Using Clinical Audit in Commissioning Healthcare Services

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Appendix 1
“As we all know, the NHS was created in 1948 with the ideal that good healthcare should be available to all, regardless of wealth. And while the NHS has been through many reorganisations since, the commitment to providing care which is safe, effective and focused on patient experience has remained the central priority. This ongoing commitment is particularly important at a time when rising demand, demographic changes and the cost of drugs and technologies mean the NHS needs to make significant efficiency savings.

Clinical Commissioning Groups (CCGs) and other care commissioners are increasingly under pressure to focus on better value and commission cost-effective services that meet the needs of local people, improve health outcomes and reduce inequalities.

Utilising quality improvement (QI) tools assists commissioners in fulfilling their role and achieving their objectives, and national clinical audit is a powerful part of that.

It offers the opportunity for systematic, critical analysis of specific aspects of care quality against explicit standards, using national benchmarking. It can be used as assurance that essential levels of effectiveness and safety are met and also be part of a continuous improvement process aiming to address unwarranted variations in clinical care.

To achieve the latter, effective communication, staff engagement and adequate resources that support clinical leadership are needed as well as an organisational culture that facilitates honest reflection and shared learning.

This document provides clear guidance on how clinical audit can be used by commissioners to both assure quality and drive continuous improvement. It has been developed by HQIP as part of its role in supporting the NHS around QI. The team brings together a wealth of knowledge, expertise and experience from across the NHS.

As data connectivity and sharing improves between different NHS settings, there will be even greater opportunities to use clinical audit for quality improvement across multiple providers within integrated care systems and achieve large-scale transformational improvement and change.”

Dr Victoria Tzortziou Brown
HQIP Board Trustee, Board member of the NHS Tower Hamlets Clinical Commissioning Group and RCGP Clinical Commissioning Champion
Introduction

Background

The NHS Constitution states that patients have the right to expect NHS bodies to monitor, and make efforts to continuously improve, the quality of healthcare they commission or provide. This includes improvements to the safety, effectiveness and experience of services.

NHS commissioners (Clinical Commissioning Groups (CCGs) and NHS England) are required by law to exercise their functions with a view to securing continuous improvement in the quality of services provided to individuals for, or in connection with, the prevention, diagnosis or treatment of illness. NHS commissioners must act with a view to securing continuous improvement in the outcomes that are achieved and, in particular, outcomes that show the effectiveness of their services, the safety of the services provided, and the quality of the experience of the patient. (Health and Social Care Act 2012 Section 26.)

Clinical audit is a quality improvement process that can be used by commissioners and service providers working in partnership to meet the requirements of the NHS Constitution. In addition, the findings and outcomes of clinical audits are a rich source of information that can be used to monitor the quality of the services. As parties bound by the NHS Standard Contract, commissioners should enforce the contractual obligations of healthcare providers to undertake local clinical audits (under General Condition 15.7 of the contract) and participate in national quality improvement programmes (under Service Conditions 20 and 38 of the contract, for example) (see section 1.3 below).

HQIP has developed a range of resources to assist healthcare providers in improving their practice in clinical audit (see www.hqip.org.uk/resources/). Some of the key resources are:

- **Best practice in clinical audit (HQIP, 2016a):** Criteria and checklists to assess clinical audit projects and programmes
- **Statutory and mandatory requirements in clinical audit (HQIP, 2016b):** Summarises the current statutory and mandatory requirements imposed on healthcare providers who work in the NHS in England
- **A set of resources on clinical audit management:** Including guides to developing clinical audit policy (HQIP, 2016c) strategy (HQIP, 2016d) and programmes (HQIP, 2016e)
- **Documenting local clinical audit: A guide to reporting and recording (HQIP, 2016f):** Describing how clinical audits undertaken at a local level should be documented and how information about clinical audit should be shared with stakeholders including commissioners and the public.

In 2015 HQIP hosted workshops to bring CCG commissioners together to discuss how HQIP could support them in making better use of clinical audit in commissioning. The commissioners identified a clear need for practical guidance on how clinical audit should be used. They wanted to know how to recognise good practice and how to work with providers in a collaborative way to bring about improvement. They were particularly concerned about the working relationships between commissioners and providers, which they characterised as sometimes confrontational.

The following guide has been developed to address some of these concerns. It covers both the use of clinical audit for monitoring and assurance, and for service improvement and development.
Who this guide is for

This guide is for those who commission services and for CCG quality leads. It will also be of interest to clinicians, clinical audit staff and Board members in healthcare providers who want to work effectively with their commissioners, as well as patients and members of the public who want to engage with commissioners and influence commissioning priorities.

Please note that throughout this guide, the term ‘clinician’ refers to any clinically qualified person, of any grade or profession. The terms ‘commissioner’ and ‘provider’ are used in the NHS Standard Contract to refer to the bodies that are parties to the contract. In this guide, they are used to refer both to the organisations that commission (e.g. CCGs) and provide (e.g. NHS Trusts, independent sector providers) healthcare services, and the staff who work within those organisations.

How this guide can help

This guide is based on four key principles:

<table>
<thead>
<tr>
<th>Partnership working</th>
<th>Active engagement</th>
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<tr>
<td>Commissioners and providers have a joint responsibility for the quality of healthcare services, and the most effective way to drive quality improvement is through cooperation and collaboration.</td>
<td>As key stakeholders, commissioners should engage with providers and be actively involved in developing clinical audit policy (HQIP, 2016c) supporting the implementation of the policy through the clinical audit strategy (HQIP, 2016d), and influencing the content of the clinical audit programme (HQIP, 2016e)</td>
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<table>
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<tr>
<th>Informed critical analysis</th>
<th>Facilitating and supporting change</th>
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<tr>
<td>Commissioners need the skills and expertise to understand the ways clinical audit and other quality improvement activities are governed in healthcare providers, and to undertake critical analysis of the clinical audit information and reports that are available to them.</td>
<td>Commissioners need to work with providers to facilitate and enable the changes that are necessary to improve services. This means ensuring that when clinical audits show that action is required, changes are implemented, and it also means using clinical audit to monitor quality through periods of transformational change (see section 2.3.3 below).</td>
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Part 1 of the guide is about the strengths and limitations of clinical audit outputs for monitoring and assurance. It covers:

- The audit cycle and how it relates to other quality improvement activities that are undertaken by providers
- How clinical audit functions in the governance of healthcare providers
- The duties and powers of commissioners regarding quality of service, including the quality requirements of the NHS Standard Contract
- The information on clinical audit activity and outcomes that providers should supply to commissioners including the clinical audit requirements in Quality Accounts
- How to evaluate the clinical audit information provided and determine what assurance it can give about service quality
- The powers that commissioners have to commission clinical audits from third parties or undertake audits themselves, and the information governance/data access/patient consent implications of the different approaches
- The role of HQIP in commissioning the National Clinical Audit and Patient Outcomes Programme (NCAPOP), and where to find data from national programmes that are relevant to the services that are being commissioned
- The Clinical Outcomes Publication programme, including how to access and use the published data

Part 2 is about how clinical audit can drive quality improvement. It includes case studies and practical guidance on:

- How to ensure that healthcare providers are participating effectively in national quality programmes
- How commissioners can work with providers to ensure that action is taken to address shortfalls in the quality of care identified through national and local clinical audit to improve the quality of services
- The use of clinical audit in service development, including Sustainability and Transformation Plans
- How commissioners can assess and improve the quality of clinical audit and other QI activities being undertaken in providers
Part 1

1.1 An introduction to clinical audit

Clinical audit is a quality improvement process that was developed by clinicians to enable them to ensure that they practiced in accordance with evidence-based guidance. By comparing data that they collected about their own practice with best practice standards, clinicians could identify shortfalls and take steps to rectify them. The process is often referred to as the clinical audit cycle, because the early practitioners saw repeated cycles of data collection, analysis and incremental improvement as the best way to achieve and sustain continuous improvement.

Clinical audit is only one of a range of quality improvement methodologies that healthcare providers can use. It is the most well established method, and is mentioned specifically in the NHS Standard Contract and in other relevant legislation (HQIP, 2016b).

1.1.1 The clinical audit cycle

While the cycle can be summarised as a four stage process, in practice each of the stages can be broken down into several components, all of which are necessary if the aim of quality improvement is to be achieved.

1. Preparation and planning

First an aspect of service delivery must be selected that is suitable for quality improvement through clinical audit. One of the key issues is whether there are evidence-based standards that can be audited against. For example, an audit on the use of a particular drug treatment may be planned to improve compliance with NICE guidance. The standards must be reviewed and the data, which will be required to measure compliance, identified. The best method of collecting this data from patient records must be agreed. Can the data be downloaded from electronic records, or must they be extracted from paper records? Must data collection be carried out by clinically qualified staff, or can clinical audit or administrative staff help? HQIP has published guidance on ensuring data quality in clinical audits (HQIP, 2011b.)

2. Measuring performance

All members of the clinical team whose practice is being audited should be aware of the project and should have had the opportunity to contribute to the development of the audit methodology. The plans should also have been signed off at an appropriate level within the organisation. Measuring performance should simply involve carrying out the plans made in stage 1, and collecting and analysing the data to compare actual practice with the standards of best practice.

3. Implementing change

This stage in the audit cycle often exposes challenges. Shortfalls and discrepancies between actual practice and best practice can be identified from the analysed audit data, but this does not necessarily reveal the causes. Without understanding the underlying causes, it is very difficult to make effective changes that will result in better compliance with standards, and therefore improved quality of service. See Part 2 on page 20.
4. Sustaining improvement (including re-audit)

Once changes in practice have been made, it is essential to monitor their effects to ensure that they have actually produced the desired improvement in compliance with standards, and that the improvement is sustained. The clinical audit cycle has not been completed until evidence has been obtained to show that compliance with standards has improved, and this is a key factor in assessing the effectiveness of clinical audit projects and programmes – see Part 2.

1.1.2 Patient and public involvement in clinical audit

Patients and the public offer a unique voice to service development, identifying required improvements and inefficiencies first-hand as experts by experience. HQIP is fully committed to the principle that patients and the public should be involved as key stakeholders in clinical audit and other methods of quality improvement. Members of the HQIP Service User Network (SUN) work alongside HQIP staff in helping develop patient and public involvement (PPI) and quality improvement work, and the SUN also acts as an expert consultation group to HQIP on all relevant projects. See www.hqip.org.uk/involving-patients/

HQIP has published a comprehensive updated guide to the benefits of PPI in quality improvement projects and how to implement PPI effectively (HQIP, 2016g). Involving patients and the public in clinical audit is a marker of best practice, and should be acknowledged in all clinical audit reports (HQIP, 2016a).

1.1.3 Local and national clinical audit

Local clinical audit means clinical audit carried out by clinical teams working within healthcare providers, in accordance with local priorities. Standards are selected, data are collected and analysed, and changes to practice are carried out by the members of the clinical team, sometimes with the support of clinical audit specialists. Healthcare providers may collaborate to carry out regional audits – for example, all of the acute hospitals in a geographical region may choose to carry out the same local audit at the same time, in order to be able to compare their findings and collaborate on planning improvements.

National clinical audit means a clinical audit that is carried out at a national level. HQIP commissions and contract manages the NCAPOP projects on behalf of NHS England (see section 1.7 below) but there are other national clinical audits (or NCAs) – for example, those carried out by the Royal College of Psychiatrists Prescribing Observatory for Mental Health (POMH-UK). Once a topic has been agreed, a national audit provider works with stakeholders to agree on the standards to be audited, and design the data collection process. Healthcare providers register with the audit, then collect and submit their data to the national audit provider who carries out the analysis. The audit findings are reported at both the national and local level, and it is then the role of local healthcare providers to act on those findings to achieve improvements.

A full list of known national clinical audits can be found in the HQIP National Clinical Audit and Enquiries Directory.

1.2 The role of clinical audit in the governance of healthcare providers

HQIP has collaborated with the Good Governance Institute to publish ‘Clinical audit: a guide for NHS Boards and partners’ on the use of clinical audit in Board assurance and service management (HQIP, 2015a). Clinical audit serves two main functions in the governance of healthcare provider – quality improvement and quality assurance.
1.2.1 Clinical audit and quality improvement

Quality improvement is the function that clinical audit was originally designed to fill. In order to meet the expectations of the NHS Constitution, every healthcare provider should have in place a programme of activities aimed at continuously improving the quality of the services they provide. The NHS Standard Contract (see section 1.4 below) includes specific references to a clinical audit programme:

The ‘National Clinical Audit and Patient Outcomes Programme’ is defined in the contract as ‘a set of centrally commissioned national clinical audits that measure Provider performance against national quality standards or evidence-based best practice, and allows comparisons to be made between provider organisations to improve the quality and outcomes of care. See www.hqip.org.uk/national-clinical-audits-managed-by-hqip/’ (see section 1.7 below)

HQIP has produced guidance on the development of a clinical audit programme (HQIP, 2016e) that will address both local and national priorities for improvement. Many NHS Trusts and other providers are now developing quality improvement programmes that include clinical audit together with other quality improvement and service development activities.

As key stakeholders, commissioners have an important role to play in working with providers to implement these programmes. This includes ensuring that the programmes are properly resourced and supported by the relevant provider. Commissioners need to understand how the providers they work with develop their programmes, so that they can engage with the process at an early stage. In this way, commissioner priorities can be built into the programme, rather than added later.

The following is a summary of the steps that a healthcare provider should take in compiling their programme, and is adapted from section 3.5 of ‘Developing a clinical audit programme’ (HQIP, 2016e)

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>Forward plan using all sources of ‘must do’ audits* to ascertain what should be included for the forthcoming financial year. This should include a review of existing commissioner requirements</td>
</tr>
<tr>
<td>2</td>
<td>Populate the clinical audit programme database with ‘must do’ audits and incomplete priority projects from the previous year</td>
</tr>
<tr>
<td>3</td>
<td>Discuss the initial draft programme with audit lead clinicians in directorates/divisions/services and agree timetables for new projects</td>
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<td>4</td>
<td>Invite proposals for new audits from all stakeholders, including commissioners</td>
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<tr>
<td>5</td>
<td>Work with audit leads in directorates/divisions/services to review and prioritise proposals. Commissioners may want to influence priorities and may need to consider the resource implications of their requests</td>
</tr>
<tr>
<td>6</td>
<td>Combine prioritised lists from all directorates/divisions/services, identify areas of overlap and discuss with audit leads in order to minimise duplication of effort</td>
</tr>
<tr>
<td>7</td>
<td>Review of the draft programme by the relevant committee. Commissioners may be represented on this committee - see 1.2.2 below</td>
</tr>
<tr>
<td>8</td>
<td>Final draft directorate/division/service programmes are referred back to the relevant clinical/management body for sign off</td>
</tr>
<tr>
<td>9</td>
<td>Final programme is signed off by the medical director/chief executive/provider Board in accordance with clinical audit policy</td>
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Note: * ‘must do’ audits are those clinical audits that are essential elements of the clinical audit programme. They include audits that are statutory or contractual requirements (See HQIP, 2016e)
1.2.2 Clinical audit and quality assurance

While the primary function of clinical audit is quality improvement, it also has a role to play in providing assurance to the management and Boards of healthcare providers about the quality of their services. It can fulfil the same role for commissioners.

There are two aspects of clinical audit that can provide assurance. First, the audit provides evidence of compliance with audit standards. The assumption that underlies all clinical audits is that care that complies with evidence-based standards will deliver the best outcomes and experience for service users. The limitation on this assurance is that clinical audit only measures those aspects of care that are included in the audit standards.

For example, a local clinical audit might measure compliance with a piece of NICE technical guidance on the use of a particular drug. The analysed data might show that all of the clinical requirements in the guidance have been met. However, there may be other aspects of the treatment of patients who are eligible to be prescribed this drug that fall outside the clinical guidance. This is where patient and public involvement can be important, in ensuring that aspects of care that matter to patients are included in clinical audits. If there are no auditable standards relating to these other aspects of care, then the clinical audit data must be supplemented by other information to get a full picture of the quality of service. This might include patient surveys, or information on adverse incidents or complaints.

Secondly, the clinical audit should provide assurance of improvement, and this is often overlooked. Consider the case where data collected for a clinical audit measures compliance with NICE guidance on a particular topic. The initial audit findings show 90% compliance with the guidelines. If the audit is described as ‘for assurance’, the view might be taken that 90% compliance is good enough, so there is no need for further action. The difficulties of trying to understand why some patients are not receiving care that is compliant with the standards, or trying to implement changes that might increase compliance, are avoided, but the opportunity to improve care is lost. The only assurance that the provider – or the commissioner – has is that one in 10 patients are receiving care that is not in compliance with best practice standards. Full assurance means having evidence that effective action has been taken to improve compliance with standards – in other words, that the clinical audit cycle has been completed.

1.3 The duties and powers of clinical commissioners regarding quality of service

As stated in the introduction, commissioners have a duty to act in a manner that can secure continuous improvement in the outcomes that are achieved and, in particular, outcomes that show the effectiveness of their services, the safety of the services provided, and the quality of the experience of the patient. Commissioners do not have regulatory powers, but the NHS Standard Contract gives them significant contractual rights to require healthcare providers to carry out local clinical audits and participate fully in national clinical audits. Section 39 of the NHS England Standard Contract Technical Guidance (NHS England, 2016) gives an overview of the use of the contract to manage quality.

‘It is essential that commissioners use the tools within the Contract to set high standards for providers and to monitor service quality continually, alongside expenditure and activity levels – and that they maintain a constant and close dialogue with providers about any issues relating to service quality.’ Section 39.3

1.3.1 The quality requirements of the NHS Standard Contract


Under the terms of the contract, providers must:

- Implement an ongoing, proportionate programme of clinical audit as described in section 1.2.1 above (General Condition GC15.7.1)

Note: * For standard contract queries email nhsccb.contractshelp@nhs.net
• Participate in the NCAPOP audits that are relevant to the services they provide, and make national clinical audit data available to support the publication of consultant level outcomes (Service Condition SC26.1.2 and SC26.1.3)

• Implement and/or respond to all relevant recommendations of any appropriate clinical audit (General Condition GC15.5.3).

• Provide to the co-ordinating commissioner on request the findings of any audits (General Condition GC15.7.3)

This means that providers of NHS-funded healthcare under the NHS Standard Contract must participate in all of the NCAPOP projects that are relevant to the services that they provide. Failure to do so is a breach of the terms of the NHS Standard Contract, and it is for commissioners as parties to the contract to ensure that the provider remedies such a breach. Commissioners need to be familiar with the NCAPOP projects that are relevant to the services that they commission (see the HQIP national clinical audits and enquiries directory www.hqip.org.uk/national-programmes/national-clinical-audits-and-enquiries-directory/).

It should be noted that commissioners have no power to ‘allow’ providers not to participate in NCAPOP audits. Commissioners do not have the power to vary the terms of the Standard Contract.

The co-ordinating commissioner has the power to appoint an auditor to audit quality and outcomes and the recording and coding of clinical activity (General Condition GC15.8) – see 1.6 below.

In addition to these sections that make specific reference to clinical audit, Schedule 4C of the Contract Particulars allows commissioners to specify local quality requirements (LQR). Where applicable, commissioners can specify clinical audit as the method of measurement for meeting LQR – see 1.3.3 below.

1.3.2 Enforcing the quality requirements of the NHS Standard Contract

Commissioners and providers should work together to ensure that the quality requirements set out in the NHS Standard Contract are met. If it becomes necessary, commissioners have powers to enforce the terms of the contract, including the power to impose sanctions in respect of any breach of the local or national quality requirements (Service Condition SC36.37). Section 40 of the NHS Standard Contract Technical Guidance (NHS England, 2016) provides detailed advice on the application of financial sanctions, and the effects of the Sustainability and Transformation Fund.

‘As a general rule, focussing on a small number of key indicators is likely to be more effective than requiring dozens of separate indicators to be monitored. It is important for commissioners to bear in mind the burden which Local Quality Requirements may create for providers, in terms of service management and data collection and reporting.’

The key issue here is to ensure that commissioners and providers work together to decide whether the quality requirement is one of measurement and monitoring, where straightforward data collection will suffice, or of quality improvement. If a service requires improvement, then both sides need to agree how that improvement can be best achieved. This might be through local clinical audit, through a CQUIN scheme under Service Condition 38, or a local Quality Incentive Scheme under Service Condition 37 – see Part 2. In either circumstance, commissioners and providers need to work together to ensure that adequate resources are available to meet the requirements.
1.4 Information that healthcare providers should supply to commissioners

1.4.1 Information obtained through engagement with providers

The Standard Contract Technical Guidance reference to ‘a constant and close dialogue’ between commissioners and providers (see section 1.3 above) implies a free exchange of information, and this is a reflection of the key principles of partnership-working and active engagement.

Commissioners who are fully engaged with the quality improvement activities that are undertaken in providers – for example, through membership of the Clinical Effectiveness Committee or its equivalent – will see a substantial quantity of information about clinical audit and other quality improvement activities automatically. This should include full details of the provider’s policy and strategy, and regular updates on the clinical audit programme including summary reports on all completed audits. Commissioners then have the option to ask for full reports on any audits that are of particular interest, and if necessary they can make formal requests under General Condition GC15.7.3 of the NHS Standard Contract (see 1.3.1 above).

Clinical audit findings and outcomes should feature in the performance reports that are submitted on a regular basis for provider Board review, and commissioners need to consider not just the content of these reports but also any discussion that takes place at Board level. Many providers will produce an annual clinical audit report, that may include summaries of all completed local clinical audits and a review of progress in completing the clinical audit programme (Appendix 2 of HQIP’s ‘Developing a clinical audit policy’ (HQIP, 2016c) is an example format for an annual clinical audit report).

1.4.2 Summary versus detailed reports

Clinical audit as a process generates a great deal of information. In addition to the clinical data that are collected, there is information about the audit standards, the methodology and how it has been developed, the analysis and findings, action planning and how changes have been made, and evidence about the impact of those changes generally obtained through a second round of data collection. HQIP’s ‘Documenting local clinical audit: A guide to reporting and recording’ (HQIP, 2016f) includes a template for a full clinical audit report, together with advice on how it should be compiled as part of the conduct of an audit.

The full report is essential for two main purposes:

- It provides a detailed record of the audit process that allows the audit to be repeated accurately, meaning that later rounds of data collection produce comparable results
- It provides multidisciplinary teams with all of the information that they need to be able to evaluate the accuracy of the audit findings, discover and understand the underlying causes for any shortfalls in compliance with standards, and make effective changes in practice to bring about improvement

If a clinical audit has wide-ranging implications or addresses a critical area of concern, it may be necessary for the full report to be reviewed by a wide range of stakeholders, including the Board and senior managers of the provider, commissioners and others. In most cases, it is not appropriate or indeed possible for every clinical audit report to be reviewed in full in this way. Summary reports are generated and the information that reaches the Board is much more limited. The HQIP reporting guide (HQIP,2016f) states:

Given the volume of clinical audits that are undertaken, these summary reports will inevitably lack the detail included in the full documentation. While in most cases a standard summary report will be sufficient, there may be occasions when a more detailed report is required. It is the responsibility of both the audit lead and the clinical lead to ensure that the report that is reviewed by the committee contains all the necessary information to highlight any areas of particular concern, and that appropriate action is taken.
It is for commissioners to decide if the audit reports they receive contain sufficient information to give assurance of service quality. If not they should ask to view the full audit report.

1.4.3 Clinical audit requirements in quality accounts

Under the Health Act 2009, providers of NHS-commissioned healthcare have a statutory obligation to publish an annual quality account. The main exceptions are for providers of primary care, or small providers as defined in the legislation. The quality account should provide a range of information about service quality, and the Act and the regulations made under it specify the format that must be used for clinical audit information.

The key content for clinical audit includes:

- The number of national clinical audits and national confidential enquiries that the provider has participated in/participation rate
- The number of national and local clinical audit reports reviewed by the provider Board
- Actions the provider intends to take to improve services

The first round of quality accounts were published in 2010 and were described by the Department of Health as being of ‘varying quality’, with most Trusts failing to present details of any actions to improve quality following the review of a national clinical audit reports. As a result, the Department produced the Quality Accounts Toolkit that remains in force. Extracts from the legislation and the toolkit and full references can be found in HQIP’s ‘Statutory and mandatory requirements for clinical audit’ (HQIP, 2016b)

Note that unlike the NHS Standard Contract, which requires providers to participate in the NCAPOP (under Service Condition 26), the quality accounts legislation makes no distinction between the NCAPOP and other national clinical audits. It does not require providers to participate in non-NCAPOP national clinical audits – simply to report on whether or not they have participated. This has caused some confusion, not least because at the time quality accounts were introduced there was no authoritative source of information about how many non-NCAPOP clinical audits existed.

Following the publication of the Quality Accounts Toolkit, the Department of Health began publishing an annual list of national clinical audits that providers could consult while preparing their quality account. Some providers have felt under obligation to participate in all of the projects on this list, but if the audit is not a part of the NCAPOP, providers can choose not to participate. In that case they should publish their reasons for non-participation in their quality account. If commissioners believe their reasons are not valid, they can seek to require participation in a non-NCAPOP national clinical audit as a LQR in the NHS Standard Contract.

In recent years the quality accounts list has been published by HQIP on behalf of NHS England, and more information is available on the HQIP website: [www.hqip.org.uk/national-programmes/quality-accounts/](http://www.hqip.org.uk/national-programmes/quality-accounts/)

1.5 Evaluating clinical audit information – what quality assurance can it give?

There are two main types of clinical audit information that commissioners can use to evaluate the quality of the services that they commission. The first is published information from national clinical audits and other national initiatives, and this is reviewed in more detail in sections 1.7 and 1.8 below. This section focuses on the second type, which is local clinical audit information and includes:

- Provider clinical audit policy and programme
- Progress reports on the clinical audit programme
- Summary information published in quality accounts and annual clinical audit reports
- Detailed reports on completed clinical audits

1.5.1 Putting clinical audit reports into context – key questions to consider

Clinical audit information should not be viewed in isolation. Commissioners also have access to a range of other information about service quality, including internal performance management reports, CQC inspection reports, information about claims and complaints and evidence from local Healthwatch representatives. This other information can help to put the findings and outputs from local clinical audit into context.
Commissioners will also need to consider clinical audit reports in the context of the governance and management of the provider.

Key questions for commissioners to consider when putting the reports into context include:

1. Does the provider have an up-to-date, implemented and effective clinical audit policy in place?
2. Is there a clear governance process in place to ensure that clinical audit and other quality improvement activities are effective?
3. Does the content of the clinical audit programme reflect clinical and organisational priorities? Does it show that clinical audit is being used effectively for service development and to address acknowledged quality concerns?
4. Do performance monitoring reports on the clinical audit programme show that good progress is being made?
5. Is there evidence that the provider is monitoring the quality of clinical audits?

More detailed checklists to assess organisational arrangements and clinical audit programmes were published with HQIP's 'Best practice in clinical audit' (HQIP, 2016a)

If commissioners are fully engaged with the governance of clinical audit in providers, they will be aware of the providers’ processes to assure the quality of clinical audit activities and reporting. If they are satisfied that the provider has effective arrangements in place they can have greater confidence in the content of clinical audit reports.

1.5.2 Evaluating clinical audits and obtaining assurance

Commissioners must be able to assure themselves about the quality of clinical audits. The checklist for assessing completed clinical audits published with HQIP’s ‘Best practice in clinical audit’ (HQIP, 2016a) may be used. Section 2.3 below addresses the issue of how to support providers in improving their practice.

Once the commissioner is satisfied about the quality of the clinical audit, there are two issues to consider, as mentioned in section 1.2.2 above.

First, what does the audit say about how current practice compares with the best practice standards? What assurance does this give about the quality of service?

Secondly, what actions have been taken to improve practice, and have they been effective? What assurance does this give about the provider’s ability to improve quality?

1.6 Commissioning clinical audits

1.6.1 Requiring a provider to carry out a clinical audit

Commissioners should collaborate with providers in developing the clinical audit programme, to ensure that all of their requirements are met in both the content and prioritisation of the programme. Commissioners might require providers to carry out audits because they have concerns about the quality of a particular service, or as part of a programme of service development. If necessary, commissioners can ensure providers carry out a particular clinical audit by including it as a LQR under Schedule 4C of the NHS Standard Contract Particulars (see section 1.3.1 above).

Commissioners should work with providers to ensure that their requirements are met, and Appendix 1 describes the roles that both commissioners and providers should take in developing and carrying out a clinical audit.

Commissioners should not ask for clinical audits to be carried out if there are other more appropriate ways of improving a service. For example, if they are concerned more about delays in service delivery rather than actual clinical care, it may be more appropriate to ask for run charts or a control chart of waiting times. Alternatively the provider could be asked to process map the care pathway to identify possible inefficiencies. HQIP’s ‘Guide to quality improvement methods’ (HQIP, 2015b) describes a range of alternatives to clinical audit.

Commissioners should be cautious about requesting clinical audits ‘for assurance’ when what they actually want is data on aspects of performance. As mentioned in 1.3.3 above, clinical audits should be requested when the aim is quality improvement, and the term ‘clinical audit’ should not be used in connection with straightforward requests for data (for example, a request under Service Condition 28 of the NHS Standard Contract).
1.6.2 Appointing an auditor to carry out a clinical audit

There are circumstances where commissioners may feel it necessary to appoint auditors to carry out a clinical audit. They may feel that the provider lacks the capacity or capability to carry out an effective audit, or there may have been past failures to deliver a clinical audit. In this situation it is essential that commissioners are open and transparent with providers about their views and intentions, and offer justification for their decisions.

General Conditions GC15.8 of the NHS Standard Contract states ‘The Co-ordinating Commissioner may at any time appoint an Auditor to audit: (15.8.1) the quality and outcomes of any Service’. This power is ‘subject to any applicable Service User consent requirements’, and this caveat is important because commissioners do not have an automatic right of access to patients’ confidential data. Auditors appointed by commissioners are bound by the same constraints so their access to patients’ confidential data is similarly limited. The reasons are explained in the text box below. The practice of issuing honorary contracts to auditors does not change this situation. If commissioners or their appointed agents wish to obtain access to confidential data, they must get explicit consent from the patients, and have all the necessary information governance and data protection controls in place. HQIP's 'Information governance in local clinical audit' (HQIP, June 2017) contains more information and a case study example illustrating the process.

The term ‘auditor’ is defined in the NHS Standard Contract as ‘an appropriately qualified, independent third party auditor appointed by the Co-ordinating Commissioner in accordance with GC15.8 (Governance, Transaction Records and Audit)’. Once a suitably qualified independent third party auditor has been appointed, the commissioner should take the lead in developing a collaborative working arrangement between the healthcare provider and the auditor. Roles and responsibilities should be clearly defined by reference to the audit cycle. The commissioner should ensure that the clinical team responsible for providing the service to be audited is actively involved in working with the independent auditor.

Access to patients’ confidential data for clinical audit

In order to carry out clinical audits, it is necessary to collect clinical data from patient records. If the data are collected by the clinical staff who are providing care, then there is no need for patients to give separate consent for their data to be used for audit purposes. There is an assumption that as clinical audit is a part of good medical practice, the patient’s consent to treatment also covers their consent to have their data used for audit.

The Department of Health’s 2013 Information Governance Review (Caldicott 2) (Department of Health, 2013) report states: ‘The use of personal confidential data for local clinical audit is permissible within an organisation with the participation of a health or social care professional with a legitimate relationship to the patient through implied consent.’ (paragraph 13.13)

As part of the review, commissioners explained that they wanted access to confidential personal data to check the quality of care at every stage of a patient pathway, as the individual moves among a series of health and social care providers. They suggested that the surest way of doing this was to look at a sample of personal files. However, the review panel concluded there did not appear to be a robust case for commissioners holding personal confidential data, and any exceptions should be argued on an individual case-by-case basis. (sections 3.3, 3.7 and 7.3.2)
1.7 The National Clinical Audit and Patient Outcomes Programme (NCAPOP)

HQIP commissions, manages and develops the National Clinical Audit and Patient Outcomes Programme (NCAPOP) on behalf of NHS England, the Welsh Government and in some cases other devolved authorities. HQIP uses best management and procurement practice to ensure robust results and actionable recommendations.

NCAPOP includes the National Clinical Audit Programme, the Clinical Outcome Review Programmes and the National Joint Registry.

Full information about all of the NCAPOP projects, including access to all of the published reports, can be found on the HQIP website [www.hqip.org.uk/national-programmes](http://www.hqip.org.uk/national-programmes).

Healthcare providers are obliged to pay subscription charges to participate in NCAPOP projects. More information about subscription charges can be found on the HQIP website [www.hqip.org.uk/national-programmes/a-z-of-nca/subscription-funding/](http://www.hqip.org.uk/national-programmes/a-z-of-nca/subscription-funding/).

### 1.7.1 The National Clinical Audit Programme

The National Clinical Audit Programme comprises more than 30 clinical audits and related projects that review care provided to adults and children with a wide range of medical, surgical and mental health conditions. Their purpose is to engage clinicians in systematic evaluation of clinical practice against standards and encourage improvement in the quality of treatment and care. The full list of current audits can be found here: [www.hqip.org.uk/national-programmes/a-z-of-nca/](http://www.hqip.org.uk/national-programmes/a-z-of-nca/).

HQIP seeks to ensure all national clinical audits are timely in providing response on a local level, effective in driving change in practice, led by clinicians and offer value for public money.

### 1.7.2 The Clinical Outcome Review Programmes

These programmes are designed to help assess the quality of healthcare, and stimulate quality improvement. Rather than using a clinical audit methodology, they use data collection and peer review to enable clinicians, managers and policy makers to learn from adverse events and other relevant data.

HQIP currently commissions eight programmes on behalf of NHS England, NHSSPS Northern Ireland, and the health departments of the Scottish and Welsh governments, Channel Islands and Isle of Man:

- Child death review database
- Child head injury project
- Child health outcome review programme
- Learning disability mortality review programme
- Maternal, newborn & infant outcome review programme
- Medical and surgical outcome review programme
- Mental health outcome review programme: suicide and homicide
- National mortality case record review programme

HQIP is in the process of commissioning an additional Learning Disability Mortality Review programme of work to run until 2018. The full list of current CORP projects can be found here: [www.hqip.org.uk/national-programmes/a-z-of-clinical-outcome-review-programmes/](http://www.hqip.org.uk/national-programmes/a-z-of-clinical-outcome-review-programmes/).

### 1.7.3 The National Joint Registry

The National Joint Registry (NJR) for England, Wales, Northern Ireland and the Isle of Man monitors the performance of hip, knee, ankle, elbow and shoulder joint replacements to improve clinical outcomes for the benefit of patients, clinicians and industry. It was set up in 2002 by the Department of Health and Welsh Government to monitor the safety of hip and knee replacements. Ankle joint replacements have been collected since April 2010 and elbow and shoulder joint replacements have been collected since April 2012. Northern Ireland joined the registry in 2013 and the Isle of Man in July 2015. The registry now holds over 2 million records and with the increasing volume and quality of data it is possible to make accurate analysis available to all stakeholders and contribute significantly to good practice and patient safety.

1.7.4 The use of NCAPOP data by the Care Quality Commission (CQC)

The National Clinical Audit Benchmarking (NCAB) project is a result of a collaborative project begun with the Care Quality Commission (CQC) in 2015. The CQC worked with a number of National Clinical Audits to distil what can be necessarily complex reporting into six key metrics per audit topic to make the data more accessible to CQC inspection teams. Results are presented in an easy to understand visual form, specific for each Trust, hospital and in some cases ward, often against national benchmarks.

This high-level visual snapshot will also be beneficial for medical directors (providing at-a-glance results) and local clinical audit teams (reducing the burden of collating and re-presenting National Clinical Audit data locally). As such, HQIP will be making slides available on a specially designed web portal, beginning in mid-2017 with six national clinical audits.

Information about NCAB and the portal can be found here: www.hqip.org.uk/national-programmes/clinical-audit-benchmarking/

Commissioners may also find it helpful to review the National Clinical Audit data in this format and will be able to do so through the publicly accessible website.

1.8 The Clinical Outcomes Publication programme

The Clinical Outcomes Publication (COP) programme is an NHS England initiative, managed by HQIP, to publish quality measures on NHS Choices and MyNHS at the level of individual consultant, team and unit level using national clinical audit and administrative data. The MyNHS directory in particular provides easy to click through directories of services/specialties for which data are available: www.nhs.uk/service-search/Performance/Search and background information can be accessed via the HQIP website: www.hqip.org.uk/national-programmes/clinical-outcomes-publication/

COP began with 10 national clinical audits in 2013. In each case, clinical specialists were asked to publish data showing, for each consultant, how many times they had performed a procedure and what their mortality rate was for that procedure. Each specialty decided which procedures to include, and what measure of mortality to show, based upon what was most relevant to their patients and what data had been collected. The analyses were supported by thorough narratives explaining how to understand the results.

By the end of June 2017, the programme will have published more than 100 indicators from 17 clinical specialties, covering more than 1m episodes of care.

Further specialities will be added to the programme every year. Central to the programme is making national clinical audit data easily available to key stakeholders including commissioners. This will make some of the activities HQIP advises commissioners on in relation to NCA easier through making access to the relevant data for their provider organisations easier. Other key goals of COP are:

- Stimulate improvement in the quality of clinical care
- Improve monitoring of consultant’s outcomes and governance arrangements for managing outlying data
- Reassure patients that the quality of clinical care is being actively monitored and improved
- Support shared decision-making involving patients, including choice of provider, general practitioners, and consultants
- Further the cultural shift wherein medical specialty associations are becoming increasingly patient-focused
- Support the increasing involvement of individual Trust executives, especially the medical directors, in understanding their role in assuring the quality of their individual services and assuring that participation is as close to 100% as possible
- Support consultant appraisal and hence revalidation
- Promote and continue to develop standards for audits in relation to issues such as outlier management and data validation
- Support a wide range of audits in a positive improvement journey to enhance the overall quality of national audits to enable a wider range of data to be published
2.1 Case studies – using clinical audit to improve the quality of services

Clinical audit is a quality improvement process, but it can only deliver improvements if the clinicians who are responsible for delivering care act on clinical audit findings and make the necessary changes in their practice. Commissioners can have a major role to play in leading and supporting the process of change, and the following case studies illustrate some of the ways commissioners and providers can work in partnership to improve services.

Case Study 1 – Improving access to rheumatology services in Liverpool

This case study was submitted by Dr Claire Dubois, consultant rheumatologist and audit lead for rheumatology, Royal Liverpool and Broadgreen Hospital.

“The National Rheumatoid and Early Inflammatory Arthritis Audit was commissioned by HQIP and is led by the British Society for Rheumatology. It aims to help clinicians improve quality of care for their patients, as well as facilitate negotiations with their Trusts and commissioners in order to improve services. The audit looks at key NICE quality standards in the management of early inflammatory arthritis (EIA). More information about the audit is available on the HQIP website: www.hqip.org.uk/national-programmes/a-z-of-nca/arthritis-rheumatoid-and-early-inflammatory/

The key findings and recommendations of the audit nationally relate to access to rheumatology services, emphasising the importance of early recognition and referral. One of the audit standards states that patients should be seen in the rheumatology service within three weeks of referral by their GP. Unfortunately our hospital was identified as an outlier for this standard, with a lower than expected proportion of patients seen within three weeks (13% versus 38% nationally). Analysis of the results suggested one reason was the quality of referrals from GPs, which makes it difficult to identify and prioritise patients with suspected EIA.

As a result of the audit findings we wrote to the CCG and organised a meeting. CCG representatives, GP leads and rheumatologists from our hospital and another local Trust attended. We presented the audit results, with examples, and discussed ways to improve the quality of referrals. This resulted in a preliminary action plan. A smaller sub-group was then formed to take the project forward.

As a result of this collaborative working a new, simple, electronic referral pathway has been agreed. We anticipate that this simple change will lead to a significant improvement in the service we offer patients with suspected EIA, within our given resources. CCG involvement has been crucial to implement the IT necessary to facilitate the change in referral process. Working together in this way, face-to-face, meant that the “stakeholders” understood each other's needs and that we have quickly achieved a simple solution to a significant issue. We plan to continue to monitor and audit our referrals and share the results with our CCG colleagues, to further improve our service.”

Part 2
Case Study 2 – Improving diabetes care in Walsall

This case study was submitted by Dr Andrew Askey, St John’s Medical Centre, Walsall.

“As the diabetes lead in Walsall, I have always carefully considered the reports from the National Diabetes Audit (NDA). I have usually downloaded CCG level data and compared this with national data, and presented a summary to the CCG diabetes task and finish group with a challenge to see what could be improved. I think this approach has been well received in the CCG and has given a strong clinical input into the discussion.

When Walsall CCG reviewed the NDA report for 2013-2014, it was noted that:

- There was a sharp fall in the percentage of people with diabetes being screened for microalbuminuria
- This further impacted on the overall percentage of people with diabetes completing all eight care processes
- The percentage of people with diabetes in Walsall with a cholesterol level of 5mmol/l or less had fallen compared with previous years

Working with a task and finish group, I helped to develop a local incentive scheme (LIS) to improve diabetes care. The targets included:

- Increasing screening for microalbuminuria (target to 90% of patients to be screened)
- Increasing the percentage of patients completing all eight care processes for diabetes
- Increasing the percentage of patients with diabetes with cholesterol of 5mmol/l or less (as set in the Quality Outcomes Framework) and 4mmol/l or less – a more challenging stretch target

The LIS was agreed by the CCG diabetes task and finish group and approved by the CCG Board. The CCG was able to demonstrate support for change with the LIS, which provided a small financial incentive to engage.

EMIS prompts, protocols and reports were developed centrally and the CCG IT team supported the development and testing. The EMIS protocol included prompts for screening and for treatment if screening outcomes showed it to be necessary. The LIS and the practical support that had been developed were shared with practices at locality CCG meetings, and practice nurse forums. I was able to help in communicating the need for change with GPs as colleagues understand and respect my involvement with diabetes over many years while still being a full time GP.

The LIS has been successful in increasing the percentage of people with diabetes attaining NDA treatment targets (2014 – 37%, 2015 – 41.3%, 2016 (part year) – 43.4%). This means improved consistency of care for people with diabetes, more patients having the care processes carried out and more people reaching treatment targets. The project has also increased awareness among clinicians of the importance of consistency and quality of care.

While this was ongoing, I was also recruited to be one of the four local clinical leads for the Royal College of General Practitioners NDA Quality Improvement Project in diabetes, which helped me to learn new ways of considering data reporting to measure change over shorter periods of time (monthly reports rather than annually) and to work with five other practices to support them in quality improvement work. In the future I hope to extend the project by considering other aspects of diabetes care to improve, and considering how a similar approach could be used to improve other conditions.”

2.2 Ensuring effective participation in national quality programmes

2.2.1 The meaning of ‘participation’

It is a common misapprehension that participation in national clinical audit (as mentioned in the NHS Standard Contract, see section 1.3.1 above) simply means submitting data to national projects as required. In fact, full participation by a healthcare provider means ensuring that the whole of the clinical audit cycle is completed. Without this, the full potential of national clinical audits to deliver quality improvement will not be realised.

2.2.2 Submitting data and ensuring data quality

Every national project has rules and requirements for collecting and submitting data to the national provider. Each healthcare provider should take steps to ensure that they meet the requirements, both in the quantity and quality of the data. Providers should appoint clinical leads for every national clinical audit, who should be responsible for overseeing the collection and submission of data.

Commissioners should challenge providers who fail to submit full data sets. Any discussions about a provider’s performance in a national clinical audit should include a review of the arrangements that the provider has in place to ensure the quality of data submitted to the national audit team.

2.2.3 Acting on national clinical audit reports

Commissioners should ask healthcare providers to demonstrate how they respond to the outputs from national clinical audits. Commissioners should have in place their own arrangements for reviewing the reports of national clinical audits and should work in partnership with providers to ensure appropriate actions are taken in response to the findings and recommendations.

In 2013 HQIP commissioned Improvement Science London to analyse and report on engaging clinicians in quality improvement through national clinical audit. You can access the full report, alongside HQIP’s narrative response and other information, on the HQIP website www.hqip.org.uk/national-programmes/engaging-clinicians-in-clinical-audit/

A key finding was that organisational structures, governance, staffing and culture all had a strong influence on the take up of clinical audit and on whether data were used to encourage improvement. Commissioners should work in partnership with providers to review their arrangements.

A healthcare provider should have in place a robust framework for national clinical audit reporting and action plan implementation, and monitoring, that is embedded across the organisation. For an NHS Trust provider, the objectives of the framework should be to ensure that:

1. National clinical audit results are:
   - Analysed, and presented, against national and peer data, where available, to enable a comparison of provider performance against the national average
   - Presented using a standardised format

2. Provider performance in, and actions arising from, all national clinical audits are presented to the appropriate provider committees from clinical specialty level to Board level in a timely manner

3. Any areas in which clinical and/or process improvements can be made are identified and action is planned to improve

4. Action plan implementation is routinely monitored by the appropriate committees at regular intervals

5. All quality of care issues identified are rapidly escalated to the appropriate committees as required

6. Assurance is provided both internally to the Trust Board and externally to commissioners, as well as statutory and regulatory bodies, that participation in national clinical audits has led to improved patient outcomes, safety and experience

Commissioners should engage in this process, and the case study examples given in section 2.1 above show how commissioners can work with providers to achieve improvements.

2.2.4 Contributing to the development of national programmes

A common criticism by clinicians of national programmes is that they feel their views and concerns are not taken into account during project development. This can lead to disengagement and unwillingness to participate.
In fact, HQIP actively encourages clinical specialists to participate in the development of specification for new NCAPOP projects.

If commissioners have any questions about national clinical audits and enquiries, they can contact the audit provider by using the contact information in the HQIP national clinical audits and enquiries directory [www.hqip.org.uk/national-programmes/national-clinical-audits-and-enquiries-directory/](http://www.hqip.org.uk/national-programmes/national-clinical-audits-and-enquiries-directory/).

For NCAPOP projects, they can also contact the HQIP project manager, who can be identified from the HQIP website (see [www.hqip.org.uk/national-programmes/a-z-of-nco/](http://www.hqip.org.uk/national-programmes/a-z-of-nco/) and [www.hqip.org.uk/national-programmes/a-z-of-clinical-outcome-review-programmes/](http://www.hqip.org.uk/national-programmes/a-z-of-clinical-outcome-review-programmes/)).

### 2.3 Facilitating change and improvement

#### 2.3.1 Investigating shortfalls in the quality of care

Shortfalls in the quality of care may be identified from national clinical audit reports, or from data collected for local clinical audits. In both cases, the first step that must be taken in order to make improvements is to understand why clinical audit data show a shortfall in compliance with the audit standards. There are a number of approaches that clinical teams can take – e.g. peer review of the medical records of patients who did not receive treatment in accordance with the standards, or root cause analysis techniques (See HQIP, 2016h). The aim is to identify the underlying causes that can then be addressed through effective action plans. Commissioners should challenge providers if they believe the action plans they are presented with are not based on a clear understanding of the reasons for shortfalls, because inadequate action plans will not result in improvement.

For example, an action plan might include ‘Remind staff of the need to’ carry out a particular care process. This implies that the fault lies with the staff, when in fact there may be underlying factors that make it difficult for staff to carry out the process. The action plan needs to change the process. In Case Study 1, the secondary care team identified an apparent problem with waiting times, but the underlying cause was a problem with the referral process. The local CCG was able to support a change to the process.

The importance of putting clinical audit findings into context for quality assurance was mentioned in section 1.5.1 above, and it is equally important for quality improvement. Commissioners have an overview of the local health economy that can help in identifying patterns of service quality across similar providers and along pathways of care. This can reveal underlying reasons for poor quality, and also help to target improvement plans.

#### 2.3.2 Planning and implementing changes in practice – overcoming obstacles

Commissioners can support and facilitate the process of changing practice in a variety of different ways, some of which are highlighted in the case studies. The following table lists some of the possible obstructions to change, with suggestions for ways in which commissioners can help to overcome them.
2.3.2 Planning and implementing changes in practice – overcoming obstacles

Commissioners can support and facilitate the process of changing practice in a variety of different ways, some of which are highlighted in the case studies. The following table lists some of the possible obstructions to change, with suggestions for ways in which commissioners can help to overcome them.

<table>
<thead>
<tr>
<th>Obstructions to change</th>
<th>How commissioners can help</th>
</tr>
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</table>
| Lack of motivation for change, clinical disengagement and reluctance to change | Clinical teams want to deliver the best possible care for their patients, and a clinical audit that shows that they are not achieving best practice standards is in itself motivation for change. However the clinical team may be reluctant to change if it does not have confidence in the audit, or does not believe it addresses priority issues. Commissioners can:  
  • Influence the content of the clinical audit programme to ensure clinical priorities are addressed  
  • Work with providers to ensure clinical audits are carried out in accordance with best practice (see 2.3 below)  
  • Demonstrate their support for change by introducing local incentive schemes |
| Lack of resources to make changes | When clinical audit findings demonstrate a clear need for investment in order to improve services, commissioners need to work with providers to address this. In some situations, it may be appropriate for a provider to make internal savings in order to fund necessary investments or to re-prioritise the allocation of existing resources from commissioners. In others, clinical audit findings may prompt development of a business case for additional investment by commissioners. Commissioners can also provide direct support to local clinical audit teams and resources to facilitate the change process – e.g. the IT support that the CCG was able to provide in Case Study 2. |
| A single provider has limited influence over the whole patient pathway | Commissioner's overview of patient pathways means that they can facilitate change in aspects of the patient journey that are outside the control of any one provider. This is illustrated in Case Study 1. |

2.3.3 Monitoring change and measuring improvement

A clinical audit is not complete until evidence has been obtained to show that changes in practice have been effective in delivering improvements. In the traditional clinical audit cycle, this evidence comes from repeating the data collection and comparing the results with the first round. However, there are many other ways in which change can be monitored and improvement quantified. Regular monitoring of waiting times or length of stay, prescription rates for specific drugs or attendance levels at clinics, could be monitored by the provider over time, with full scale re-audit only carried out if these measures crossed a pre-set threshold.

Commissioners should work with providers in determining the most effective ways of monitoring the implementation of clinical audit action plans, and measuring the improvements made.

2.4 Using clinical audit in service development

Clinical audit is generally viewed as an incremental process, with repeated cycles of data collection and change bringing about gradual improvements over time. As such, it may be overlooked when services are going through a period of transformational change and service redevelopment. In fact, it can have a vital role to play in making sure quality of service is monitored, maintained or improved through major service re-designs.

The effect of failing to carry out this kind of monitoring was highlighted in the Francis inquiries into events at Mid Staffordshire NHS Foundation Trust. The 2010 report (Independent Inquiry into care provided by Mid Staffordshire NHS Foundation Trust, 2010) describes a project to reconfigure wards in the Trust known as the Clinical Floors Project. It was
believed that this reconfiguration would improve services for patients and achieve financial savings (see pp. 211 et seq.). The report discusses at length the problems that resulted from this project and on page 224 the inquiry Chair comments:

Professor Hutton suggested to me, and I agree, that the evidence strongly suggests that the whole clinical floors project was planned and implemented without due regard for the staff's legitimate concerns and without monitoring of the scheme once in operation. This would have shown up the deficiencies vividly described by witnesses to the Inquiry.

The 2010 report was critical of the Trust's failure to use clinical audit effectively. One of the key recommendations was that the Trust Board must take responsibility for overseeing clinical audit.

**Recommendation 5:** The Board should institute a programme of improving the arrangements for audit in all clinical departments and make participation in audit processes in accordance with contemporary standards of practice a requirement for all relevant staff. The Board should review audit processes and outcomes on a regular basis. (Independent Inquiry into care provided by Mid Staffordshire NHS Foundation Trust, 2010)

Commissioners must work in partnership with providers through periods of transformational change. Part of the planning for the implementation of changes must include consideration of how service quality will be monitored, maintained and improved, and this includes planning for the implementation of Sustainability and Transformation Plans (see www.england.nhs.uk/bunwork/futurenhs/deliver-forward-view/stp/ for more information on these plans). Clinical audit has a key role to play, and commissioners should work with providers to ensure that provider clinical audit programmes reflect the need to monitor and improve services through periods of change.

### 2.5 Improving the quality of local clinical audit practice

Every aspect of clinical audit practice can have an impact on both the level of assurance that commissioners can take about service quality, and the effectiveness of the audit in delivering quality improvement. Commissioners should work with providers to ensure that clinical audit is carried out in accordance with best practice. Mention has already been made of the best practice checklists (HQIP, 2016a) and Board evaluation tools (HQIP, 2015a) and other resources that HQIP has published to support local clinical audit practice.

The clinicians who are responsible for leading clinical audit in clinical services and at senior levels in healthcare organisations have a key role to play in ensuring that clinical audit delivers improvements in the quality of care. HQIP has published a guide that sets out the requirements of the role (HQIP, 2016b) By involving clinical audit managers and clinical audit leads in any discussions about service quality, commissioners can ensure that their requirements for clinical audit are taken into account in forward planning.

Commissioners should support provider engagement in regional and national activities to improve clinical audit practice. Involvement in the development of the NCAPOP is covered in section 2.4 below. Providers should be encouraged to join and take part in the meetings, conferences and training events provided by the regional clinical audit networks, and the National Quality Improvement and Clinical Audit Network (NQICAN). NQICAN brings the Chairs of the regional networks together with NHS England, HQIP, national audit providers and other stakeholders. More information including contact details for all of the networks can be found on the HQIP website www.hqip.org.uk/resources/audit-and-qi-networks/ and on the NQICAN website www.nqican.org.uk/

Note that membership of the networks is open to quality improvement staff working in commissioning organisations – please contact the relevant network chair for more information.
References

11. HQIP, 2016e. Developing a clinical audit programme www.hqip.org.uk/resources/developing-a-clinical-audit-programme/
16. HQIP, awaiting publication. Information governance for local clinical audit HQIP (in development)
# Appendix 1

## How to develop specifications for a clinical audit

<table>
<thead>
<tr>
<th>Commissioner role</th>
<th>Provider role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop consensus among commissioners and describe the following to the provider:</td>
<td>Preferably working with the provider’s clinical audit lead for the service involved and the clinical audit manager —</td>
</tr>
<tr>
<td>• The specific concerns about quality related to the subject</td>
<td>• Discuss with the commissioners whether or not a clinical audit is the best method for meeting their concerns and expectations. Suggest other methods that might be more appropriate than a clinical audit, if other methods would be more suitable</td>
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<tr>
<td>• The exact group of patients or service users that the audit should focus on</td>
<td></td>
</tr>
<tr>
<td>• What the commissioners would like to achieve in terms of quality improvement and quality assurance in as precise a way as possible</td>
<td>• Design the clinical audit with the clinical team involved in delivering the service</td>
</tr>
<tr>
<td>• Any evidence-based practice or national or professional guidance that the commissioners believe is relevant to the patient or service user group</td>
<td>• Develop the quality-of-care measures to be used in the audit, using evidence-based practice or national or professional guidance, as relevant</td>
</tr>
<tr>
<td>• The timeframe for completion of the clinical audit, including repeating data collection to show the effects of any changes made in practice</td>
<td>• Draft a data collection tool and estimate the time involved in collecting data for the audit, given the design and measures</td>
</tr>
<tr>
<td>Support the provider in developing the design and quality-of-care measures for the audit, preferably including the expertise of the clinical audit lead for the service and the clinical audit manager</td>
<td>Submit the design and measures for the proposed clinical audit to the commissioners for feedback, including the estimate of the time involved in collecting and collating data and any other resource considerations</td>
</tr>
<tr>
<td>Review the proposed design and measures for the audit, and the estimate of time needed to collect and collate the data</td>
<td>Respond to any feedback provided by the commissioners on the proposed audit and time involved</td>
</tr>
<tr>
<td>Provide any comments on the proposed audit and time and resources involved to those responsible for carrying out the audit</td>
<td>Carry out the audit in accordance with the agreed design and measures</td>
</tr>
<tr>
<td>Work with the clinical team to support the implementation of changes to improve practice</td>
<td>Work with the clinical team involved in interpreting the findings of data collection, analysing and acting on any problems revealed about the quality of care</td>
</tr>
<tr>
<td>Review the report of the clinical audit when it is available and provide feedback to the provider about the way forward, based on the clinical audit experience</td>
<td>Monitor the implementation of action plans and gather evidence (including where necessary repeating data collection) to confirm the effectiveness of any changes to practice</td>
</tr>
<tr>
<td></td>
<td>Submit a report of the completed clinical audit to the commissioner</td>
</tr>
</tbody>
</table>