In partnership with

Good Governance Institute

HQIP
Healthcare Quality Improvement Partnership

Clinical audit:
a guide for NHS boards and partners

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HQIP Healthcare Quality Improvement Partnership

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HQIP Healthcare Quality Improvement Partnership

Good Governance Institute

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Clinical audit: a guide for NHS boards and partners

What is this guide and who is it for?

This new guide provides guidance to those commissioning, delivering and scrutinising the added value of clinical audit and other assurance systems. It builds on a previous HQIP/GGI collaboration, reflecting the changes in architecture in the NHS in England, the Health and Social Care Act 2012, the lessons from Mid-Staffordshire and Keogh Reviews and the enhanced focus on well-led organisations.

The guide is accompanied by the new Good governance handbook,[1] which is focused on assisting NHS boards and those developing governance systems to decide what is most appropriate for the specific needs of their organisation. Emphasising the developing role of clinicians in management and resource allocation, the Good governance handbook aims to help existing and aspirational clinical, nurse and medical directors as well as those who support and challenge them to understand and apply good governance in the rapidly changing environment of the NHS in England.

Clinical audit is important but is just one tool of any wider quality improvement strategy aimed at providing assurance of delivery best practice. A broader quality improvement framework should include tests that determine whether clinical audit might provide the best methodology to achieve the desired outcomes with the available expertise on the ground. There is a need for national standardisation and professionalisation of quality improvement of and beyond clinical audit, and better quality improvement governance structures. Standard practice should enable effective clinical audit and should provide clear guidance on where, how and when to use such resources effectively. Clinical audit should be able to extend beyond organisational boundaries following the pathway of care, constitute an outcome-focused process that is transparent, explaining choice of audit, action plans and impact.

Clinical audit is under threat with false economies compromising the scale and breadth of activity. To be revitalised it needs to capture the imagination of boards, clinicians and commissioners as a worthy, cost effective and successful endeavour. It needs to provide assurance of safe and improving service delivery both within and beyond professional, departmental and organisational boundaries.

The guide identifies 10 simple rules and then goes on to develop each of these highlighting the importance of linking actions between the board, divisions and departments and how to implement improvements. Each rule has a simple Q&A section presenting at board, division and departmental levels common but unacceptable response and a more mature response. At the end of the document are sets of these Q&As for use at the various levels as well as a maturity matrix to provide an overall perspective on how well we are doing now and what needs to be achieved in coming months.

1. Corbett-Nolan, A. et al., 2014, *Good governance handbook*

Clinical audit: 10 simple rules for NHS boards

1. Use clinical audit as a tool in strategic management as part of the broader quality improvement programme; obtain assurance that the strategy for clinical audit is aligned to broader interests and targets that the board needs to address
2. Consider the full range of quality improvement tools and choose clinical audit if its methodology is best suited to assess the issue at hand and develop an improvement plan
3. A clinical audit strategy must include a combination of national and local priorities with sufficient resources to complete the cycle for each element of the programme
4. Agree on the timescale and resources required for each clinical audit activity upfront but have a process in place to deal with variations and additional requirements
5. Operate a rolling clinical audit programme that covers the different stages of individual projects on a continuous basis focused on outcome improvements for each area
6. Ensure the professionalism of clinical audit by agreeing what constitutes unacceptable variation in clinical audit results compared to evidence based standards, outcomes at similar organisations, or with standards developed within the organisation where national guidelines are not available
7. Ensure with others that clinical audit crosses care boundaries and encompasses the whole patient pathway
8. Develop a clear strategy to ensure patient and stakeholder engagement at the different stages of the clinical audit cycle, make clinical audit reports patient-friendly and publicly available, and disseminate summaries of results to stakeholders and patients in a variety of ways
9. Share clinical audit results with other providers, commissioners, regional clinical networks and local patient networks. Publish outcome statistics and evaluations
10. Provide sufficient education and training in clinical audit beyond the clinical audit team, and use junior doctor clinical audit and quality improvement projects as a valuable resource

1 Use clinical audit as a tool in strategic management as part of the broader quality improvement programme; obtain assurance that the strategy for clinical audit is aligned to broader interests and targets that the board needs to address

Participation in national clinical audits and publication of outcome statistics is now required by the NHS England Standard Contract[2] and CQC guidance.[3] We have seen a considerable expansion and enhancement of the portfolio of national clinical audits in recent years posing new capacity challenges as demand of clinicians and the NHS is increasing. We need to ensure that the outcomes of our clinical audit programme balance these demands with the broader strategic interests of the organisation and wider strategic priorities. We should identify where clinical audit can provide assurance to the board and commissioners and where there are gaps these are addressed in forthcoming plans and budgets. The board, with input from divisional levels, shape the overall quality strategy to address concerns and interests inviting a costed, time limited plan to deliver these requirements. The board will want assurance that there is alignment of quality improvement, audit activity (both internal and clinical) and cost reduction measures.

Boards should:

- Recognise the requirement for providers in the NHS England Standard Contract[4] to participate in national clinical audits within the National Clinical Audit and Patient Outcomes Programme (NCAPOP) and make national clinical audit data available to support national publication of consultant-level activity and outcome statistics in accordance with HQIP guidance[5]
- Develop the role of a chief quality officer on the board to provide leadership, vision, inspiration and oversight of quality in the trust and be accountable for the assessment and improvement of quality; expertise in quality management (assessment and improvement) including technical and behavioural/organisational aspects
- Question whether clinical audit is used as a strategic quality improvement tool, and if there is a clinical audit strategy that is aligned to the organisations commissioning and development plans. Wider quality intelligence informs the use of clinical audit. Wider quality intelligence measures include performance, experience, safety and safeguarding, contracting, and quality schedules
- Question whether the outcomes of clinical audit programmes inform the Board Assurance Framework, specifically in relation to assuring clinical quality of clinical care

TOP TIPS:

- ✓ Understand external clinical audit requirements from contracts, quality schedules, performance measures, commissioning strategic plans and clinical network initiatives
- ✓ Embed clinical audit into the quality strategy and connect it to that of your commissioners and pathway delivery partners
- ✓ The clinical audit strategy should support organisation development plans and be informed by wider quality intelligence

2. www.england.nhs.uk/wp-content/uploads/2013/12/sec-b-cond-1415.pdf
3. Care Quality Commission, 2014, *The state of heal care and adult social care in England 2013/14*
4. *NHS Standard Contract*, 2014/15, Service Conditions, pp. 18-19
5. www.hqip.org.uk/national-clinical-audits-managed-by-hqip/

Is our clinical audit strategy aligned to the organisation's broader strategic interests and used as assurance in our board assurance framework?	Unacceptable answer	Acceptable answer
Boards	Clinical audit is planned and conducted by our clinical audit team, which reports back to the board. Clinical audits may provide assurance where they coincide with strategic priorities	We ensure that our clinical audit programme is aligned to the broader strategic interests of the organisation and other aspects of our strategic management. We have identified where clinical audit can provide assurance to commissioners and us, gaps are addressed in forthcoming plans and budgets. The board shapes the audit strategy to address wider strategic priorities
Divisions	We have a backlog of audits that we are tackling	The board has identified major concerns where performance or assurance is lacking and prioritises these. We respond with a plan or raise resourcing issues. Ad hoc urgent requests are responded to within the same year
Departments	No, probably not	We aim to balance departmental needs with strategic and national requirements, escalating any resourcing or traction issues

2 Consider the full range of quality improvement tools and choose clinical audit if it's methodology is best suited to assess the issue at hand and develop an improvement plan

The board will want to be assured that the overarching quality strategy clearly sets out the range of improvement methodologies that can be used and when it is preferable to use them. The strategy might endorse the view that clinical audit should be the quality improvement methodology of choice when measuring clinical quality inputs or outcomes. The board will commit the organisation to participate in a portfolio of national clinical audits.

However, clinical audit is by no means the only methodology available and clinicians and management will need to understand a range of improvement tools. Methods chosen should routinely be reviewed to ensure that the best approach is used for the issue, developing a locally owned best-fit approach. Staff should aim to learn from reviews and improve ability to apply the best-fit approach. Management will want to provide assurance to its audit committee that the organisation has in place a coherent system of prioritising, initiating, completing and acting upon all forms of improvement activity. See HQIP's Quality improvement methodologies guide updated in 2015.[6]

TOP TIPS:

- ✓ The quality strategy should describe how clinical audit fits into a range of other quality improvement methods and how each method can achieve different forms of improvement

Has clinical audit been selected as the methodologically most suitable tool for the issue at hand?	Unacceptable answer	Acceptable answer
Boards	Clinical audit is our standard quality improvement tool	Yes, within our broader quality improvement strategy, we have a robust process for ensuring that each quality improvement method is chosen for its merit and impact. Clinical audit is utilised when it has been identified as the most effective tool to improve and assure the quality of the service delivered
Divisions	Staff tend to use the approach they are comfortable with	We have trained staff in a range of improvement tools and we routinely review that the best approach is used for the issue. We aim to learn from mistakes and improve best-fit approach
Departments	We are used to clinical audit and this is the approach we normally use	We have adopted a best-fit guide to check we are using the best approach for each quality issue

6. www.hqip.org.uk

3 A clinical audit strategy must include a combination of national and local priorities with sufficient resources to complete the cycle for each element of the programme

The clinical audit strategy describes how wider quality intelligence informs the local clinical audit programmes. It describes how local programmes are prioritised against predefined criteria reflecting the local health economy commissioning plan and our development plans, balancing the national and local components of our clinical audit programme. The board should shape the strategic plan ensuring sufficient funds and resources are earmarked for relevant clinical audit activity and follow up.

Divisions should identify a rolling programme of clinical priorities for audit and ensure that all clinicians within the division are involved in clinical audit and other improvement projects as part of their continuing professional development.

In addition:

- The audit committee must consider the clinical objectives and risks in the assurance framework and report to the board on the controls and assurances in relation to these[7]
- While provider trusts are concerned with the clinical care provided, commissioners need to take account of the arrangements made by their providers and the extent to which the clinical quality review groups can obtain confirmation of assurances
- Commissioners tend to advocate that providers take part in all national clinical audits to maximise assurance. Yet, this is often neither a feasible nor desirable use of resources. A conversation between the provider and commissioners about which national and local clinical audits should be prioritised is therefore imperative
- The focus should always be on how clinical audits can effectively be used to improve quality. Findings of national clinical audits need to be put into the local context to inform action plans addressing areas where quality improvements can be made
- The result of clinical audit projects should be used as evidence in the Board Assurance Framework (BAF) taking into account trusts' individual risks and national policies
- Clinical effectiveness, patient safety, internal audit, education, risk management, research and development should be identified within the plan providing assurance that all activity is aligned and actioned
- Local clinical audit programmes should be informed by local health and social care commissioning plans, agreed best practice tariffs and monitoring of Commissioning for Quality and Innovation CQUINs schedules

TOP TIPS:

The clinical audit strategy should include a balancing of priorities:

- ✓ **National:** clinical audits, quality issues, new national clinical guidelines, clinical performance measures
- ✓ **Health and Social Care Economy:** commissioning operational plans (one-two year), strategic (five year) commissioning plans, integration initiatives (Better Care Fund), health and wellbeing board reports, annual public health report, joint strategic needs assessment, clinical and care data intelligence
- ✓ **Local External:** contracting requirements, quality initiatives (CQUINs), service development improvement plans (SDIPs), best practice tariffs
- ✓ **Local Internal:** clinical and care data intelligence, patient feedback systems, safety systems, performance measures, organisational development plans

7. For a more detailed description of the role of the audit committee, the remuneration and appointments committee, the risk/investment committee, the quality committee and the task and finish groups, see Corbett-Nolan, A. et al., 2014, *Good governance handbook*, p. 9

DEVELOPING A QUALITY AND GOVERNANCE ASSURANCE FRAMEWORK:[8]

- ✓ Each national clinical audit has a designated audit lead (a senior clinician) responsible for co-ordinating participation, ensuring data quality, reviewing the audit report, and driving improvement
- ✓ Any issues that may result in non-participation are addressed within the division, and immediately escalated to the Clinical Effectiveness Committee as necessary
- ✓ All national clinical audits are subject to review with the aim of identifying any areas in which clinical and/or process improvements can be made, and taking action to address these
- ✓ The Clinical Effectiveness Committee produces an executive summary for each national clinical audit report published within four to six weeks of publication
- ✓ The national clinical audit headline results and key actions are reported to the Patient Outcomes Committee, the Quality and Governance Committee, the board of directors, and commissioners

Do we have a clinical audit strategy with a balanced combination of national and local priorities?	Unacceptable answer	Acceptable answer
Boards	We have an existing clinical audit plan, mostly focused on national clinical audits, which often does not leave resources for additional local audits	Balancing the national and local components of our clinical audit programme, the board shapes the audit strategy to address wider priorities with sufficient funds and resources earmarked for relevant local audit activity and follow up
Divisions	Clinicians are aware of their responsibilities to be involved when other priorities permit	We identify a rolling programme of clinical priorities for audit and ensure that all clinicians within the division are involved in clinical audit and other improvement programmes as part of their training and revalidation
Departments	We simply do not have the time to engage other than in mandatory national audits	We have a suite of audits at different stages of development for trainees to choose from and we ensure that all clinicians meet their training and revalidation requirements in a timely fashion

8. King's College Hospital NHS Foundation Trust www.hqip.org.uk/case-studies/

4 Agree on the timescale and resources required for each clinical audit activity upfront but have a process in place to deal with variations and additional requirements

Boards will want assurance that audits have been completed, actioned and re-audited with processes in place to review those that are not completed or delayed. Divisions will track the delivery of audits across all of its specialities/departments. Clinical audits should be logged with the clinical audit lead, resources and timescales prioritised. The roles and responsibilities of the non-executive directors, lead clinicians, the audit committee and the quality improvement team should be clearly described in clinical governance and induction arrangements. All these systems should themselves be subject to routine audit.

In addition, we recognise:

- Clinical audit resources are a valuable commodity; they should be used wisely with effective prioritisation processes
- Clinical audit projects should use a consistent currency of project days to estimate the time required to effectively deliver the whole audit cycle
- The outcomes of clinical audit may be used to inform other internal functions in a constructive way. There is a clear line of responsibility and accountability from front line clinicians to board level committees
- Key clinical positions can play an important role in overcoming the wide-spread disconnect between the board and clinical staff by providing assurance for quality improvement as part of the overall quality strategy

TOP TIPS:

- ✓ Clinical audit programmes should be scoped with clear timescales for delivery
- ✓ Clinical audit support resources should be deployed on a project day basis, with projected costs and managed using forward loading plans

What proportions of approved clinical audits have been completed to time and budget?	Unacceptable answer	Acceptable answer
Boards	The time and budget allocated for clinical audit is sometimes not sufficient to cover the whole clinical audit cycle and does not leave resources for additional pathway and re-audits	We are assured by a delegated sub-committee of the board that x% of re-audits are completed. Where there is a lack of assurance the appropriate committee identifies and reviews action plans. Clinical audits that are economy wide or have a strategic impact on clinical services are presented to the board
Divisions	We do not have a budget but undertake a considerable range of audits each year	Clinical audits are logged with the clinical audit lead, resources and timescales are identified and allocated. Variations and requests for pathway audits are logged and reported to the lead clinician. The division tracks the delivery of audits across all of its specialities/departments
Departments	Consultants decide what audits are completed	The department tracks the delivery of its agreed clinical audit programme and escalates issues and concerns to the division leads

5 Operate a rolling clinical audit programme that covers the different stages of individual projects on a continuous basis focused on outcome improvements for each area

The purpose of clinical audit is improvement. Organisations should operate a rolling programme, which covers all audit stages on an on-going basis, and allows prioritisation and stakeholder involvement.

In addition:

- There should be a governance system in place to monitor the delivery of the on-going audit programme (national and local), which systematically includes all clinical areas. This should include clear responsibilities and remits for individuals and decision-making groups and an escalation process
- The clinical audit is not completed when the initial results are reported. An effective action plan implementing the recommendations arising from these results should not be a wish list'. It needs to be a plan with a clearly defined timeline for specific measures and actions, and clearly defined roles of team members responsible for their implementation. The action plan should be based on a clear understanding of the reasons why the audit has shown shortfalls in the quality of care, and all stakeholders should have the opportunity to contribute to the process of developing the action plan
- The action plan is a live document, detailing a process that is kept under regular review. The implementation of every part of the plan needs to be monitored so that any unforeseen consequences can be identified and any unforeseen barriers addressed
- Often not all findings resulting from clinical audits are implemented, sometimes there are plausible reasons for this. These should in any case be communicated clearly to ensure that decision-making in relation to the implementation of quality improvement measures is transparent for staff, patients and commissioners
- Successful implementation should be recognised and held up as an example across the organisation, while failures should be acknowledged and learnt from. Francis, Keogh and Berwick[9] reports all highlighted the need for NHS organisations to learn from failures
- We should routinely share the outcomes of our clinical audits with others in the health and care economy and routinely hold improvement events across the whole pathway of care. We encourage our commissioners to use the outputs of clinical audits to inform their commissioning and contracting decisions

TOP TIPS:

- ✓ There should be a governance system for tracking progress of all clinical audit activity, including the delivery of actions plans and re-audit
- ✓ Progress and outcomes should be routinely shared across the local health and social care economy with improvement events engaging the whole pathway

9. The Mid Staffordshire NHS Foundation Trust Public Inquiry – Chaired by Robert Francis QC., 2013, *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry* – www.midstaffspublicinquiry.com/report. Berwick, D., 2013, *Treating patients and service users with respect, dignity and compassion – Protecting patients from avoidable harm* – www.gov.uk/government/publications/berwick-review-into-patient-safety

Are our clinical audit cycles comprehensive, timely and outcome-focused?	Unacceptable answer	Acceptable answer
Boards	Our annual audit cycle is usually larger than resources permit and inevitably creates a backlog	Yes, the purpose of clinical audit is improvement. We operate a trust-wide rolling audit programme, which covers all stages of the audit cycle, but allows prioritisation and stakeholder involvement in-year. We do not consider audits complete until we have re-audited and reported improvement
Divisions	We have a wish list of topics but rarely cover them all. New audits are getting in the way of re-auditing old ones	We have a plan with a clearly defined timeline for specific measures and actions, and clearly defined roles of team members responsible for their implementation. The action plan recognises and addresses the reasons for shortfalls in the quality of care
Departments	We are getting overwhelmed with requests for new audits and frankly have to ignore them	We complete what we start and raise exception notes for delays and unfinished audits. Identified variation is never left unattended to

6 Ensure the professionalism of clinical audit by agreeing what constitutes unacceptable variation in clinical audit results compared to evidence based standards, outcomes at similar organisations, or with standards developed within the organisation where national guidelines are not available

The effectiveness and quality of clinical audit throughout the organisation can be evaluated by subjecting its systems and procedures to external validation. This might be a national or local health economy developed system or simply a formal review by internal audit.

Best practice would be to formally adopt a professional approach to clinical audit setting, auditable procedures for delivering audit-based improvement in any area. This would allow the board to determine materiality (risk, value and return) and trigger points for escalation to board as well as benchmarking to compare with norms and emerging better practice.

Whilst there are now well-documented standards for many procedures, this is not universal but this should not inhibit audit. Where there are no national guidelines or published evidence, minimum standards can be agreed locally at the outset and peer review should be used to test these thresholds. Trigger points for prompt escalation of unacceptable variation should be in place or worked up for each condition.

TOP TIPS:

- ✓ Obtain an external validation or accreditation around the quality of clinical audit systems and processes
- ✓ Have a documented process to agree how the organisation deals with unacceptable clinical variation and how thresholds are set when there are no clinical guidelines

Has the board agreed what constitutes materiality, unacceptable variation in clinical audit results against standards and comparisons with others?	Unacceptable answer	Acceptable answer
Boards	Clinical audit has guidelines but no system of accreditation so we are left to ourselves in determining whether we consistently follow best practice	We have adopted a professional approach to clinical audit by setting auditable procedures for selecting and delivering audit-based improvement in any area. This allows the board to determine materiality (risk, value and return) and trigger points for escalation to board as well as benchmarking to compare with norms and emerging better practice
Divisions	NICE and others provide some condition based standards but we do not have identified trigger points for early escalation of unacceptable variation. The lack of national standards prevents us from implementing an audit of some areas of concern	We follow our agreed professional standards in conducting audit working where possible with other organisations to gauge acceptable and improved practice and outcomes. Trigger points for prompt escalation of unacceptable variation are being worked on
Departments	We follow national guidelines on conducting audit but have not reviewed compliance	We follow our agreed professional standards in conducting audit which has allowed us to review and improve compliance

7 Ensure with others that clinical audit crosses care boundaries and encompasses the whole patient pathway

In future our quality improvement programmes will need greater focus on the patient pathway, working in partnership with other health and social care providers and commissioners involved in developing, commissioning or delivering these pathways. This will require relationship development at all levels from board to department.

In addition:

- Clinical audit should consider the clinical quality across the complete health and care pathway irrespective of organisational boundaries. It should build on the national NHS Pathways[10] work and draw upon clinical and care data from across the system
- Commissioners should drive whole system clinical audits to inform commissioning improvement
- Commissioners need to consider the whole patient pathway and the wider implications of the long-term improvements that effective clinical audits can provide for the quality and cost effectiveness of the services they commission
- Commissioners will want to use contracting mechanisms including CQUINs which are supported by economy wide clinical audits
- Pathway audits across sectors are of crucial importance to improve the integration of different levels of care and to reduce commissioning gaps and quality issues arising from a lack of integration

TOP TIPS:

- ✓ Clinical audits should focus on the whole pathway and not be limited to the handover between organisations
- ✓ Providers should work with commissioners and draw upon clinical and care data from across the system to identify opportunities for quality improvement
- ✓ Providers and commissioners should work with information governance specialists to facilitate the sharing of data for clinical quality improvement

10. NHS Pathways – www.systems.hscic.gov.uk/pathways

Do we engage with other organisations during the clinical audit process?	Unacceptable answer	Acceptable answer
Boards	We are not accountable once the patient has left the care of our organisation. Individual clinicians may engage with colleagues in other departments or providers where necessary	Our quality improvement programme is focused on the patient pathway, working in partnership with other health and social care providers and commissioners (involved in these pathways) proven to improve overall care in our community. We invite external organisations to peer review our approach
Divisions	Our audit programme is insufficiently aligned to involve more than one department. We would not know what other organisations are doing to conduct joint audits	We have a good relationship with our commissioners, both specialist and local providers to allow us to extend our audits along patient pathways. We have learnt and seen improvement using this approach
Departments	No	In developing audits we always go the extra mile to ensure at least the interface with other departments or even external organisations is covered

8 Develop a clear strategy to ensure patient and stakeholder engagement at the different stages of the clinical audit cycle, making clinical audit reports patient-friendly and publicly available and disseminate summaries of results to stakeholders and patients in a variety of ways

Boards will want assurance that patient and stakeholder representatives including Healthwatch are involved in the audit programme development. Individual projects are part of the decision making process through the governance structure. Clinical audit reports should include a summary of the processes and improvements resulting from audits and these should be shared with stakeholders, the public and patients as part of the organisation's communication plan.

In addition:

- Patients' views must be sought regularly, and they should be enabled to come to an informed view in relation to their care and treatment[11]
- Patient and public involvement (PPI) should include dissemination of results to staff, commissioners and patients. This may be via patient panels, patient-friendly clinical audit reports, third sector engagement, hard-to-reach groups, websites and newsletters
- Stakeholder engagement in audit and re-audit processes and the involvement of Healthwatch in particular should now be a standard part of every clinical audit programme
- Patient experience and outcome measures should be used wherever possible
- Patient and stakeholder engagement is multi-faceted in clinical audit:
  - Alongside the technical clinical measurement there should be a patient-centric measurement; good quality care includes looking at the patient holistically
  - Patient and stakeholders should inform the design of the audit, but also contribute to developing the improvement plan
  - Outputs from clinical audits should contribute to informing patient choice both in terms of the organisational culture as a whole and the area of care audited

CASE STUDY ON STAKEHOLDER ENGAGEMENT:[12]

- ✓ Involvement of a patient panel in clinical audit in the trust's Clinical Audit Patient Representative Initiative (CAPRI). CAPRI won a nomination at HQIP's 2011 clinical audit awards in the patient and public involvement category
- ✓ CAPRI members are involved in audits from the planning phase to the final completion

TOP TIPS:

- ✓ Patients, patient representatives, stakeholder representatives and Healthwatch should be engaged in clinical audit activity
- ✓ Clinical audit measures should be patient-centred
- ✓ Outputs from the clinical audits should be available to inform patient choice

11. Care Quality Commission, 2010, *Guidance about compliance: Essential standards of quality and safety*, pp. 144-145
12. Calderdale and Huddersield NHS Foundation Trust, 2011, *A stroke of genius – a new approach to improve care* www.hqip.org.uk/assets/PPE/Case-Studies-and-templates/capri2pdf.pdf

Are patients and stakeholders engaged in the clinical audit process?	Unacceptable answer	Acceptable answer
Boards	The results of our clinical audits are publicly available and we disseminate a summary of them to commissioners and stakeholders	To ensure PPI, we involve patient and stakeholder representative in our audit programme development, individual projects and decision making process through the governance structure. Our clinical audit reports have become more patient-friendly and a summary of the processes and improvements resulting from audits are shared with stakeholders and patients in public meetings and our newsletter
Divisions	We receive family and friend and complaint summaries but these are not used to influence audits	We routinely receive quality alerts generated by referring GPs and our complaints systems and seek to reflect these in selecting and designing audits and other improvement approaches
Departments	No	We have systematic feedback from service users and these are used in both selecting and designing audits. We advise service users of changes made from their suggestions

9 Share clinical audit results with other providers, commissioners and regional clinical networks including local patient networks, and publish outcome statistics and evaluations

Clinical audits should be open and transparent in terms of plans, processes and results, with the outcome reports being routinely shared with the wider health and social care economy. Whole system improvement events should become the norm where commissioner, providers, clinical networks and patients come together to develop plans to improve whole pathways.[13] This should include Clinical Commissioning Groups and Health and Wellbeing Boards and take account of:

- Locally developed protocols for sharing confidential information across health and social care to facilitate detailed discussions on improvements identified in both national and local audits
- Promotion of a single set of data and data transmission standards to facilitate a nationwide exchange of health information on care.data[14] held securely within the Health and Social Care Information Centre
- Clinical digital data should inform improvement activities throughout the patient pathway. The use of the NHS number is critical to this work
- Information governance guidelines and requirements have changed significantly with NHS England monitoring the digitalisation process of each provider and the Health and Social Care Information Centre increasingly publishing outcomes data on care.data
- Monitor's new Risk Assessment Framework[15] constitutes a useful guide for providers and commissioners
- Clinical Digital Maturity Index[16] developed by NHS England with EHI Intelligence, enables the identification of the scale of digitalisation in each provider, including the use of the NHS number[17]
- Routinely sharing results with our clinical networks and partners and hold health and social care economy wide improvement events

TOP TIPS:

- ✓ Organisations individually and collectively should be using clinical digital data to identify areas for clinical improvement and clinical audit routinely
- ✓ The outputs from improvement activity should be routinely shared with commissioners, pathway delivery partners, clinical and patient network

13. See also Corbett-Nolan, A. et al., 2014, *Good governance handbook*, p. 15
14. care.data – http://www.england.nhs.uk/ourwork/tsd/care-data
15. Monitor, 2014, *Risk Assessment Framework*
16. Clinical Digital Maturity Index developed by NHS England with EHI Intelligence – www.england.nhs.uk/ourwork/tsd/sst/cdmi/
17. NHS England, 2013, *Everyone Counts: Planning for Patients 2014/15* – 18/19, p. 12

Do we share our clinical audit results with other providers and commissioners, and publish our audit outcome statistics and evaluations?	Unacceptable answer	Acceptable answer
Boards	We publish the outcome statistics of national clinical audits, but share outcomes of local clinical audits only with partner organisations or commissioners	We share our results with local partners (providers/commissioners) and with our regional clinical and patient networks. We are working with our commissioners and others in planning whole system audits. Outcome statistics of our performance in national clinical audits are published online, with commentaries to make them easily accessible and understandable
Divisions	Unfortunately we are unable to provide outcomes other than anonymised summaries for discussion	We have developed data sharing protocols for discussing confidential information across health and social care and are now able to facilitate detailed discussions on improvements identified in both national and local audits
Departments	Detailed results are confidential	The local protocols have allowed much greater discussion on whole system improvements and have facilitated cross boundary work

10 Provide sufficient education and training in clinical audit beyond your clinical audit team, and use junior doctor clinical audit and quality improvement projects as a valuable quality improvement resource

Clinical audit should be recognised as an important feature of induction and further training programmes on clinical governance and quality. Boards might consider a cost improvement regime that allows divisions to retain a proportion of savings for training and improvement activities.

Clinical audit is also an important pathway improvement tool. Managers, commissioners and clinicians should all have an understanding of its purpose and what it can achieve.

Those who are responsible for running clinical audit programmes (clinicians and improvement facilitators) need to have well developed understanding of how to apply its methodology. A poorly designed audit can provide false assurance.

The Foundation Programme requires foundation doctors to describe opportunities for improving the reliability of care following audit, adverse events or near misses; to recognise how the audit cycle relates to the improvement of clinical care; to make audit links explicit to learning or professional development portfolios; to recognise the features of an effective audit that makes real changes in practice; to reflect on an audit or health improvement project related to a patient safety issue.[18]

Junior doctor clinical audit and quality improvement projects are a valuable quality improvement resource, and can focus on issues that have been identified as benefiting from examination.

TOP TIPS:

- ✓ The strategy that encompasses quality improvement methods, including clinical audit articulates the knowledge and competencies expected of each staff group and how education and training is provided to enable staff to meet the competencies
- ✓ Clinical audit programmes support doctors in meeting the Foundation Programme objectives

18. The UK Foundation Programme Curriculum, 2012, p. 24

Do we provide sufficient education and training in clinical audit, and use junior doctor quality improvement projects effectively?	Unacceptable answer	Acceptable answer
Boards	Budgets have been cut so training is now limited to mandatory requirements. We rely on the medical schools to provide appropriate training	Clinical audit is recognised as an important feature of our induction and further training programmes on clinical governance and quality. We have developed a cost improvement regime which allows divisions to retain a proportion of savings for training and improvement activities
Divisions	We have trained clinical audit facilitators and others in the quality improvement team. Junior doctor clinical audit and quality improvement projects involve a training exercise yet to be completed	We have regular clinical audit workshops and invite our staff to participate in further speciality specific external training and networking. Junior doctor clinical audit and quality improvement projects are a valuable quality improvement resource, and focus on issues that have been identified as benefiting from examination
Departments	No, budgets have been cut so training is now very ad hoc and limited to mandatory requirements	The junior doctor quality improvement projects approach has had a significant impact in providing focus for listening and improving services

Barriers to effective use of clinical audit

- **Insufficient resources:** the lack of resources is perhaps the greatest obstacle to the effective conduct of a clinical audit cycle. Clinical audits are often undertaken in services where a lack of resources has already been acknowledged, either in the hope that they will identify actions that will relieve the pressure on resources, or that they will provide evidence to support a claim for additional resources. Both outcomes are possible, but it is also possible that the audit findings will highlight a resources issue, which hasn't previously been considered, acknowledged and planned for.
- **Too many audits:** realistic costing and the allocation of sufficient clinician time, clinical audit practitioner time and overheads, are crucial to ensuring that the whole clinical audit cycle can be completed and the results evaluated effectively to inform the quality strategy. Many organisations find themselves conducting too many audits but not being able to make effective use of them due to a lack of resources. Too often, clinicians simply do not find enough time to conduct clinical audits appropriately because they are not allocated enough time. There is generally insufficient investment in clinical audits.
- **Roles, responsibilities and skills:** effective clinical audit requires clinicians, audit facilitators and senior management to fully understand their roles and responsibilities within quality improvement. If audit staff lack the skills required in the quality improvement process, this may cause anxiety and ineffective use of tools and resources. Therefore, identifying training needs and facilitating adequate training for all staff members involved in clinical audit are crucial.
- **Good and well-focused administrative support:** time and resources can be more efficiently used if clinicians and members of the audit committee and the board receive good and well focused administrative support. Too much time is lost on inefficient data collection systems and paper work.
- **Primary aim is to improve the quality of care:** staff members' scepticism – sometimes even cynicism – about clinical audit can be an additional barrier to its effectiveness. Often staff members do not agree with set standards or do not regard compliance with them as a priority, perhaps because they have not been involved in the process of agreeing these standards in the first place. It is imperative to ensure that all staff members understand that the primary aim of clinical audit is to improve the quality of care, instead of regarding it as irritating or an obligatory bureaucracy. Focusing the aims of clinical audit on quality improvement and patient safety instead of mere compliance with guidelines, can improve staff members' support for clinical audit.
- **Teamwork focused on change and improvement:** clinical audit needs to be seen as a team activity where clinical audit facilitators should be supported by the board and lead clinicians. Often the clinical audit team does not feel confident to push for change in the organisation, hence it is important that other members of the team and/or of the board take on the task to implement the recommendations arising from clinical audit results. The emphasis needs to be on change and improvement, not on maintaining the status quo.

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Assurance questions, with possible answers
Board level

	Question	Unacceptable answer	Acceptable answer
1	**Is our clinical audit strategy aligned to the organisation's broader strategic interests and used as assurance in our board assurance framework?**	Clinical audit is planned and conducted by our clinical audit team, which reports back to the board. Clinical audits may provide assurance where they coincide with strategic priorities	We ensure that our clinical audit programme is aligned to the broader strategic interests of the organisation and other aspects of our strategic management. We have identified where clinical audit can provide assurance to commissioners and us, gaps are addressed in forthcoming plans and budgets. The board shapes the clinical audit strategy to address wider strategic priorities
2	**Has clinical audit been selected as the methodologically most suitable tool for the issue at hand?**	Clinical audit is our standard quality improvement tool	Yes, within our broader quality improvement strategy, we have a robust process for ensuring that each quality improvement method is chosen for its merit and impact. Clinical audit is utilised when it has been identified as the most effective tool to improve and assure the quality of the service delivered
3	**Do we have a clinical audit strategy with a balanced combination of national and local priorities?**	We have an existing clinical audit plan, mostly focused on national clinical audits, which often does not leave resources for additional local audits	Balancing the national and local components of our clinical audit programme, the board shapes the audit strategy to address wider priorities with sufficient funds and resources earmarked for relevant local audit activity and follow up
4	**Are our clinical audit cycles comprehensive, timely and outcome-focused?**	Our annual clinical audit cycle is usually larger than resources permit and inevitably creates a backlog	Yes, the purpose of clinical audit is improvement. We operate a trust-wide rolling audit programme, which covers all stages of the audit cycle, but allows prioritisation and stakeholder involvement in-year. We do not consider audits complete until we have re-audited and reported improvement
5	**What proportions of approved clinical audits have been completed to time and budget?**	The time and budget allocated for clinical audit is sometimes not sufficient to cover the whole clinical audit cycle and does not leave resources for additional pathway and re-audits	We are assured by a delegated sub-committee of the board that x% of re-audits are completed. Where there is a lack of assurance the appropriate committee identifies and reviews action plans. Clinical audits that are health economy wide or have a strategic impact on clinical services are presented to the board

	Question	Unacceptable answer	Acceptable answer
6	**Has the board agreed what constitutes materiality, unacceptable variation in clinical audit results against standards and comparisons with others?**	Clinical audit has guidelines but no system of accreditation so we are left to ourselves in determining whether we consistently follow best practice	We have adopted a professional approach to clinical audit, setting auditable procedures for selecting and delivering audit-based improvement in any area. This allows the board to determine materiality (risk, value and return) and trigger points for escalation to the board as well as benchmarking to compare with norms and emerging better practice
7	**Do we engage with other organisations during the clinical audit process?**	We are not accountable once the patient has left the care of our organisation. Individual clinicians may engage with colleagues in other departments or providers where necessary	Our quality improvement programme is focused on the patient pathway, and working in partnership with other health and social care providers and commissioners involved in these pathways, has proven to improve overall care in our community. We invite external organisations to peer- review our approach
8	**Are patients and stakeholders engaged in the clinical audit process?**	The results of our clinical audits are publicly available and we disseminate a summary of them to commissioners and stakeholders	To ensure Patient and public involvement (PPI), we involve patient and stakeholder representatives in our clinical audit programme development, individual projects and as part of the decision making process through the governance structure. Our clinical audit reports have become more patient-friendly and a summary of the processes and improvements resulting from audits is shared with stakeholders and patients in public meetings and in our newsletter
9	**Do we share our clinical audit results with other providers and commissioners, and publish our audit outcome statistics and evaluations?**	We publish the outcome statistics of national clinical audits, but share outcomes of local clinical audits only with partner organisations or commissioners	We share our results with local partners (providers/commissioners) and with our regional clinical and patient networks. We are working with our commissioners and others in planning whole system audits. Outcome statistics of our performance in national clinical audits are published online, with commentaries to make them easily accessible and understandable
10	**Do we provide sufficient education and training in clinical audit, and use junior doctor quality improvement projects effectively?**	Budgets have been cut so training is now limited to mandatory requirements. We rely on the medical schools to provide appropriate training	Clinical audit is recognised as an important feature of our induction and further training programmes on clinical governance and quality. We have developed a cost improvement regime which allows divisions to retain a proportion of savings for training and improvement activities

Assurance questions, with possible answers
Division level

	Question	Unacceptable answer	Acceptable answer
1	**Is our clinical audit strategy aligned to the organisation's broader strategic interests and used as assurance in our board assurance framework?**	We have a backlog of audits which we are tackling	The board has identified major concerns where performance or assurance is lacking and prioritises these. We respond with a plan or raise resourcing issues. Ad hoc urgent requests are responded to within the same year
2	**Has clinical audit been selected as the methodologically most suitable tool for the issue at hand?**	Staff tend to use the approach they are comfortable with	We have trained staff in a wide range of improvement tools and we routinely review the best approach for the issue. We aim to learn from mistakes and improve best fit approach
3	**Do we have a clinical audit strategy which balances a combination of national and local priorities?**	Clinicians are aware of their responsibilities to be involved when other priorities permit	We identify a rolling programme of clinical priorities for audit and ensure that all clinicians across the local health and care economy are involved in clinical audit and other improvement programmes as part of their training and revalidation
4	**Are our clinical audit cycles comprehensive, timely and outcome-focused?**	We have a wish list of topics but rarely cover them all. New audits are getting in the way of re-auditing old ones	We have a plan with a clearly defined timeline for specific measures and actions, and clearly defined roles of team members responsible for their implementation. The action plan recognises and addresses the reasons for shortfalls in the quality of care
5	**What proportion of approved clinical audits has been completed to time and budget?**	We do not have a budget but undertake a considerable range of audits each year	Clinical audits are logged with the clinical audit lead, resources and timescales are prioritised. Variations and requests for pathway audits are logged and reported to the lead clinician. The division tracks the delivery of audits across all of its specialities/departments

	Question	Unacceptable answer	Acceptable answer
6	**Has the board agreed what constitutes materiality, unacceptable variation in clinical audit results against standards and comparisons with others?**	NICE[19] and others provide some condition based standards but we do not have identified trigger points for early escalation of unacceptable variation. The lack of national standards prevents us from implementing audits of some areas of concern	We follow our agreed professional standards in conducting audit, working where possible with other organisations to gauge acceptable and improved practice and outcomes. Trigger points for prompt escalation of unacceptable variation are being worked on for each condition
7	**Do we engage with other organisations during the clinical audit process?**	Our audit programme is insufficiently aligned to involve more than one department. We would not know what other organisations are doing to conduct joint audits	We have a good relationship with our commissioners and both specialist and local providers to allow us to extend our audits along patient pathways. We have learnt and seen improvement using this approach
8	**Are patients and stakeholders engaged in the clinical audit process?**	We receive family and friend and complaint summaries but these are not used to influence audits	We routinely receive quality alerts generated by referring GPs. Our complaints systems seek to reflect these in selecting and designing audits and other improvement approaches
9	**Do we share our clinical audit results with other providers and commissioners, and publish our audit outcome statistics and evaluations?**	Unfortunately we are unable to provide outcomes other than anonymised summaries for discussion	We have developed protocols for sharing confidential information across health and social care and are now able to facilitate detailed discussions on improvements identified in both national and local audits
10	**Do we provide sufficient education and training in clinical audit, and use junior doctor quality improvement projects effectively?**	We have trained clinical audit facilitators and others in the quality improvement team. Junior doctor clinical audit quality improvement projects involve a training exercise yet to be completed	We have regular clinical audit workshops and invite our staff to participate in further speciality specific external training and networking. Junior doctor clinical audit and quality improvement projects are a valuable quality improvement resource, and focus on issues that have been identified as benefiting from examination

19. National Institute for Health and Care Excellence – www.nice.org.uk

Assurance questions, with possible answers

Department level

	Question	Unacceptable answer	Acceptable answer
1	**Is our clinical audit strategy aligned to the organisation's broader strategic interests and used as assurance in our board assurance framework?**	No, probably not	We aim to balance departmental needs with strategic and national requirements, escalating any resourcing or traction issues
2	**Has clinical audit been selected as the methodologically most suitable tool for the issue at hand?**	We are used to clinical audit and this is the approach we normally use	We have adopted a best-fit guide to check we are using the best approach for each quality issue
3	**Do we have a clinical audit strategy that balances a combination of national and local priorities?**	We simply do not have the time to engage other than in mandatory national audits	We have a listing of planned and completed local audits for each trainee and ensure that all clinicians meet their training and revalidation requirements in a timely fashion
4	**Are our clinical audit cycles comprehensive, timely and outcome-focused?**	We are getting overwhelmed with requests for new audits and frankly have to ignore them	We complete what we start and raise exception notes for delays and unfinished audits. Identified variation is never left unattended to
5	**What proportion of approved clinical audits has been completed to time and budget?**	Consultants decide what audits are completed	The department tracks the delivery of its agreed clinical audit programme and escalates issues and concerns to the divisions

	Question	Unacceptable answer	Acceptable answer
6	**Has the board agreed what constitutes materiality, unacceptable variation in clinical audit results against standards and comparisons with others?**	We follow national guidelines on conducting audit but have not reviewed compliance	We follow our agreed professional standards in conducting audit which has allowed us to review and improve compliance
7	**Do we engage with other organisations during the clinical audit process?**	No	In developing audits we always work hard to ensure at least the interface with other departments or even external organisations is covered
8	**Are patients and stakeholders engaged in the clinical audit process?**	No	We have systematic feedback from service users and these are used in both selecting and designing audits. We inform users of changes made from their suggestions
9	**Do we share our clinical audit results with other providers and commissioners, and publish our audit outcome statistics and evaluations?**	Detailed results are confidential	The local protocols have allowed much greater discussion on whole system improvements and facilitated cross boundary work
10	**Do we provide sufficient education and training in clinical audit, and use junior doctor quality improvement projects effectively?**	No, budgets have been cut so training is now very ad hoc and limited to mandatory requirements	The junior doctor quality improvement projects approach has had a significant impact in providing focus for listening and improving services

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