SECTION TWELVE
CLINICAL AUDIT

This section considers:

- Clinical Audit Strategy
- improving the quality of care through clinical audit activity
- building prioritised clinical audit requirements into commissioning contracts.

Clinical audit – challenge and opportunity

Clinical audit is a:

'... quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery'.

NICE/CHI/RCN/University of Leicester, 2002

This definition is endorsed by the National Institute for Clinical Excellence. Clinical audit is now widely recognised as one of the key components of clinical governance.

'When done well, clinical audit has provided a way in which the quality of the care can be reviewed objectively, within an approach that is supportive and developmental. Changes in society have subjected all areas of professional practice to question and challenge. Clinical audit provides practitioners with a systematic response that compares the care provided to best practice while preserving the central role of the clinical team in agreeing and implementing plans for change. Clinical governance presents a new challenge – to take audit 'at its best' and incorporate it within organisation-wide approaches to quality.'

NICE/CHI/RCN/University of Leicester, 2002

This is an important opportunity as well as a challenge. Although there has long been evidence of extensive audit activity, in both the acute and primary sectors, evidence of improvements in patient care as a consequence of audit outcomes has been slower to accumulate. The Commission for Health Improvement expressed some concern about clinical audit in the overwhelming majority of the (predominantly acute) reviews published to December 2002.

Partly as a result of this renewed focus upon the importance of audit within the wider clinical governance agenda, a new national strategic framework for clinical audit will be published later this year by the Department of Health. It will make clear to all NHSTs, including PCTs that they are expected actively to participate in systematic and targeted national and local audit programmes – and to ensure that they act appropriately on the outcomes of such programmes to ensure improvements in both the safety and the quality of care. Significant support to this process has already been provided via the publication of the NICE *Principles for Best Practice in Clinical Audit* – which provides evidenced and detailed guidance for professionals across the NHS.

Key learning from the pilot programme

For PCTs, clinical audit is currently the most challenging of the 'technical components' of clinical governance.

The new national framework on clinical audit will provide an opportunity to offer implementation guidance and support to help all PCTs to focus their audit activities upon clinical priority topics; to secure multi disciplinary engagement with clinical audit and; to use audit as a lever for co-ordinated improvement in the quality of the overall patient journey via collaborative audit across organisational and system boundaries.

Across all the PCTs in the pilot programme the section on Clinical Audit proved to be the most challenging, scoring only 4.0 on the progress scale (range 2.5 to 5.8).

The most recently formed PCTs find clinical audit more problematic. The 25 PCTs that were under a year old when they completed the questions scored an average of 3.9 whilst the remainder scored an average of 4.1.

Most PCTs, at the point when they completed the questionnaire, had not developed a clear audit strategy that was explicitly linked to their clinical governance priorities, nor did they have a comprehensive and timetabled action plan for audit implementation.

This was in part because the overwhelming majority of PCTs do not have the organisational audit infrastructure that exists in almost all acute settings. Accordingly, not only time, but specific expertise in the construction, process management, data analysis and follow up of clinical audit is thinly distributed across the PCT community.

As a result many were unable readily to identify examples of:

- multi-professional audit
- audit that followed the patient journey (as opposed just to the episode of care)
- change processes
- quality improvement, in outcomes or patient experience, resulting from audit.

Only a handful of PCTs were able to point to evidence of purposeful audit undertaken by dentists, pharmacists or optometrists. Desirable aspects of clinical audit, such as the active participation of patient groups in the definition of audit priorities, are currently only distant aspirations.

PCTs will need significant support in this area if they are routinely and systematically to exploit clinical audit to deliver the intelligent clinical information about standards of care that the new Commission for Health Audit and Inspection will expect organisations to gather and use as the basis of their plans and actions (see Section 7).

Establishing clinical audit priorities

Audit should routinely proceed from the agreed clinical priorities of the PCT and must generate robust evidence against national benchmarks and the emergent National Service Frameworks. Audit activity needs to be effectively resourced, managed and supported if evidenced gains in the overall quality of care are to repay the time invested by professional and other staff.

'If the potential of clinical audit is to be harnessed, it is essential that audit strategy and specific activity:

- actively engages all stakeholders, including patients and other service users
- is explicitly derived from the clinical governance strategy and priorities of the PCT
- is explicitly linked, wherever appropriate, to national clinical priorities
- embraces, over time, all of those services which the PCT provides and all of those services which it commissions
- is explicitly linked to other activity and priorities which seek to improve clinical effectiveness and the overall quality of care directly (e.g. clinical risk management, evidence-based practice) or indirectly (commissioning, education, training and CME/CPD)
- is co-ordinated, wherever necessary, across the boundaries of the local health (and social care) economy
- is not viewed as an end in itself, but leads to evidenced improvements in the quality of care
- has the sustained support of the PCT, PEC and Board.
- 'Clinical Audit must be fully supported by Trusts.'

Department of Health, 2002

Some additional factors are more likely to promote change. These include, for example:

- small scale projects, at least initially, that make use of PDSA cycles
- drivers for change which are already in place
- identification of champions
- explicit support from the Board and the PEC.

REFLECTION

Is there evidence of a prioritised clinical audit strategy that derives from the overall clinical priorities of the PCT?

The enthusiasm and energy of staff can all too easily be blunted if the overall preconditions for change do not exist. In more than half of the Trusts that it has visited, CHI has noted that audit activity was not linked to the Board's clinical governance priorities.

'Many projects that may have been well designed have taken place without any tangible senior support and commitment. This has made the conduct of audit an uphill struggle as enthusiastic teams find their ambitious plans thwarted by organisational inertia.'

NICE/CHI/RCN/University of Leicester, 2002

Targeted implementation of clinical audit in practice

Given the richness and variety of the clinical activities carried out on behalf of a PCT, the list of potential audit topics is almost limitless. The Trust's clinical governance priorities provide an essential starting point in determining where the focus of clinical audit activity should be – in current and in subsequent years. In its pilot PCT activity, CHI expressed concern that audit strategies and policies had not been formulated.

'As part of local arrangements for clinical governance, all NHS organisations are required to have a comprehensive programme of quality improvement activity that includes clinicians participating fully in audit. Clinical audit is the component of clinical governance that offers the greatest potential to assess the quality of care routinely provided for NHS users – audit should therefore be at the very heart of clinical governance systems.'

NICE/CHI/RCN/University of Leicester 2002

In preparing a clinical audit strategy to support the implementation of the overall clinical governance strategy, it is important to identify and balance:

- the (sometimes competing) claims of national and regional priorities,
- the views of the PCT's own clinical staff
- the views of the wider patient community.

Participation in the cancer and CHD parts of the National Clinical Audit Support Programme (NCASP), for example, is identified as a priority in the PPF 2002/3.

PCTs must consider the services provided in community dentistry, pharmacy and optometry as well as the historical core of PCT medical services, nursing and AHP services when considering the targets for audit. The NICE *Principles for Best Practice in Clinical Audit* sets out a clear five-stage process for moving from strategy to implementation:

'Stage One: preparing for audit

Stage Two: selecting criteria

Stage Three: measuring level of performance

Stage Four: making improvements

Stage Five: sustaining improvement'

NICE/CHI/RCN/University of Leicester, 2002

The criteria determining the ultimate selection of specific topics (and the order in which they will be addressed) should be transparent. Staff are then clear from the outset about what will be audited, when and why

'The process of clinical audit ... should be at the core of a system of local monitoring of performance.

Bristol Royal Infirmary Inquiry, 2001

There is clear evidence from CHI reviews in the acute sector that organisations do not always select audit topics according to clinical governance priorities. CHI raised concerns about audit not addressing clinical governance concerns in nearly three quarters of reviewed organisations to the end of December 2002 and it was also concerned that, in some organisations, audit was not linked to other clinical governance components such as risk management and research. Many of these concerns have been echoed in more recent CHI reviews of PCTs.

The clinical audit task confronting PCTs, within the boundary of any defined time cycle, can be considerably eased if a number of Clinical Governance priorities have been identified and explicitly owned within and across the PCT and, where possible, the local health economy (these issues are dealt with more comprehensively in Section 8). These priorities need to address:

- compliance with NICE guidance
- implementation of NSFs
- national, local and regional priorities.
- education for staff about clinical audit and change management.

'The strategy must explain how clinical audit activity is prioritised and who conducts that process.'

Clinical Governance Bulletin, 2002

Efforts to initiate and evaluate clinical audit findings and action can then be co-ordinated around concrete clinical priority issues and a repeat audit can support, monitor, measure and evaluate the impact of change management actions.

The overall targeting needs to take into account all of the complex factors associated with and included in an effective clinical audit cycle.

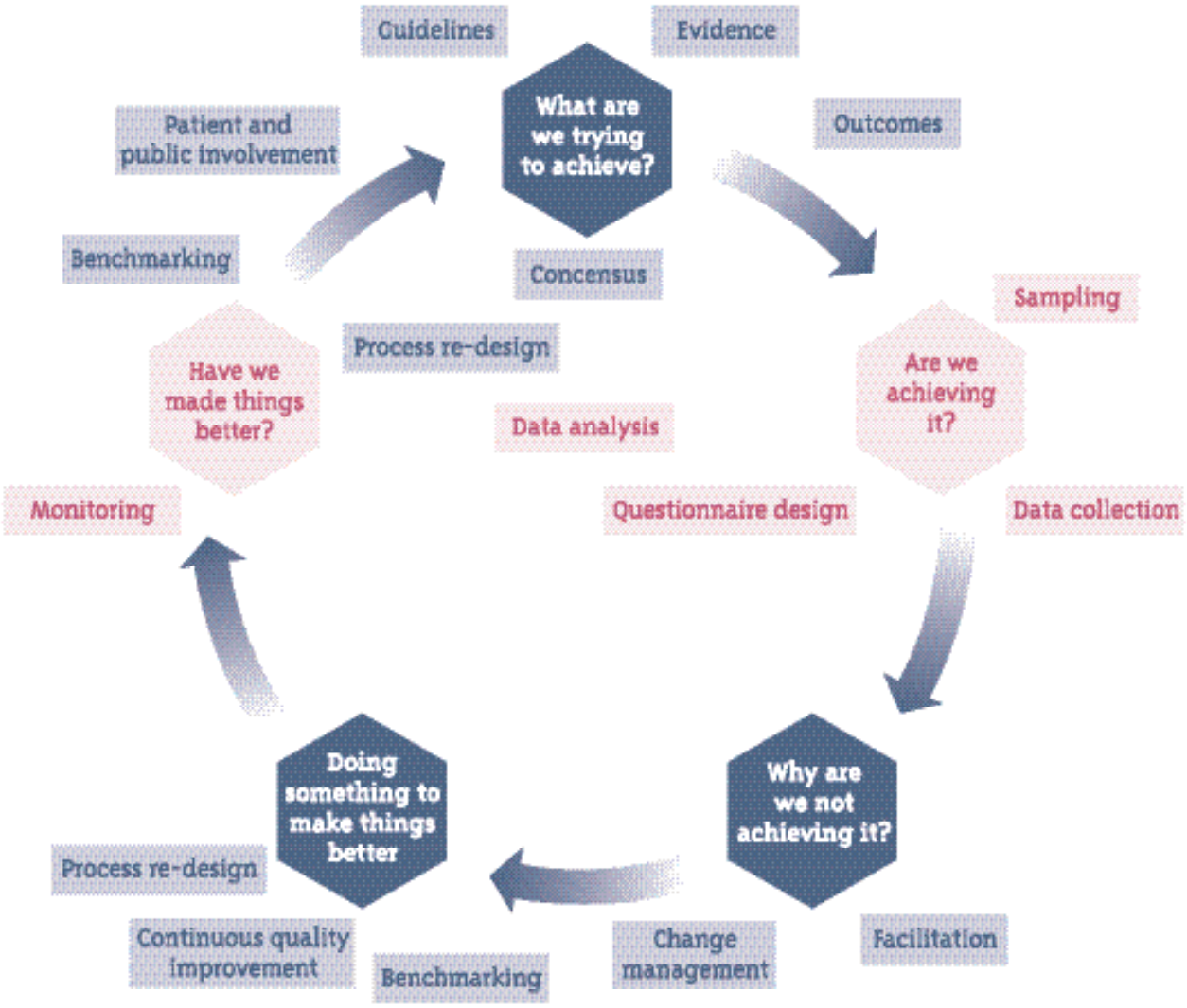

Figure 12.1. The clinical audit cycle.
From: Principles for Best Practice in Clinical Audit *NICE/CHI/RCN/University of Leicester, 2002*

Identifying lead responsibility for clinical audit

Every PCT is required to identify and appoint a designated clinical audit lead. It is essential that the identified leads' authority is sufficient for them to discharge the responsibilities inherent in this important agenda.

'Each Trust has a lead individual with responsibility for clinical audit and all doctors are required to participate in clinical audit programmes.'

Department of Health, 2002

The PCT must judge whether the clinical audit lead requires the support of a formal committee or merely acts wisely in ensuring that appropriate consultation and collaboration with others in planning and implementing the audit cycle. In either case the PCT must have clear policies setting out

- how audit priorities will be corporately approved
- how all groups of professional staff will be involved in audit

- how the progress and outcomes of audit will be reported back to the Clinical Governance committee, the PEC and the Board.

'Reporting mechanisms specified within the strategy should focus on ensuring that the audit loop is always closed and that systems exist to track implementation.'

Clinical Governance Bulletin, 2002

Ensuring that patients have an active voice in all stages of the audit cycle

The views of patients and local communities must contribute to the definition of the overall clinical governance priorities of a PCT. It is also important that the patient voice and experience help to shape and inform the setting of audit priorities – and the nature and micro-focus of the audit process. For the overwhelming majority of PCTs in the pilot programme, however, this was currently no more than an aspiration.

Because of some of the technical and scientific demands of robust audit, to turn this aspiration into reality it will be necessary to develop strategies that ensure that patients have an informed rather than merely token voice. This will demand imagination and commitment from the PCT's professional community.

'The focus of any audit project must be those receiving care. Users can be genuine collaborators, rather than merely sources of data.'

Balogh et al., 1995

'The concerns of users can be identified from various sources, including:

- letters containing comments or complaints
- critical incident reports
- individual patients' stories or feedback from focus groups
- direct observation of care
- direct conversations.

...Users are increasingly involved as members of clinical audit project teams. Where users are involved in this way, careful thought needs to be given to issues of access, preparation and support.'

Kelson, 1998

Appropriate links to the Expert Patient programme, or to local or national groups which support or represent patients suffering from the targeted clinical condition, may also provide possible ways forward.

Making the most pragmatic and effective use of available resource

Some forms of 'retrospective clinical audit' can begin from a structured critical analysis of data which already exists – albeit not previously in an aggregated form. This can make excellent use of scarce time and human resources.

Rather than generating original and unique audit protocols it makes good sense to draw upon (and adapt where necessary) those which have already been developed and validated, such as those to be found at www.pcnow.info/list_of_audit_protocols.htm

Engaging the multi-disciplinary team

Most primary care involves more than just one single professional (or profession). Whenever an audit topic directly or indirectly impinges upon the work of a multi-disciplinary team, it is essential that all of them become 'active and informed' participants in the audit process. This is most likely to occur when the overall organisational culture is one that promotes critical reflection and widespread ownership of a common approach to quality – and where staff have the necessary technical knowledge about effective audit.

'Efforts must be made to ensure that the NHS creates the local environment for audit. Second, the NHS needs to make sure that it uses audit methods that are most likely to lead to audit projects that result in real improvement.'

NICE/CHI/RCN/University of Leicester, 2002

The GMC and a number of other key professional bodies now have an explicit requirement that individuals must provide evidence of their active engagement with and participation in clinical audit as a precondition of re-registration. Nevertheless in more than half of the Trusts reviewed to date, including PCTs, CHI has called for organisations to take action because audit is not planned or conducted with the involvement of all relevant disciplines, with consequences for staff and patients. It has suggested that all organisations should consider how they could:

- improve the planning for multi-disciplinary involvement of staff
- ensure that staff had the necessary audit knowledge and skills (particularly in primary care).

'Trusts should ensure that healthcare professionals have access to the necessary time, facilities, advice and expertise in order to conduct audit effectively.'

Bristol Royal Infirmary Inquiry, 2001

Notwithstanding the disruption that has happened in some places as a result of structural changes, a great deal of good work has been carried out by primary care audit groups/medical audit advisory groups that have continued to exist (for example the Leicester PCAG and the audit Groups at Sheffield SW PCT) and by the National Audit and Governance Group. Their knowledge, expertise and experience have made a valuable contribution in supporting the development of PCT clinical audit programmes.

Audit and the commissioning process

Boards and PECs must take all reasonable steps in their commissioning arrangements to ensure that:

- good clinical audit practice is embedded in all of those organisations that provide services to their patients
- they have built explicit and key audit activities into their commissioning requirements
- they, or their delegated sub-committees or nominated individuals, see the results of audits undertaken by their commissioned providers (where appropriate) and the actions that follow from it.

Auditing across system boundaries and frontiers

Audit is an important means to improvements in the overall quality of care. Much of patient's overall care is delivered by a range of organisations in the health and social care 'chain'. In determining their commissioning arrangements with acute and other providers, PCTs need to ensure that they negotiate and agree audit activities that will generate evidence of the effectiveness of these services. Where General Practitioners are working in Special Interest areas, it is particularly important that they are involved in regular integrated audit meetings with the multi-disciplinary team of secondary care colleagues.

Providing appropriate care to patients often demands managing a transition from one provider to another. The audit process should follow and map the patient journey, rather than focussing exclusively upon that part of the process which occurs within the boundary of any one organisation. This relies on collaboration and co-ordination between partners in the local health and social care economy. It will, however, provide concrete evidence of partnership in action for patients' benefit.

'In North Tyneside, there was an acknowledgement that stroke patients were receiving fragmented care. A multidisciplinary audit revealed that baseline data were not available, there were few agreed outcomes measures and stroke care was seen as purely hospital based. A multidisciplinary stroke pathway was implemented across the whole medical and elderly directorate, followed by a community stroke pathway, piloted at a local general practice. Evaluation showed consistently high levels of use of the pathway by professionals. Use of the tool was regarded as one of the major components in bringing about what proved to be a successful change, reorienting services towards an approach which was multidisciplinary, more community- focused, susceptible to audit- and, crucially, centred on the needs of patients and carers.'

Curless, 1998

CHI has expressed concern that its reviews to date have found relatively few examples such as this where audit addresses the patients' total experience of care. This issue is likely to be pursued vigorously by the new Commission for Health Audit and inspection, which lays significant emphasis upon the patient's experience of her/his journey through and across the care system.

Ensuring that audit findings lead to action

Whether or not a properly constructed clinical audit programme uncovers serious problems or shortcomings, it will almost certainly identify a number of ways in which either the process or outcome of care could be improved. At this stage a report back to the PEC and Board is an essential link in the chain of effective audit. Useful as this information is, unless targeted and managed activity to generate sustained change ensues, there will be no actual improvements in care to repay the cost of the activity. CHI has expressed concern that, in many cases, little evidence exists that this loop has been properly closed.

'In many cases audit projects have failed to emphasise in their plans the need to devote just as much attention to changes that need to flow from audit as they have given to data collection and analysis. The failure to follow through audit towards improved practice has sometimes been the result of design problems, sometimes lack of senior support and commitment.'

NICE/CHI/RCN/University of Leicester, 2002

The guidance incorporated in the NICE Principles for Best Practice in Clinical Audit describes a number of models and processes that can effectively close this loop – and builds on findings from the earlier Royal College of Physicians/NHS Executive audit project.

Action on Clinical Audit Key Findings

' Generating significant and sustainable clinical change

A change management strategy must be – 'built in rather than bolted on to project design'

The reverberative impact of audit led change on other parts on the intra or inter organisational system needs to be thought through- 'identifying, from the outset, everyone whose clinical behaviour might need to change was vital'

Outcomes and results need to be 'marketed' – 'we learned how important it was to target, to involve and to persuade''

Royal College of Physicians/NHS Executive, 2000

Ensuring that action is co-ordinated

Because change in any one part of the health or social care system often reverberates on other parts of the system, sustained change is only possible where these impacts are identified early, so that complementary and co-ordinated change can occur 'downstream'. Otherwise, 'back up' will result and attempts at improvement will be frustrated.

Priorities for action

Now that you have finished reading through this section, please identify three priorities for the PCT in relation to clinical audit and relate them to the model process checklist set out below.

1

2

3

Checklist: Model clinical audit strategy development process

1 The PEC in conjunction with the PCT clinical audit lead determines when and how the overall clinical audit strategy should be drawn up, and who (including patients and relevant partner organisations and groups) must be consulted, as a part of this process when the draft must be presented to the PEC.

2 The PEC debates the strategy, identifies resource, education and training and other implications, and adopts the strategy (which may then be endorsed by the Clinical Governance Committee and the PCT Board).

3 The PEC/Clinical Governance Committee, in conjunction with the PCT clinical audit lead, identifies who will initiate specific clinical audit programmes, the requisite resources, the time frame and the fit with PEC/CG Committee reporting cycle.

4 An analysis of the audit data is undertaken or, where necessary, commissioned, and the implications for clinical and organisational practice are identified, including those that have a bearing upon other technical components of clinical governance (i.e. risk management, education and training).

5 The PEC/CG Committee, in conjunction with the PCT clinical audit lead, identifies and agrees actions necessary as a result of the data analysis from specific audits, and mandates whoever will carry out the specific actions (including identifying and acting upon the implications for other clinical governance functions).

6 After an appropriate interval, the PEC/CG Committee, in conjunction with the PCT clinical audit lead, initiates a re-audit to identify sustained improvement/slippage, and mandates any necessary action.

7 The PEC/CG Committee in conjunction with the PCT clinical audit lead undertakes a meta-analysis of the outcomes of all audits undertaken within the cycle to identify 'underlying themes' which may require action.

8 The PCT clinical audit lead ensures that these activities and outcomes are reflected in the Annual Audit Report and that this is incorporated into the Annual Clinical Governance Report.

References

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Bristol Royal Infirmary Inquiry 2001. *Learning from Bristol: The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995*, BRI Inquiry Final Report, Bristol: BRI Inquiry

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Curless R. 1998. (Quoted in) *Making informed decisions on change*, National Co-ordinating Centre for NHS Service Delivery and Organisation R & D

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Kelson, M. 1998. *Promoting Patient Involvement in Clinical Audit: Practical guidance on Achieving Effective Involvement*, London: College of Health

NICE/CHI/RCN/University of Leicester 2002. *Principles for Best Practice in Clinical Audit*, Oxford: Radcliffe Medical Press

Royal College of Physicians/NHS Executive 2000. *Action On Clinical Audit*, London: Royal College of Physicians/NHS Executive

Resources

Indicators underpinning the performance assessment framework

Quality and performance in the NHS: high level performance indicators and clinical indicators

www.doh.gov.uk/indicat.htm

NHS Performance Indicators: Acute NHS Hospitals Trusts

www.doh.gov.uk/nhsperformanceindicators/2002

www.pcnow.info/list_of_audit_protocols.htm

The NICE 'Principles for Best Practice in Clinical Audit' Radcliffe Medical Press 2002 includes an exhaustive and systematic set of references to the literature and to key support materials

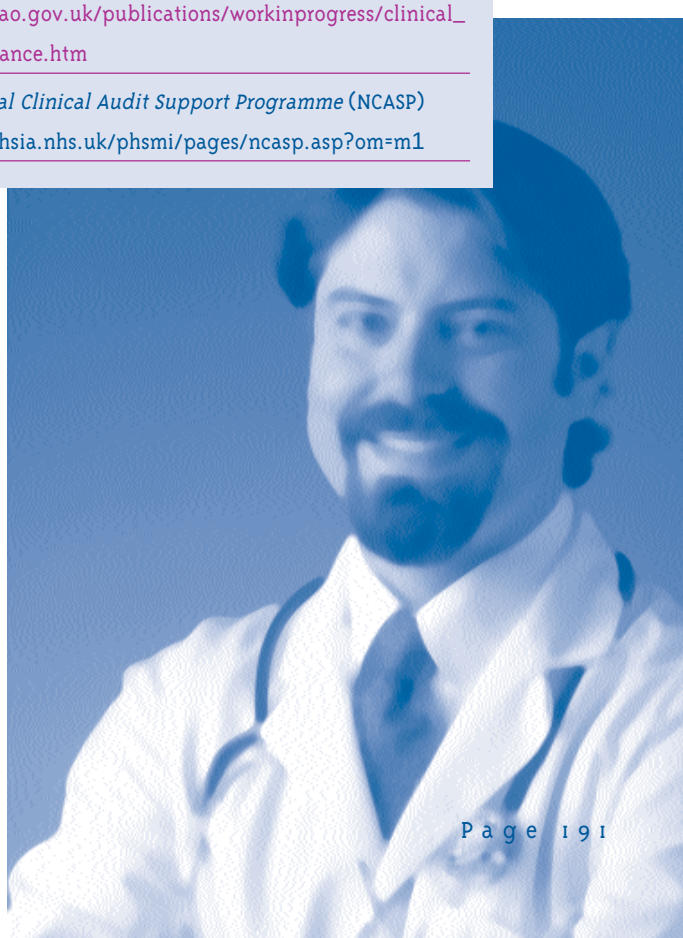
www.miart.co.uk/i-medicine.info/audit.asp

National Audit Office

www.nao.gov.uk/publications/workinprogress/clinical_governance.htm

National Clinical Audit Support Programme (NCASP)

www.nhsia.nhs.uk/phsmi/pages/ncasp.asp?om=m1



Rating the PCT's current stage of development

Please rate the PCT's current stage of development in relation to the following questions.

Remember to use the Response Sheet provided for your answers.

12.1 To what extent does the PCT have an explicit clinical audit strategy derived from local and national clinical priorities?

12.2 To what extent are all professional staff groups involved in multi-professional audit activity?

12.3 To what extent does any PCT-led activity audit the complete patient journey?

12.4 To what extent is there evidence of change as a result of clinical audit outcomes?