



HQIP

Healthcare Quality
Improvement Partnership

Guide for Clinical Audit Leads

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Clinical audit tool to promote quality for better health services



Contents

1	Introduction	1
1.1	Who this guide is for	1
1.2	How the guide is intended to help	1
2	What's involved in being a Clinical Audit Lead	1
2.1	Purposes, responsibilities and accountabilities of the role	1
2.2	Responsibility for junior doctors' and junior dentists' involvement in clinical audit	2
3	Getting started as a Clinical Audit Lead	2
3.1	Clarifying requirements, expectations and future needs	2
3.2	Gathering evidence on the effectiveness of clinical audit	4
3.3	Drawing conclusions about your priorities	5
3.4	Learning about resources and support available	6
3.5	Identifying your learning and support needs	6
3.6	Defining your accountability	7
4	Getting a clinical audit plan or programme established and carried out	7
4.1	Producing or assessing an existing clinical audit programme	7
4.2	Developing priorities for locally-generated clinical audits	8
4.3	Checking that proposed clinical audits are worth doing	9
4.4	Accommodating additional proposed clinical audits	10
4.5	Planning how to carry out the clinical audit programme	10
4.6	Involving junior doctors and junior dentists in the clinical audit programme	11
4.7	Setting and negotiating timetables	11
4.8	Reviewing the designs of proposed clinical audits	12
5	Monitoring and managing a clinical audit programme	15
5.1	Monitoring progress	15
5.2	Facilitating the implementation of needed changes in practice	16
6	Supporting colleagues to do clinical audit	17
6.1	Meeting learning needs about clinical audit	17
6.2	Motivating people to complete clinical audits	18
7	Leading meetings involving clinical audit	18
7.1	Shifting the focus of meetings on clinical audits	18
7.2	The clinical audit meeting calendar	19
7.3	A core agenda for clinical audit meetings	22
7.4	Advising staff on presenting individual clinical audits at meetings	23
8	Communicating about the clinical audit programme	24
8.1	Meeting your trust's needs for information about clinical audits	24
8.2	Reports of individual clinical audits	25
8.3	Sharing learning and celebrating success about clinical audit	25
9	Handling ethics and risk-related issues in clinical audit	26
9.1	The importance of being aware of ethics in clinical audit	26
9.2	Possible ethics and risk-related issues related to clinical audits	26

10	Troubleshooting for Clinical Audit Leads	27
10.1	Problems Clinical Audit Leads might face and possible actions	27
	References	30
	Acknowledgements	30
	Appendix 1. Sample role description for Clinical Audit Lead	31
	Appendix 2. Knowledge and skills related to the role of Clinical Audit Leaders	33

1 Introduction

1.1 Who this guide is for

This guide is primarily for clinicians who have assumed responsibility for leading clinical audit in a clinical service or setting, directorate, division or healthcare organisation. The word clinician includes doctors, dentists, nurses, pharmacists, therapists, psychologists and any other healthcare professionals who may take on this role.

It also should be helpful for medical and clinical directors to provide guidance for their Clinical Audit Leads on the role and to know important aspects of the role for appraisal purposes. Staff members who support clinical audit and members of committees that have responsibility for clinical audit also may find the guide useful.

1.2 How the guide is intended to help

NHS trusts need to manage the conduct of clinical audits in clinical services. Trusts need to have evidence that clinical audits are being designed, assessed for technical quality, monitored for progress, and acted on when audits show the need for improvement. Often, individual clinicians are asked to 'lead' clinical audit in their services, divisions, directorates or specialties to enable the trust, in coordination with the trust's clinical governance team, to ensure that clinical audits are being carried out effectively in all clinical services.

This guide describes how Clinical Audit Leads can manage the conduct of clinical audits in their clinical services so that the clinical audits carried out provide benefits for patient care and are recognised as valuable by clinical colleagues and the trust. The guide includes the following:

- what can be involved in being a Clinical Audit Lead
- how to get started in the role
- systems and support that should be available from an NHS trust for Clinical Audit Leads
- how to develop a plan for clinical audits to be carried out and implement the plan, including encouraging staff to involve patients or their representatives in relevant clinical audits
- how to monitor, manage and facilitate achievement of the intended outcomes of clinical audits carried out
- how to support colleagues in carrying out clinical audits
- how to communicate about the clinical audit programme and what it is achieving
- how to ensure that risks associated with clinical audits are recognised and handled properly
- problems Clinical Audit Leads can encounter and suggestions for handling the problems.

2 What's involved in being a Clinical Audit Lead

2.1 Purposes, responsibilities and accountabilities of the role

The key **purpose** of the role of a Clinical Audit Lead is to **provide leadership** in a clinical service for the completion of clinical audits. Leadership of clinical audit can involve any or all of the responsibilities in the box on the next page.

Key possible responsibilities of a Clinical Audit Lead

Explain and **promote the importance** of clinical audit and the **trust's approach** to clinical audit **and policies** related to clinical audit to colleagues.

Develop a **forward plan or programme** of clinical audits to be carried out in a clinical service, which reflects the organisation's and the clinical service's priorities, and ensure that people working in the service carry out the designated audits.

Monitor and manage progress on carrying out clinical audits in the plan.

Facilitate any communication or **processes needed to act on findings** of clinical audits in order to achieve needed improvements in the quality or safety of patient care.

Support colleagues to carry out individual clinical audits, including junior doctors and junior dentists.

Ensure that the **work** being carried out related to clinical audits **is communicated** within the clinical service, to clinical service management, and to the trust.

Ensure that any **problems** associated with the clinical audit programme **are addressed** responsibly.

See Appendix 1 for a sample role description for a Clinical Audit Lead.

2.2 Responsibility for junior doctors' and junior dentists' involvement in clinical audit

If your clinical service has doctors or dentists' in training, clarify responsibility with clinical and educational supervisors for ensuring that Foundation Programme doctors, Specialty Registrars and Senior House Officer and Specialty Registrar dentists are actively involved in clinical audits. See *Guide for Involving Junior Doctors in Clinical Audit* at www.hqip.org.uk for specific guidance on the way that junior doctors can carry out clinical audits for a clinical service.

3 Getting started as a Clinical Audit Lead

3.1 Clarifying requirements, expectations and future needs

When you are asked to be a Clinical Audit Lead, you may wish to clarify the requirements, expectations and future needs that have an impact on the role of the Lead. The requirements will consider the trust's policies, objectives and priorities in relation to clinical audit and quality improvement. For information on key external requirements, see the Care Quality Commission's standards, *Essential Standards of Quality and Safety*, at www.cgc.org.uk and the NHS Litigation Authority Standards, *NHSLA Risk Management Standards*, at www.nhsla.com.

The way the terms requirement, expectation and future needs are being used, and examples of what to clarify, are in the box on the next page.

Requirements, expectations and future needs related to clinical audit in a clinical service

Term	Meaning	Examples
Requirement	Any essentials that must be done or delivered about clinical audit in the clinical service	<p>The trust's objectives and priorities related to clinical audit and quality improvement</p> <p>Having clinical audits done in the clinical service consistent with the trust's policy document on clinical audit</p> <p>A 'forward plan' of clinical audits to be carried out in the next year</p> <p>Participation by the clinical service in the Trust-wide clinical audit on record keeping</p> <p>Participation in national clinical audits that relate to the clinical service</p> <p>Involvement of junior doctors and junior dentists in clinical audit</p> <p>Involvement of patients or patient representatives in relevant clinical audits</p> <p>National requirements relating to clinical audit, such as the NHS Litigation Authority Risk Management Standards</p>
Expectation	Any perception that colleagues or the management have of how (and how well) clinical audit is done now in the clinical service — positive and negative impressions or attitudes people might have about the audits done in the service	<p>'We have changed a few things as a result of particular clinical audits'.</p> <p>'Nothing ever changes as a result of any clinical audit done in the service'.</p> <p>Some of the so-called clinical audits are just collations of data about how many patients have had a particular service.</p> <p>The junior doctors don't have time to 'complete the cycle' during their rotations in the service.</p>
Future need	What the clinical service may have to do about clinical audit in the future — gaining an understanding of and responding to what will be required or expected some time from now	<p>Have evidence that actions recommended as a result of clinical audits have been implemented (as required in new NHS Litigation Authority standard on clinical audit)</p> <p>Have evidence that actions needed as demonstrated by the service's participation in a national clinical audit have been implemented and practice or patient outcomes have improved (may be reported as part of a trust's Quality Accounts)</p> <p>Future Commissioner requirements related to clinical audit</p>

You can learn the requirements, expectations and future needs by having brief conversations with any or all of the following:

- the director of the clinical service
- the trust's medical director
- the head of governance in the trust
- the person(s) who was (or were) in the Clinical Audit Lead role previously
- representative clinical colleagues in all professional groups that work in the clinical service
- representative junior doctors and junior dentists
- clinical audit or clinical governance staff who work in the clinical service or in the trust.

You will find it useful to make contact with your organisation's clinical audit department early on in your role. A clinical audit manager or facilitator can:

- guide you on accessing technical or administrative support for clinical audits in your service
- inform you about the processes that support clinical audit in the organisation
- help you access information about clinical audits carried out previously in your clinical service
- give you key information resources about clinical audit
- advise you on technical aspects of the clinical audit process.

3.2 Gathering evidence on the effectiveness of clinical audit

You also may want to gather your own evidence on how clinical audit has been working in the clinical service by accessing records or reports of clinical audits that have been carried out in the service or minutes or notes of meetings at which clinical audits have been presented. Examples of questions you could ask yourself are in the box.¹

Questions about the effectiveness of clinical audit in the clinical service

Is clinical audit **being done properly** in the clinical service that is, is the approach taken to clinical audit in the service **consistent and does it represent best practice in the clinical audit process**?

Are clinical audits being done on **important clinical subjects**, that is, subjects that will benefit patient care by leading to improving quality and/or reducing the risk of harm to patients?

Has participating in or doing a clinical audit appeared to staff to be a **personally or professionally satisfying** experience?

Do clinical audits routinely include **specific measures of quality**, that is, standards, criteria or indicators? Do they appear to refer to current evidence, where evidence is likely to exist?

Has the **data collection and collation process** been **transparent** and likely to **produce reliable data** that clinicians would be willing to act on?

Have the clinical audits completed so far been **worth the time and effort** taken to carry them out?

Have the clinical audits carried out in the service **led to improvements** in practice or patient care, if needed? If not, what appear to have been the barriers to implementing change?

Is clinical audit in the clinical service **benefiting patient care, confirming good practice, or serving any other important purpose?**

Has **data collection** routinely and quickly been **repeated** to see if action to improve patient care has worked?

Have **meetings** to discuss clinical audits been perceived as a **valuable use of clinical time?**

Have **patients or their representatives** been **included** in any way in any part of the clinical audit programme?

For more information on carrying out clinical audit effectively, see *Criteria and Indicators of Best Practice in Clinical Audit* at www.hqip.org.uk and *New Principles of Best Practice in Clinical Audit* available via www.hqip.org.uk. For more information on data quality for clinical audit, see *Guide to Ensuring Data Quality in Clinical Audits* at www.hqip.org.uk.

3.3 Drawing conclusions about your priorities

Use the information you gather about requirements, expectations and future needs for clinical audit in your clinical service, and your observations about current practice in clinical audit to decide what you want to achieve as a Clinical Audit Lead. Examples of what a Clinical Audit Lead could decide to set as priorities are in the box.

Sample work objectives for a Clinical Audit Lead

Meet the trust's requirements for clinical audit in your clinical service.

Get junior doctors, junior dentists, nurses, pharmacists, therapists and other healthcare professionals working in the clinical service **actively involved** in carrying out the **'must-do' clinical audits**.

Put **more emphasis on trying out changes in practice on a short-term pilot basis** in order to achieve needed improvements through clinical audit.

Avoid having audits **'stop'** at reporting findings and recommendations for action.

Arrange for high quality training in evidence-based practice in clinical audit for interested clinical staff.

Given the diversity of activities that are inappropriately being referred to as clinical audits, **clarify** with colleagues what type of activities should be recognised as **clinical audits** and how to handle other types of activities, such as service evaluations.

Re-structure clinical audit meetings so that the emphasis shifts from presentations of data to how we are going to achieve improvements in care or service.

Inform colleagues about the extensive list of externally-imposed **requirements** the trust has to meet concerning clinical audit.

Encourage staff to include **consideration of the patient experience** in a clinical audit.

3.4 Learning about resources and support available

Learn what resources are available to support the delivery of a clinical audit programme. These resources can include, but are not limited to, the following:

- clinical audit committee members who can provide expertise and experience with clinical audit
- the clinical audit manager and staff who work in the clinical audit department who can refer to resources available in the trust and provide advice and training
- clinical and educational supervisors
- patient records manager and staff who can facilitate access to patient records
- information systems access and advice.

The support available in the trust may include any or all of the following:

- the trust's policy documents on clinical audit, including policies on involving junior doctors, junior dentists and other clinical staff in training such as pharmacists or therapists in clinical audit, handling ethics issues related to clinical audits, training available related to clinical audit, and patient and public engagement related to clinical audit
- training on the clinical audit process and how to design and carry out clinical audits
- online proposal system and database on clinical audits
- reference materials on clinical audit available in the trust or online
- templates for planning and reporting on clinical audits
- advice on the technical aspects of carrying out a clinical audit.

3.5 Identifying your learning and support needs

There can be a tendency for management in an NHS trust to assume that a newly appointed Clinical Audit Lead 'will just get on' with the job. However, if you are the newly appointed Clinical Audit Lead, it is important for you to recognise what you might need to learn and the support you might need to carry out the role, and take responsibility for arranging to meet your learning and support needs.

This guide provides suggestions and advice for leading the implementation of clinical audit programmes. A list of knowledge and skills that a Clinical Audit Lead might need is in Appendix 2. Your learning and support needs could include any of the following, for example:

- the clinical audit process, including what's involved in quality improvement and current evidence-based practice related to clinical audit and reporting on clinical audits
- strategy, structure, culture and technical support needed for a robust clinical audit programme

- programme or project management processes
- leadership and management processes and skills
- meeting management skills
- mechanisms to support communication and dissemination of good practice related to clinical audit
- negotiating processes and skills.

After you assess your training or support needs, you can request training or the opportunity for development. You also can visit or shadow a more experienced Clinical Audit Lead to help you to develop your knowledge and confidence in the role.

3.6 Defining your accountability

Finally, as part of getting started in your role as Clinical Audit Lead, it will be important to define to whom you are accountable and for what outcomes. Normally, a Clinical Audit Lead is accountable to the director of a clinical service. In some NHS trusts, Leads also may be accountable to the trust's medical director or senior executive responsible for governance and assurance.

Clarify if the time needed to carry out the Clinical Audit Lead role is to be recognised in the trust and if your performance in the role is to be acknowledged as part of your personal performance profile and appraisal.

Negotiate with the person or people to whom you are accountable for carrying out the role how your learning and support needs as a Clinical Audit Lead are going to be met.

4 Getting a clinical audit plan or programme established and carried out

4.1 Producing or assessing an existing clinical audit programme

NHS trusts face a large number of requirements and expectations for clinical audits from both external and internal sources. Funding organisations, professional bodies, regulators, professional training programmes, patient groups and others are examples of external organisations expecting clinical audits to be carried out. Within a trust, the need to demonstrate compliance with national guidelines, concerns about quality or safety of care, patterns of incidents or complaints, or desires to improve care or service within a clinical team generate pressures internally for clinical audits.

To produce or assess an existing clinical audit programme for your service, follow the guidance in the box on the next page.

Steps to produce or assess a clinical audit programme for a clinical service

1. Consult with the trust's governance or assurance department to **learn the specific requirements ('must-do's') for clinical audits for your clinical service.**
2. Identify **any national clinical audits** that relate to your clinical service and check on the status of your service's participation in the audit. These are usually regarded as 'must-do's' in an NHS trust.
3. Find out **which clinical audits are already under way** in your clinical service **and their current status.** Check with a previous Clinical Audit Lead, a member of the clinical audit staff, or the trust's clinical audit database for your clinical service, which usually is held in the governance or clinical audit department in the trust if it is not available online.
4. Review the clinical audits carried out in the past year or so and identify any **clinical audits that now need repeat data collection** to determine if action taken has been effective in improving patient care.
5. Identify **how many junior doctors or junior dentists** work in the service (and can be assigned clinical audits to carry out) **and other staff** who could be asked to carry out or participate in a clinical audit.
6. **Assemble a small multi-professional team to decide on the clinical audits that staff working in the clinical service should or want to carry out** because of known or suspected problems in service or a desire by staff to achieve improvements in an aspect of the service.

Also see *Clinical Audit Programme Guidance Tools* at www.hqip.org.uk.

4.2 Developing priorities for locally-generated clinical audits

Create a small multi-professional team of staff working in the clinical service to set priorities for locally-generated clinical audits. Use a systematic approach, focusing on the potential of producing improvements in care. Techniques that can be used to identify potential subjects and to set priorities are in the box.²⁻⁴ If you are not familiar with how to use the techniques, ask a member of the clinical audit department's staff to facilitate a short meeting for you, using one or more of the techniques.

Techniques to identify and set priorities for clinical audits

Technique	Description
Brainstorming	Generate the maximum number of ideas among all the people involved, promoting free association and not considering the validity and practicality of the ideas.
Information gathering	Collect ideas from reports of incidents and complaints or problems previously identified in the service.
Nominal group process	Collect ideas via information gathering or brainstorming. Then set priorities among the ideas in the list by having each person in the team rank the ideas using a 'rule' such as 'place the ideas in rank order of importance to patients'. Cumulate the totals of each person's ranks to find the team's priorities.

Delphi process Collect **ideas** via information gathering or brainstorming. Then set priorities among the ideas in the list by having **each person** in the team **rate** the ideas using a 'rule' and a scale such as 'rate the ideas using a scale of 1 to 3 (1 meaning low and 3 meaning high) based on the importance of achieving improvements related to the subject in the next six months'. Cumulate the totals of each person's ratings to find the team's priorities.

Quality impact (risk-benefit) analysis Set **criteria** to be used to analyse a service such as 'problem areas' or 'risk areas' or 'frequent services'. Generate **ideas** for possible subjects **under each criterion**. Then set priorities by **rating** the subjects using the **criteria and a scale** such as 'rate each subject using a scale of 1 to 3 (1 meaning low and 3 meaning high) for each criterion, that is, how problematical, how risky for patients and how frequent the care is provided'. Select ideas that have the **highest cumulative total of ratings** across the criteria.

Try to have at least one clinical audit in the programme that includes consideration of the patient experience and/or that actively involves patients or their representatives. Consider how patients and carers can contribute to your clinical audit programme. Involving patients and the public in clinical audit brings to the process a perspective other than that of clinicians and healthcare organisations. Patients experience care delivery first-hand, so they are able to reflect on what works well or not-so-well in their experiences. Patients and carers can suggest aspects of quality that should be measured and improved. For more information on involving patients and the public, see *Patient and Public Engagement (PPE)* at www.hqip.org.uk.

4.3 Checking that proposed clinical audits are worth doing

Check on the appropriateness and feasibility of completing effective audits for the subjects identified for clinical audit. Use the questions in the box to consider the appropriateness and feasibility of the clinical audits proposed for inclusion in the clinical audit programme for the year.

Questions to analyse proposed clinical audits

1. **Does each clinical audit relate directly to the quality of patient care**, for example, does it relate to clinical effectiveness, patient safety, the patient experience or efficiency of care?
2. **Is the purpose of each audit to improve or to confirm the quality of patient care?**
3. For each audit, is the group or the management of the clinical **service committed to making improvements in care** if the clinical audit findings show the need for improvement?
4. If the answer to any of the first three questions is **No**, is it **possible to amend the subject or objectives or commitment to improvement** for a proposed audit?
5. For the clinical audits for which the answer to questions 1, 2 and 3 is **Yes**, is it going to be **feasible to carry out all of the audits** in the programme?
 - If **No**, would it be feasible if the audits were amended to be highly focused with one or two objectives only?
 - If still **No**, use one of the priority-setting techniques to agree on the highest priority audits to be carried out in the service.

When you and the team you have put together to develop the clinical audit programme are satisfied with the proposed programme, discuss the programme at a meeting with your colleagues, explaining where the subjects for the audits in the programme have come from and asking for any comments. When the programme is agreed by consensus within the clinical service, submit the proposed clinical audit programme through established channels of communication within the trust.

4.4 Accommodating additional proposed clinical audits

A clinical audit programme for a clinical service is a plan for carrying out clinical audits in a designated time period. As with all plans, this programme is subject to change as priorities in the clinical service change. New subjects for clinical audits may emerge in the service and may be added or substituted for audits that are no longer thought as being of high priority. Check on the appropriateness and feasibility of any additional proposed clinical audits. Communicate any changes made to the agreed plan through the established mechanisms in the trust.

4.5 Planning how to carry out the clinical audit programme

After a clinical audit programme for the clinical service is agreed:

- clarify or make assignments to carry out the audits in the programme
- agree with the people involved on a timetable for completion of the work
- arrange for any support needed to carry out the work, for example, that needed patient records can be retrieved on a timely basis.

You can assign carrying out a clinical audit to an individual or to a group of staff members who may share the work involved. If a person or a group has proposed a clinical audit in the programme, confirm that the person or group is willing to carry out the audit. If a group proposed the audit, consider if the composition of the group is appropriate for the objective(s) of the audit. For example, decide if key stakeholders in the audit, that is, those who may be affected by the audit, are involved and if not, recommend to the group others to include. Consider the questions in the box when making assignments to carry out clinical audits.

Considerations when assigning clinical audits to people in the clinical service

Is there a person or a group of people who ...

- is/are recognised as the **champion(s) for the subject** of the clinical audit?
- is/are one of the **key stakeholders** in the subject of the clinical audit?
- is/are **interested in leading or participating** in a clinical audit?
- would **benefit professionally** from the opportunity to lead or work on a clinical audit?
- **has/have** the **experience** leading a clinical audit **and** have the **skills** needed to lead the audit, for example, for a complex audit?
- has/have participated in numerous clinical audits and **should be given a break?**
- has/have not participated in previous clinical audits and **should be invited to participate in sharing the work** related to delivering the clinical audit programme?
- is/are **available** during the life of the clinical audit project or with whom arrangements to carry on the project could be made?

Discuss support that might be available for your colleagues on the design and conduct of clinical audits with staff in your organisation's clinical audit department.

4.6 Involving junior doctors and junior dentists in the clinical audit programme

Junior doctors and junior dentists need to experience first-hand that clinical audit is a quality improvement process. Foundation Programme doctors need to demonstrate that they have the knowledge, skills, attitudes and behaviours to use audit to improve patient care. For Foundation Programme doctors, by the end of their F1 year, they need to have participated in clinical audit meetings and by the end of their F2 year, they need to have undertaken a clinical audit under supervision. The Postgraduate Medical Education and Training Board (PMETB) has established participation in clinical audit as among the mandatory training requirements for doctors training at Registrar levels. The UK Committee of Postgraduate Dental Deans and Directors (COPDEND) has recognised clinical audit as among the mandatory requirements for trainee dentists. In addition to meeting training requirements at the current level of training, carrying out clinical audits is one way that an individual doctor or dentist can demonstrate initiative, interest, and commitment to progress in his or her career.⁵

A summary of actions you can take to involve junior doctors or junior dentists is in the box.

Summary of actions to involve junior doctors and junior dentists in individual clinical audits

Determine the number and level of junior doctors or junior dentists, if any, who will be working in your service in the next year.

Consider what clinical audits in your clinical audit programme junior doctors or junior dentists could do or participate in doing. You could do any of the following:

- assign clinical audit subjects from your programme
- ask junior doctors or junior dentists to design audits related to the subjects of audits in your audit programme to augment the 'main' audit
- encourage junior doctors or junior dentists to design an audit on a subject of their own choosing for your approval.

For clinical audits that will take more time to complete than an individual junior doctor's rotation in your service, decide how the audit can be handed over to an incoming doctor.

Plan how you will provide advice and support to the junior doctors or junior dentists throughout the audit process, particularly on achieving needed improvements in patient care.

For a more detailed description of involving junior doctors in individual clinical audits, see *Guide to Involving Junior Doctors in Clinical Audit* at www.hqip.org.uk.

4.7 Setting and negotiating timetables

When you have the clinical audit programme agreed and people agreed to carry out the programme, agree with those involved the timetables for designing and carrying out the clinical audits in the programme. Guidance is in the box on the next page.

Actions to agree on timetables for completion of the clinical audit programme

1. Ask the people who are going to carry out the clinical audits to **submit a proposed design and timetable** for carrying out the clinical audit and agree on a **date** by which the **proposal** should be submitted.
2. **Assess** the **proposed audit designs** (see the next section for guidance).
3. **Review** the proposed **timetables** for practicality.
4. Set out a master **month-by-month timetable** showing where each audit is planned to be based on the proposed timetables, so that you can **relate** work on the **audits to regular meetings** to consider clinical audit designs, findings and actions (see section 7). Include **both** local and national clinical audits from your planned programme.
5. Consider the **resources needed and available** to carry out all audits in the programme. Make arrangements for any resources needed that are not available.
6. **Negotiate** with the lead person or the group if there is a discrepancy regarding your expectations for the **design and timetable** for the audit and what the group or individual has proposed.
7. **Agree on amendments** to the designs for the clinical audits and the master month-by-month timetable for the clinical audit programme as needed.
8. **Arrange for** the **designs** of clinical audits to be **presented to colleagues and key stakeholders** as appropriate (see section 7).

4.8 Reviewing the designs of proposed clinical audits

As you review the designs of the clinical audits, make decisions about the following:

- Is the clinical audit **well designed**?
- Are the **data collection tools and protocol likely to provide reliable data** and support efficient data collection?
- Is the **proposed data analysis appropriate**, given the objective(s) of the audit?
- Is there an **explicit intention to act** on the findings of the audit?

Give feedback that is encouraging but will deliver well-designed clinical audits. Questions you can use to review the design for a proposed clinical audit are in the box.³

Part of the clinical audit	Questions to check on the design
Subject or topic	Is it clear what aspect(s) of care or service is(are) being audited ? Is the subject in the clinical audit programme ?
Objective(s)	Is the purpose directed at quality of patient care?

Is the **purpose to confirm patients are now getting quality care and/or to improve care** to patients if needed?

Is it **clear** what **feature** or features of **quality** are being audited, for example, appropriateness of clinical decision-making, timeliness of care or safety of a process?

Is the audit **well-focused**, that is, only one or a few objectives?

Stakeholders Have the **key stakeholders** in the audit been identified, that is, people who provide services covered by the audit or who will be affected by the audit?

Is the way the **stakeholders** will be **involved** in the audit appropriate and realistic?

Population or sample Is the **population or sample relevant** to the audit subject and objective(s)?

If a **population** is being proposed, that is, all patients, events or things occurring in a given time period, is it **feasible to identify and find all cases**?

If a **representative sample** is being proposed, that is, some patients, events or things from a population drawn to be representative of the population, **can all cases in the population be identified** and is an **appropriate method** being used to draw the sample?

If a sample is being proposed and the sample being drawn is to be **non-representative**, is an **appropriate method** being used to draw the sample?

If the **findings are to be generalised** to a population, is the sample a **representative sample** and sufficiently large to meet a **desired confidence level**?

Is it **feasible** in terms of **resources and time frame** to find and collect data from the number of cases proposed?

Time period Is the **time period** from which cases are to be drawn **appropriate** for the audit objective(s)?

Is there **any potential for bias** due to timing?

Data collection strategy If a **retrospective** strategy is to be used, are the **data** available in the past **complete and accurate**?

If data are to be collected **concurrent** with patient care, is there a **potential for bias**?

Is it **feasible** in terms of resources and time frame to implement the **data collection strategy**?

If the audit involves **getting or sharing information from other organisations**, are there plans for **meeting information governance requirements** for security and confidentiality of the data?

Standards Is it **clear** for **each standard** what will be looked for as evidence of quality?

Is it **clear** for each standard **how frequently** the 'evidence' should be present?

Is it clear for each standard if there are **any cases or circumstances** that would be clinically justified **exceptions** for the lack of evidence?

Are the **definitions and instructions for data collection** for each standard **complete** and **likely to promote reliable data**?

Is **each standard valid** given the audit subject and objective(s)?

Is it likely that **each standard** will be a **sensitive and specific measure of quality**?

Are the **data source(s)** for the standards appropriate?

Is it **possible to find the data** needed in the data sources specified?

You can decide if you will also assess the data collection tools and protocol for the likelihood of yielding reliable data and being efficient to use. Although the reliability and efficiency cannot be known until the tools are tested, for example in a pilot test, you can use the questions in the box to check on design features.

Questions to assess proposed data collection tools and protocol for a clinical audit

Does the data collection form **NOT** include any **identifiable data** such as patient, clinician or clinical area names?

Does the data collection form appear to be **set up logically**, for example, questions related to a data source are grouped together?

Is it entirely clear **how decisions about standards** or answers to questions **are to be recorded**?

Is there **any part** of the form that **seems confusing** to use or for which there are **no directions** on how to complete?

Does the data collection protocol specify the steps for **ensuring anonymity and confidentiality** of data and are these appropriate?

Does the protocol explain **data sources** to use, **how to select cases**, **when to collect data** and **where to store the data**, and are these appropriate?

For more information on data quality for clinical audit, see *Guide to Ensuring Data Quality in Clinical Audits* at www.hqip.org.uk. For a more detailed description of information governance related to clinical audits, including data protection and confidentiality, see *An Information Governance Guide for Clinical Audit* and *A Quick Guide to Undertaking an Information Governance Compliant Clinical Audit Project* at www.hqip.org.uk. For more information about the use of patient information and regulations on patient confidentiality, see *Guidance on Standards* at www.hqip.org.uk.

After you have assessed a proposal for a clinical audit, feed back your observations to the individual or group responsible for the audit. Use the opportunity to explore the thinking behind some of the decisions made, to teach technical aspects about clinical audit as appropriate, and to motivate the individual or group to move ahead to carry out the audit.

5 Monitoring and managing a clinical audit programme

5.1 Monitoring progress

Set up your own system and processes for monitoring progress on carrying out the clinical audits in the programme. You will need the project plans for the clinical audits and a simple tracking system.

You could compile the individual project plans into an overall clinical audit programme plan to give you a high-level picture of what is to be done by when. The master programme plan allows you to know what should be accomplished each week or month for each of the clinical audits in your programme.

Your trust may have a template to document the activities and timing and responsibilities associated with a clinical audit. If there is no established system, you could use a simple activity plan or a Gantt chart.³ An activity plan lists in column format each key activity to be done, when it is to be done and who is responsible. A Gantt chart has the same information, but shows it graphically by using bars to indicate when an activity starts or stops. Examples of an activity plan and a Gantt chart are in the box.

Examples of an activity plan and a Gantt chart			
Activity plan			
Activity	Responsibility	Started by	Completed by
1 Collect and collate data	AB and CD	18 March	15 April
2 Analyse any shortcomings in care to find root causes	AB and CD	15 April	13 May
3 Present findings and causes at meeting to discuss actions needed	AB and CD		20 May
4 Implement actions agreed	AB, CD and TU	20 May	30 June
5 Repeat data collection and report on findings	AB and CD	30 June	17 July
6 Prepare report on audit	AB and CD		25 July

Gantt chart		Weeks from start												
Activity	Who	1	2	3	4	5	6	7	8	9	10	11	12	13
1 Data collection	AB and CD	■												
2 Analysis	AB and CD				■									
3 Presentation	AB and CD						■							
4 Actions	AB, CD and TU						■							
5 Repeat data collection	AB and CD										■			
6 Report	AB and CD												■	

Create a system for you to track how the clinical audits are progressing so you can anticipate actions you should take and discussions needed at meetings on clinical audits. For each clinical audit, you will need to know:

- if the audit is proceeding as planned in terms of activities and time
- any barriers the person or group doing the audit is facing
- any interventions you need to make to help the audit progress
- any concerns about the completion of the clinical audit given your interventions.

Your tracking system doesn't have to be complex. For example, you can set up template email messages to leads for each clinical audit asking for a brief progress report on the audit, particularly to find out if the work is going to time and if there are any problems the person or group is experiencing.

5.2 Facilitating the implementation of needed changes in practice

When data collected for clinical audits in your programme show the need for improvement in the quality of patient care, you need to see that action is taken that will result in the needed improvement. You may have three roles in relation to getting action taken:

- advising colleagues carrying out clinical audits on the right way to analyse problems to find their true root causes and to identify the right action given the root causes of shortcomings in patient care
- representing the need for the right action to be taken to more senior people in your clinical service or the trust
- reviewing data collected after actions have been taken and judging and offering advice on the effectiveness of the actions taken.

You may need to modify some 'bad habits' that have developed among some clinical groups when they have collected data for a clinical audit, including any of the following:

- acting on a pattern of data without learning why the pattern is occurring, that is, not using accepted root cause analysis tools to learn the true reasons for shortcomings in patient care
- thinking they already know what the 'problem' is and assuming that the 'problem' is lack of resources, which cannot be addressed in the current climate
- providing recommendations for action that are simply restatements of the standards that are to be met, rather than a definitive action plan to achieve a change in practice that will result in improvement
- believing that changing practice is too hard to achieve and they don't have the time or the will to attempt it.

You can coach colleagues through these stages in the clinical audit process by suggesting that they carry out the steps in the box on the next page.

Steps needed to analyse findings of clinical audit and identify action needed for improvement

1. Make a **list of the problems** revealed by the clinical audit. Describe a **'problem'** as the **number or percentage of patients who DID NOT receive care consistent with the standards** used in the audit.
2. If the audit has revealed many problems (there are several standards that are not being met), **decide on the priorities** for resolving the problems and explain how the priorities were set.
3. Use one or more **root cause analysis tools to identify the potential or actual causes** of the shortcomings in patient care.
4. Based on the root cause analysis findings, identify the **actions needed to resolve the causes** of the shortcomings in patient care.
5. Develop a **plan for implementing the actions needed**, including the objectives of the action, who would need to take action, when and how. For example, 'train staff' would not be acceptable; rather the plan should spell out exactly what staff need to be trained to do differently, who would be appropriate to provide the training, when the training needs to be provided, and how it will be provided.
6. **Plan repeat data collection** in order to determine if the actions have been effective in achieving needed improvement in patient care.

6 Supporting colleagues to do clinical audit

6.1 Meeting learning needs about clinical audit

Based on your assessment of clinical audit in your service, you may learn that the people who have agreed to carry out clinical audits aren't confident of their knowledge and skills related to clinical audit. If this is the case, decide if you have the time to teach or coach them through the clinical audit process. Not all advice needs to be provided at the start of a clinical audit. You may not have the time to take colleagues through the clinical audit process in detail and it can be too much information for people to take in. You can provide advice on a just-in-time basis when people are ready and motivated to take on the advice.

You may have decided that the people involved in clinical audits would benefit from training on how to carry out a clinical audit properly. Contact your trust's clinical audit staff to see what training is available currently in the trust or can be made available. It will be helpful for you to identify the stages in the clinical audit process where colleagues appear to need the most help, as this information can focus training sessions to be more productive for clinical audit.

For guidance documents and support available, including online training on clinical audit, see www.hqip.org.uk.

6.2 Motivating people to complete clinical audits

Keeping people motivated to do the work after they have submitted a clinical audit proposal is a challenge and one of your main responsibilities. Motivators you can try are in the box.

Possible motivators for staff carrying out a clinical audit

Remind people about:

- having a **sense of achievement** about improving patient care
- their ability to **see something actually being done** about an aspect of care that has concerned them
- for some individuals, the enjoyment of a **challenge**
- the contribution of the work to **furthering progressing careers**
- the need to **meet colleagues' expectations**
- the **mental stimulation** of working on the audit.

Set an **expectation or target** for **completing a part of the clinical audit** that is challenging but achievable.

Be **highly motivated** and **enthusiastic** to see the audit to completion.

Provide positive feedback for the work already done.

Help when someone has encountered a problem in carrying out the clinical audit or doesn't know what to do next.

7 Leading meetings involving clinical audit

7.1 Shifting the focus of meetings on clinical audits

Many clinicians think of clinical audit meetings as consisting of one or more presentations of data collected on specific subjects. Meetings that follow this model 'freeze' the clinical audit process at the stage of data collation. The following stages in the process may or may not be carried out at or between meetings:⁶

- making an explicit decision on whether or not patient care provided for a particular group of patients, situations, circumstances or events is acceptable clinically
- investigating the specific problems that are affecting the quality of patient care
- analysing the true causes of problems or shortcomings in the provision of patient care
- exploring possible actions to resolve the problems revealed and making a commitment to taking action
- agreeing to a specific plan of action to achieve needed improvements in patient care.

What may be needed is a change in the way clinicians think about clinical audit meetings — a paradigm shift from presentation of data to achieving improvement — as described in the box on the next page.⁶

Paradigm shift for clinical audit meetings	
Shift clinical audit meetings from	To
A clinical audit is 'presented' once at a meeting	Clinical audits in different stages of completion are discussed at several meetings.
Many clinical audits are presented each year by individual clinicians to whom they were assigned.	The clinical audits undertaken are from the clinical service's clinical audit programme and reflect an intention to have each audit completed through improvement and repeat data collection stages as needed.
Few clinical audits are presented with repeat data collection showing whether or not there has been a change in practice.	Every clinical audit that shows the need for improvement is discussed to develop an action plan and has repeat data collection with repeat measurement findings discussed and judgements made about whether or not action taken was effective.
Few clinical audits are presented that show evidence of improvement in practice.	Most clinical audits that initially show the need for improvement eventually show that the improvement has been achieved , and when improvement is not achieved, it is clear what is happening about the issues represented.

7.2 The clinical audit meeting calendar

To ensure that each clinical audit in the clinical audit programme stands every chance of being completed, it may be desirable to discuss individual audits at several stages of their completion.

The purposes for the discussion may be to offer advice about the design or execution of an audit, raise awareness of the issues the clinical audit could highlight about the quality of patient care, continuously motivate the people working on the audit, contribute to the analysis of findings and problems or shortcomings in patient care, or suggest or 'sound out' actions needed to achieve improvements.

Instead of considering an individual clinical audit only at the data reporting stage, you could consider presenting an audit several times in different meetings. The ways in which an individual audit could be an agenda item for a meeting are in the boxes on the following pages.

Stages to discuss a clinical audit at a meeting

Stage	Purpose for discussion
<p>The proposed design of the audit, including the following for presentation and discussion:</p> <ul style="list-style-type: none">• why the subject was selected• the objective(s)• the specific quality-of-care standards to be used• the population or sample for the audit, why it was chosen, and how individual cases will be selected• the strategy for data collection• the plan for data collection and analysis	<p>Seek feedback on the technical design of the audit.</p> <p>Confirm that the proposed activity is a clinical audit and not a service evaluation or a research project.</p> <p>Raise awareness of the issues the audit might highlight.</p> <p>Gain support for the completion of the clinical audit.</p> <p>Motivate the people carrying out the audit to collect the data needed for the audit.</p>
<p>The preliminary findings of the audit and any individual cases that were flagged for further review because care fell short of the standards used in the audit</p>	<p>Allow for discussion of the reasons individual cases did not meet standards (which can suggest causes of shortcomings and actions needed).</p> <p>Ensure that clinically acceptable justifications for cases not meeting a standard are identified and not counted as poor care.</p> <p>Help colleagues to be aware of performance of the clinical service.</p> <p>Allow for questions and discussion about both the preliminary and adjusted findings.</p>
<p>The analysis and/or investigation of problems or shortcomings in patient care and their causes</p>	<p>Involve colleagues in thinking about and contributing to discussion of true root causes of shortcomings in patient care.</p> <p>Allow for suggestions on areas for further investigation or analysis that would contribute to having a sound action plan.</p>
<p>The proposed detailed action plan</p>	<p>Give colleagues an opportunity to consider their personal commitment to the actions proposed.</p> <p>Allow for discussion on the feasibility of the action plan, barriers to implementing the action and how the barriers could be addressed.</p> <p>Raise awareness of other stakeholders whose support might be needed for the action plan.</p>
<p>Progress report on implementation of the action plan</p>	<p>Inform colleagues about how the action plan is proceeding.</p>

	<p>Allow for discussion on any barriers encountered that were not previously anticipated and develop resolutions to the barriers</p> <p>Raise awareness of other stakeholders whose support might be needed for the action plan.</p>
Findings of repeat data collection and the implications	<p>Inform colleagues about the effectiveness of the action plan previously discussed and agreed.</p> <p>Identify possible causes of the shortcomings not previously recognised.</p> <p>Discuss the need for different or further action needed to achieve improvement.</p>

An example of considering individual clinical audits in stages across meetings is in the box.

Sample clinical audit calendar					
April	May	June	July	August	September
Audit 1: Design	Audit 1: Preliminary findings	Audit 1: Analysis of problems and detailed action plan	Audit 1: Progress report on action	Audit 1: Findings of repeat data collection for one month	Audit 1: Completion of repeat data collection and submission of report
Audit 2: Design	Audit 3: Design	Audit 2: Preliminary findings and some cases to review	Audit 2: Run charts of audit data and analysis of variation in practice and decision on direction for action	Audit 2: Detailed action plan and plan for repeat data collection for high-risk issues	Audit 2: Progress report on implementation of action
	Audit 4: Design	Audit 3: Revised design	Audit 4: Preliminary findings	Audit 3: Preliminary findings, analysis of problems and action plan	Audit 3: Progress report on action
					Audit 4: Findings of analysis of causes of shortcomings in care

7.3 A core agenda for clinical audit meetings

It may be useful to decide on agenda items that could be included in each clinical audit meeting. The advantages of having an agreed core agenda are that colleagues know:

- what will happen at each meeting
- that there will be a need to take action at each meeting
- how work on individual clinical audits will fit into meetings and that colleagues carrying out clinical audits will be supported at one or more meetings.

Possible items that could be included as core agenda items are in the box.

Possible items for a core agenda for clinical audit meetings	
Subject	Purpose
Clinical audit programme (overall)	<p>Involve colleagues in suggesting or deciding on the clinical audits that should be in the clinical audit programme for your clinical service.</p> <p>Reach consensus on the programme.</p> <p>Review progress on completion of the audits in the programme.</p> <p>Acknowledge modifications that need to be made to the programme, including clinical audits deleted or added and the reasons for the changes.</p>
Individual clinical audits	<p>Discuss the audits at various stages of their completion.</p>
National clinical audits related to the service	<p>Present and discuss the service's performance on any relevant national clinical audits.</p> <p>Analyse reasons for any shortcomings in performance and identify actions needed.</p> <p>Review the status of implementation of actions and evidence of the effectiveness of any actions taken.</p>
Trust-wide clinical audits	<p>Plan or describe how the service will participate in these audits.</p> <p>Present and discuss the service's performance on trust-wide clinical audits.</p> <p>Analyse reasons for any shortcomings in performance and identify actions needed.</p> <p>Review the status of implementation of actions and evidence of the effectiveness of any actions taken.</p>
Clinical audits carried out in other clinical services	<p>Learn from other clinical services about clinical audits carried out that might be of interest or relevance to your clinical service, especially if significant improvements in patient care have been achieved.</p>

7.4 Advising staff on presenting individual clinical audits at meetings

You may find it desirable or useful to give a short briefing to colleagues who are asked to present their work on clinical audits at meetings. As you give such advice, remind colleagues to consider:³

- what **they want to achieve** by presenting their work at the meeting
- what **will have to happen** at the meeting for the colleague(s) to achieve the objective(s)
- what **information, materials or support** the colleague(s) may need to **achieve the objective(s)** at the meeting.

An example of possible objectives and activities for the presentation of an individual clinical audit after data have been collected is in the box.

Objectives and activities for presentation of an individual clinical audit at a meeting	
Objectives	<i>Clinicians attending the meeting should:</i> <ol style="list-style-type: none">1. Know the overall compliance with the standards used in the clinical audit<ul style="list-style-type: none">• Standard-by-standard• Across all standards (the percentage of patients whose care was consistent with all standards in the audit)2. Know that the individual cases that did not comply with a standard were reviewed and whether or not any cases of additional clinical exceptions were found3. Understand that there was significant variation in patient care for two of the standards used in the audit and the type of variation4. Accept that there are shortcomings in the delivery of quality care to patients covered by the audit and that care needs to be improved5. Agree to investigate to learn the true causes of the shortcomings.
Activities	<ol style="list-style-type: none">1. Presentation on:<ul style="list-style-type: none">• The final findings, in comparison to standards set for the audit, adjusted for any individual cases that did not comply with the standards but were found to be clinically acceptable• Summary of individual cases that did not comply with the standards• Run charts on variation for the two standards for which there was significant variation and appropriate interpretation of the charts• A list of shortcomings in care revealed by the audit2. Questions about the presentation3. Discussion about the shortcomings identified leading to agreement to analyse the problems and report back on their causes

Clinical audits can be presented at regular and ad hoc clinical meetings and at study days.

8 Communicating about the clinical audit programme

8.1 Meeting your trust's needs for information about clinical audits

Your NHS trust has a number of needs for information about clinical audit in your clinical service in order for the trust to meet external assurance requirements of the Care Quality Commission, the NHS Litigation Authority and other regulatory and oversight bodies. Typical requirements are listed in the box.

NHS trust requirements for information on clinical audit in a clinical service

The clinical audit programme for the year, and any modifications made to the programme throughout the year

The design, findings and report for each clinical audit, normally done through 'registration' or entry into a database of each audit, using the trust's system

Evidence of implementation of actions indicated by your clinical service's performance in any national clinical audits relevant to your service and evidence of improvement

Evidence of actions being taken as indicated by findings of local clinical audits being carried out

Evidence of improvements achieved through clinical audits

The information required may be reported directly to the clinical audit or clinical governance department or may go through a clinical governance group or committee that oversees all governance and assurance functions for your clinical service. Your trust's clinical audit department staff can inform you of the mechanisms for reporting and any templates available to provide the needed information.

Examples of possible reports on clinical audit that could be useful are in the box.³

Possible types of reports on clinical audit in a clinical service

Report	Content
Clinical audit activity status	A running summary of all clinical audit activities underway and the current status of the activities
Problem and actions status	A running summary all problems identified as a result of clinical audits and the current status of the problems and actions taken to address the problems
Referred problems and action	A running summary of problems that required others outside of the clinical service to act and the status of problem resolution
Improvements achieved	A running summary of improvements in the service achieved as a result of clinical audits

8.2 Reports of individual clinical audits

To meet the trust's needs for information about clinical audit, you will need to ensure that people carrying out clinical audits complete reports on the audits. Reports need not be lengthy and can be written simply, but should include the content listed in the box.³

Content for a report on an individual clinical audit
Title of the clinical audit
Background to the clinical audit, that is, reason for selection of the subject of the audit
Design of the clinical audit including: <ul style="list-style-type: none">• Aim and/or specific objective(s) to express clearly the intention of the audit• Patients, events, situations or circumstances included and excluded from the audit and if a sample was used, how it was defined and selected• Time period for data collection• Data collection strategy, ie, retrospective, concurrent or prospective• Standards used to measure quality in the audit
Process of data collection including: <ul style="list-style-type: none">• How data were collected• How data quality was ensured, for example, if pilot testing, inter-rater reliability testing, and data monitoring were done and actions taken on any problems in data collection
Findings of BOTH initial and repeat data collection cycles, possibly including any relevant summarised information about the population or sample used in repeat data collection cycles
Analysis of the findings including: <ul style="list-style-type: none">• Problems or shortcomings in patient care identified• Root causes of the problems• Specific improvements needed
Actions needed and taken, including any barriers to the implementation of the action plan
Summary of improvements achieved, as demonstrated by the repeat data collection

Also see *Template for Clinical Audit Report* at www.hqip.org.uk.

8.3 Sharing learning and celebrating success about clinical audit

You will want to encourage colleagues to present their work on clinical audits outside regular clinical audit meetings in your clinical service. Other ways for disseminating information about clinical audit are in the box.

Ways to communicate about clinical audit	
Article in trust's newsletter	Article on your service's web page
Article on the trust's intranet pages on clinical audit or governance or quality improvement	Presentation at a trust meeting or conference
Participating in trust competition on clinical audits or quality improvements	Poster in staff, clinic or ward areas or for trust event on clinical audit
	Grand rounds presentation

In addition, you may encourage colleagues to submit their work on a clinical audit as a poster or paper at a national or international conference or to submit a paper for publication in a journal or other professional publication. Learn your trust's policy on submitting papers for presentation at external conferences and for publication related to clinical audit and quality improvement and share this information with your colleagues.

9 Handling ethics and risk-related issues in clinical audit

9.1 The importance of being aware of ethics in clinical audit

Many people think that there is no need for ethics oversight of clinical audits or quality improvement activities. However, there are several reasons why NHS trusts should have an ethical oversight system for clinical audit and QI including:⁷

- Clinical audits can potentially impose burdens on or risks to patients or carers. Some activities may benefit some patients at the expense of others or may not represent priorities based on risk-benefit analysis from a patient care perspective. Ethical oversight is needed to avoid these possibilities.
- Clinical audits can create potential conflicts of interest when findings indicate shortfalls in care attributable to lack of resources. The ethical duties of a healthcare organisation to all its patients need to be considered formally in such situations.
- Some healthcare professionals are not trained in clinical audit. Audits they carry out may be poorly designed and unlikely to yield useful results, in which case the activity is not ethically justified.
- Clinicians, intentionally or unintentionally, can avoid the research ethics review process by designating a project as a clinical audit rather than as research. Patients can be put at risk if this happens.
- True research on the clinical audit process itself may not be recognised as research and may not have appropriate oversight.

9.2 Possible ethics and risk-related issues related to clinical audits

There are three stages at which a clinical audit should be reviewed to identify any possible ethics issues:

- as a proposal
- following analysis of data gathered
- following action.

The possible reasons for review are in the box on the next page.⁷

Stages of a clinical audit that may involve an ethics issue	
Stage	Reason for review
Proposal	<p>Is there a situation in the proposal that requires ethics review because of the nature of the audit, the direct involvement of patients or carers, or possible confidentiality or security of data issues?</p> <p>Is the proposed design and standards on the quality of care or service valid and is the method for data collection likely to produce reliable data?</p> <p>Does the subject of the clinical audit itself have any ethical implications, and if so, are the proposed design and measures completely consistent with the trust's policies on the subject?</p>
Following analysis of data	<p>Do the findings of the clinical audit:</p> <ul style="list-style-type: none"> • pose any risk for patients whose care was reviewed in the clinical audit or for other similar patients, for example, if care was not provided consistent with good practice? • identify any patients for whom a life-threatening or quality-of-life threatening shortcoming in care occurred? • disclose any data that could be used to identify any patient or any practitioner? • reveal any clinically significant departure from usual clinical care?
Following action	<p>Has the action taken been effective in achieving needed improvement?</p> <p>Are patients at risk if care continues to be inconsistent with the standards used in the clinical audit?</p>

For more information about ethics issues in clinical audit, see *Review of Ethics Issues related to Clinical Audit and Quality Improvement Activities, Ethics and Clinical Audit and Quality Improvement (QI) — A Guide for NHS Organisations*, and *Template for Ethics and Clinical Audit and Quality Improvement Policy* at www.hqip.org.uk.

10 Troubleshooting for Clinical Audit Leads

10.1 Problems Clinical Audit Leads might face and possible actions

Clinical Audit Leads can face several problems in carrying out the Lead role. A summary of possible problems and possible actions to avoid or minimise the effect of the problem is in the box on the next page.

Possible problems and approach for Clinical Audit Leads

Problem	Possible approach or action
<p>Colleagues have not had positive experiences with clinical audit and are cynical about the process.</p>	<p>You can't undo negative experiences or perceptions quickly or easily.</p> <p>Concentrate on a few clinical audits on subjects on which colleagues are likely to agree that improvements are needed and drive audits on these subjects through completion.</p>
<p>There are so many expectations for clinical audits to be carried out in the service that the staff working in the service cannot deliver on all the expectations.</p>	<p>Unfortunately, there is considerable pressure on NHS trusts to 'demonstrate compliance' with national guidelines and managers think that clinical audit is the only way to meet the external requirements. Some options for dealing with this situation include:</p> <ul style="list-style-type: none">• See if you can negotiate within the trust on the audits that are of highest priority for the service to carry out. Rate each of the 'required' audits in terms of benefits to patients or minimisation of risk to patients. Suggest that audits that do not affect a large number of patients or that do not pose more than normal risk to patients are of lower priority and will be done when time and resources permit.• If a large number of audits are simply required, limit each audit to only one or two objectives and therefore the measurement of only one or two aspects of care, preferably the highest priority aspects of care from a benefit-risk perspective.• Allocate required audits to junior doctors or junior dentists and other staff who are expected to participate in clinical audit.• Propose that other methods, such as run charts or control charts, be used to monitor compliance with standards, rather than the extensive use of clinical audit for this purpose.• Negotiate the time of clinical audit staff from the trust to help with the workload.
<p>Colleagues agree to carry out clinical audits but then can't find the time to do the work involved.</p>	<p>Use your monitoring system to detect this situation as rapidly as possible. Offer the colleague(s) any of the following options:</p> <ul style="list-style-type: none">• having additional members of staff to work with to complete the audit• extending the time to complete the audit• completing a stage of the audit and seeing what help is needed to complete the next stage.

Junior doctors agree to carry out audits but rotate to another clinical service before the audit can be completed through action and repeat data collection.

Often, junior doctors are willing to complete the audits even when they move to another clinical service, as long as they have support from the original service for implementing action.

Staff carry out clinical audits but don't get around to preparing reports on the audits.

Arrange for the junior doctors involved to **hand over** their **clinical audits** to junior doctors coming into their rotations, if necessary. Both doctors or teams of doctors can cite their work on the clinical audit in their learning logs.

You don't have time to carry out all the work a Clinical Audit Lead should do, with your current clinical commitments and the trust's expectations for your clinical service.

Make the report as easy as possible to submit, for example, ask for a one or two-page report with the key parts of the audit, such as the proposal, the findings of data collection, the analysis of problems, the actions, etc, all appended to the report as attachments.

Call the situation to the attention of the person to whom you are accountable for your performance of the Clinical Audit Lead role.

Your clinical director expects you to be responsible for taking action to address problems revealed by a clinical audit because you are the Clinical Audit Lead.

Ask for some **time** to be allocated from a **clinical governance or clinical audit facilitator** in your clinical service, directorate or the trust to help you with time-consuming parts of your role, such as developing the clinical audit programme, chasing up on progress on clinical audits being carried out in the service, or organising clinical audit meetings.

Call the situation to the attention of the person to whom you are accountable for your performance of the Clinical Audit Lead role.

People in the clinical service agree to take action but actually don't implement the agreed action.

Clinical Audit Leads cannot assume the authority or responsibility of a clinical service director, unless it is made perfectly clear to everyone concerned that the director is delegating responsibility for resolving a particular situation to the Clinical Audit Lead, and the Lead has the time available to accept the responsibility.

Call the situation to the attention of the person to whom you are accountable for your performance of the Clinical Audit Lead role.

A very senior colleague proposes to do a 'clinical audit' that is not really a properly designed clinical audit.

You can't be responsible for the clinical audit programme **without the continuous support of those responsible** for directing and managing the clinical service.

Handle the proposal as you would any other proposal for clinical audit. Refer to the trust policies on clinical audit and national guidance on best practice in clinical audit to explain your feedback.

Encourage your colleague to carry out the activity, if it appears to be of value, but to label it properly, for example, as a service evaluation or an observational research study.

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HQIP Clinical Champions

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Appendix 1. Sample role description for Clinical Audit Lead

Aims for the Clinical Audit Lead role

A Clinical Audit Lead should aim to achieve:

- understanding among colleagues of the correct use of the clinical audit process to produce improvements in the quality and safety of patient care
- involvement in clinical audits by all levels of staff working in the service, directorate or division, including junior doctors or junior dentists and all the professions who contribute to the delivery of care in the service or directorate
- completion of clinical audits in the agreed clinical audit programme for the service or directorate through at least one cycle of repeat data collection showing the effects of acting to achieve improvement
- actual evidence of achievement of improvements in the quality and safety of patient care through application of the clinical audit process
- support of the clinical audit process in the business and governance processes in the service, directorate or division, including approval of actions indicated as needed through clinical audit findings.

Clinical Audit Lead roles

Key Clinical Audit Lead roles are to:

- arrange for the following:
 - an appropriate clinical audit programme in the clinical service, directorate or division that is carried out, consistent with known best practice in clinical audit
 - national clinical audits and trust-wide clinical audits relevant to the clinical service being carried out
 - national, trust-wide and clinical service-specific clinical audits presented and discussed at regular meetings involving clinical staff
 - advice, support and/or training for colleagues who are carrying out clinical audits
 - support needed to carry out clinical audits in the programme
- facilitate the implementation of action to produce improvements in the quality or safety of patient care as a result of clinical audits carried out
- ensure that the trust is informed as needed of the clinical audits being carried out and of the progress of achieving the clinical audit programme and has reports available of individual clinical audits carried out on a timely basis
- disseminate and enable the recognition of the work of colleagues to carry out clinical audits that benefit patient care or service
- participate actively in the clinical service's, directorate's, division's or trust's clinical audit or equivalent committee that is responsible for setting policies related to clinical audit
- maintain a productive working relationship with clinical audit and/or clinical governance staff in the trust.

Clinical Audit Lead responsibilities

A Clinical Audit Lead should:

- ensure that the clinical audit process and making quality improvements based on clinical audit findings are established as part of the business and governance processes of the service, directorate or division
- ensure that there is a clinical audit programme for the service, directorate or division, preferably based on an analysis of benefit-risk to patients
- check that the clinical audits in the service, directorate or division programme are focused on confirming or improving patient care and are of high quality, that is, are consistent with best practice in clinical audit, and arrange for improvement of the design and execution of clinical audits that aren't consistent with best practice
- meet or arrange for meeting the learning needs of staff in the service, directorate or division relating to clinical audit
- ensure that junior doctors and junior dentists are participating in the clinical audit programme with the aim of achieving improvements in care
- encourage a multi-professional approach and teamwork to carrying out clinical audits as appropriate
- encourage the inclusion of the patient experience in clinical audits carried out in the clinical service and the inclusion of patients or patient representatives as appropriate in relevant clinical audits
- review proposals for individual clinical audits and provide feedback on the proposed designs and measures as needed
- recognise and handle appropriately any ethical issues embedded in proposed clinical audits, including the failure to take action on findings that could represent a risk to patients or staff
- ensure that clinical audits being carried out are 'registered' through the trust's system
- engage continuously with the people carrying out clinical audits to ensure that the findings of audits in the clinical audit programme are being acted on effectively and that repeat data collection is being carried out to demonstrate the effectiveness of actions and reported on to the clinical service or directorate
- organise and manage meetings within the service, directorate or division to discuss clinical audit designs, findings, problems identified, actions needed or the effectiveness of actions taken to achieve improvements
- represent the clinical audits at meetings at which actions needed to address findings of clinical audits need to be approved as needed
- participate in clinical audit-related meetings in the service, directorate or trust as required
- communicate about the service's, directorate's or division's clinical audit work as required through reports or presentations
- liaise as needed with the director of the service, directorate or division about the clinical audit programme and any support needed for the programme or for actions needed.

For specific examples of role descriptions for Clinical Audit Leads, see the following references:

Clinical audit policy. Tameside NHS Foundation Trust. Available at: www.tamesidehospital.nhs.uk/Documents/clinicalauditpolicy.pdf. Last accessed 4 March 2011.

Clinical audit policy. Pennine Care NHS Foundation Trust. Available at: www.penninecare.nhs.uk/documents/CL89-Clinical-Audit-Policy-V1.pdf. Last accessed 4 March 2011.

Clinical audit policy and procedure. Bath and North East Somerset NHS Primary Care Trust. Available at: www.banes.nhs.uk/aboutus/policies/Pages/PoliciesandProcedures.aspx. Last accessed 4 March 2011.

Directorate/specialty clinical audit lead roles and responsibilities. Eastern and Coastal Kent NHS Primary Care Trust. Available at: www.ekclinicalauditservice.nhs.uk. Last accessed 4 March 2011.

Appendix 2. Knowledge and skills related to the role of Clinical Audit Leaders*

Key roles and responsibilities

- Lead clinical audit
- Set culture for clinical improvement
- Set up, maintain, and sustain clinical audit within or across specialties, directorates or divisions
- Ensure that resources for quality improvement and clinical audit are made available
- Act as change agents
- Understand professional requirements with respect to clinical audit

Key education, training and development needs as leaders

Clinical leaders need to have the following knowledge and skills:

- Developed leadership skills and understanding of change management
- An understanding of the quality improvement agenda in both national and local contexts including trust and primary care perspectives
- An understanding of political and national agenda around quality improvement and clinical audit and links to quality drivers, e.g. Care Quality Commission
- Awareness of clinical audit issues
- An understanding of what constitutes good quality audit
- An understanding of how to involve key stakeholders

Outcome measures

Clinical leaders can demonstrate:

- Being proactive about supporting and encouraging clinical audits in their clinical area
- Responsibility for assessing need for clinical audit in their clinical areas
- Ability to forge and build relationships with corporate departments responsible for clinical audit, quality and governance
- Ability to inspire and empower staff to undertake clinical audit
- Ability to enable staff to train and develop competencies to undertake clinical audit activities
- Responsibility for informing the Board of clinical audit priorities through established channels
- Ability to set a clinical improvement agenda in their clinical areas
- Able to more effectively take on leadership roles within and across their organisations

Knowledge related to clinical audit

- How quality of care can be defined and measured
- What clinical audit is about
- How clinical audit relates to quality assurance approaches in business and industry
- How the clinical audit process works to drive quality improvement
- What rapid-cycle clinical audit is about and why it is important
- Types of information learned from clinical audits and the how the information should be used
- How clinical audit relates to the following:
 - Evidence-based practice
 - Quality improvement
 - Measuring compliance with standards
 - Patient experience
 - Clinical risk management

- Appraisal and continuing professional development
- Patient safety
- Accountability for quality and safety of patient care
- Differences among descriptive studies, surveys, service evaluations, research and clinical audit
- Ethics and clinical audit
- Data protection and clinical audit
- An overview of research evidence related to organisational development and quality improvement in healthcare organisations

Knowledge related to organisational strategy, structure, culture and technical support for clinical audit

- The differences between organisational strategies that are compliance versus improvement driven
- The components in the sphere of accountability (directorates, departments, committees, etc) that carry responsibility for clinical audit and quality improvement and their responsibilities and accountabilities for achieving improvements in the quality and safety of patient care
- The nature of the organisation's culture in relation to clinical audit and quality improvement
- Ways to influence culture in a healthcare organisation and/or service and/or profession
- Tools available to measure the quality, patient safety or clinical governance culture or climate of the organisation
- The nature and amount of the support available in the organisation to support clinical audit and quality improvement and the nature of the competence represented by the support

Knowledge related to clinical audit programme

- The components of an appropriate and effective clinical audit programme
- What a clinical audit programme should look like

Knowledge related to clinical audit reports

- The components of a clinical audit report, whether for an individual clinical audit or an annual report (for the services in the sphere of accountability)
- How to interpret data on the quality or safety of patient care appropriately, including data presented using statistical process control (SPC) tools
- How to interpret reports related to clinical audit, including reports that present data using SPC tools
- How to identify shortcomings in patient care from existing reports
- The nature of actions that may need to be taken by senior clinical leaders in response to findings of clinical audits or quality improvement activities

Knowledge related to leadership and management

- What makes up evidence of effective leadership and engagement
- What makes up evidence of effective leadership and engagement by a senior clinical leader
- What makes up evidence of effective leadership and engagement for quality improvement by a commissioning organisation
- What makes up evidence of effective leadership and engagement by a clinician
- What makes up evidence of effective leadership

Skills related to the clinical audit process

- Recognise valid measures of aspects of quality, including clinical effectiveness, patient safety and patient experience-related measures
- Challenge the use of measures of quality that are not likely to be sensitive or specific
- Recognise the difference between a good and a not-so-good clinical audit and act on the awareness by questioning not-so-good clinical audit practice
- Explain rapid-cycle improvement to others and strongly encourage them to follow the approach
- Ensure that there is effective and accurate analysis of various governance and assurance-related activities and identify opportunities for clinical audit and improvement, particularly those that involve more than one part of the organisation or more than one profession
- Recognise and direct opportunities to relate clinical audit to other activities
- Recognise the differences between descriptive studies, surveys, service evaluations, research and clinical audit, explain them to others and guide others to carry out the most appropriate activity
- Ensure that there are robust audit approval and oversight systems in place, communicated to relevant staff and implemented for all the activities
- Recognise the differences between clinical audit and monitoring of the quality or safety of patient care, explain them to others and guide others to carry out the most appropriate activity
- Ensure that ethics issues related to clinical audit are identified and handled properly within the sphere of accountability
- Ensure that data protection issues related to clinical audit are identified and handled properly within the sphere of accountability

Skills related to evidence on achieving and sustaining clinical quality

- Recognise the implications of the evidence for the healthcare organisation
- Make efforts to implement evidence-based practice in relation to clinical audit and quality improvement

Skills related to organisational strategy, structure, culture and technical support related to clinical audit

- Develop or contribute to the development of an organisational strategy for improvement (in addition to compliance) of the quality and safety of patient care
- Ensure that the organisation's strategy to drive quality and safety improvement is:
 - Communicated to all staff in the sphere of accountability, e.g. directorate, nursing service, etc
 - Implemented throughout the sphere of accountability
 - Reported on effectively on a timely basis
- Analyse terms of reference of existing components in the organisation's structure for explicit responsibilities and accountabilities for achieving improvements in the quality and safety of patient care and make changes in terms of reference as needed
- Direct or guide the available structure to drive implementation of the strategy to focus on improvements that benefit patients
- Change or recommend changes in the organisational structure to drive the implementation of the quality and safety improvement strategy
- Influence the culture of the clinical staff to focus on delivering improvements in the quality and safety of patient care
- Be responsive to patient care issues raised by clinical teams that are outside the authority of the team to resolve
- Measure the organisation's culture of quality and/or safety and take action to develop the organisation's culture as needed

- Ensure that the number and technical competence of staff is sufficient to achieve the organisation's strategy for clinical audit and quality improvement in the sphere of accountability
- Ensure that the processes in place in the sphere of accountability for supporting clinical audit and quality improvement are robust

Skills related to clinical audit programme

- Endorse clinical audit programmes developed within specialties or spheres of accountability
- Intervene if a clinical specialty has not developed a clinical audit programme
- Oversee the implementation and effectiveness of the programme in leading to measured improvements in the quality or safety of patient care
- Intervene when it becomes clear that the clinical audit process is not being done or is not effective in leading to improvements in the quality or safety of patient care in services that are within the sphere of accountability

Skills related to clinical audit reports

- Interpret a clinical audit report appropriately and draw appropriate conclusions about the quality or safety of patient care provided and the effectiveness of resolution of problems identified
- Interpret the presentation of data in a clinical audit report
- Interpret data presented using statistical process control (SPC) tools accurately and completely
- Identify questions about clinical practice raised by the presentation of data about clinical practice
- Identify shortcomings in patient care or services that cut across more than one department or service and act to lead resolution of the shortcomings
- Act on findings of clinical audits or other quality improvement activities that are outside the scope of authority of specialties, wards, etc
- Report to senior management and the board, as appropriate, actions needed to achieve improvements in the quality or safety of patient care that are outside the scope of authority of the senior clinical leader

Skills related to leadership and management

Act effectively in engaging staff working in the sphere of accountability in clinical audit and quality improvement

- Serve as a role model for resolving problems that impede the provision of high quality safe patient care
- Be perceived as actively leading the directorate, department, service in its efforts to implement the organisation's quality improvement strategy and to improve the quality and safety of patient care
- Be seen to respond to staff about issues related to the quality or safety of patient care when situations are reported to the senior clinical leader

* Abstracted from *Education, Training and Development Strategy for Clinical Audit, Final Draft, 2009*. Healthcare Quality Improvement Partnership, 2009. Available at: www.hqip.org.uk. Last accessed 4 March 2011.