



HQIP

Healthcare Quality
Improvement Partnership

Clinical Audit Programme Guidance Tools

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Clinical audit tool to promote quality for better health services

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1 Product Overview

The purpose of this guide is to provide users with guidance and tools for generating and managing a trust-wide annual clinical audit programme.

It describes the processes of choosing and prioritising topics for clinical audit projects that reflect key national and local drivers for quality improvement (“top-down” requirements) balanced against directorate/division/service priorities and the interests of clinicians (“bottom-up” initiatives).

The guide also proposes a model for the performance management of directorate/division/service participation in and progress with agreed clinical audits featured on the trust annual clinical audit programme.

The guidance and tools are not prescriptive and can be adapted for local use.

1.1 Introduction

The Healthcare Quality Improvement Partnership (HQIP) is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. Our purpose is to promote quality in healthcare, and in particular to increase the impact that clinical audit has on healthcare quality in England and Wales.

Clinical audit may be defined as “a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery.”¹

In order to facilitate this, HQIP have funded the development of a number of clinical audit support tools to help local teams deliver local clinical audit activity. They are intended to be used as reference material or toolkits to help with the clinical audit process.

This document should be read in conjunction with the following:

- the separate glossary provided
- other relevant tools produced as part of this collection by HQIP.

1.2 External monitoring requirements

There are a number of ways that provider organisations are regulated to ensure that they are providing optimum patient care, e.g.:

Monitor — The independent regulator of NHS foundation trusts ensuring that NHS foundation trusts comply with the conditions they signed up to, including the requirements to meet healthcare targets and national standards.

Care Quality Commission — From April 2009 health and social care providers, including for the first time NHS providers, are required to register with the Care Quality Commission (CQC) in order to provide healthcare directly to patients. The registration requirements that all providers must meet are consistent across both health and adult social care.

Organisations are measured on important issues to patients and the public, focusing on levels of safety, clinical quality and patient experience.

The DH introduced the *Standards for Better Health* (SfBH) in 2004 and the CQC will be utilising and building on these standards from 2009 onwards in order to fulfil the statutory duty to provide an annual rating of the performance of all English NHS organisations. Evidence of participation in clinical audit by all clinical professional groups is currently required to meet a trust's declaration of compliance with core standard C5d for SfBH, 'Healthcare organisations should ensure that clinicians participate in regular clinical audit and reviews of service' and core standard C5a "Healthcare organisations ensure that they conform to NICE technology appraisals and, where it is available, take into account nationally agreed guidance when planning and delivering treatment and care". More specifically, SfBH identifies a number of topics areas as priorities for audit activity across NHS Trusts. These include:

- NICE technology appraisals
- NICE clinical guidelines
- National Clinical Audit and Patient Outcomes Programme (NCAPOP)
- National Service Frameworks (NSFs)
- Other national guidance (e.g. NHS Litigation Authority, National Patient Safety Agency, recommendations from National Confidential Enquiries (NCEs), NICE public health guidance, high level enquiries)

Integration of the above topics into a structured annual audit programme will greatly enhance the likelihood of an organisation being compliant with SfBH (and its successor).

New national targets and existing commitments are used to assess whether levels of service set through the 2008–2011 planning round are being maintained. Assessment of performance against the existing commitments and national priorities are components of the CQC's periodic review in 2009/10 for PCTs, acute and specialist trusts, and ambulance trusts. Mental health trusts and learning disability trusts will be assessed against one national priorities component.

PCT Commissioners — The primary role of PCTs is to commission (buy) public health and health care services for the communities they serve that are both clinically and cost effective. The commissioned services include primary and secondary care, ambulance services, mental health services, voluntary or third sector care and private sector care.

Commissioning organisations have the responsibility to deliver the content of effective clinical audit programmes that must respond to requirements of external scrutiny bodies. The introduction of World Class Commissioning launched in December 2007 will influence the long-term strategic development of quality programmes including clinical audit. It introduced 11 organisational competencies that set out the knowledge, skills, behaviours and characteristics commissioners need to turn the Government's vision into reality.

Each autumn, a commissioning assurance process will assess whether PCTs are achieving better health outcomes for the local population. Part of this process will be an assessment of how well PCTs are performing against each of the 11 competencies.

A robust clinical audit programme agreed between commissioners and providers will be an essential component in ensuring that the local population has access to high quality health care services. The requirements by NHS commissioners should be reflected in appropriate contracts and service agreements with PCT provider unit services, primary care contractors (providers of a wide range of services that are not contracted by the NHS, such as pharmacists) and services commissioned from Trusts providing health and social care.

For more information please refer to *Clinical Audit and Commissioning* available from HQIP.

2 Identification of appropriate topics for the trust annual clinical audit programme

Trust clinical audit departments are driven by a plethora of initiatives and influences, both external and internal, which constitute the annual working of the departments. The first step in developing a comprehensive annual programme is the identification of all audit topics relevant to the particular health care sector and organisation through scrutiny of key web sites, consultation with national bodies and reference to local strategy and directorates/divisions/services. This way both national and local priorities should influence the development of clinical audit programmes.

It is essential to ensure that externally monitored audits driven by commissioning and quality improvement are all included (see Priority 1, page 5).

A clinical audit programme should reflect:²

- NCAPOP funded by the DH
- NICE guidance
- NSFs
- Local areas of clinical priority and interest

All of these should be important considerations when identifying clinical audit topics for the trust annual clinical audit programme.

In Lord Darzi's publication, *High Quality Care for All*,³ the production of annual quality accounts promises to provide the public with information on the quality of care provided by the NHS provider organisation. As previously mentioned, indicators covering the DH existing national priorities, as set out in the NHS Operating Framework and the supporting Vital Signs indicator set, and regulatory activities are likely to form the list for mandatory publication in quality accounts and should be used as a basis for identifying topics for clinical audit.

Each PCT commissioning body is governed by a number of national and local drivers, national standards and targets, all of which should be used to source appropriate topics. These include:

- *Core Standards for Better Health*
- NICE guidance
- NSFs
- NCAPOP
- NCEs
- NHS Litigation Authority Risk Management Standards
- National Patient Safety Agency (NPSA) Alerts
- DH e.g. Health and Social Care Act (hygiene)
- Recertification/revalidation for all clinical staff
- World Class Commissioning
- NHS Operating Framework 2008/2009–2010/2011
- Darzi report, *High Quality Care for All*
- Independent provider contracts, e.g. local commissioning for quality innovation (CQUINs).

In addition to national clinical audit topics the choice of further topics should be based on the classic criteria of high risk or high profile identified by trust management or trust clinical audit strategy documents. Many of these projects will emanate from trust governance issues.

It is important to ensure that the views of users, clinical staff, support staff and managers are represented in the selection process for topics of local interest.

The process for the identification of clinical audit priorities will therefore be a combination of “bottom up” via clinical staff and “top down” via trust committees, business groups or external requirements. Priorities should be reflective of organisational objectives for clinical audit as outlined in their local strategy (*see Clinical Audit Policy and Clinical Audit Strategy* available from HQIP).

3 Setting priorities

3.1 Prioritisation of topics and development of the annual trust clinical audit programme

Each trust should have a framework to support effective clinical audit that relies on strategic planning and prioritisation. Audit projects should contribute to the overall priorities of the organisation and be clear about how patient care will be improved.

However, resources are finite; both in terms of clinician time and central support function resource and this places a limit on the number of audits that can be carried out over the course of a year. This means that when all the various sources have been considered, the topics suggested need to be prioritised in a systematic way.

A clear approach must be agreed for the development of the clinical audit programme and its local application. Below is a 4-step prioritisation model for application at local level and suitable for both primary and secondary care organisations. The process of prioritisation used

in this model assumes a hierarchy of importance, with priority one being the most important. The first three priorities contribute to the bulk of the annual clinical audit programme. The fourth relies on the availability of local resources over and above those required to deliver the first three priorities and this will vary between trusts.

It is recommended that this model of prioritisation is adopted by both provider and commissioner so that each year, the commissioner produces a programme of clinical audit for the provider to conduct, which aligns with provider priorities. For more information, refer to *Clinical Audit and Commissioning* available from HQIP.

3.1.1 Priority 1 — External ‘must do’ audits

It is essential to ensure that externally monitored audits that are driven by commissioning and quality improvement are treated as the priority and that appropriate resources are provided to support these. Failure to participate or deliver on these externally driven audits may carry a penalty for the trust (either financial or in the form of a failed target or non-compliance — hence “must-do” audits). These are externally monitored and assessed by the CQC and in some areas by the local PCT commissioner.

The annual clinical audit forward plan should be determined at directorate/division/service level, and should be based around topics identified via the process outlined in Section 2. Example topics to include at this priority should be:

- New national targets and existing commitments (e.g., participation in heart disease audits, stroke, Myocardial Ischaemia National Audit Programme (MINAP), Engagement in Clinical Audit)
- NCAPOP
- Audits demonstrating compliance with regulation requirements e.g. audits with the aim of providing evidence of implementation of NICE technology appraisals, clinical guidelines and public health guidance, NSFs and other national guidance such as that coming from NPSA alerts or NCEs
- Regional CQUINS and other commissioner priorities
- DH statutory requirements, such as infection control monitoring
- External accreditation schemes, e.g., NHS Litigation Authority, cancer peer review audit
- The Productive Series from the NHS Institute for Innovation and Improvement
- Re-audits of any of the above.

3.1.2 Priority 2 — Internal ‘must do’ audits

In addition to national clinical audit topics, the choice of further topics should be based on the classic criteria of high risk or high profile identified by trust management or trust clinical audit strategy documents. They may include national initiatives with trust-wide relevance but no penalties exist for non-participation. Many of these projects will emanate from trust governance issues or high profile local initiatives and will include:

- Priorities reflective of organisational objectives for clinical audit as outlined in local clinical audit strategy
- Clinical risk issues
- Serious untoward incidents/adverse incidents

- Organisational clinical priorities
- Priorities identified via Patient and Public Involvement initiatives
- Complaints
- Access
- Patient Safety First Campaign
- Re-audits of any of the above.

3.1.3 Priority 3 — Directorate priorities

Directorates/divisions/services are asked to suggest projects that are priority pieces of work and important to them – local priorities. They may include DH initiatives and be directorate/division/service specific but no penalties exist for non participation. Directorate priorities may include:

- Local clinical interest audit agreed by directorate/division/service as a priority
- National audits not part of NCAPOP, e.g. some Royal College initiated projects lie outside of NCAPOP
- Locally adopted clinical standards benchmarking e.g., Essence of Care
- Re-audits of any of the above.

3.1.4 Priority 4 — Clinician interest

The priorities set up above should not stifle projects that emerge during the year that contribute to improvements in care. Some of these projects registered later in the year will slot into one of the above categories. However, there will be a number of projects that will not fall into any of the above priorities. It is fully recognised that there is a need to maintain a degree of locally initiated projects. These projects often cannot be determined at the outset of the financial year. They represent innovative ideas from clinicians and can provide valuable educational experience for junior staff. All this leads to the need to develop a transparent system for decision-making about whether or not (and to what extent) a locally conceived project should attract support from clinical audit resources. Organisations may wish to update the annual trust clinical audit programme (see Appendix 1) to reflect new clinician interest projects throughout the year or, alternatively record these on a separate but complementary directorate/division/service clinical audit programme (see Appendix 5).

3.2 Quality impact analysis

One way to prioritise “clinician interest” projects is to use some form of Quality Impact Analysis (QIA). It has been stated in *Principles for Best Practice*¹ that topics for clinical audit need to be prioritised in a systematic way. This could be done by ranking topics in order of importance, such as a QIA. This allows for the use of questions to help determine priorities among topics for audit. Some organisations weight criteria, so some criteria carry more significance or importance in comparison with others. You may wish to consider the following criteria⁴ when applying QIA to clinical audit generated by local healthcare professionals (see Appendix 2).

- **High frequency/volume of service** — most frequent reasons for referral, admission or treatment or most frequent procedures performed

- **High risk** — services or aspects of services with higher than average risk potential to staff or patients, due either to the nature of the treatment or procedure or the potential risk if the service is delivered inappropriately
- **High cost** — aspects of a service that involve higher than average costs or which could involve high costs if not provided properly
- **Potential for change** — the anticipated potential for change arising from the project with the support of those individuals who can effect change
- **Existence of evidence-based guidelines/standards** – the level by which the project is comparing current practice against evidence based practice/guidelines
- **Direct impact on patients** — a judgement based on the anticipated outcomes of the project, taking into account direct patient benefit
- **Direct involvement with patients/families** — does the project directly include patients or families?
- **Multidisciplinary project** — the level of involvement between different disciplines
- **Interface project** — the level of involvement at the interface between two or more NHS establishments or organisations, particularly the primary care/secondary care interface.

It should be the responsibility of a delegated individual such as a clinical audit lead (or local clinical governance team) within the clinical area to assess potential projects on the above criteria, so that a decision is made as to whether or not a project should be carried out. This can ensure that good quality projects are being undertaken. Directorate/division/service audit projects could be identified from this process.

3.3 Steps in creating an annual trust clinical audit programme

To develop this programme, clinical audit staff should (see Appendix 3):

- forward plan using all sources of external “must do” audits to ascertain what should be included for the forthcoming financial year
- populate the trust clinical audit programme template (see Appendix 1) with incomplete priority projects from previous year and new project priorities
- discuss programme plus commissioner suggestions with Audit Leads in directorates/divisions/services and take any queries to senior team to resolve
- agree inclusion of internal “must do” audits e.g. Trust-wide audits that should be a trust priority on all directorate/division/service programmes
- include multi-speciality audits where there is genuine involvement and work carried out by more than one directorate on all relevant programmes (indicated ‘lead directorate’ or ‘participant’)
- inform all directorates/divisions/services of current clinician interest audits that are ongoing and registered centrally. Agree whether these will be included as part of the overall trust clinical audit programme or as part of the specific directorate/division/service clinical audit programme

- agree with directorates/divisions/services one or two priority audits to be performance managed alongside “must do” audits using the Clinical Governance Performance Management Tool (see Appendix 4). Flexibility is required bearing in mind the number of commissioned audit projects. The final number of projects should be determined locally.
- for directorates/divisions/services with no “must-do” obligation, a minimum of 2 directorate priority audits will suffice
- if a directorate/division/service has a large commissioned list suggest that one or two of these could double up as directorate priority audits i.e., no need for more
- there should be one final Healthcare Governance or equivalent Performance Management Tool sign off sheet (see Appendix 4) per directorate/division/service.
- allow directorates/divisions/services to agree who signs off, as this will differ depending on local directorate set up. Directorates/divisions/services may decide to do this at a formal meeting e.g. management team or clinical governance meeting
- process for sign off:
 - clinical audit staff put a draft together
 - pass to Unit manager for checking
 - directorate staff sign off
 - unit manager to provide final sign off and accountability to healthcare governance or equivalent.

4 Internal monitoring arrangements

The trust clinical audit programme should be approved by the trust healthcare governance committee (or equivalent) and implementation monitored corporately quarterly via the trust clinical audit/effectiveness committee, at directorate level via the Clinical Governance Performance Management Tool (see Appendix 4) and on an agreed basis by the PCT Commissioner. All this activity is captured and reflected each year in an annual report.

Clinical governance is viewed as “a framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish”. Through benchmarking, performance can be measured against set standards for agreed clinical indicators and outcomes compared at local and national levels. This should enable safeguarding of high standards of care, while at the same time identifying areas that need improvement.

The use of a clinical dashboard is a tool that can be employed to monitor the implementation of principles of clinical governance ‘on the ground’. It can be used to benchmark activity and monitor performance on a monthly basis against standards agreed locally.

The first three priorities constitute the directorate’s performance managed programme, which include the commissioned work and directorate priorities. The priority 4 work represents non-performance managed topics; these will be the ‘ad hoc’ projects that do not slot into the other 3 categories. On a quarterly basis the programme will be reviewed to ascertain progress made with the annual programme. Progress with each of the projects will be assessed and monitored using a traffic light system (see below and Appendix 1).

Red	Cause for concern. No progress towards completion. Needs evidence of action being taken
Amber	Delayed, with evidence of actions to get back on track
Green	Progressing to time, evidence of progress
Blue	Completed, evidence of compliance with standards or action plans to achieve compliance
White	Audit not planned to start this quarter

References

1. National Institute for Clinical Excellence. *Principles for Best Practice in Clinical Audit*. Abingdon: Radcliffe Medical Press; 2002.
2. Clinical Governance Support Team. *A practical handbook for clinical audit*; 2005. Available at: www.hqip.org.uk/assets/Downloads/Practical-Clinical-Audit-Handbook-CGSupport.pdf. Accessed 7 May 2009.
3. Department of Health. *High Quality Care for All. NHS Next Stage Review Final Report*; 2008. Available at: www.dh.gov.uk. Accessed 9 June 2009.
4. Rowan K. Prioritising clinical audit projects: A Clinical Audit Prioritising System (CAPS). *Journal of Clinical Excellence* 2001;3:83–89, and Dixon N, Pearce M. *Clinical Audit Manual*. Romsey: Healthcare Quality Quest; 1993.

Resources

Department of Health. *Good Doctors, Safer Patients: Proposals to Strengthen the System to Assure and Improve the Performance of Doctors and to Protect the Safety of Patients*; 2006. Available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4137232. Accessed 9 June 2009.

Department of Health. *Quality Accounts Frequently Asked Questions*; 2009. Available at: www.dh.gov.uk. Accessed 9 June 2009.

Department of Health. *Guidance on the Routine Collection of Patient Reported Outcome Measures (PROMS)*; 2009. Available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_092647. Accessed 9 June 2009.

Appendix 1. Trust Clinical Audit Programme 2009/10

Red	Cause for concern. No progress towards completion. Needs evidence of action being taken
Amber	Delayed, with evidence of actions to get back on track
Green	Progressing to time, evidence of progress
Blue	Completed, evidence of compliance with standards or action plans to achieve compliance
White	Audit not planned to start this quarter

Number or Release Date		Project Start Date	Database Registration Number	CE Contact	Lead Directorate/ Division	Clinical Project Lead	Quarter 1	Quarter 2	Quarter 3	Quarter 4
	NICE TECHNOLOGY APPRAISAL AUDITS									
	NICE CLINICAL GUIDELINE AUDITS									
	NCAPOP									
	OTHER NATIONAL GUIDANCE									
	REGIONAL/COMMISSIONER PRIORITIES									

Appendix 2. Quality Impact Analysis

There will be a number of projects that will not fall into priorities 1 to 3 of the model outlined in this document. It is fully recognised that there is a need to maintain a degree of locally initiated projects. These projects often cannot be determined at the outset of the financial year. They represent innovative ideas from clinicians and can provide valuable educational experience for junior staff. All this leads to the need to develop a transparent system for decision making about whether or not (and to what extent) a locally conceived project should attract clinical audit resources. The below list provides criteria (weighted for importance) in scoring projects for priority.

	No relevance (0)	Some relevance (1)	Almost met (2)	Met fully (3)	Score
High frequency/ volume					
High cost					(x2)
High risk					(x2)
Potential for change					(x2)
Existence of evidence-base					(x2)
Direct involvement with patients					
Wide variation in practice					
Multidisciplinary project					
Interface project					(x2)
Total score =					

If the criterion has no relevance, score = 0

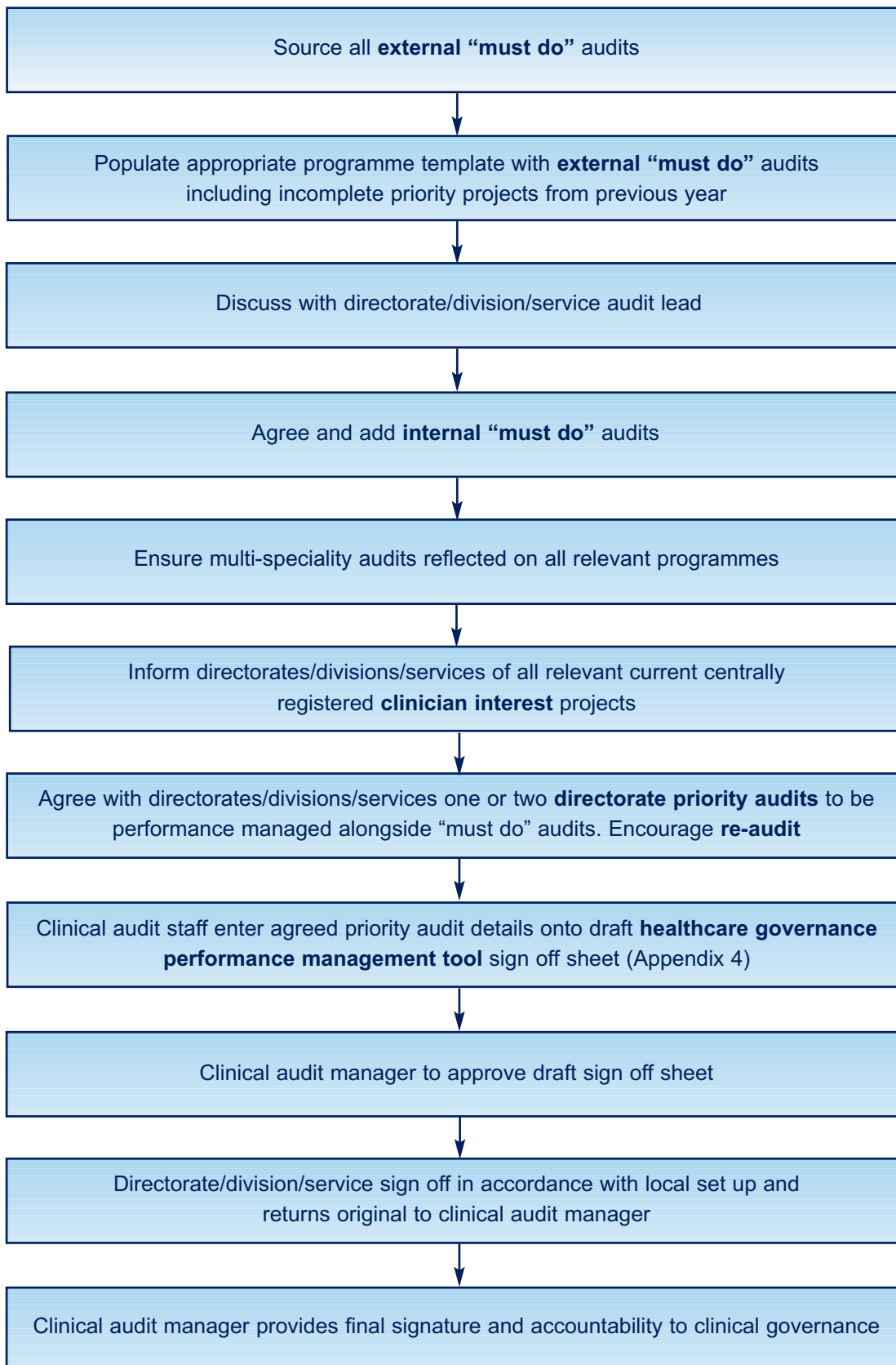
If the criterion has some relevance, score = 1

If the criterion is met in parts, score = 2

If the criterion is fully met, score = 3

The scores can range between 0 and 42, with higher scores demonstrating higher priority.

Appendix 3. How to create trust or directorate/division/service clinical audit programme



Appendix 4. Healthcare Governance Performance Management Tool for Clinical Audit

Care group		Directorate	
Contact name		Contact Details	Phone
			Email
			Bleep
External and internal priorities			
Project title		Project reference number	
Directorate priority audits			
Project title		Project reference number	
Signature of clinical director (or designated representative)			
Name:			
Title:		Date:	
Signature of general manager (or designated representative)			
Name:			
Title:		Date:	
Signature of clinical audit representative			
Name:			
Title:		Date:	

PROGRAMME OF CLINICAL AUDIT FOR XXXXXXXXXX

Red	Cause for concern. No progress towards completion. Needs evidence of action being taken
Amber	Delayed, with evidence of actions to get back on track
Green	Progressing to time, evidence of progress
Blue	Completed, evidence of compliance with standards or action plans to achieve compliance
White	Audit not planned to start this quarter

PRIORITY LEVEL	SUPPORT LEVEL
1 External "must do"	I Low support – Registration and advice only
2 Internal "must do"	II Moderate support – Patient info and case note retrieval
3 Directorate/division/service priority	III High support – Facilitation throughout project
4 Clinician interest	

1 Performance managed audits

1.1 External and internal "must do" audits

Project reference number	Project title (NICE TA, NICE CG, NSF, other national guidance/audit)	Clinical audit contact	Lead directorate/division/service	Project start date	Current Status				Comments	Priority level	Support level
					Q1	Q2	Q3	Q4			

1.2 Directorate priority audits

Project reference number	Project title	Clinical audit contact	Lead directorate/division/service	Project start date	Current Status				Comments	Priority level	Support level
					Q1	Q2	Q3	Q4			

2 Non-performance managed audits

Project reference number	Project title	Clinical audit contact	Lead directorate/division/service	Project start date	Current Status				Comments	Priority level	Support level
					Q1	Q2	Q3	Q4			

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- Gloucestershire Primary Care Trust
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- NHS South West Essex
- Norfolk, Suffolk and Cambridgeshire
- Northumberland NHS Care Trust
- Surrey Primary Care Trust
- The Christie NHS Foundation Trust.

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