



Commission for Health Improvement

A guide to clinical governance reviews

Primary care trusts
March 2003

The Commission for Health Improvement (CHI) is a non departmental public body. It was established under the 1999 Health Act as part of the government's reforms to help improve patient care. It has statutory powers and is accountable to government for its work, but operates independently. It has been apparent for some time that the standard of care offered by the NHS varies greatly. It can vary between hospitals, between primary care organisations and at practice level.

There is not always an obvious reason for this variation. CHI's purpose is to assist the NHS in England and Wales to address unacceptable variations in patient care and to assure, monitor and improve the quality of clinical care. It collaborates closely with the NHS as well as with other bodies such as the royal colleges, professional organisations and regulatory and voluntary bodies.

Its main functions are:

- to provide independent scrutiny of local clinical governance arrangements to support, promote and deliver high quality services. CHI is carrying out a rolling programme of reviews of clinical governance arrangements in every NHS organisation
- to carry out studies that monitor and review the implementation of national service frameworks, National Institute of Clinical Excellence (NICE) guidance and other key NHS policy priorities
- to provide national leadership to develop and disseminate clinical governance principles and to identify and share good practice

CHI has adopted six key principles that underpin all its work:

- the patient's experience is at the heart of CHI's work
- CHI will be independent, rigorous and fair
- CHI's approach is developmental and will support the NHS in continuous improvement
- CHI's work is based on the best available evidence and focuses on improvement
- CHI will be open and accessible
- CHI will apply the same standards of continuous improvement to itself that it expects of others

PREFACE

CHI has written this guide mainly for those involved in the clinical governance review process, including managers, clinical and non clinical staff. It may be of interest to government departments, other regulatory and audit agencies in the NHS, academics and NHS commentators, patient representative bodies and members of the public. It is available on CHI's website www.chi.nhs.uk (See appendix A for contact details).

The clinical governance review process explained in this edition of the guide has recently been improved. It is more efficient, reducing the time taken to conduct a review to 17 weeks. We have done this by making existing tools more effective, introducing new methods and removing those components that have not worked so well.

This guide is part of CHI's commitment to being open and accessible in all its work. It describes what is involved in the clinical governance review process and explains CHI's methods. It sets out the review framework and process, the data and documents required and the rationale for each stage of the process.

Primary care trusts (PCTs) will benefit most from reviews if they are well prepared in advance. We hope that this guide will be a useful contribution to that preparation and assist PCTs in their progress in implementing clinical governance. In addition, it includes appendices that show in detail the issues CHI will be focusing on during a review.

The new review approach has been tested at eight pilot sites in 2002 (appendix B). CHI will continue to refine its review methods, meaning that aspects of the methodology will develop as CHI carries out more clinical governance reviews.

CHI would like to thank all those who helped to develop clinical governance reviews, including the PCTs where the review methods were piloted. A key feature of the reviews is the involvement of NHS professionals as review team members and we are grateful both to them and to their seconding organisations. Each team also includes a lay member, who can take the viewpoint of patients and the public and we are fortunate to have their involvement. They all have the opportunity to encourage good practice throughout the NHS and thus be a force for change and continuous improvement in patient care.

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1. THE CLINICAL GOVERNANCE REVIEW FRAMEWORK

Reviewing primary care trusts

Reviewing clinical governance in primary care trusts (PCTs) presents CHI with new challenges. As 'transformational' organisations, PCTs are at the forefront of ambitions for modernisation and improvement in the NHS and greater integration of health and social care. By 2004, PCTs will control around 75% of the NHS budget with substantial leverage to influence the delivery of health care in their local area.

At the same time, CHI recognises that these organisations are still new and developing. PCTs have inherited very different legacies from the past, for example, a PCT may be starting with an unfavourable financial position or have a strong local history of partnership working to build on. Unlike other NHS organisations, PCTs are responsible for managing and developing primary care services that, in the main, are provided by independent contractors (such as GPs) over which they have no direct managerial control.

Clearly, primary care trusts must develop their capacity and expertise rapidly in order to fulfil their responsibilities to patients and carers safely, not only in terms of the primary and community services they provide, but also, in the way in which they work with partner organisations, drive health improvement and commission health care on behalf of the local population. CHI reviews will cover the clinical governance arrangements that are in place across the organisation as a whole.

To ensure that the assessment of PCTs is fair and robust, CHI was advised by a team of external professionals with collective expertise in primary and community care, public health and social care. National stakeholders, including a variety of patient representative groups took part in two consultation events where the methods were discussed. These methods were piloted at eight PCTs. This process has now been evaluated and some changes have been made to the review process. CHI continues to develop relationships with key national stakeholders so that the review teams are kept up to date with new developments in the field. As a developmental organisation, CHI will continually use its learning to improve the PCT reviews.

What is clinical governance?

The Government's white paper, A First Class Service, and the Welsh Office paper, Quality Care and Clinical Excellence, defined clinical governance as "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."¹

The purpose of clinical governance is to ensure that patients receive the highest quality of NHS care possible. It covers the organisation's systems and processes for monitoring and improving services, including:

- patient and public involvement

¹ A First Class Service: Quality in the New NHS, Department of Health, 1998.

- risk management
- clinical audit
- clinical effectiveness programmes
- staffing and staff management
- education, training and continuing personal and professional development
- use of information to support clinical governance and health care delivery

Effective clinical governance should therefore ensure:

- continuous improvement of patient services and care
- a patient centred approach that includes treating patients courteously,
- involving them in decisions about their care and keeping them informed
- a commitment to quality, which ensures that health professionals are up to date in their practices and properly supervised where necessary
- a reduction of the risk from clinical errors and adverse events as well as a commitment to learn from mistakes and share that learning with others

Aims of clinical governance reviews

CHI's rolling programme of clinical governance reviews will cover every NHS organisation in England and Wales. The reviews look at the effectiveness of organisations' clinical governance arrangements and have five principal aims:

- to provide the public and people using NHS services with objective and fair assessments of NHS organisations' progress towards introducing effective clinical governance
- to help the NHS achieve evident and continuous improvements in the quality of patient care
- to help the NHS reduce unacceptable variations in the quality of clinical services
- to identify and disseminate good practice in clinical governance
- to increase understanding of clinical governance and the factors that determine its effectiveness

Guiding principles

CHI's reviews of clinical governance incorporate the six key principles that guide all its work.

The patient's experience is the central focus. The inclusion of a lay member in every review team reinforces this focus. Reviews capture information about the direct experience of NHS patients across the services they use in a NHS organisation. They also look at how the organisation perceives the experiences of the patients it treats. CHI is particularly interested in waiting times, how care is organised, whether patients are treated with privacy, dignity and respect, environmental issues such as cleanliness and clinical effectiveness and outcomes.

CHI has designed the review process to be **independent, rigorous and fair**. CHI and its review teams collect, analyse and assess evidence according to a consistent framework (see 'Assessing clinical governance' in this chapter). The health care professionals in the review team work within the NHS and understand the overall context of NHS organisations but do not work in the region in which the

organisation under review is located. All review team members undergo a rigorous selection process and are chosen for their ability to take an objective and independent standpoint.

The review process is about development and support for continuous improvement. CHI helps NHS organisations to plan and prepare for the review, using existing information wherever possible. This process helps the organisation to look carefully at its own performance. CHI also shares good practice identified during reviews.

CHI's work is evidence based and focused on achieving improvement. Review findings are based on robust evidence collected before and during the review. Review reports do not contain specific recommendations for change. Instead they highlight areas for action. The PCT also receives a separate document containing a structured evidence summary to help them work out the most appropriate means of achieving change in its specific context. The organisation then produces an action plan, in response to the review.

CHI is publishing this guide as part of its commitment to being open and accessible about every aspect of the review process and its development. In addition, all review reports are published in hard copy and on the internet, once the PCT has agreed their factual accuracy.

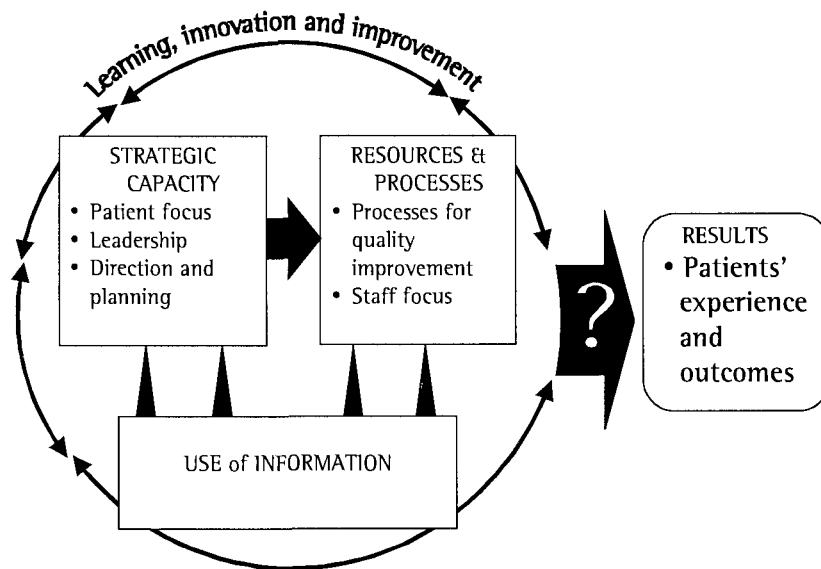
CHI applies the principle of continuous improvement to itself and its review methods. It recognises that there is much to learn from other review and inspection bodies and seeks to combine their best practice with its own. Using the lessons learned since the review programme began in April 2000, CHI has redesigned its clinical governance review process, drawing on the experience of both CHI staff and NHS organisations – this new process was introduced in January 2002.

Assessing clinical governance

CHI has developed a systematic framework for assessing clinical governance in NHS organisations so that judgements made in reports of reviews are reliable, fair and consistent. The assessment framework was developed with the NHS Clinical Governance Support Team in England and the Clinical Effectiveness Support Unit in Wales to ensure that consistent messages are given to trusts about clinical governance. (See appendix A for contact details).

CHI's model for clinical governance (figure one) illustrates its belief that effective clinical governance depends upon a culture of continuous learning, innovation and development and will improve patient experience of care and treatment in the NHS. CHI uses the information it accumulates from reviews to help determine which aspects of clinical governance are the most important for improving patients' experience and outcomes.

Figure one: CHI's model for clinical governance



Work is in progress to identify the dimensions of the patient experience and outcomes under the 'RESULTS' part of the model so that CHI can assess the information it collects about what it is like to be a patient and interpret information about clinical processes and care outcomes. CHI looks specifically at the environment, privacy and dignity, clinical effectiveness and outcomes, access and organisation of care.

CHI evaluates clinical governance by exploring three key interlinked areas identified in the model:

- **strategic capacity:** how far does the PCT's leadership set a clear overall direction that focuses on patients? How well is it integrated throughout the organisation?
- **resources and processes:** how robust are its processes for achieving quality improvement, such as consultation and patient involvement and clinical audit? How effective are the PCT's arrangements for staff management and development?
- **use of information:** what information is available on patients' experience, outcomes, processes and resources, and how does the PCT use it strategically and at the level of patient care?

Each of these areas comprises a number of components that CHI examines in every NHS organisation. CHI has so far identified seven components of 'RESOURCES AND PROCESSES' and 'USE OF INFORMATION' (figure two). Work is being carried out to identify the components of 'STRATEGIC CAPACITY'.

Figure two:
Components of clinical governance – resources and processes and use of information

	COMPONENT
Resources and processes (i) processes for quality improvement	Patient and public involvement
	Clinical audit
	Risk management
	Clinical effectiveness programmes
(ii) staff focus	Staffing and staff management
	Education, training and continuing personal and professional development
Use of information	Use of information to support clinical governance and health care delivery

- CHI's review teams assess how well clinical governance is working throughout the PCT by making enquiries about each of these seven components at corporate and directorate levels and in clinical teams. This involves collecting information systematically about review issues that have been defined for each component. To help with analysis and reporting the review issues are grouped into themes:
 - accountability and structures
 - strategies and plans
 - application of policies, strategies and plans
 - quality improvements and learning
 - resources and training for staff

The full set of review issues for each component and their grouping into themes is included in appendix C.

CHI will introduce similar methods to assess information collected about components of 'STRATEGIC CAPACITY' in future rounds of reviews. Dimensions may include: partnership working, leadership, direction and planning, and patient involvement.

On the basis of the evidence collected, CHI's reviewers assess each component of clinical governance against a four point scale:

- I = little or no progress at strategic and planning levels or at operational level
- II = worthwhile progress and development at strategic and planning levels but not at operational level
or:
worthwhile progress and development at operational level but not at strategic and planning levels
or:

worthwhile progress and development at strategic and planning levels and at operational level but not across the whole organisation

- III = good strategic grasp and substantial implementation. Alignment of activity and development across the strategic and planning levels and operational level of the organisation
- IV = excellence – coordinated activity and development across the organisation and with partner organisations in the local health economy that is demonstrably leading to improvement. Clarity about the next stage of clinical governance development.

There is wide variation within PCTs in progress made developing the component parts of clinical governance. At this stage of development, CHI believes it is most useful to PCTs to assess each component separately to help them prioritise their development of clinical governance. It will not make judgements to produce an overall rating for an organisation.

Review phases

Reviews take approximately 17 weeks to complete from the time the review manager takes over (phase two) to the final preparation of the report. Prior to this, the PCT has three months (phase one) in which to collect data and information requested by CHI. This timescale is long enough to collect and rigorously analyse data, but intensive enough to mean that the evidence on which the review findings are based is current and useful.

There are four key phases in a review: phase one (information and data collection), phase two (review preparation and visit), phase three (reporting and action planning), and phase four (improvements and monitoring). Each review follows the same timetable:

- **Phase one (weeks –12 to 0)**

During this phase, CHI sends the PCT an information manual detailing the data and information required, conducts a staff survey and a primary care practice survey and collects the data and information requested from the PCT.

- **Phase two: pre visit preparation (weeks one to seven)**

Between weeks one and seven, CHI holds an initial meeting with the PCT, collects information from stakeholders, analyses data, identifies the areas for detailed review during the visit week and gives the PCT preliminary feedback.

- **Phase two: site visit (week eight)**

A CHI review team visits the PCT to interview staff, observe practice, verify information already obtained and gather further information. Feedback on the issues identified during the visit will be given to the PCT on the final day of the visit.

- **Phase three: reporting and action planning (weeks nine to 17)**

With the information gained from the review, the review manager writes a report on CHI's findings. The report is quality assured internally and then sent to the PCT for comments on factual accuracy, finalised and published in week 17. The report is publicly available in hard copy and on CHI's website. The PCT develops an action plan in response to the key areas for action outlined in CHI's report. The action plan is signed off by the strategic health authority in consultation with CHI.

- **Phase four: monitoring**

The PCT delivers improvements in line with the agreed action plan. The strategic health authority monitors the delivery of these improvements. In addition, CHI will assess progress made against CHI action plans by receiving progress reports from the strategic health authority.

Each of these phases is described in more detail in chapters three to seven.

2. THE REVIEW PROGRAMME

Selecting organisations for review

CHI's rolling programme of clinical governance reviews started with acute trusts but is now expanding into all NHS organisations across England and Wales. CHI will review all PCTs, NHS trusts, NHS Direct sites and, in future, local health boards in Wales on a similar basis.

CHI selects organisations to review in two ways:

- on a random basis, using a sampling technique that ensures that the number of organisations selected is spread proportionately across a regional area
- where appropriate, by grouping acute, PCTs, ambulance and mental health organisations geographically

Reviews are not normally triggered by special concerns. However, CHI has the capacity to fast track clinical governance reviews of certain organisations and bring these forward in the programme. Fast track clinical governance reviews may be triggered by a request from an individual or organisation, a recommendation made as a result of a CHI investigation or where a request is made for an investigation but a review is more appropriate. All requests for fast track reviews and investigations are assessed against a set of guiding principles. If a decision is made to fast track a review, the trust is informed.

In addition, CHI liaises regularly with each strategic health authority, the regional directorates of health and social care and the Welsh Assembly Government to look back at completed reviews and to discuss the future review programme. This enables CHI to identify organisations where the review should be delayed, for example because of an impending merger or change of management.

CHI teams

Three different teams work with the PCT during the review process: the CHI phase one team, the CHI internal team and the CHI review team.

The **phase one team** deals with the information and data request period before the review begins and is an organisation's first point of contact for help and advice until the review begins.

The **internal team** comprises a review manager, a review coordinator, analysts and a communications officer. Their roles are as follows:

- the review manager works with the PCT throughout the review, ensures that all relevant evidence is collected and analysed, leads and supports the review team during the visit week and writes the report
- the review coordinator ensures the efficient running of a review, liaising closely with the PCT and CHI teams
- the analysts analyse data provided by the PCT and other national data. They also support the review by undertaking ad hoc analyses as requested and by reviewing the PCT's information systems

- the communications officer advises the CHI team and, where applicable, the PCT on internal and external communications issues. They will also publicise the review and help to identify stakeholders

The review team, led by the review manager, carries out clinical governance reviews and is multidisciplinary. The review team normally includes: a nurse, a doctor, a social care reviewer, an NHS manager, a lay member and another clinical professional who is not a doctor or a nurse, for example a pharmacist, physiotherapist, dentist or optometrist. CHI informs the PCT of the membership of the team in advance of the site visit

CHI recruits reviewers through national advertising. It requires high standards of its reviewers and operates a rigorous competency based selection process. Potential reviewers attend a one day selection centre.

Once selected, all reviewers attend an intensive two and a half day training course simulating the clinical governance review process. It provides reviewers with a thorough grounding in CHI's review methods and helps develop the skills needed for reviewing, such as interviewing and listening, note taking and analysis. CHI requires all its reviewers to comply with its code of conduct. They also sign a confidentiality agreement that continues after they have finished working for CHI as a reviewer, as well as a declaration of interests.

Reviewers are on short term secondments. They spend around 10 days on each review and normally carry out one or two reviews per year while remaining in their current job within the NHS. This means that they are up to date with current practice and understand the context within which NHS organisations work. They can also help spread identified good practice within their own organisations. In addition, the lay reviewers bring the patient's and the public's perspective to the review.

CHI welcomes applications from those interested in becoming a reviewer. Please contact the human resources team at CHI or consult CHI's website, which contains details of vacancies.

3. PHASE ONE (WEEKS –12 TO 0)

During this phase, CHI collects data and information, both from the PCT and from national and other sources. The framework for assessing clinical governance determines the data to be collected. CHI analyses the data to build up a picture of the PCT and to identify areas to focus on during the visit week. These include areas of good practice and areas for further development.

CHI aims to minimise the work for the PCT during this phase, ensuring that they have sufficient time for data collection (a copy of the data request is available on the CHI website). The PCT is sent a comprehensive information manual explaining CHI's data requirements and can gain further advice and support from the CHI phase one team. Over time, CHI will reduce the data it requires by careful targeting so that the supply and analysis of data is more economical and effective. The redesigned clinical governance review process has already started this process, reducing and focusing the number of documents required.

Key to the review's success is visible commitment from the PCT's senior management and communication to staff. CHI's communications team has prepared a handbook for NHS organisations to help them with the internal and external communications aspects of the review. CHI also offers assistance to NHS organisations in media handling and other communications issues when reports are published.

Contacting the organisation

At the start of phase one, the PCT is formally informed of its selection and of the timing of the review team visit to the PCT. CHI sends an information manual to the PCT at this point. The manual contains information to support the PCT through the review including guidance, a PCT questionnaire, a data and information request, a communications handbook and timetabling information.

CHI also asks the PCT to nominate a key contact – the trust coordinator – to collect information and arrange local meetings. This is a crucial role (figure three) in ensuring that the review runs smoothly – review teams value the trust coordinator's assistance highly. The time commitment required for this role will vary from organisation to organisation, but on average it will involve around 30–40 days of the coordinator's time from start to finish. The trust coordinator should have an understanding of how the organisation as a whole operates and be senior enough to have influence at board level. Appendix D describes the role of the trust coordinator in more detail.

Figure three: Role of the trust coordinator

<p>The trust coordinator:</p> <ul style="list-style-type: none"> ▪ acts as a link between CHI and the PCT ▪ communicates information throughout the PCT about CHI and the review process ▪ works with the CHI review manager to make sure that the review process runs as smoothly as possible ▪ coordinates the return of PCT data and documents ▪ organises the briefing and initial findings meetings ▪ coordinates the response to the CHI presentation at the initial findings meeting ▪ arranges the timetable for the review team's visit and schedules appointments ▪ is available throughout the site visit ▪ coordinates the return of comments on the factual accuracy of the report to CHI ▪ arranges the action planning workshop
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Collecting data and documents

To inform the review, CHI collects and uses national data sets such as clinical indicators. It also asks the PCT to provide:

- **documentation from internal sources.** This includes information on the PCT's profile, strategies and business plans and information about the individual components of clinical governance, such as clinical audit and patient surveys
- **documentation from external sources.** This includes reports of other external organisations that visit the PCT, for example, royal colleges, external auditors and Investors in People

The request for data and documents is comprehensive in its coverage of clinical governance and there should not normally be a need for the PCT to provide documentation in addition to that which CHI has requested. Looking at this data and these documents helps to focus the review visit and avoid duplicating work already carried out by the PCT or other external reviewers.

CHI asks the PCT to return the data and documents in electronic form before the start of the review phase. CHI analysts begin to produce a summary of evidence. This will be used to guide the reviewers during the review week both in terms of the areas they will visit (for example, a general practice or a community clinic) and the themes they will explore.

CHI also asks the PCT to complete a questionnaire about its progress towards implementing clinical governance, including public and patient involvement. This tool provides further important background information to the review team and helps to inform the planning of the visit week. It is also an opportunity for the PCT to highlight areas of good practice as well as those that may require further development.

Staff survey

The staff survey is an important component of the clinical governance review and enables CHI to gain a comprehensive picture of a number of clinical governance issues through the beliefs, attitudes and perceptions of staff working in the PCT. The survey is carried out by means of a questionnaire sent to a random sample of directly employed staff. The survey is confidential and the responses are anonymous.

To enable CHI (or a nominated organisation carrying out the work on CHI's behalf) to carry out the staff survey, CHI asks the PCT to provide a database of all staff currently employed by the PCT. CHI uses the staff database to draw the sample of staff and send out the questionnaires. The completed questionnaires are then analysed and the results considered alongside all the other sources of information gained during phase one.

Primary care practice survey

The primary care practice survey provides CHI with information on:

- clinical governance activity in primary care at the practice and community pharmacy level, and
- the type of clinical governance support that the PCT is providing to primary care professionals and staff

This information provides a snapshot against which to assess the priorities, plans and progress of the PCT. The survey is confidential.

One questionnaire is sent to each general practice, dental practice, community pharmacy and optometry practice within the PCT. Different questionnaires have been designed for general practice, dental practice, community pharmacy and optometry. Sample copies of the questionnaires are included in the start up pack.

Patient stakeholder involvement

Patients, service users and carers are key stakeholders in healthcare services, and CHI is committed to taking their views into account in the clinical governance review. As part of this work we would like to invite a selection of patients and carers to attend the CHI stakeholder meetings in order to give their views on services directly provided by the PCT.

We ask that the PCT coordinates, via its general practices, the process of writing to a selection of patients to invite them to attend the stakeholder meetings. A total of 200 patients will be invited. This will be divided equally between all general practices in the PCT. The invitation letters will be provided by CHI in pre paid envelopes so that there are no additional costs incurred by the practices or the PCT.

The information we gather from patients will be pooled with a range of other data to enable us to assess the clinical governance arrangements for primary care locally. Individuals and practices are never named in the final CHI report.

CHI is researching and developing a strategy for reaching patients who might have difficulty in making their views heard. This might be because they do not speak or read and write English or because they have a sensory or physical disability. The review process in the future will include methods for seeking these people's views.

4. PHASE TWO: PRE VISIT PREPARATION (WEEKS ONE TO SEVEN)

Initial meeting

Once phase one is complete, phase two begins with the CHI review manager, analyst, review coordinator and communications officer meeting with the PCT to discuss the review. The meeting will normally include the chief executive, the clinical governance lead, the nominated trust coordinator, chairman, non executive directors, medical director, director of nursing or equivalent, director of human resources, director responsible for allied health professionals, leads for pharmacy, dentistry and optometry, as well as chair/representatives of professional executive committees, director of public health, and head of communications. The aim is to explain the process, the trust coordinator's role, the preparation needed and the support that CHI's communications team will provide to the PCT, as well as answer any queries.

Meetings with stakeholders

Achieving an understanding of the PCT's local context and external perspectives on the PCT's clinical governance arrangements is a significant feature of the review. CHI therefore spends around three days meeting with local people and non statutory organisations with an interest in the PCT. They include members of the public, voluntary and not for profit organisations, staff associations and trade unions. Staff from the PCT may also attend. CHI holds the meetings at a local venue with disabled access and conducts them privately. Information may also be received by letter, telephone or email.

CHI spends a further day conducting formal meetings with the strategic health authority, the community health council, local authorities with social services responsibilities and the external auditors. In addition to providing context and helping to focus the review, these meetings help to raise local awareness of the review and action planning processes.

Structured evidence summary

CHI analyses the internal and external documents provided by the PCT, the staff survey, the primary care practice survey, the PCT questionnaire and the results from stakeholders and summarises the evidence into a table. Its purpose is to provide background information to the CHI review team and to help identify key issues and areas of good practice to follow up through the site visit. It provides initial findings on patient outcomes and experience, strategic capacity, resources and processes and use of information (see 'Assessing clinical governance' in chapter one).

The summary of evidence is a working document that is constantly updated throughout the review process and shared with the PCT prior to the visit week. It informs the site visit, supports CHI's eventual findings and is used as the basis for the final report. It collates information in a way that the PCT can use to assess its own performance.

CHI uses the summary of evidence, including information gathered from the organisation questionnaire for the CHI review team to look at in depth. The aim is to

test whether clinical governance arrangements are working at 'grass roots' level, not to carry out service reviews. CHI also gives the PCT the opportunity to highlight good practice worthy of sharing elsewhere. The trust coordinator can start scheduling interview appointments with staff at the end of week three.

Briefing the CHI reviewers

In week five, to help the review team to understand both the PCT's context and how it is approaching clinical governance, CHI sends each reviewer information about the PCT and a summary of findings to date.

Preliminary feedback

In week six, the review manager, analyst, review coordinator and the CHI review team visit the PCT. The purpose of this visit is to present the data, information and emerging issues identified so far to the PCT in a **preliminary feedback** meeting. The PCT can also use this meeting to present their progress on clinical governance and update CHI on relevant information.

5. PHASE TWO: VISIT WEEK (WEEK EIGHT)

The purpose of the visit week is to test out areas selected in the earlier stages of the review, to validate information already collected and to gather further evidence about the PCT's progress with clinical governance. Visiting the PCT also allows the review team to assess the softer issues, such as communication between and within teams and relationships within the PCT, for example between managers, clinicians and other staff.

The review manager, review coordinator, analyst and the review team spend an intensive five days on site, including at least one visit to an out of hours service. An indicative timetable for a site visit is shown at appendix E.

For the first three to four days of the week long visit, CHI reviewers interview staff, observe what happens in areas of the PCT, and fill in any data or information gaps. The reviewer team works in a collaborative and non confrontational way.

Every day during the site visit, the review team meets with the review manager to discuss their findings. This allows team members to exchange notes and highlight any issues to follow up in the next round of interviews. It also enables them to identify any further evidence needed to complete the assessment.

The final days of the visit are spent conducting any necessary additional interviews.

The review manager plays an important role in coordinating the reviewer team's work during the visit. He or she may also participate in the interview sessions.

The review manager's main tasks are to:

- act as the formal link between CHI, the review team and the PCT
- manage the process and make sure it runs as smoothly as possible
- provide leadership and support to the review team
- quality control the process and the reviewers' activities
- facilitate review team discussions and run debriefing and planning sessions with the review team throughout the week
- work with the analyst and reviewers to analyse information on site, allowing more immediate and structured feedback to the PCT at the end of the week

Interviewing staff

The review team interviews a cross section of staff of all grades and professions, including non clinical staff, in scheduled interviews lasting between half an hour and an hour. Most interviews are carried out by reviewers in pairs, allowing one person to ask questions while the other takes notes. Some interviews are group interviews, but the majority are with an individual member of staff.

The structured interviews cover the main components of clinical governance. For example, as part of assessing consultation and patient involvement, interviews would seek to find out whether:

- staff are aware of patients' views of the service and whether action is taken as a result
- staff are committed to keeping patients and carers informed of progress
- patient privacy and dignity are respected
- patients are involved in the planning and delivery of their care
- care is organised around patients' needs
- lessons are learned from patient complaints and changes made as a result

At the end of each interview, the reviewer completes a site visit recording form.

Information provided by individual members of staff is non attributable in CHI's final report. However, if a member of staff raises serious issues, such as allegations of professional misconduct, CHI has a responsibility to act and it may not be possible to guarantee that person's anonymity. CHI provides training and consistent guidance to all reviewers on the procedure to follow in such situations.

Observation

In addition to interviewing staff, the review team carries out observation sessions in a variety of areas. For example, waiting rooms and reception areas and patient toilets. The review team does not observe within consulting rooms or treatment areas.

These sessions involve talking to staff who have not been included formally on the visit timetable. They enable the review team to capture information about privacy, dignity and respect for patients, patient confidentiality, communication between professionals, management of environmental risks and how facilities meet patients' needs.

The review team will only talk to patients after consultation with, and with the agreement of, the member of staff in charge. Reviewers will not talk to patients without the patient's verbal consent.

6. PHASE THREE: REPORTING, ACTION PLANNING AND PROGRESS MONITORING (WEEKS NINE ONWARDS)

Report writing

After the visit week, the review manager drafts a report. The audiences for the report are the health and social community and its users, and it is made publicly available. It is therefore written in a clear, accessible and jargon free style.

The purpose of the report is:

- to provide a picture of where clinical governance is working well and where the PCT needs to take action
- to highlight areas of good practice
- to provide information for the PCT to use in identifying its priorities for improvement

CHI considers the evidence gathered throughout the review process (from the data and information request, the PCT questionnaire, the staff survey, stakeholders, interviews and observations during the visit week). In reaching conclusions, CHI weighs carefully the robustness of the evidence. This ensures that judgements made in reports are supported by information from a number of sources (figure four).

Figure four: Evaluating supporting evidence

Degree of confidence	Amount of evidence and sources	Reporting back to the PCT ✓ = include in written report or verbal feedback ✗ = does not appear in written report or verbal feedback ? = may appear in written report or verbal feedback
Very confident	A number of sources: data, documents, interviews, observation	✓ Report ✓ Verbal feedback
Confident	Several items of information from the same source type (for example, interviews) from different areas or organisations One interview or observation confirmed by an independent source	✓ Report ✓ Verbal feedback
Some confidence	Several items of information from the same source type (for example, interviews) from the same area or organisation	? Report ✓ Verbal feedback
Little confidence	One interview or observation only	✗ Report ? Verbal feedback

The report contains key findings and action points, as well as examples of good practice. It does not contain recommendations. This enables the PCT to consider the best way of achieving change in its specific context and circumstances.

The PCT receives the full summary of evidence table to assist them in action planning but this does not appear in the report.

Quality assurance

The report is subjected to extensive quality assurance by CHI staff before it is sent to the PCT to comment on for factual accuracy. These staff include assistant directors, the communications team, members of the review team and analysts. The report is then sent to the Department of Health before being sent to print.

Publishing

The report will be published in week 17 of the review.

CHI communications will liaise with the PCT on publication dates and, where necessary, help with media handling. They will also publicise the publication of the report.

Action planning

The PCT is required to generate an action plan in response to the key areas for action outlined in the CHI report. It is the responsibility of the strategic health authority to sign the plan off in consultation with CHI.

Action plans should have:

- clarity about the action required and accountability for the action agreed
- clear and measurable outcomes which focus on continuous improvement to the patient experience
- clarity about the system for monitoring the action plan

To help develop the action plan, CHI asks the PCT to run a workshop with staff, the strategic health authority and other partners in the health community. It is the responsibility of the PCT to organise the workshop.

The workshop takes place in either:

- week 13 of the review, when the chief executive of the PCT and the review manager are confident that the discussion of key themes emerging can be inclusive and encompass all those in the health community
- or within three weeks of the CHI report being published

Once the action plan has been finalised, it is placed on the CHI website alongside the report.

7.PHASE FOUR: IMPROVEMENTS AND MONITORING

Process for assessing progress for trusts with older CGR reports

This is a brief description of the process CHI, with strategic health authorities, will adopt to assess progress against action CHI will notify Strategic Health Authorities (StHAs) which trusts in their area have older CGR reports, and are to have their progress assessed.

For each trust, based on analysis of the CGR report and action plan, CHI will prepare a series of key questions. CHI will supply this list of questions to the StHA for each trust together with a matrix for recording progress.

StHAs will undertake their performance assessment with each trust (collecting and assessing evidence using the CHI matrix to record progress against the action plan). They will produce a draft progress report for consideration by CHI. CHI assistant CGR directors will visit each StHA, to discuss their assessment and the evidence they have collated in support of it.

GLOSSARY

Audit: A review that establishes how well a service meets predetermined standards or criteria

Clinical audit: The continuous evaluation and measurement by health professionals of how far they are meeting standards that have been set for their service (standards can be set by health professionals, themselves, or others). Successful clinical audit also involves changing practice to meet the standards

Clinical effectiveness: For individuals, this means the degree to which a treatment achieves the health improvement for a patient that it is designed to achieve. For whole organisations, it means the degree to which the trust is ensuring that 'best practice' is used wherever possible

Clinical governance: A First Class Service (DoH) and Quality Care and Clinical Excellence (Welsh Office) define clinical governance as "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" (it is about the systems the trust has for ensuring high quality care)

Clinical governance review: A systematic review of the arrangements an organisation has put in place to implement clinical governance

Clinical governance review report: CHI's published findings of each clinical governance review, which are available to the public. The purpose of the report is to identify areas for improvement and to encourage the spread of good ideas

Clinical indicators: Selected measurements of clinical care, which help NHS staff to judge how well they are doing

Clinical information: Any information about treatments or services, which can be used, by patients or health professionals to help take decisions about patient care

Clinical risk management: The systematic use of information and expertise of individuals within the trust to identify and reduce clinical risks to patients

Community health council (CHC): CHCs represent the public interest in the NHS and have a right to be consulted on health service changes in their area

Health and social care economy: The collection of organisations that plan and provide health services in an area including strategic health authorities, NHS trusts, primary care trusts and voluntary health organisations

Lay member: A person from outside the NHS who brings an independent voice to CHI's work

National data sets: A standard set of data items (statistical evidence), concepts and definitions to enable the production of national and nationally comparable data

National indicators: Statistics recorded by the Department of Health (DoH) on a range of specific treatments to allow comparison and measurement of NHS organisations

Performance indicators: Nationally agreed standards and measures to indicate how well an organisation is performing

Qualitative: Data that can not be expressed using numbers, for example, interview statements, diagrams, documents

Quantitative: Data, which can be measured in terms of numbers

Sampling technique: A way of selecting a small group that is representative of a bigger group or the total population

APPENDIX A

Contact details

Commission for Health Improvement

For further details about clinical governance reviews, please contact one of the following:

Kieran Sweeney – Assistant Director
John Dennis – Assistant Director
Andrea Groom – Assistant Director
Jane Farleigh – Assistant Director
Sue Ward – Assistant Director

At:

Commission for Health Improvement
Finsbury Tower
103-105 Bunhill Row
London EC1Y 8TG
Telephone: 020 7448 9200
Fax: 020 7448 9222
Minicom: 020 7448 9292

Or:

Email CHI at the following address:
information@chi.nhs.uk

You can also consult CHI's website, which includes a full description and a complete range of documents relating to the clinical governance review process, and other information about CHI's work at:

www.chi.nhs.uk

Clinical Governance Support Team

The NHS Clinical Governance Support Team runs a series of unique programmes to support the implementation of clinical governance on the ground. Clinical governance is the framework, which helps NHS organisations provide safe and high quality care. Fundamental to making this happen is creating and enabling a cultural, change within the NHS. Through its innovative programmes, the support team enables a wide variety of NHS organisations to involve staff and patients in improving services and to continue to do so. Clinical governance is about changing the way people work, demonstrating that leadership, teamwork and communication is as important to high quality care as risk management and clinical effectiveness.

For further information about its work in England please contact:

Clinical Governance Support Team
2nd Floor, 6 Millstone Lane
Leicester LE1 5ZW
Telephone: 0116 261 9062
Or access its website at: www.cgsupport.org

APPENDIX B

Pilot sites

CHI piloted its initial acute review process in full at four pilot sites, starting in April 2000. They were:

Southampton University Hospitals NHS Trust
City Hospitals Sunderland NHS Trust
North West Wales NHS Trust (Bangor)
Chesterfield and North Derbyshire Royal Hospital NHS Trust

The PCT redesigned review process was tested in eight pilot sites, starting in January 2001: They were:

Central Manchester Primary Care Trust
Fenland Primary Care Trust
North Peterborough Primary Care Trust
South Peterborough Primary Care Trust
South Manchester Primary Care Trust
North Manchester Primary Care Trust
Herefordshire Primary Care Trust
Hillingdon Primary Care Trust

We are very grateful to the management and staff of all trusts for their help in developing the reviews and in our evaluation of the review methods.

APPENDIX C

The clinical governance review process is underpinned by CHI's components of clinical governance. CHI uses a framework of review issues to assess each component. The components and review issues are listed below.

In PCT reviews, the review team additionally considers evidence on the PCT's capacity to implement clinical governance, on the basis of:

- its strategic capacity
- securing service delivery (commissioning)
- health improvement and protection
- patient experience

Work is ongoing at CHI to develop further its conceptual framework in these areas.

REVIEW ISSUES

Patient and public involvement

Accountabilities and structures

- committee responsibilities for patient/service user/carer and public involvement
- staff responsibilities for patient/service user/carer and public involvement work
- reporting and monitoring – to/by management teams, committees and the board, for example of trends in patient/service user initiated areas of concern and complaints

Strategies and plans

- strategy and implementation plans for patient/service user and public involvement work
- connection of the strategy with wider clinical governance and quality improvement programmes
- involvement of patient/service users/carers, or their representative organisations, in policy and planning of services, for example through: public participation groups, citizen juries, stakeholder conferences, lay/citizen and patient/service user/carer representation on board and clinical governance committees
- involvement of partners in strategy development and implementation plans
- resources (staff and budget) to support the implementation of the strategy for patient/service user and public involvement

Application of policies, strategies and plans

- information to the wider public about what the organisation is doing e.g. communications work, reporting on involvement work
- information to the wider public about how well the organisation is doing, for example, performance information

- 'customer' care practice to ensure patient/service users' privacy, dignity and confidentiality about themselves and their treatment, for example codes of conduct, attitudes and behaviours of staff
- availability and quality of written or other information for patient/service users about treatments, services and facilities
- involvement of patient/service users or carers in treatment choices, including processes for patient/service users to consent to treatment
- arrangements to meet patients/service users' particular needs, for example, cultural or dietary
- support to patients and carers in self management of their care and treatment, for example 'expert patient'
- access by patient/service users to information about their care, for example shared care plans patient held records, copies of correspondence between health professionals
- arrangements for patient/service user/carers to voice concerns, issues and compliments about services, for example comment cards, suggestion boxes
- systems for individual patient/service user and carers to seek redress, for example complaints system, patient advice and liaison service (PALS), Independent Complaints Advisory Service

Quality improvements and learning

- involvement of patient/service users, carers and the public in monitoring the quality of care, for example research into patient/service user/carers' views, monitoring and evaluation of services from patient/service user/carers' perspectives
- analysis of all feedback (including complaints) from individual patient/service users on their experience of the organisation
- improvements to the quality of service outcomes (performance) and to the quality of decision making (governance) as a result of patient/service user involvement work
- dissemination of lessons learnt from consultation and patient/service user involvement activities

Resources and training for staff

- training for staff in patient/service user (customer) care, communication skills, obtaining patient/service users' consent to treatment, confidentiality issues, complaints handling
- support for individual patient/service users, for example patients' advocates, support for carers, interpreters, translation services, signers, link workers

Clinical audit

Accountabilities and structures

- committee structure for clinical audit
- staff responsibilities for clinical audit
- reporting and monitoring – to/by management teams, committees and the board

Strategies and plans

- strategy for clinical audit – including priority given to participation in national, regional and local audits – and programmes
- integration of clinical audit with quality improvement programmes, for example to audit compliance with evidence based practice protocols, guidelines and care pathways
- involvement of patient/service users and carers in clinical audit strategy and programme development
- involvement of partners in cross organisational clinical audit
- support and resources for clinical audit including:
 - central clinical audit unit to support audit design, data collection and analysis
 - budgets for clinical audits

Application of policies, strategies and plans

- clinical audits carried out including:
 - connections with other clinical governance activities
 - staff awareness and involvement
- participation in national confidential enquiries

Quality improvements and learning

- processes to consider the results of clinical audits
- compliance with evidence based practice shown by audits
- quality improvements as a result of clinical audits
- dissemination of lessons learnt from clinical audit

Resources and training for staff

- training and development for staff in audit skills

Risk management

Accountabilities and structures

- committee structure for clinical risk management
- staff responsibilities for risk management
- reporting and monitoring – to/by management teams, committees and the board
- strategy and implementation plans for risk management

Strategies and plans

- integration of all risk management activities (clinical, non clinical, health and safety)
- integration of risk management with audit and quality improvement programmes
- consideration of risk in decision making processes
- involvement of patients, service users in carers in risk management
- involvement of partners in developing risk management strategies where risk is to patients/service users who are cared for by more than one organisation, for example other health organisations, social services, police
- resources for risk management including:
 - budgets for risk management activities
 - specialist teams and support, for example for infection control and pressure sore control and tissue viability

Application of policies, strategies and plans

- risk assessment, including:
 - the collation of information from all sources about risks and monitoring of incidents and trends
 - inclusion of information from patient/service users e.g. from complaints
 - involvement of partners, for example at discharge meetings for users at risk
- incident and near miss reporting and investigation
- risk management, including use of trigger events, protocols
- prevention and control of specific risks, for example for: misuse of drugs, use of medical devices, lone workers, infections, pressure sores, violence/self harm

Quality improvements and learning

- analysis of individual risks and events and trends
- quality improvements as a result of risk management activities
- dissemination of lessons learnt from risk management activities

Resources and training for staff

- training and education for staff in risk prevention and management

Education, training and continuing personal and professional development

Accountabilities and structures

- committee structure for education, training and continuing personal development issues
- staff responsibilities for education, training and continuing personal development
- reporting and monitoring – to/by management teams, committees and the board
- strategy and plans for education, training and continuing personal development

Strategies and plans

- links between training and continuing personal development programmes and wider quality improvement programmes, and with individuals personal development plans
- partnerships with educational establishments, joint training programmes with partners, for example other health organisations, social services, police
- budget for professional development, education and training (excluding SIFT and MADEL)

Application of policies, strategies and plans

- personal development planning
- mandatory training including cardiopulmonary resuscitation (CPR), manual handling
- work based training schemes
- continuing personal development programmes
- schemes for obtaining relevant professional, or further, qualifications

Quality improvements and learning

- improvements to services and facilities following external assessments (for example by royal colleges) and internal evaluations of training and education programmes
- dissemination of knowledge of effective education, training and continuing personal development methods

Resources and training for staff

- time, financial and other support for staff undergoing formal education and for individuals' continuing personal development activities

Clinical effectiveness programmes

Accountabilities and structures

- committee responsibilities for clinical effectiveness programmes
- staff responsibilities for clinical effectiveness programmes
- reporting and monitoring of implementation of, and compliance with, evidence based practice– to/by management teams, committees and the board

Strategies and plans

- strategy and programmes for clinical effectiveness work, including research to identify effective clinical practice
- coordination of clinical effectiveness strategy and programmes with the wider clinical governance and quality improvement programmes
- involvement of partners in clinical effectiveness strategy development and programmes
- involvement of patient/service users and carers in clinical effectiveness strategy development and programmes
- resources (staff and budget) to support research, development and implementation of the effective clinical practice

Application of policies, strategies and plans

- collection and distribution of evidence based practice to the relevant teams and staff, including:
 - results of the organisation's own research
 - published evidence of effective practice, including national service frameworks and guidance issued by National Institute for Clinical Excellence (NICE)
- research projects to identify effective clinical practice
- implementation and application of effective clinical practice, for example integrated care pathways, evidence based guidelines for disease management
- monitoring the effectiveness and application of evidence based practice, for example cycle of data collection, use of performance indicators, clinical audit, team discussion, guideline amendment

Quality improvements and learning

- improvements to the patient/service user experience as a result of the implementation of evidence based practice
- dissemination of learning from the implementation of evidence based practice

Resources and training for staff

- accessibility of research results and evidence of effective practice, for example libraries, internet, journals, intranet (or other local electronic library)
- training for staff, for example in critical appraisal skills, literature, database and internet search skills

Staffing and staff management

Accountabilities and structures

- committee structure for staffing issues
- staff responsibilities for staffing
- reporting and monitoring – to/by management teams, committees and the board

Strategies and plans

- strategy and workforce planning for staffing including:
 - delivery of national priorities including targets in Working Together and Improving Working Lives
 - links to service plans
 - current and future number requirements, skill requirements
- joint approaches to staffing with partner organisations, including compatible systems, for example with social services

Application of policies, strategies and plans

- human resources employment processes, for example:
 - equality of opportunity
 - good race relations
 - checking qualifications and registration
 - disciplinary and grievance procedures
- workplace induction
- individuals' performance appraisal
- clinical supervision and mentoring schemes
- systems for dealing with cases of poor performance (including procedures for whistle blowing)
- deployment of appropriate staffing and skills, for example:
 - minimum 'safe' numbers and mix
 - schemes of delegation and supervision
 - protocols for staff working in extended roles (such as nurse prescribing)
- compliance with working time directives
- assessment and management of risk to staff, for example violence to staff, workplace health and safety

Quality improvements and learning

- systems for staff feedback, for example from staff attitude surveys, staff appraisal processes, exit interviews
- consideration of feedback from staff and improvements to the patient/service user experience as a result
- dissemination of lessons learnt from staff feedback

Resources and training for staff

- employee support services, for example:
 - occupational health services
 - independent confidential advice services
 - support against bullying and harassment

Use of information to support clinical governance and health care delivery

Accountabilities and structures

- committee responsibilities for information management and technology (IM&T)
- staff responsibilities for IM&T
- reporting and monitoring of performance targets and achievements– to/by management teams, committees and the board

Strategies and plans

- strategy and plans for IM&T
- priority given to IM&T in strategic plans for clinical governance and to the needs of clinical governance in strategic plans for IM&T
- identification of the clinical and other information needed by the board, executive team, management teams, and clinical teams to support clinical governance and health care delivery
- involvement of patients in identifying information needs
- involvement of partner organisations in IM&T (such as the local implementation strategy)
- resources (staff and budget) to support the implementation of the IM&T strategy

Application of policies, strategies and plans

- information used:
 - to monitor performance and outcomes
 - to support performance review and improvement
 - to inform clinical governance activities
 - to support implementation of policies and guidelines, for example the Mental Health Act
- information management systems (including links to enable sharing of information with staff from other organisations)
- health care records systems, including electronic patient/service user records (including communication of patient information with staff from other organisations)
- processes to ensure confidentiality of information about patient/service users, for example Caldicott guardianship, application of Data Protection Act
- process and systems for assuring data quality

Quality improvements and learning

- use of information to review and improve clinical practice, for example clinical indicators
- dissemination of methods of effective use of information

Resources and training for staff

- training and support for staff in the interpretation and use of clinical information
- analytic support to users of information

APPENDIX D

The role of the trust coordinator

Explanatory note

What is a trust coordinator?

The coordinator plays an important role in the success of the Commission for Health Improvement (CHI) clinical governance review. He or she acts as the main point of contact between our phase one and review teams and the PCT, assisting with collecting information, planning the review, and helping ensure the visit runs smoothly. Their help will be greatly valued by the review teams.

Who should be a coordinator and how much of their time needs to be allocated to the role?

The coordinator selected by the PCT will need to have an understanding of how the PCT operates as a whole and knowledge of clinical governance arrangements in the organisation would be helpful. The trust coordinator will also need good organisational and communication skills.

We recommend that a trust coordinator should be dedicated to the review on a full time basis. It will also be helpful if the trust coordinator continues as the main point of contact during the reporting and action planning stages.

What does a trust coordinator do?

The trust coordinator will assist in the first three phases of a review. During phase one, we ask the coordinator to publicise the review to staff and patients. CHI will work closely with the PCT communications staff to supply methods of publicising the review. We also ask that the trust coordinator ensures that all information requested by CHI during phase one is sent to the phase one team on time, and that they coordinate the process of writing to patients to invite them to attend the stakeholder meetings. The trust coordinator will be asked to help with the practical arrangements for the review, such as scheduling and arranging work areas, and catering for the review team during the site visits.

The trust coordinator will have a key role during collection of data and documents requested by CHI in phase one. We will give the trust coordinator a checklist to help him/her through the data collection process. This checklist will log and identify every document the PCT needs to return to CHI and full instructions for its completion are supplied within the document Pre visit request for existing data and information.

The trust coordinator will also have a key role in coordinating, via general practices, the process of writing to a selection of patients to invite them to attend the stakeholder meetings. The necessary guidance and materials will be sent to the trust coordinator, who will have responsibility for distributing them to general practices and ensuring their collaboration.

During the review week, the trust coordinator will be asked to assist in any logistical arrangements, such as organising guides to accompany the review team members from appointment to appointment and rearranging interviews if necessary.

After the review week, the trust coordinator should coordinate comments on the factual accuracy of CHI's draft report, and may wish to assist with the action planning for the PCT.

What information is available for the trust coordinator?

During phase one, all communication will be via the phase one team, who will be happy to provide help and advice. The team can be contacted on 020 7448 9377.

The trust coordinator will find a number of guidance documents, including a mock timetable to use as a basis for scheduling meetings and visits during the site visit, in the review information manual.

At the initial meeting, the CHI review manager will clarify the details of the review process and will offer support and guidance throughout the review and report writing phase.

APPENDIX E

Indicative timetable for site visit

Day 1 – 3

- interviews/observations to start Monday morning
- out of hours visits carried out
- daily team debriefing for review manager and reviewers
- reviewer notes typed, coded and sorted
- themes identified on Wednesday afternoon

Day 4: AM

- 'mop up' interviews if required

Day 4: PM

- CHI team will synthesize data, evidence and assessments
- team debriefing

Day 5

- CHI team refine evidence base ready for report writing