since diagnosis (yr): .....

#### Issues of care:

Page references are to North of England Guidelines (1997)

Has this patient been treated with short acting $\beta_2$ -agonists? on an "as required" basis	Yes <input type="checkbox"/>	No <input type="checkbox"/>	(See p15)
Has this patient required inhaled short acting $\beta_2$ -agonists for more than 2 to 3 doses a day?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	(See p28)
If Yes, has this patient also been treated with inhaled corticosteroids?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	(See p28)
Has this patient had an exacerbation of their asthma?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	(See p63)
If Yes, has this patient been treated with oral corticosteroids?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	(See p63)
	<b>Contraindicated</b> <input type="checkbox"/>		
Has this patient been advised to stop smoking?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	(See p71)
	<b>Non-Smoker</b> <input type="checkbox"/>		
Has this patient been offered education about their condition and its management?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	(See p72)
Has this patient had their inhaler technique checked?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	(See p55)

For further information about this project, please contact:

Public Health,  
ScHARR,  
University of Sheffield  
Regent Court, 30 Regent Street  
Sheffield S1 4DA (0114) 222 0795

This form may be freely photocopied

## Stable Angina Data Collection Sheet

Health Authority .....

Doctor Name ..... (will be kept in confidence, but is essential for return of information)

Please place tick  in the box to indicate a positive response. If you make an error,  
please fill in the box with a cross

### Patient details:

Sex: Male  Female 

Age: .....

Postcode: .....

Patient Visit (e.g. first visit): .....

Length of time since diagnosis (yr): .....

### Clinical assessment:

Page references are  
to North of England  
Guidelines (1997)

Has this patient had their blood pressure measured?    Yes     No     (See p19)

Has this patient had their serum lipids measured?    Yes     No     (See p18)

Has this patient had an exercise test?    Yes     No     (See p14)

Not appropriate   
(e.g.: reason not to refer)

### Therapy:

Has this patient been treated with aspirin 75mg daily?    Yes (75–150mg)     No     (See p27)

Other dose   
Contraindicated

Has this patient been treated with short acting nitrates?    Yes     No     (See p28)

Contraindicated

Has this patient been treated with  $\beta$ -blockers?    Yes     No     (See p28)

Contraindicated

### Advice:

Has this patient been advised to stop smoking?    Yes     No     (See p20)

Non-Smoker

*For further information about this project, please contact:*

Public Health,  
SchARR,  
University of Sheffield  
Regent Court, 30 Regent Street  
Sheffield S1 4DA (0114) 222 0795

This form may be freely photocopied

## Appendix 5

# Outcome questionnaires for asthma and angina

PUBLIC HEALTH



**ScHARR**  
SCHOOL OF HEALTH AND  
RELATED RESEARCH

### YOUR ASTHMA

Please complete all sections of this questionnaire and return in the enclosed pre-paid envelope

**This questionnaire is being sent to you as part of a project entitled “How to Monitor Guideline Use in Primary Care”, undertaken by the Department of Public Health in the Faculty of Medicine at the University of Sheffield**

**Should you have any queries, or would like further information then please contact**

Thank you for your help with this research

## About these questions

These questions are about your asthma. They ask about your symptoms over the past month.

Each question describes a possible symptom of asthma and asks you to say how often in the past month you have felt like that.

For each question, please circle the number that best describes how you have been in the past month. Please make sure that you circle only one number for each question.

- 
1. In the **past month**, on how many **days** have you been short of breath **during exercise** (for example going upstairs, walking up hill, gardening, taking part in sports)?
 

Never	On one or a few days	On several days	On most days	Every day
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
  2. In the **past month**, on how many **days** have you been short of breath **during the day** at times when **you were not exercising**?
 

Never	On one or a few days	On several days	On most days	Every day
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
  3. In the **past month**, on how many **days** have you been wheezed **during the day**?
 

Never	On one or a few days	On several days	On most days	Every day
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
  4. In the **past month**, on how many **days** have you coughed **during the day**?
 

Never	On one or a few days	On several days	On most days	Every day
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
  5. In the **past month**, on how many **nights** have you wheezed?
 

Never	On one or a few days	On several days	On most days	Every day
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
  6. In the **past month**, on how many **nights** have you been short of breath?
 

Never	On one or a few days	On several days	On most days	Every day
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
  7. In the **past month**, on how many **nights** have you coughed?
 

Never	On one or a few days	On several days	On most days	Every day
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
  8. In the **past month**, on how many **nights** have you had problems sleeping because of a cough or chest problems (for example, bother getting to sleep or being woken in the night)?
 

Never	On one or a few days	On several days	On most days	Every day
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
  9. In the **past month**, on how many **days** has your chest felt tight?
 

Never	On one or a few days	On several days	On most days	Every day
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>



PUBLIC HEALTH



**ScHARR**  
SCHOOL OF HEALTH AND  
RELATED RESEARCH

## **YOUR ANGINA**

Please complete all sections of this questionnaire and return in the enclosed pre-paid envelope

**This questionnaire is being sent to you as part of a project entitled “How to Monitor Guideline Use in Primary Care”, undertaken by the Department of Public Health in the Faculty of Medicine at the University of Sheffield**

**Should you have any queries, or would like further information then please contact**

Thank you for your help with this research, the results  
**of which will hopefully benefit patients in the future**

## About these questions

The following is a list of activities that people often do during the week. Please read the activities listed below, and tell us how much limitation you have had **due to chest pain, chest tightness or angina** over the past 4 weeks.

Please place a cross in one box on each line

Activity	Severely Limited	Moderately Limited	Somewhat Limited	A Little Limited	Not Limited	Limited, or did not do for other reasons
Dressing yourself						
Walking indoors on level ground						
Bathing or showering						
Climbing a hill or a flight of stairs without stopping						
Gardening, vacuuming or carrying groceries						
Walking more than a hundred yards at a brisk pace						
Lifting or moving heavy objects (for instance, furniture, children)						

## About these questions

These questions are about your angina. They ask about your symptoms over the past month.

For each question, please **tick the answer** that **best** describes how you have been in the past month. Please make sure that you tick **only one** answer for each question.

1. Compared with 4 weeks ago, how often do you have **chest pain, chest tightness or angina** when doing your **most strenuous** level of activity?

I have had chest pain, chest tightness or angina.....

<b>Much more</b> often	<b>Slightly more</b> often	About the <b>same</b>	<b>Slightly less</b> often	<b>Much less</b> often
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Over the **past 4 weeks**, how many times have you had **chest pain, chest tightness or angina**?

I get chest pain, chest tightness or angina.....

4 or more times per day	1-3 times per day	3 or more times per week but not every day	1-2 times per week	Less than once per week	None over the past 4 weeks
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. How satisfied are you that everything possible is being done to treat your **chest pain, chest tightness or angina**?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Highly satisfied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. How satisfied are you with the explanations your doctor has given you about your **chest pain, chest tightness or angina**?

Not satisfied at all	Mostly dissatisfied	Somewhat Satisfied	Mostly Satisfied	Highly satisfied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. Overall, how satisfied are you with the current treatment of your **chest pain, chest tightness or angina**?

Not satisfied at all	Mostly dissatisfied	Somewhat Satisfied	Mostly Satisfied	Highly satisfied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. Over the past 4 weeks, how much has your **chest pain, chest tightness or angina** interfered with your enjoyment of life?

It has <b>severely</b> limited my enjoyment of life	It has <b>moderately</b> limited my enjoyment of life	It has <b>slightly</b> limited my enjoyment of life	It has <b>barely</b> limited my enjoyment of life	It has <b>not</b> limited my enjoyment of life
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. If you had to spend the rest of your life with your **chest pain, chest tightness or angina** the way it is right now, how would you feel about this?

Not satisfied at all	Mostly dissatisfied	Somewhat Satisfied	Mostly Satisfied	Highly satisfied
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



## Appendix 6

### Cost literature search terms

#### Literature review

A systematic review on this topic was conducted on the English and North American literature using the search terms listed in *Table 10*. The search was conducted on several relevant computerised databases and websites, and a number of research journals were handsearched; these are also listed in *Table 10*. These articles were also cross-referenced.

A number of individuals and organisations working within the field of audit or economic

evaluation were also contacted directly to identify existing work. This included individuals representing general practices or medical audit advisory groups, operational researchers, health economists, health service researchers, and medical, clinical audit and Royal College organisations. A call for information was put out onto the clinical audit mailbase list.

A review of the abstracts of the papers yielded very few relevant papers, suggesting that overall limited work had been done, or was being done, in the analysis of costs incurred in audit.

**TABLE 10** Details of the literature review to identify information on costs

Search terms	Databases	Websites	Journals
Cost	EMBASE	Centre for Health Economics	<i>Health Services Research Journal</i>
Cost analysis	MEDLINE	Public Health on the Internet	<i>Health Economics</i>
Cost evaluation	BIDS	National Centre for	
Economics	NHS CRD – Dare and	Clinical Audit	
Economic evaluation	Economic Evaluation	National Audit Office	
Primary care	CRIB	Audit Commission	
Audit	Econlit	Netting the Evidence	
Guidelines		Royal College of Physicians	
Monitoring		Royal College of General Practitioners	
		Oxford University	
		York University	
		McMaster University	
		Aberdeen University	





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## Diagnostic Technologies & Screening Panel

### Members

<p><b>Chair,</b> <b>Dr Ron Zimmern</b>, Director of the Public Health Genetics Unit, Strangeways Research Laboratories, Cambridge</p>	<p>Dr David Elliman, Consultant in Community Child Health, London</p> <p>Dr Andrew Farmer, Senior Lecturer in General Practice, Institute of Health Sciences, University of Oxford</p> <p>Dr Karen N Foster, Clinical Lecturer, Dept of General Practice &amp; Primary Care, University of Aberdeen</p> <p>Professor Jane Franklyn, Professor of Medicine, University of Birmingham</p> <p>Professor Antony J Franks, Deputy Medical Director, The Leeds Teaching Hospitals NHS Trust</p>	<p>Mr Tam Fry, Honorary Chairman, Child Growth Foundation, London</p> <p>Dr Susanne M Ludgate, Medical Director, Medical Devices Agency, London</p> <p>Dr William Rosenberg, Senior Lecturer and Consultant in Medicine, University of Southampton</p> <p>Dr Susan Schonfield, CPHM Specialised Services Commissioning, Croydon Primary Care Trust</p> <p>Dr Margaret Somerville, Director of Public Health, Teignbridge Primary Care Trust, Devon</p>	<p>Mr Tony Tester, Chief Officer, South Bedfordshire Community Health Council, Luton</p> <p>Dr Andrew Walker, Senior Lecturer in Health Economics, University of Glasgow</p> <p>Professor Martin J Whittle, Head of Division of Reproductive &amp; Child Health, University of Birmingham</p> <p>Dr Dennis Wright, Consultant Biochemist &amp; Clinical Director, Pathology &amp; The Kennedy Galton Centre, Northwick Park &amp; St Mark's Hospitals, Harrow</p>
<p>Dr Paul Cockcroft, Consultant Medical Microbiologist/Laboratory Director, Public Health Laboratory, St Mary's Hospital, Portsmouth</p> <p>Professor Adrian K Dixon, Professor of Radiology, Addenbrooke's Hospital, Cambridge</p>			

## Pharmaceuticals Panel

### Members

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## Therapeutic Procedures Panel

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### **Feedback**

The HTA Programme and the authors would like to know your views about this report.

The Correspondence Page on the HTA website (<http://www.nchta.org>) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

***We look forward to hearing from you.***