

Guide for Clinical Audit Leads





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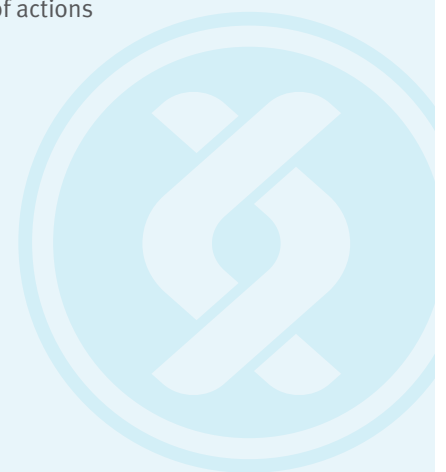
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Key points in this guide

- The purpose of a Clinical Audit Lead (CAL) is to lead a clinical service in the completion of clinical audits, including through facilitating the implementation of actions needed to improve patient care when required
- When you are asked to be a CAL, clarify the requirements, expectations and future needs of the lead role with the clinical service director or others. Define to whom you are accountable and for what outcomes related to clinical audit in your clinical service
- If your clinical service has doctors or dentists or other healthcare professionals in training, clarify responsibility with clinical and educational supervisors for ensuring that the trainees are actively involved in clinical audits
- Contact the organisation's clinical audit manager or equivalent to learn what resources are available in the organisation to support clinical audit and how the organisation needs to be informed about clinical audits
- Assess the strengths and weaknesses of clinical audits done recently in your clinical service before deciding on your approach to leading clinical audit
- Set priorities for the objectives you want to achieve as a CAL
- Identify your own learning needs and the support you might need to carry out the role and arrange with your clinical director to meet your needs
- Develop a clinical audit programme for your clinical service, considering any clinical audits for which participation is mandatory and working with a multi-professional team to set priorities for audits that meet the needs of the clinical service. Assign small teams, as needed, to carry out the audits in the programme and set out a timetable for completion of the audits with the teams involved. Ensure that staff in training roles are actively involved in the clinical audit programme
- Establish a process for reviewing the appropriateness and feasibility of proposed clinical audits. Give feedback to proposers about the design of the proposed audits, including the validity of proposed measures of quality and the likely reliability of data collected
- Consider how patients and carers could contribute to the clinical audit programme, as feasible
- Establish a way to monitor progress on the clinical audits in the programme, using a simple tracking system
- Use clinical audit meetings to discuss in stages:
 - The designs of clinical audits
 - The findings of data collection
 - What happened to the patients whose care is not consistent with quality-of-care measures
 - The problems identified by audits and their root causes
 - The improvements in care needed and the actions to achieve the improvements
 - Progress in implementing actions
 - Evidence from repeat data collection on the effectiveness of actions



Introduction

Who this guide is for

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

It should also be helpful for:

- Medical and clinical directors to give guidance to their CAL and to understand the role for appraisal purposes
- Clinical audit staff and members of committees with responsibility for clinical audit

How the guide is intended to help

NHS Trusts have to manage the conduct of clinical audits in clinical services so that when audits show shortcomings in the quality of patient care, effective actions are taken to achieve improvements. Often, individual clinicians are asked to lead clinical audit in their services, specialties, directorates or divisions. The leads become responsible for ensuring that clinical audits are being carried out effectively.

Clinical staff can sometimes doubt the value of carrying out clinical audits. However, there is 'substantial evidence that audit... can effectively improve quality of care.'¹ CALs can enhance the effectiveness of clinical audits by managing the conduct of audits so that the process engages in a focused way with overcoming resistance to making changes in clinical practice.²

CALs contribute to the success of clinical audit by ensuring that best practice in clinical audit is applied, including providing for the following attributes of the process to be met:³

- Desired clinical performance is defined and is aligned with clinical and organisational priorities

- Valid data are available on recent clinical performance compared with accepted good practice
- Performance of current practice is fed back to colleagues by someone who is trusted by colleagues in different formats (oral and written)
- Improvements in practice are identified and are possible for colleagues to achieve
- Cycles of collecting data are repeated to see if changes in practice are being achieved

This guide is intended to help CALs carry out the role of leading clinical audit activities in their services. It includes:

- **What is involved** in being a CAL
- How to **get started**
- **Systems and support** that should be available
- How to develop a **plan for clinical audits** and how to implement it
- 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
- How to encourage staff to **involve patients** or their representatives in relevant clinical audits
- How to **monitor, manage and facilitate the intended outcomes** of clinical audits
- **Problems** CALs can encounter and suggestions for handling the problems
- How to contribute to supporting the **appraisal** process for doctors, as relevant
- How to contribute to supporting the provision of information about clinical audit for **Quality Accounts**

What's involved in being a Clinical Audit Lead

Purpose, responsibilities and accountabilities of the role

The **purpose** of a CAL is to **lead** a clinical service in the completion of clinical audits, including through facilitating the implementation of actions to improve patient care when needed. Leadership of clinical audit can involve any or all of the responsibilities in the box.

See [Appendix 1](#) for a sample role description for a CAL.

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

If a 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 officers 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.

Key responsibilities of a CAL

- Explain and **promote the importance** of clinical audit and the **Trust's policies** relating to clinical audit to colleagues, including doctors and other healthcare professionals in training
- Lead the development of a **plan or programme** of clinical audits to be carried out in a clinical service, which reflects the Trust's and the service's priorities
- Ensure that **people** working in the service **carry out clinical audits**
- **Monitor and manage progress** on clinical audits
- **Facilitate both the analysis of shortcomings of patient care shown by clinical audits and the resulting actions** aimed at improving the quality or safety of care
- **Support colleagues** to carry out individual clinical audits, including junior doctors or junior dentists
- **Ensure** that the **work** being carried out on clinical audits **is communicated** within the clinical service including to management and governance-related groups, as well as to the Trust's clinical governance functions
- Ensure that any **problems** associated with the clinical audit programme **are addressed** responsibly

Getting started as a Clinical Audit Lead

Clarify requirements, expectations and future needs

When you are asked to be a CAL, clarify the requirements, expectations and future needs of the lead role. Guidance and examples are in the box below.

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

- The clinical director
- The medical director
- The head of governance
- The person/s who was/were in the CAL role previously
- Clinical colleagues in all professional groups that work in the clinical service

- Junior doctors or junior dentists
- Clinical audit or clinical governance staff who work in the clinical service or in the Trust

Contact your Trust's clinical audit department early on in your role. A clinical audit manager or facilitator can:

- Inform you about support for clinical audit in your service
- Ensure that you know about processes that support clinical audit in the Trust and statutory requirements related to clinical audit
- Help you access clinical audits carried out previously in your clinical service
- Give you key information resources on clinical audit
- Advise you on technical aspects of the clinical audit process

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 relating to clinical audit in the clinical service	<ul style="list-style-type: none"> • The Trust's objectives and priorities relating to clinical audit and quality improvement • Meeting the Trust's policy on clinical audit in the service • A clinical audit programme to be carried out in the next year • Participation by the clinical service in any Trust-wide clinical audits • Participation in national clinical audits related to the clinical service • Involvement of junior doctors or junior dentists in clinical audit • Involvement of patients or patient representatives in relevant clinical audits • National requirements relating to clinical audit as specified by the Care Quality Commission (CQC), NHS Improvement, NHS England or the General Medical Council (GMC)
Expectation	Any perception that colleagues or the management have of how (and how well) clinical audit is currently executed in the clinical service — including positive and negative impressions or attitudes colleagues might have about the process	<ul style="list-style-type: none"> • 'We have changed a few things as a result of particular clinical audits' • 'Nothing changes as a result of any clinical audit done in the service' • Some of the so-called clinical audits are just collations of data about patient care • The junior doctors don't have time to 'complete the cycle' during their rotations in the service
Future need	What the clinical service may have to do about clinical audit in the future — demonstrating that needed improvements in the quality of care, as indicated by clinical audits, are being made and sustained	<ul style="list-style-type: none"> • Have evidence that actions recommended as a result of local or national clinical audits have been implemented and practice or patient outcomes have improved • Meet commissioner and other requirements related to national and local clinical audit

Gather evidence on the current effectiveness of clinical audit

Gather your own evidence on how clinical audit has been working in your clinical service. Scan 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. Assess audits carried out in the service using the questions in the box.⁴

For more information on carrying out clinical audit effectively, see [Criteria and Indicators of Best Practice in Clinical Audit](http://www.hqip.org.uk) at www.hqip.org.uk, [New Principles of Best Practice in Clinical Audit](http://www.amazon.co.uk) available via www.amazon.co.uk, or [Getting Clinical Audit Right to Benefit Patients](http://www.hqq.co.uk) at www.hqq.co.uk. For more information on data quality for clinical audit, see [Guide to Ensuring Data Quality in Clinical Audits](http://www.hqip.org.uk) at www.hqip.org.uk.

Questions about the effectiveness of clinical audit in a clinical service

Assess the effectiveness of clinical audits carried out in your clinical service in the past year by ticking the level of compliance.

For reference:

- 'Full' means that every audit routinely meets the aspect described
- 'Partial' means that some audits meet the aspect. You can estimate the percentage of audits that do so
- 'No' means that audits do not routinely meet this aspect

Clinical audits:	Full	Partial	No	Not applicable (Q 10 only)
1. Are on subjects that could potentially provide benefit or minimise risk to patients				
2. Are focused on an important aspect of quality or patient safety, such as appropriateness of treatment, effectiveness of care, safety or timeliness				
3. Use appropriate and well-defined populations or samples of cases				
4. Have an objective for the audit that explicitly refers to improvement of patient care, if improvement is needed				
5. Use clinically valid quality-of-care measures (criteria, standards, etc) as a basis for data collection				
6. Include complete written instructions for data collectors that spell out in detail exactly how to make yes-no decisions about whether or not a case complies with a quality-of-care measure				
7. Have a written protocol that describes exactly how the entire data collection and analyses processes are to be carried out				
8. Train or check that data collectors know exactly how to make decisions about compliance with measures and how to record data				
9. Test the reliability (consistency) of data collection, if more than one person is involved in data collection				
10. When clinical care is being measured, ensure clinicians review individual cases that do not comply with the quality-of-care measures to determine why the measures were not met				(N/A if the audit uses rate-based (target) standards)

Clinical audits:	Full	Partial	No	Not applicable (Q10 only)
11. Name explicitly shortcomings in the quality of care when the clinical audit is presented or reported (shortcomings refer to the percentage of patients NOT receiving the care specified in the quality-of-care measures.)				
12. Include a root cause analysis when a clinical audit shows that care has not been consistent with the quality-of-care measures				
13. Take effective actions to address the root causes of the shortcomings that were identified				
14. Include repeat data collection promptly following implementation of actions to determine if the actions were effective in achieving improvement				
15. Are reported with evidence of repeat measurement to demonstrate if needed improvements in care have been achieved				

Set priorities

Use the information you gather to decide what you want to achieve as a CAL:

- What the requirements, expectations and future needs are for clinical audit in your clinical service

- How well clinical audit is currently executed in the service

Examples of priorities for CALs are in the box.

Sample objectives for a CAL

- **Meet the Trust's requirements** for clinical audit in the clinical service
- Involve more clinical staff to lead clinical audits in sub-specialties or professional groups
- Form a clinical audit/quality improvement team to decide on and lead the service's clinical audit/quality improvement programme
- **Get junior doctors, junior dentists, nurses, pharmacists, therapists or other healthcare professionals** working in the clinical service **actively involved** in carrying out or acting on findings of **clinical audits**
- Put **more emphasis on trying out changes in practice on a short-term (rapid-cycle) basis** to achieve needed improvements
- **Avoid having audits 'stop'** at the point of 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 called **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
- **Inform colleagues about externally-imposed requirements** the Trust or service has to meet relating to clinical audit
- **Encourage** staff to include **consideration of the patient experience** in clinical audits

Learn about resources and support available

Learn what resources and support are available for clinical audit. Resources available may include any or all of the following:

- **Policy** documents on:
 - The clinical audit process
 - Involving junior doctors, junior dentists and other clinical staff, such as pharmacists or therapists, in clinical audits
 - Handling ethics issues relating to clinical audits
 - Involving patients in clinical audits
- **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 in the Trust or online
- **Templates** for planning and reporting on a clinical audit
- **Advice** on technical aspects of carrying out a clinical audit

Support can include:

- Clinical audit committee members who have expertise and experience with clinical audit
- A clinical audit manager and staff who can tell you about available resources
- Internal or externally accessible training on clinical audit
- Clinical and educational supervisors who oversee junior doctors, dentists or other healthcare professionals' training
- Patient records manager and staff who can facilitate access to patient records when paper records are needed for a clinical audit
- Information systems access, particularly to learn about the Trust's performance on national clinical audits and to access local audits

Identify your learning and support needs

There can be a tendency for directors to assume that newly appointed CALs will just 'get on with' the job. However, if

you are the newly appointed lead, it is important for you to identify your own learning needs as well as the support you might require to carry out the role, and take responsibility for arranging for these needs to be met.

Your learning and support needs could include any of the following:

- A greater understanding of the clinical audit **process**, including what's involved in the quality improvement cycle and current evidence-based practice related to clinical audit
- **Strategy, structural, cultural and technical support** needed for a robust clinical audit programme
- **Programme** or project **management processes**
- **Leadership and management** processes and skills
- **Meeting management skills**
- **Communication skills** and ways to disseminate good practice in clinical audit
- **Developing negotiating** processes and skills

A list of knowledge and skills a CAL might need is in [Appendix 2](#).⁵

After you assess your training or support needs, request training or the opportunity for development in these areas. You could visit or shadow a more experienced CAL to help you to develop your knowledge and confidence in the role.

Define your accountability

Finally, as part of getting started in your role as CAL, define **to whom you are accountable and for what outcomes**. Normally, a CAL is accountable to a clinical director.

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

Negotiate with the person to whom you are accountable how your learning and support needs for this role are going to be met.

Getting a clinical audit plan or programme established and carried out

Develop or assess a clinical audit programme

NHS Trusts face a large number of requirements and expectations for clinical audits from both external and internal sources. Commissioners, professional bodies, regulators, professional training programmes and patient groups are just some of the 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.

Use the guidance in the box to develop or assess an existing clinical audit programme for your service.

Also see [Clinical Audit Programme Guidance](http://www.hqip.org.uk/Clinical-Audit-Programme-Guidance) at www.hqip.org.uk.

Develop priorities for locally-generated clinical audits

Working with a small multi-professional team, set priorities for locally-generated clinical audits. Use a systematic approach, focusing on the potential for improving care. Techniques that can be used to identify potential subjects and to set priorities are in the box on the next page.⁵⁻⁷ If you are not familiar with how to use the techniques, ask a member of the clinical audit staff to facilitate a short meeting for you, using one or more of the techniques.

Also, see [Guide to Using Quality Improvement Tools to Drive Clinical Audits](http://www.hqip.org.uk/Guide-to-Using-Quality-Improvement-Tools-to-Drive-Clinical-Audits) at www.hqip.org.uk.

How to develop 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 for clinical audits in 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. Your clinical service must participate if a National Clinical Audit and Patient Outcomes Programme (NCAPOP)⁸ and your service is part of an NHS Trust or an organisation that provides services to the NHS. Your clinical service is required to report on your participation in these national clinical audits and other activities as part of the Trust's annual Quality Account.⁹ For up-to-date information on the NCAPOP projects and Quality Accounts requirements, see www.hqip.org.uk/national-programmes/quality-accounts/
3. Find out **which clinical audits are already underway** in your clinical service **and their current status**. Check with a previous CAL, the clinical audit staff, or the Trust's clinical audit database, 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 and identify any **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 subjects of clinical audits to be completed**. Team members could be CALs in sub-specialties or professions

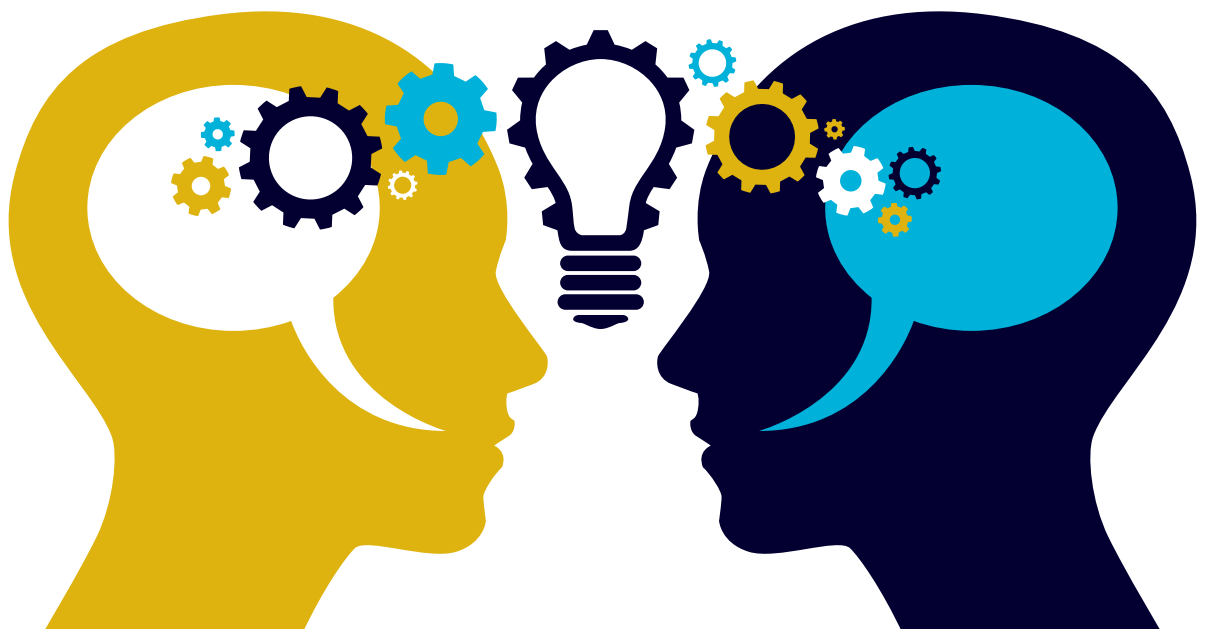
Techniques to identify and set priorities for clinical audits

Technique	Explanation
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, complaints and patient surveys, clinical guidelines that should be implemented in the service, 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 based on the importance of achieving improvements using a scale of 1 to 3 (1 meaning low and 3 meaning high) in the next six months.’ Cumulate the totals of each person’s ratings to find the team’s priorities
Quality impact (risk-benefit) analysis	Agree on criteria 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 problematic, how risky for patients and how frequently the care is provided.’ Select ideas that have the highest cumulative total of ratings across the criteria

Check that proposed clinical audits are worth doing

Check the appropriateness and feasibility of completing effective audits for the subjects identified. Use the questions in the box on the next page to consider the proposed clinical audits.

When you and the team are satisfied with the proposed programme, discuss the programme at a meeting with your colleagues, explaining where the subjects for the audits 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 lines of reporting within the Trust.



Questions to analyse proposed clinical audits

1. **Does the clinical audit relate directly to the quality of patient care**, for example, does it relate to clinical effectiveness, patient safety or the patient experience?
2. **Is the purpose of each audit stated explicitly as 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 by focusing on just one or two objectives?
 - If still **No**, use one of the priority-setting techniques to agree on the highest priority audits to be carried out in the service

Accommodate additional proposed clinical audits

A clinical audit programme is a plan for carrying out clinical audits in a designated time period. As with all plans, the 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 to be 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 lines of reporting in the Trust.

Include provision for national clinical audits

As described in the box on page 12 in this Guide, review the status of your clinical service's participation in national clinical audits and ensure that effective processes are in place to participate fully in any national clinical audits that are relevant to your service. Effective processes include the following:

- There is at least one clinician in the service named as responsible for each national clinical audit. The clinician may form a multi-professional team for an NCA that involves the work of more than one professional group
- Each national clinical audit lead's responsibilities include: registering for participation in the national clinical audit, collecting data or ensuring that data are collected accurately, submitting data or ensuring that data are submitted in accordance with established deadlines, and assuming responsibility for actions to be taken on the findings that are relevant to the local clinical service in order to achieve needed improvements in patient care or service
- Each national clinical audit lead reports to colleagues about progress on the national clinical audit
- Each national clinical audit suggests any local clinical audits that may be needed to support improvement, based on findings of an national clinical audit that are relevant to the clinical service
- Each national clinical audit lead works with the CAL for the service to ensure that information required for Quality Accounts is supplied on time

For an example of how to manage national clinical audit at organisational level, see: www.hqip.org.uk/resources/case-study-whose-shoes-matexp-maternity-experience/.

Plan how to carry out the clinical audit programme

After a clinical audit programme 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, ensure that patient care information, if required, can be retrieved on a timely basis

You can assign the implementation of a clinical audit to an individual or to a group of staff 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 colleagues 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 the option to step back and support other staff in the audit process?
- Has/have not participated in previous clinical audits and **should be invited to participate in sharing the work**?
- 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 the organisation's clinical audit staff.

Involve 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

competences needed to use audit to improve patient care. Foundation Programme year two (F2) doctors are expected to complete a quality improvement project. Curricula for medical and dental specialty trainees refer to the expectation that trainees will actively participate in and carry out clinical audits.

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

For a more detailed description of involving junior doctors in individual clinical audits, see [Guide to Involving Junior Doctors in Clinical Audit](http://www.hqip.org.uk) at www.hqip.org.uk.

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 which clinical audits in your programme junior doctors or junior dentists could do or participate in. 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 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 junior 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

Involve patients in the clinical audit programme

Consider how patients and carers can contribute to your clinical audit programme. Try to have at least one clinical audit in the programme that includes consideration of the patient experience and that actively involves patients or their representatives.

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 [PPI Resources](#) at www.hqip.org.uk.

Set and negotiate timetables

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

Review the designs of proposed clinical audits

Review the designs of proposed clinical audits to decide 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 on page 18.⁵

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 completing the 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** for all audits using the proposed timetables, so that you can **relate** work on the **audits to regular clinical audit meetings** (see page 26)
5. Consider the **resources needed and available** to carry out all audits in the programme. Make arrangements for any resources 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 page 25)



Questions to check the design of a proposed clinical audit

Part of the clinical audit	Questions
Subject or topic	<p>Is it clear what aspect/s of care or service is/are being audited?</p> <p>Is the subject important to the quality of patient care?</p>
Objective/s	<p>Is the purpose of the audit directed at quality of patient care?</p> <p>Is the purpose to confirm patients are now getting quality care and/or to improve care to patients if needed?</p> <p>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?</p> <p>Is the audit well-focused, that is, have only one or a few objectives?</p>
Stakeholders	<p>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?</p> <p>Is the way the stakeholders will be involved in the audit appropriate and realistic?</p>
Population or sample	<p>Is the population or sample relevant to the audit subject and objective/s?</p> <p>If a population is being proposed, that is, all patients or events occurring in a given time period, is it feasible to identify and find all cases?</p> <p>If a representative sample is being proposed, that is, patients or events 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?</p> <p>If a sample is being proposed and the sample is to be non-representative, is an appropriate method being used to draw the sample?</p> <p>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?</p> <p>Is it feasible in terms of resources and time frame to find and collect data from the number of cases proposed?</p>
Time period	<p>Is the time period from which cases are to be drawn appropriate for the audit objective/s?</p> <p>Is there any potential for bias due to timing?</p>
Data collection strategy	<p>If a retrospective strategy is to be used, are the data available in the past complete and accurate?</p> <p>If data are to be collected concurrent with patient care, is there a potential for bias?</p> <p>Is it feasible in terms of resources and time frame to implement the data collection strategy?</p> <p>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?</p>
Quality-of-care measures	<p>Is it clear what will be looked for as evidence of quality for each aspect of care being measured?</p> <p>Is it clear how frequently the 'evidence' should be present if quality is being provided?</p> <p>Is it clear if there are any cases or circumstances that would be clinically justified exceptions for any of the quality-of-care measures?</p> <p>Do the definitions of terms and instructions for data collection say exactly how to make yes-no decisions about compliance with the evidence of quality?</p> <p>Is each measure valid given the audit subject and objective/s?</p> <p>Is it likely that each measure will be a sensitive and specific measure of quality?</p> <p>Are the data source/s appropriate?</p> <p>Is it likely that the data needed will be available in the data sources specified?</p>

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 pilot tested, you can use the questions in the box below to check on design features.

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 description of information governance

requirements related to clinical audits, including data protection and confidentiality, see 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.

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 location 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 compliance** with quality-of-care measures 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?

Monitoring and managing a clinical audit programme

Monitor progress

Establish a method to monitor progress on the clinical audits in the programme, using the project plans for individual clinical audits and a simple tracking system. Include progress on any national clinical audits being carried out in your clinical service in this monitoring system, working with the clinicians responsible for any national clinical audits.

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 which dates. The master programme plan

allows you to know what should be accomplished each week or month for each of the clinical audits.

Your Trust may have a template to document activities, 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.² 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 horizontal bars to indicate when an activity starts and stops. Examples of an activity plan and a Gantt chart are in the following boxes:

Example of an activity plan			
Activity plan			
Activity	Responsibility	Started by	Completed by
1. Design the audit and get approval	AB and CD	16 February	23 February
2. Collect and collate data	AB and CD	23 February	16 March
3. Analyse any shortcomings in care to find root causes	AB and CD	16 March	30 March
4. Present findings and causes or shortcomings in care at meeting to discuss actions needed	AB and CD	30 March	6 April
5. Implement actions agreed	AB, CD and TU	30 March	ongoing
6. Repeat data collection and report on findings	AB and CD	20 April	18 May
7. Prepare report and final presentation on audit	AB and CD	4 May	18 May

Example of a Gantt chart

Gantt chart		
Activity	Who	Weeks from start
		1 2 3 4 5 6 7 8 9 10 11 12 13
1. Audit design	AB and CD	█
2. Data collection	AB and CD	█
3. Analysis	AB and CD	█
4. Presentation	AB and CD	█
5. Actions	AB, CD and TU	█
6. Repeat data collection	AB and CD	█
7. Report and presentation	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 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 they are experiencing any problems.

Facilitate the implementation of changes in practice

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

- **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.

How 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 quality-of-care measures** used in the audit
2. If the audit has revealed many problems (there are several measures 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 which staff need to be trained, what they need to learn to do differently, who will provide the training, when the training needs to be provided, and how it will be provided
6. **Plan repeat data collection** to determine if the actions have been effective in achieving needed improvement in patient care

Supporting colleagues to do clinical audit

Meet 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 in the area. 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 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 an audit properly. Contact your Trust's clinical audit staff to see what

training is available 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 guidance documents and support available, including online training on clinical audit, see www.hqip.org.uk/resources/elearning/

Motivate 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.

How to motivate 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 **further progress 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 completed
- **Help** when someone encounters a problem in carrying out the clinical audit or doesn't know what to do next

Leading meetings involving clinical audit

Shift 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:

- Making an **explicit decision** on **whether or not** patient **care** provided for a particular group of patients, situations, circumstances or events **is clinically acceptable**
- **Identifying** 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 take action
- Agreeing to specific **actions** that are likely to be **practical and effective** 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 what needs to be changed and evidence of improvement** — as described in the box.

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
Clinical audits are selected and presented by individual clinicians	The clinical audits undertaken are from the clinical service’s clinical audit programme and can be carried out by a team
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: <ul style="list-style-type: none"> • Is discussed to agree on actions to be taken • 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 this is not the case, it is clear what is happening about the issues represented

The clinical audit meeting calendar

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

Instead of considering an individual clinical audit only at the data collection 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 box on the following pages. Purposes for discussion are also provided.

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 measures 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 quality-of-care measures</p>	<p>Allow for discussion of the reasons individual cases did not meet measures of quality (which can suggest causes of shortcomings and actions needed)</p> <p>Ensure that clinically acceptable justifications for cases not meeting a measure of quality 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 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 analysis that would contribute to a sound action plan</p>
<p>The detailed actions needed</p>	<p>Give colleagues an opportunity to consider their personal commitment to the actions</p> <p>Allow for discussion on the feasibility and effectiveness of the actions, barriers to implementing the actions and how the barriers could be addressed</p> <p>Raise awareness of other stakeholders whose support might be needed for the actions</p>

Stages to discuss a clinical audit at a meeting

Stage	Purpose for discussion
Progress report on implementation of the actions	<p>Inform colleagues about how the actions are progressing</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 actions</p>
Findings of repeat data collection and the implications	<p>Inform colleagues about the effectiveness of the actions 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 how to consider individual clinical audits at varying stages at meetings in which clinical audits are discussed:

Sample clinical audit calendar

May	July	September	November	January	March
Audit 1: Design	Audit 1: Preliminary findings	Audit 1: Analysis of problems and detailed actions needed	Audit 1: Progress report on actions	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 actions	Audit 2: Detailed actions and plan for repeat data collection for high-risk issues	Audit 2: Progress report on implementation of actions
	Audit 4: Design	Audit 3: Revised design	Audit 4: Preliminary findings	Audit 3: Preliminary findings, analysis of problems and actions	Audit 3: Progress report on actions
				Audit 5: Design	Audit 4: Findings of analysis of causes of shortcomings in care
					Audit 6: Design

A core agenda for clinical audit meetings

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 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 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 the 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>

Advising staff on presenting at clinical audit meetings

Prior to clinical audit meetings, give a short briefing to colleagues who are asked to present their work at the meetings.

As you give advice, remind colleagues to consider:⁵

- What **they want to achieve** by presenting their work at the meeting, that is, the **objective for the presentation**
- What **will have to happen** at the meeting to achieve the meeting objective

- What **information, materials or support** are needed to **achieve the objective** at the meeting

See the example below of possible objectives and activities for the presentation of an individual clinical audit after data collection.

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

Example of objectives and activities for presentation of an individual clinical audit at a clinical audit meeting

Objectives	<p><i>Clinicians attending the meeting should:</i></p> <ol style="list-style-type: none"> 1. Know the overall compliance with the quality-of-care measures used in the clinical audit: <ul style="list-style-type: none"> • Measure-by-measure • Across all measures (the percentage of patients whose care was consistent with all measures in the audit) 2. Know that the individual cases that did not comply with a quality measure were reviewed and whether or not any cases of additional clinical exceptions were found 3. Understand if there was significant variation in patient care for any of the quality measures used in the audit and the type of variation (using run charts) 4. Accept that there are shortcomings in the delivery of quality care to patients covered by the audit and that care needs to be improved 5. Agree 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 quality-of-care measures set for the audit, adjusted for any individual cases that did not comply with the measures but were found to be clinically acceptable • Summary of individual cases that did not comply with the measures • Run charts on variation for any measures for which there was significant variation and appropriate interpretation of the charts • A list of shortcomings in care revealed by the audit 2. Questions about the presentation 3. Discussion about the shortcomings identified and agreement to analyse the problems and report back on their causes

Communicating about the clinical audit programme

Meet 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. The Trust needs to meet external requirements of the CQC, NHS Improvement and commissioners.

In addition, your Trust Board needs assurance about the quality of clinical care provided in every clinical service. The Board also needs to support improvements if areas of concern require resources to be committed.

Your Trust's annual Quality Accounts require a considerable amount of information about your service's performance in

national and local clinical audits. Typical requirements are listed in the box.

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 service. Your Trust's clinical audit staff can inform you of the mechanisms for reporting and any templates available to help provide the required information.

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

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 participation in any national clinical audits relevant to your service, implementation of actions needed given the service's performance in relevant national clinical audits, and evidence of improvements
- Evidence of actions being taken as indicated by findings of local clinical audits being carried out
- Evidence of improvements achieved through clinical audits

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 of 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
National clinical audit performance	An analysis of your service's performance in relevant national clinical audits , including the status of actions identified as required to achieve improvements

CALs may be requested to support the provision of information about consultants' participation in clinical audit and quality improvement activities for purposes of appraisal and revalidation.

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 such audits complete reports. Reports need not be lengthy and can be written simply, but should include the content in the box on the next page.⁵

Also see [Template for Clinical Audit Report](http://www.hqip.org.uk) at www.hqip.org.uk.

Sharing learning and celebrating success about clinical audit

Encourage colleagues to present their work on clinical audits outside regular clinical audit meetings in your service. Other ways for disseminating information are in the box on the next page.

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

Design of the clinical audit including:

- **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**, that is, retrospective, concurrent or prospective
- **Quality-of-care measures** used in the audit

Process of data collection including:

- **How data were collected**
- How **data quality** was ensured, for example, pilot testing, inter-rater reliability testing, data monitoring and actions taken on any problems in data collection

Findings of BOTH initial and repeat data collection, possibly including any relevant summarised information about the population or sample used in repeat data collection cycles

Analysis of the findings including:

- **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

Ways to communicate about clinical audit

Article in Trust's newsletter

Article on the Trust's intranet pages on clinical audit or governance or quality improvement

Participating in Trust competition on clinical audits

Article on your service's web page

Presentation at a Trust meeting or conference

Poster in staff, clinic or ward areas or for Trust event on clinical audit

Grand rounds presentation

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 addition to specialty journals, journals that may publish a clinical audit that has evidence of improvement in patient care are in the box.

Learn your Trust's policy on submitting papers relating to clinical audit and quality improvement for presentation at external conferences and for publication and share this information with your colleagues.

Journals that may publish a clinical audit with evidence of improvement

American Journal of Medical Quality
(<http://ajm.sagepub.com/>)

BMJ Quality and Safety
(<http://qualitysafety.bmj.com/>)

BMJ Quality Improvement Reports
(<http://qir.bmj.com/>)

International Journal for Quality in Health Care
(www.intqhc.oupjournals.org)

Joint Commission Journal on Quality and Safety
(www.jcrinc.com/the-joint-commission-journal-on-quality-and-patient-safety/)

Journal for Healthcare Quality
(www.nahq.org/Quality-Community/journal/jhq.html)

Journal of Clinical Audit
(www.dovepress.com/clinical-audit-journal)



Handling ethics and risk-related issues in clinical audit

The importance of being aware of ethics in clinical audit

Many people think that there is no need for oversight of possible ethics issues in 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:¹⁰

- 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

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.¹⁰

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>Are the proposed design and quality-of-care measures 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 national and/or Trust 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 quality-of-care measures used in the clinical audit?</p>

For more information about ethics issues in clinical audits, see HQIP's Guide to Handling Ethics Issues in Quality Improvement and Clinical Audit at www.hqip.org.uk/resources/ - due for publication late summer 2016.

Troubleshooting for Clinical Audit Leads

Problems Clinical Audit Leads might face and possible actions

A summary of possible actions CALs can take to avoid or minimise the effect of problems is in the box.

Possible problems and approaches for CALs	
Problem	Possible approach or action
Colleagues have not had positive experiences with clinical audit and are cynical about the process	<p>You can't undo negative experiences or perceptions quickly or easily</p> <p>Concentrate on a few clinical audits covering subjects about which colleagues are likely to agree that improvements are needed and drive audits on these subjects through to completion</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>Unfortunately, there is considerable pressure on NHS Trusts to demonstrate compliance with national guidelines and staff 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 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 with the Trust to use clinical audit staff to help with the workload
Colleagues agree to carry out clinical audits but then can't find the time to do the work involved	<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"> • Have additional members of staff to work with to complete the audit • Extend the time to complete the audit • Complete a stage of the audit and see 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	<p>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</p> <p>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</p>

Possible problems and approaches for CALs

Problem	Possible approach or action
Staff carry out clinical audits but don't get around to preparing reports on the audits	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
You don't have time to carry out all the work a CAL should do, with your current clinical commitments and the Trust's expectations for your clinical service	Bring the situation to the attention of the person to whom you are accountable for your performance as the CAL 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
Your clinical director expects you to be responsible for taking action to address problems revealed by a clinical audit because you are the CAL	Bring the situation to the attention of the person to whom you are accountable for your performance as the CAL CALs cannot assume the authority or responsibility of a clinical director , unless it is made perfectly clear to everyone concerned that the director is delegating responsibility for resolving a particular situation to the CAL, and the lead has the time available to accept the responsibility
People in the clinical service agree to take action but actually don't implement the agreed action	Bring the situation to the attention of the person to whom you are accountable for your performance as CAL You can't be responsible for the clinical audit programme without the continuous support of those responsible for directing and managing the clinical service
A very senior colleague proposes to do a clinical audit that is not really a properly designed clinical audit	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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Appendix 1. Sample role description for Clinical Audit Lead

Aims for the Clinical Audit Lead role

A CAL 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 to show the effectiveness of actions taken to achieve needed improvement
- Actual evidence 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 identified through clinical audit findings

Clinical Audit Lead roles

Key CAL roles are to:

- Arrange for the following:
 - An appropriate clinical audit programme in the clinical service, directorate or division that is completed in line with 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 indicated by audit findings as needed to produce improvements in the quality of patient care
- Ensure that the Trust is updated on the clinical audits being carried out and of the overall progress of the clinical audit programme, and ensure that reports of individual clinical audits are readily available on a timely basis
- Disseminate and enable the recognition of colleagues' work relating to 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 CAL should:

- Ensure that the clinical audit process, as well as any quality improvements that are 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. The CAL should arrange for improvement of the design and execution of clinical audits that aren't consistent with best practice
- Make arrangements to meet 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 and the inclusion of patients or patient representatives as appropriate
- 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. Also ensure that repeat data collection is completed to demonstrate the effectiveness of actions and that the findings of repeat data collection are reported 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 approval is being sought for actions that have been identified as necessary in the clinical audits
- 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 including support for the implementation of actions necessary to improve services

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

Knowledge and skills involved in clinical audits	
Knowledge	Skills
<i>The clinical audit process</i>	
What clinical audit is about	
How the clinical audit process works to drive improvement	Explain the clinical audit process to others and why clinical audit is important
What rapid-cycle clinical audit is about and why it is important	Recognise when a clinical audit is or is not being carried out according to the rapid-cycle approach
How clinical audit relates to the following: <ul style="list-style-type: none"> • Evidence-based practice • Quality improvement • Assuring compliance with standards • Patient experience • Patient safety • Clinical risk management • Appraisal and continuing professional development • Accountability for quality and safety of patient care 	Explain to others how clinical audit relates to other activities concerned with the quality and safety of patient care and recognise opportunities to relate clinical audit to other activities
Differences among descriptive studies, service evaluations, surveys, research and clinical audit	Design a clinical audit (not a descriptive study, service evaluation, survey or research study)
How patients and service users can be involved in clinical audit activities	Advise staff on involving patients and service users in clinical audit activities
<i>About designing a clinical audit</i>	
What is included in the design of a clinical audit	
Sources for clinical audit subjects	
Ethically-based criteria for selecting subjects for clinical audit	
Why it is important to involve colleagues in setting priorities and objectives for clinical audits	
Tools and techniques to involve teams in setting priorities for clinical audits	Use various tools and techniques to involve colleagues in selecting appropriate subjects for clinical audits
What should be included in an objective for a clinical audit	

Knowledge and skills involved in clinical audits

Knowledge	Skills
Types of features of quality of care or service a clinical audit could be about and what they mean, for example, effectiveness, appropriateness, safety	
How to write an objective for a clinical audit	Write one or more objectives for a clinical audit properly
Why it is important to consider in advance who may be affected by a clinical audit and whether or not those affected, including patients, should be included in carrying out the audit	Identify stakeholders in a clinical audit and decide how to involve them in the audit
Why it is important to carefully specify the patients, cases, events, situations or circumstances to be included in and excluded from a clinical audit	
How to specify the patients, cases, events, situations or circumstances to be included in and excluded from a clinical audit	Define the patients, cases, events, situations or circumstances to be included in and excluded from a clinical audit
Why it is important to select carefully a population or a sample for a clinical audit	
The difference between a population and a sample	
How to decide whether to use a population or a sample for a clinical audit	
The difference between representative and non-representative samples	
Types of representative samples	
Types of non-representative samples	
How to select a type of sample for a clinical audit	
How to select the size of a sample for a clinical audit	Select the population or sample for a clinical audit appropriately
Types of data collection strategies (retrospective, concurrent, prospective) for a clinical audit	
Factors affecting the selection of a data collection strategy for a clinical audit	
How to select a data collection strategy for a clinical audit	Select a data collection strategy for a clinical audit that is likely to result in complete and reliable data
About measuring quality	
How quality of care can be defined and measured	Recognise valid measures of aspects of quality including patient safety, patient experience and clinical effectiveness-related measures
Why it is important to have measures of quality in a clinical audit	

Knowledge and skills involved in clinical audits	
Knowledge	Skills
Purposes of quality-of-care measures	
The terms explicit measure and implicit measure and what they mean	
Words used to describe measures in clinical audit (criterion, indicator, standard)	
What should be included in a clinical audit measure, that is, the components of a clinical audit measure	
The meanings of all the words used in a clinical audit measure (for example, standard)	
The importance of having good operational definitions of terms used in a clinical audit measure and good directions for data collection	
How to draw up a clinical audit measure for different aspects of quality of care or service	Draw up a clinical audit measure correctly
Characteristics of quality-of-care measures, including validity of measures, and how the characteristics can be evaluated	
<i>About collecting data</i>	
The terms reliability and validity and what they mean as applied to a clinical audit	
How to develop and test a protocol for collecting data for a clinical audit	
Reasons why cases to be included in a clinical audit may not work out	Act appropriately on cases that are to be included in a clinical audit but don't work out
Types of forms for recording data on a case-by-case basis for a clinical audit and how to use them	Develop and test a protocol for collecting data for a clinical audit
How to collect data completely and accurately for a clinical audit	Collect or capture data completely and accurately for a clinical audit, consistent with data protection and information governance requirements
Data protection and information governance requirements relating to clinical audit data	
Why it is important to test the reliability of data collected for a clinical audit	
How to carry out inter-rater reliability testing for data collected for a clinical audit and act on the findings of the testing	Carry out and act on the findings of inter-rater reliability testing of data collected for a clinical audit

Knowledge and skills involved in clinical audits	
Knowledge	Skills
About collating data	
How to collate and display clinical audit data	
Types of data (nominal, ordinal, interval and ratio)	
Tools for displaying data (for example, table or bar chart)	Display clinical audit data using appropriate statistical tools
Tools for displaying data for the purpose of analysing variation in clinical practice (run chart or control chart)	Use tools for analysing variation correctly
Descriptive statistics and how to calculate them (for example, mean, median, mode, range, standard deviation)	Use descriptive statistics appropriately and correctly
How to calculate preliminary compliance with a clinical audit measure	Calculate preliminary compliance with a clinical audit measure properly
Different approaches to presenting findings for a clinical audit	Calculate item-by-item and all-or-none compliance with clinical audit measures
About evaluating findings and cases	
How to present preliminary findings for a clinical audit	Explain clinical audit findings to colleagues correctly
The terms specificity and sensitivity applied to a quality-of-care measure and what they mean	
When it is important to review cases that are not consistent with a clinical audit measure	
Factors that could influence how clinical audit findings and individual cases are reviewed	
How to plan for the evaluation of clinical audit findings and the review of individual cases or rates of cases with colleagues	Plan to involve colleagues in evaluating clinical audit findings and reviewing individual cases or rates of cases with colleagues
How to calculate final compliance with a clinical audit measure and with all clinical audit measures	Calculate final compliance with clinical audit measures properly
About analysing shortcomings and finding causes	
Why it is important to identify shortcomings in care or service that are shown by clinical audit findings	
How to state a shortcoming in care or a problem shown by a clinical audit	State a shortcoming or a problem in the quality of patient care as revealed by clinical audit findings completely and accurately
The difference between a shortcoming or problem in care and the cause of a problem	
How to analyse clinical audit data to find possible causes of a problem	
Tools and techniques to analyse a problem to find its causes	

Knowledge and skills involved in clinical audits	
Knowledge	Skills
How to use tools to analyse a problem to find its causes	Use tools and techniques to involve colleagues in analysing causes of problems
Types of process maps	
How to analyse a process of care or service using a process map	
How to test if potential causes are actual causes of a problem	Validate the actual causes of a problem
<i>About identifying and implementing improvements</i>	
Why it is important to be specific about the improvements required	
The difference between an action and an improvement	
How to state an improvement in practice that is needed	State a needed improvement completely and accurately
Techniques for learning and influencing people's attitudes toward change or an improvement in practice	
How to use techniques to involve and influence people to favour making an improvement in practice	Use various techniques for learning and influencing people's attitudes toward achieving an improvement in practice
The nature of actions that may be needed to respond to clinical audit findings	Identify appropriate and effective actions needed to respond to clinical audit findings
How priorities can be set for actions needed to respond to clinical audit findings	Set priorities for actions to be taken to respond to clinical audit findings and achieve improvements in the quality of patient care
Why it is important to develop a detailed operational plan to achieve a substantial improvement in practice	
Tools for making operational plans	
How to develop an operational plan to achieve an improvement in practice	Develop a detailed plan to achieve an improvement in practice
How to anticipate things that could go wrong in the implementation of an improvement in practice and develop alternative plans	Anticipate things that could go wrong in the implementation of an improvement in practice and develop alternative plans
<i>About repeating data collection and evaluating action</i>	
Why it is important to repeat data collection for a clinical audit as rapidly as possible	
How to carry out repeat data collection for a clinical audit	
How to interpret the findings of repeat data collection for a clinical audit	Carry out repeat data collection for a clinical audit and interpret the findings
How to decide if an improvement in practice has been achieved	

Knowledge and skills involved in clinical audits	
Knowledge	Skills
When it is desirable to test the statistical significance of a change in practice	
How to test the statistical significance of a change in practice	Decide if and how to test the statistical significance of a change in practice
Tools to test the statistical significance of a change in practice	Use appropriate tools to test the statistical significance of a change in practice
How to follow up on a clinical audit	Follow up on a clinical audit appropriately
The components of a clinical audit report	
How to write a report on a clinical audit	Write a report on a clinical audit
<i>About leading clinical audit (in addition to the above)</i>	
How to motivate staff to use clinical audit as a quality improvement process	Motivate staff to use clinical audit properly
Possible systems for reviewing proposals for clinical audits	Ensure that there are robust approval and oversight systems in place for clinical audits in clinical services, communicated to staff and implemented continuously
What a clinical audit programme should look like	Help clinical services develop appropriate clinical audit programmes
How to advise staff on the proper design and execution of individual clinical audits	Advise staff on the proper design and execution of a clinical audit
The structure needed in a clinical service to support achieving an effective clinical audit programme and how to create an effective structure	Plan an effective structure in a clinical service to support clinical audit as a quality improvement process
How to organise agendas for clinical audit meetings	Plan agendas for future clinical audit meetings
How to brief members of staff to make effective presentations of clinical audits	Brief members of staff to make an effective presentation of a clinical audit
How to make decisions about ethics issues related to clinical audit	Make decisions about ethics issues related to clinical audit
How to facilitate the implementation of actions needed to improve the quality of patient care based on clinical audit findings	Facilitate the implementation of actions needed to achieve improvements in the quality of patient care based on clinical audit findings
The components of a clinical audit report and how to advise staff on preparing reports on clinical audits	Advise staff on how to prepare a report on a clinical audit
How to monitor progress on achieving clinical audit programmes and intervene as needed to get things back on track	Monitor progress on clinical audit programmes and intervene if the programmes are not being achieved as planned
Organisational policies needed to support clinical audit and how to develop them	Develop organisational policies needed to support clinical audit



Further information is available at: www.hqip.org.uk

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