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Royal Cornwall Hospitals NHS Trust

Clinical Audit and NICE Guidance Policy

V4.0

May 2023

Summary

This Policy sets out how the RCHT governs its Clinical Audit Programme and all applicable NICE publications.

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Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation

The Trust has a duty under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the Data Protection Act 2018 and General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

Royal Cornwall Hospital Trust rch-tr.infogov@nhs.net

1. Introduction

1.1. Participation in both national and local clinical audit is a statutory and contractual requirement for healthcare providers. The NHS Standard Contract forms the agreement between commissioners and provides of NHS funded services. This includes the requirement to participate in relevant national clinical audits and implement an ongoing, proportionate programme of clinical audit of service in accordance with best practice.

1.2. This version supersedes any previous versions of this document.

1.3. Under the Health Act 2009, the Trust is required to produce an annual Quality Account, which must include information on participation in national and local clinical audits, and the actions that have been taken consequently to improve the services provided.

1.4. With the commitment both to providing a high-quality service and to implementing Clinical Governance, this policy has been developed to ensure that the Trust has in place a systematic and coordinated approach for reviewing the findings and recommendations from the range of nationally agreed guidelines published by the National Institute for Health and Care Excellence (NICE). It is recognised that important lessons can be learnt, and patient safety can be improved from sharing events external to the Trust.

1.5. The Trust will use national and regional audits, standards, and guidelines to review, assess and shape practice and services (including National Confidential Enquiries and Audits, NICE quality standards and guidance).

2. Purpose of this Policy/Procedure

2.1. The purpose of this policy is to develop and sustain a culture of best practice in audit and implementation of NICE guidance, clarifying the roles and responsibilities of all staff engaged in audit and NICE activities.

2.2. This policy sets out a framework for the conduct of clinical audit and the use of NICE guidance, to ensure that it is effectively applied to bring about quality improvements in service delivery. It focuses on the Trust's expectations in relation to conduct and participation in clinical audit, the rationale for undertaking clinical audit, and the procedures and expectations for registering and approving clinical audit project proposals. It includes the process that should be followed when reviewing NICE guidance, developing, and designing clinical audit projects and the support that is available centrally from the Clinical Effectiveness Team.

3. Scope

This policy applies to anyone engaged in the clinical audit or NICE guidance processes under the auspices of the Trust, including students, volunteers, and patients, as well as staff. This policy also applies when clinical audit is undertaken jointly across organisational boundaries. The Trust promotes a commitment to involving patients, carers and members of the public in the clinical audit process, either indirectly through the use of patient surveys and questionnaires, or directly through participation in projects.

4. Definitions / Glossary

4.1. “Clinical Audit is a quality improvement cycle that involves measurement of the effectiveness of healthcare against agreed and proven standards for high quality and taking action to bring practice in line with these standards to improve the quality of care and health outcomes.”. The Trust supports the view that whilst Clinical Audit is fundamentally a quality improvement process, it also plays an important role in providing assurances about the quality of services.

4.2. Quality Improvement: Quality Improvement in healthcare is a process that seeks to enhance patient experience and individual health outcomes, through measuring and improving the effectiveness and safety of clinical services.

4.3. Clinical Effectiveness: Clinical Effectiveness is one of the three dimensions of a high-quality healthcare service (along with patient experience and patient safety). Quality care is delivered according to the best evidence regarding what is clinically effective in improving an individual’s health outcomes.

4.4. Healthcare Quality Improvement Partnership (HQIP): HQIP was established in April 2008 to promote quality in healthcare, and to increase the impact that clinical audit has on healthcare quality in England and Wales

4.5. National Clinical Audit and Outcomes Programme (NCAPOP): NCAPOP is a set of centrally funded national projects that provide local trusts with a common format by which to collect audit data. The projects analyse the data centrally and feedback comparative findings to help participants identify necessary improvements for patients.

4.6. National Institute for Health and Care Excellence (NICE): An independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. NICE publishes the following types of guidance:

4.7. Technology Appraisals: Recommendations on the use of new and existing medicines and treatments within the NHS. Regulatory requirement is to implement within 90 days of publication.

4.8. NICE Guidelines: Recommendations on the appropriate treatment and care of people with specific diseases and conditions within the NHS. NICE guidelines are based on the best available evidence. Guidelines help healthcare professionals in their work, but they do not replace their knowledge and skills.

4.9. Interventional Procedures: Recommendations about whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use.

4.10. Medical Technologies Guidance: Medical technologies guidance is designed to help the NHS adopt efficient and cost-effective medical devices and diagnostics more rapidly and consistently. The types of products which might be included are medical devices that deliver treatment such as those implanted during surgical procedures, technologies that give greater independence to patients, and diagnostic devices or tests used to detect or monitor medical conditions.

4.11. Diagnostic Technologies Guidance: NICE diagnostics guidance is designed to help the NHS adopt efficient and cost-effective medical diagnostic technologies more rapidly and consistently. The programme concentrates on pathological tests, imaging, endoscopy, and physiological measurement, since these represent most of the investigations performed on patients.

4.12. NICE Quality Standards: A set of specific, concise statements that act as markers of high-quality, cost-effective patient care, covering the treatment and prevention of different diseases and conditions. Derived from the best available evidence such as NICE guidance and other evidence sources accredited by NHS Evidence, they are developed independently by NICE, in collaboration with the NHS and social care professionals, their partners and service users, and address three dimensions of quality: clinical effectiveness, patient safety and patient experience.

5. Ownership and Responsibilities

5.1. Role of the Trust Board

- To have the following responsibilities, delegated to the Quality Assurance Committee:
- To ensure that clinical audit is strategic; it happens regularly; is clinically and cost effective; and is linked to the Trust's objectives.
- To ensure that clinical audit is built into planning, performance management and reporting.
- To ensure that the recommendations of reviews and clinical audits are actioned by seeking assurance that improvements in care have been made.
- To be assured that the Trust has an appropriate process in place to deal with NICE guidance to meet regulatory requirements and ensure patient safety is maintained.

5.2. Role of the Clinical Effectiveness Group (CEG):

- To have delegated responsibility and authority to ensure that the Trust always complies with all statutory requirements on Clinical Effectiveness. To also be proactive on identifying any risks to on-going compliance and ensure timely action is taken on any issues identified:
- Clinical Effectiveness Group oversees the development of the annual audit plan.
- To gain assurance that high priority clinical audits e.g., mandatory national audits, are undertaken and completed to professional standards.
- CEG is the Group which has overall accountability for the dissemination, implementation, and monitoring of NICE guidance, supporting the organisation to achieve compliance with guidance.
- Ensure that the Escalation Process and Framework is followed as detailed

in the appendix to this Policy.

5.3. **Role of the Quality Assurance Committee (QAC):**

- The Committee has delegated responsibility and authority to ensure that the Trust always complies with all statutory requirements on Clinical Effectiveness. To also be proactive on identifying any risks to on-going compliance and ensure timely action is taken on any issues identified:

- To approve the Clinical Audit and Outcomes Programme (received from Clinical Effectiveness Group at the end of each financial year). *

5.4. **Role of the Audit and Risk Assurance Committee (ARAC):**

- The Committee has delegated responsibility and authority to ensure that the Trust always complies with all statutory requirements on Clinical Effectiveness. To also be proactive on identifying any risks to on-going compliance and ensure timely action is taken on any issues identified:

- To approve the Clinical Audit and Outcomes Programme (received from Clinical Effectiveness Group at the end of each financial year).

5.5. **Role of the Chief Medical Officer**

- Has overall accountability for clinical audit and NICE guidance within the Trust. The following are key responsibilities:

- To Chair the Clinical Effectiveness Group.

- To ensure that recommendations included in national guidance are acted on across the organisation where relevant.

- To assure the Board that all relevant national guidance is applied appropriately in the Trust.

5.6. **Role of the Care Group Management Team/Care Group Governance Lead.**

- Support the Clinical Effectiveness Team in monitoring progress made against the Care Group Clinical Audit and Outcomes Programme and implementation of NICE guidance as part of the Care Group's governance processes.

- Ensure that any risks identified by a clinical audit or related to implementation of NICE guidance are added to the Care Group risk register if appropriate. This will be achieved by the Governance Lead liaising and supporting the senior management team for the speciality to ensure the identified risks are managed appropriately.

- Ensure that the Escalation Process and Framework is followed as detailed in the appendix to this Policy.

5.7. **Role of the Head of Clinical Effectiveness.**

- Responsible for the development and implementation of governance systems, including systems for the monitoring and assessment of policies and national guidance, feeding directly into the audit prioritisation process.
- To ensure that clinical audit is part of an overall quality framework and is reported in the Trust's publicly reported Quality Accounts.
- To ensure that there are appropriate processes for instigating clinical audit as a direct result of adverse clinical events, serious incidents, and breaches in patient safety.
- Ensure that clinical audit is linked to risk and acts as a stimulus to review and improve.
- To ensure that Clinical Effectiveness is closely linked to other Trust programmes such as the Quality Improvement Programme and the Clinical School.
- Oversee all elements of the Trust's guidelines process.
- Work with the Clinical Effectiveness Team to ensure effective identification of relevant documents and recording of status information against guidance on the appropriate systems.
- Ensure appropriate reporting of status and issues to relevant committees.
- Ensure that the Escalation Process and Framework is followed as detailed in the appendix to this Policy.

5.8. **Role of the Clinical Effectiveness Team (CET):**

General

- Participate in local and national networks to ensure the Trust has the latest information relating to national guidance and practice.
- To maintain the Clinical Effectiveness intranet site and Twitter account.
- Provide training to promote the benefits of effective clinical audit as a quality improvement method and other clinical governance related topics.
- Support and provide input to other related Trust programmes such as the Quality Improvement programme and the Clinical School.

Clinical Audit:

- Maintain the online clinical audit database.
- Facilitate participation in national clinical audits and confidential enquiries.
- Encourage and assist healthcare professionals in following the standards set out in this policy.

- To provide updates of the Trust's position in relation to the Trust Clinical Audit and Outcomes Programme to Specialties, Care Groups, and relevant committees.

- Ensure that the Escalation Process and Framework is followed as detailed in the appendix to this Policy.

NICE guidance:

- Ensure the processes outlined in the standards section of this policy are followed.

- Work with the Care Group Teams to ensure that they are aware of relevant NICE guidance and any gaps are addressed.

- Work with the Specialty and Care Group Governance Leads so that Clinical Audit and Outcomes Programmes include relevant guidance activity.

- Work with the Identified Lead where there is an issue of non-compliance to ensure the exception reporting process is followed.

- Provide updates of the Trust's position in relation to NICE guidance to the relevant committees and groups, highlighting any organisational gaps in compliance and areas of organisational learning.

- Ensure that the Escalation Process and Framework is followed as detailed in the appendix to this Policy.

5.9. **Role of the Specialty Clinical Audit Lead:**

- To ensure that the processes outlined in this policy in relation to clinical audit are implemented throughout their specialty.

- To ensure that all clinical audit activity within their specialty is registered on the Trust clinical audit database and complies with nationally accepted best practice standards.

- To ensure that their specialty participates in all national clinical audits, national confidential enquiries and inquiries, and national service reviews that are relevant to the services provided.

- To work with clinicians, services managers, specialty and Care Group governance managers and the Clinical Effectiveness Team to ensure that the clinical audit programme meets all clinical, statutory, regulatory, commissioning and Trust requirements.

5.10. **Role of identified NICE Guidance lead(s):**

The identified lead for implementation of a NICE guideline has the following responsibilities:

- To ensure they follow the processes outlined in this policy in relation to NICE guidance.

- If a guideline involves several services/specialties, to work with the identified leads in other areas to provide an overall picture of compliance or to provide information in a timely manner to the person co-ordinating the responses.

- To determine what level of audit or monitoring is required to demonstrate implementation of the guidance and take appropriate action to ensure this is undertaken.

- To follow the appropriate exception reporting process where there are issues of non-compliance/partial compliance against the guidance. Where is occurs, the identified lead should ensure that an appropriate risk management strategy is in place and the issue is entered on the relevant Risk Register.

5.11. **Role of the Clinical Audit Proposer (for individual audits):**

- The proposer is often the person who will be conducting the audit.

- All staff employed by the Trust have a responsibility for the continual improvement of the quality of the service they provide, and all clinical staff are individually accountable for ensuring they audit their own practice in accordance with their professional codes of conduct and in line with the standards set out in this policy.

- The proposer will also be responsible for following the Trust Opt-Out process, where patients have requested that their data is not included within all Clinical Audit activity.

5.12. **Role of the Clinical Supervisor (for individual audits):**

- Where relevant a clinical supervisor will be identified within the specialty for each audit on the specialty clinical audit plan. The role of the nominated lead is not necessarily to conduct the audit in person.

- To ensure that the standards of performance that are audited are appropriate and give useful and effective results.

- To act as a point of contact to whom the Trust can direct questions concerning progress with the audit.

- To work with the Specialty Clinical Audit Lead to monitor progress against any recommendations/actions arising from the audit and to plan any re-audit.

6. Standards and Practice

6.1. **Trust Clinical Audit and Outcomes Programme**

- Prior to the start of every financial year, the Trust will agree an appropriate planned programme of clinical audit activity. This programme should meet the Trust's corporate requirements for assurance but must be owned by clinical services.

- The audit programme will be compiled by the Clinical Effectiveness Team in consultation with clinical services and approved by the Trust Board or delegated to the appropriate Board level committee. Regular reports on the progress of the programme will be reviewed at CEG with an annual report provided to Group at the end of the financial year.

- The clinical audit programme will reflect key national and local drivers for quality improvement and will be prioritised in line with national guidance from HQIP (as detailed in Appendix 3).

- In addition to national clinical audit topics the choice of further topics will be based on the criteria of high risk or high-profile topics identified by Trust management, many of which will emanate from governance and improvement issues.

- The Trust is committed to supporting locally determined clinical audit activity to significantly contribute to the process of continuous service quality improvement. It is acknowledged that individual clinicians may initiate a clinical audit project based on personal interest, personal development, or as part of an educational or training programme. It is important that these are registered with the Trust and reported through existing clinical governance structure to maximise organisational learning.

- The audit programme will be reviewed throughout the year and reprioritised as new issues/topics emerge.

6.2. **Approval and recording of clinical audits**

- All clinical audit activity must be registered on the clinical audit database, accessible through the Trust intranet, to ensure project consistency and to enable progress review and monitoring for quality assurance purposes.

- Each project submitted on the clinical audit database will be reviewed and approved by the relevant Specialty Clinical Audit Lead.

- Every clinical audit should have a clearly stated quality improvement aim and clearly stated objectives. The audit should measure performance against standards for process and outcomes that are based on the best available evidence and referenced, e.g., NICE guidance.

- Clinical audit must always be conducted within an ethical framework. The process for determining the choice of clinical audit projects and the way patient samples are selected, should not inadvertently discriminate against any groups in society based on their race, disability, gender, age, sexual orientation, religion or belief. Any person who has concerns regarding the ethics of clinical audit activity within the Trust should refer them in the first instance to the Head of Clinical Effectiveness.

- All clinical audits must adhere to the Trust's information governance policies and standards, paying special attention to the Data Protection Act and the Caldicott Principles.

6.3. **Process for Disseminating Audit Results/Reports/Actions**

- All Priority 1 and Priority 2 audits are required to be presented at the Clinical Effectiveness Group. This is to be done is a paper, with the required Clinical Audit reporting template. Priority 1 audits need to be presented in person – Priority 2 audits can just be reported via a paper. The arrangements for this are set out in Appendix 4.

- For each audit, the proposer must ensure that a report is produced detailing the findings and recommendations of the audit. Completed clinical audits are accepted as either a written report or as a Microsoft PowerPoint presentation. Templates are available on the Clinical Effectiveness intranet site.

- Once a round of data collection has been completed and the data has been analysed, the results and findings should be presented at specialty audit meetings, for discussion, agreement of action plans and a commitment to complete another audit cycle within a designated timeframe. The audit report agreed actions and reaudit requirements should then be added to the project record on the clinical audit database.

- Actions should be specific, measurable, achievable, and relevant. They must have clear implementation timescales, with identified leads for each action. A standardised action plan template can be accessed as part of the written report template on the Clinical Effectiveness intranet site.

- On publication of national audit results the report, along with any local results that are available, will be sent to the registered clinical lead for review and identification of actions. Leads will be expected to supply a commentary on recommendations or Trust level results and a resulting SMART action plan to address any required areas of improvement for consideration at CEG.

- Not all clinical audits will require an action plan, e.g., where an audit shows that standards are consistently and repeatedly being met, and practice is effective. For such audits there should be an explicit statement within the summary report that no further action is required, along with the reason(s) for this.

- In all cases where quality and patient safety issues highlighted by a clinical audit project cannot be resolved within the Care Group or where they affect other Care Groups, they should be discussed at CEG. Any risk issues should be entered onto the appropriate corporate or local risk register by the most appropriate manager.

- Trust audit activity, both local and national, will be reported in the annual Trust Quality Account following the format specified by NHS England/Improvement.

6.4. **Clinical Audit Training**

- Training, awareness and support programmes are available to all staff regarding the Trust's systems and arrangements for participating in clinical audit via the Clinical Effectiveness intranet website, including guides to using the clinical audit database and links to external training resources from HQIP.

- Clinical audit training will also be the provided by the Clinical Effectiveness Team upon request for staff involved in the audit process, covering the systems and processes to ensure a consistent approach to audit. This can be in the form of one-to-one support or group sessions.

6.5. **NICE GUIDANCE**

- All new guidance is reviewed by the Clinical Effectiveness Team and an appropriate lead or leads are identified. This could either be the relevant Specialty Governance Lead or a specific clinician who is known to have a special interest in the area covered by the guidance. If the initial recipient of the guidance is not the appropriate party or they feel someone else could provide a more robust response, they are asked to forward on the request and inform the Clinical Effectiveness Team. All guidance sent out will also be copied to the relevant Care Group Governance Lead(s).

- Where guidance crosses organisational boundaries, contact will be made with the relevant person, group, or committee to produce a community wide response.

- The identified lead is required to complete and return compliance information to the Clinical Effectiveness Team (copied to the relevant Care Group Governance Lead), in the form of the NICE guidance implementation questionnaire. This provides an assessment of compliance and, where partial or non-compliance is indicated, contains a section asking the lead to identify any gaps and actions required to ensure compliance/ implementation of the guidance. All responses are reviewed and centrally recorded by the Clinical Effectiveness Team and leads may be asked for further clarification on any points. Exception reports are provided to CEG to highlight any gaps or issues that may need escalation. Implementation and monitoring of actions relating to Clinical Guidelines may be incorporated into general service development, Quality Improvement, or wider service design/commissioning work.

- The NICE implementation questionnaire asks for details on how the guidance will be monitored or audited and whether local guidelines need updating. There is no specific requirement to audit NICE Guidelines or Interventional Procedures, but audit is encouraged to provide evidence against compliance statements and help identify any gaps in compliance or improvement opportunities.

- Each new Technology Appraisal will be reviewed to assess the requirement for a clinical audit to assess compliance within one year after publication. Where there are low patient numbers or sufficient monitoring systems in place e.g., the drug must be prescribed via the Bluteq prescribing system,

the lead can indicate that it may not be appropriate or necessary to audit guidance. This information is recorded on the NICE guidance status sheet and the Trust Audit and Outcomes Programme.

- Quality Standards: Audit against Quality Standards will form the foundation of specialty clinical audit programmes and feed into any Quality Improvement plans. Evidence for compliance may be available from existing national audits or monitoring processes

7. Dissemination and Implementation

7.1. This policy document will be held in the public section of the Documents Library with unrestricted access, replacing the previous version which will be archived in accordance with the Trust Information Lifecycle and Corporate Records Management Policy.

7.2. The Clinical Effectiveness Team co-ordinate the processes covered by this policy and will ensure that any staff involved in the process are aware of their roles and the requirements of the policy. The trust clinical effectiveness intranet site administered by the Clinical Effectiveness Team will include a link to the policy.

8. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Recording of actions on the audit database following completion of an audit. Process for NICE compliance information in the timescales required
Lead	Clinical Effectiveness Team
Tool	The online clinical audit database will be monitored by the Clinical Effectiveness Team – fields to be reviewed include actions recorded for completed clinical audits; audits past the anticipated end date and audits awaiting approval. The NICE guidance spreadsheets will be interrogated to identify any outliers from the agreed process.
Frequency	Annually
Reporting arrangements	The report will be presented to the CEG as described on the meeting planner
Acting on recommendations and Lead(s)	Where deficiencies have been identified, the CEG will be asked to agree corrective action and ensure that an appropriate lead is made accountable for developing and delivering an action plan that addresses these issues. The lead(s) will report back on progress to the CEG.

Information Category	Detail of process and methodology for monitoring compliance
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned within 6 months (before the next monitoring cycle) and monitored by the CEG. Where organisation-wide learning is indicated this will be disseminated by the Clinical Effectiveness Team for sharing with all relevant stakeholders.

9. Updating and Review

9.1. This policy document will be reviewed no less than every three years or more frequently following any significant process changes or national policy instruction (NHS or Department of Health).

9.2. Consultation, approval, and dissemination of subsequent revisions will follow the guidance set out in the Trust's Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies).

10. Equality and Diversity

10.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion and Human Rights Policy' or the Equality and Diversity website.

10.2. Equality Impact Assessment: The Initial Equality Impact Assessment Screening Form is at Appendix 2

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Clinical Audit and NICE Guidance Policy V4.0
This document replaces (exact title of previous version):	Clinical Audit and NICE Guidance Policy V3.0
Date Issued/Approved:	12 May 2023
Date Valid From:	May 2023
Date Valid To:	May 2026
Directorate / Department responsible (author/owner):	Head of Clinical Effectiveness
Contact details:	01872 252279
Brief summary of contents:	This policy outlines: • The organisation's values and beliefs about clinical audit and NICE Guidance. • Working definitions of clinical audit and NICE Guidance. • Key responsibilities of the staff involved in clinical audit and NICE Guidance. • A best practice framework: systems and processes. • Expectations for good governance.
Suggested Keywords:	Audit, clinical audit, quality improvement, monitoring, outcomes, NICE Guidance, national guidance
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer
Approval route for consultation and ratification:	Clinical Effectiveness Group, Then Trust Board for approval
General Manager confirming approval processes:	Richard Johnson, Head of Clinical Effectiveness

Information Category	Detailed Information
Name of Governance Lead confirming approval by specialty and care group management meetings:	Richard, Johnson, Head of Clinical Effectiveness
Links to key external standards:	Care Quality Commission, Essential Standards of Quality and Safety. Outcome 16: Assessing and monitoring the quality-of-service provision
Related Documents:	[1] HQIP (2011) New Principles of Best Practice in Clinical Audit New Principles for Best Practice in Clinical Audit. HQIP. (2020). NHS Standard Contract (2020/21) CQC Fundamental Standards of Care Health Action (UK Government, 2009) The National Health Service (Quality Accounts) Regulations (UK Government, 2010) Developing a clinical audit policy (HQIP, 2020) Best Practice in clinical audit (HQIP, 2020) Developing a clinical audit programme (HQIP, 2020) RCHT Information Governance Strategy, 2019 Development and Management of Knowledge, Procedural and Web Documents Policy (The Policy on Policies)
Training Need Identified?	Yes, this will be provided by the Clinical Effectiveness Team
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet
Document Library Folder/Sub Folder:	Clinical / Patient Safety and Clinical Effectiveness

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
08/01/19	V1.0	Previous Clinical Audit policy updated regarding Trust clinical audit processes and inclusion of Trust processes for NICE Guidance to make a new policy.	Mandy Gorton, Clinical Effectiveness Manager

Date	Version Number	Summary of Changes	Changes Made by
03/07/20	V2.0	Update of policy following publication of updated national guidance from HQIP	Mandy Gorton, Clinical Effectiveness Manager
31/10/22	V3.0	Update of Policy following Audit Southwest review of Clinical Audit governance	Richard Johnson, Head of Clinical Effectiveness.
12/5/23	V4.0	Aligned with latest Trust templates and strategy	Richard Johnson, Head of Clinical Effectiveness.

All or part of this document can be released under the Freedom of Information Act 2000

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust The Policy on Policies (Development and Management of Knowledge Procedural and Web Documents Policy). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity and Inclusion Team rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Clinical Audit and NICE Guidance Policy V4.0
Directorate and service area:	Integrated Governance
Is this a new or existing Policy?	Existing
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Richard Johnson, Head of Clinical Effectiveness
Contact details:	01872 252279

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	The Policy aims to maintain and support a culture of best practice in the management and delivery of clinical audit and compliance with NICE Guidance within the Trust.
2. Policy Objectives	• To set out clear responsibilities for staff in relation to clinical audit and NICE Guidance. • To define governance arrangements for clinical audit and NICE Guidance. • To provide a best practice framework for clinical audit and NICE Guidance
3. Policy Intended Outcomes	Effective support, monitoring and governance for all stages of clinical audit from programme planning to dissemination of results and action planning. Effective review and assessment of compliance against national best practice standards.
4. How will you measure each outcome?	Through the governance processes outlined in the policy.

Information Category	Detailed Information
5. Who is intended to benefit from the policy?	Clinical teams and patient care.
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: Yes • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	**Please record specific names of individuals/ groups:** Members of the Clinical Effectiveness Group Specialty Clinical Audit Leads Care Group Managers Care Group Governance Leads
6c. What was the outcome of the consultation?	Minor changes to wording.
6d. Have you used any of the following to assist your assessment?	**National or local statistics, audits, activity reports, process maps, complaints, staff or patient surveys:** No

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	

Protected Characteristic	(Yes or No)	Rationale
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Richard Johnson, Head of Clinical Effectiveness

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

Appendix 3. Prioritisation of Clinical Audit

The following sets out a hierarchy of importance, with priority 1 being the most important. This is modified from a model of prioritisation recommended in the HQIP publication, 'Developing a Clinical Audit Programme' (2020) available on the HQIP website.

Priority 1 — External 'must do' audits: Every healthcare provide will have several clinical audits that it must completed on a regular basis to meet external monitoring requirements. It is essential to ensure that these audits are treated as priorities and that appropriate resources are provided to support this. Failure to participate in or deliver on these externally driven audits may carry a penalty for the Trust, either financially, or in the form of a failed target, or non-compliance with regulations. External 'must-do' audits re be core to the annual clinical audit programme.

Example topics to include at this priority should be:

- NCAPOP and other national clinical audits which are relevant to the services provided and/or where participation must be reported in Quality Accounts.
- Audits demonstrating compliance with regulatory requirements e.g., audits with the aim of providing evidence of implementation of NICE guidance, and other national guidance such as that generated from the Clinical Outcomes Review Programme (CORP – covering national confidential enquiries and inquires).
- Audits required by external accreditation schemes, e.g., cancer peer review audits etc.
- Audits which must be undertaken to comply with provider policies, particularly those that are themselves subject to external review.
- Commissioner priorities including national and regional CQUIN audits.

Priority 2 — Internal 'must do' audits: internal 'must do' clinical audits are based on identified high-risk or high-profile matters arising locally. Many of these projects will arise from governance issues or high-profile local initiatives and may include national initiatives with local relevance, without penalties for non-participation.

They may include:

- Audits undertaken to meet organisational objectives and service developments.
- Clinical risk issues.
- Audits undertaken in response to serious incidents/adverse incidents /near misses/complaints, to ensure corrective actions taken to prevent a recurrence have been implemented.
- Organisational clinical priorities.
- Priorities identified via patient and public involvement initiatives.

Priority 3 — Care Group priorities: The highest priority must be given to the 'must-do' audits. Once they have been identified, the next priority should be given to projects that are important at Care Group level.

Care Group priorities may include:

- Local clinical interest audit agreed by the specialty/Care Group/service as a priority
- National audits where participation is not required to be reported in Quality Accounts
- Participation in regional audits undertaken as part of clinical specialty networks or regional clinical audit networks.

Priority 4 — Clinician interest and prioritising local audits: 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 several projects that will not fall into any of the above priorities. The lowest priority for the use of resources must be given to those audits which are proposed by individual clinicians or clinical teams. This might include audits undertaken by junior doctors for training purposes or by more senior staff as part of the revalidation process. While staff should not be discouraged from undertaking projects which can bring about real improvements in patient care, it must be made clear to all staff that the need for training or revalidation can be met by undertaking projects which also meet directorate, Care Group or organisational priorities.

Appendix 4. Clinical Audit – Priority 1 and 2 escalation arrangements

Following a review by Audit Southwest in 2022, the following arrangements are in place to ensure all Priority 1 and Priority 2 clinical audits receive scrutiny at CEG, and actions arising are tracked to completion. The following describes the escalation arrangements where this does not happen as planned.

	Requirement	Timing	Escalation arrangement
1.	**Presenting Priority 1 audits at CEG.** When a national audit is published, that this is presented by the clinical lead to CEG.	Within 4 months of the national publication.	• The Care Group Triumvirate is notified. • This omission is recorded on the Clinical Effectiveness escalation framework. • The omission is reported to CEG.
2.	**Presenting Priority 2 audits at CEG.** When the audit reaches its annual point for reporting, that this is presented by the clinical lead to CEG.	Within 4 months of the annual reporting point.	• The Care Group Triumvirate is notified. • This omission is recorded on the Clinical Effectiveness escalation framework. • The omission is reported to CEG.
3.	**CEG presentation to use required template**. A simple template has been agreed that summarises the audit and sets out agreed SMART improvement actions. Opportunities for wider learning across the Trust is also required.	Within 5 months of the national publication/annual reporting point.	• The report is NOT received at CEG. • The Care Group Triumvirate is notified. • This omission is recorded on the Clinical Effectiveness escalation framework. • The omission is reported to CEG.
4.	**Agreed actions not completed by their due date.** Each SMART action sets out what evidence is needed and the due date.	By the due date for the respective SMART action.	• The Care Group Triumvirate is notified. • This omission is recorded on the Clinical Effectiveness escalation framework. • The omission is reported to CEG.

Appendix 5. Clinical Audit – National Audit Publications and CEG reporting – Standard Operating Procedure

National Audit Publications and CEG reporting – version 27-Jun-22

Reports from national audits overseen/contracted by HQIP (audits on the NCAPOP – National Clinical Audit and Patient Outcomes Programme) are published mid-month on the HQIP site, they also send out a newsletter.

1) To access the reports:

- Go to HQIP site (works better using Chrome) https://www.hqip.org.uk/
- At the top of the page click on 'Resources'
- In the 'Resource Type' box select 'Reports' and it will filter to national audit reports only
- Clicking on one of the thumbnails will take you to a page where you can download the report
    - This will only be the overarching national report, the majority of national audits also publish trust or service level results, you will have to go to the website of the audit to find any additional reports (just google the name of the audit).

2) Folder structure:

- National audit publications are saved in folders under the appropriate year in: **S:\RCH-QSC\QSC\WIP\Clinical Effectiveness\Clinical Audit Activity\National Audits\0-NCA for reporting**
- The national audit publication tracker spreadsheet is also saved in this folder
- Go into the current year folder and each publication is saved in a separate folder named with the date of publication and the acronym for the audit.
- Set up a folder for a new publication and save all reports and communications in that folder.

3) National audit publication tracker spreadsheet:

- **S:\RCH-QSC\QSC\WIP\Clinical Effectiveness\Clinical Audit Activity\National Audits\0-NCA for reporting**
- When you set up a new folder for an audit publication add a line into the tracker
- Set up a hyperlink to the folder from the first column (title of the audit publication)
- Complete other columns

- The way I have set it up is that the last column has ‘requested for March CEG’ when the request is sent out; when the report is received these changes to ‘Added to Mar CEC’ and I highlight the whole row in purple; after CEG, as long as the report was presented, highlight the whole row in green

- Rows in grey are for publications that aren’t relevant to RCH, or the report isn’t one that includes any kind of patient data or anything that can be actioned.

- There is a different tab for each financial year.

CEG papers request

- Send out an email request to the clinical lead, copying in the Care Group governance/Service Manager/Audit Lead as appropriate
- Previous email requests are in the individual audit folders
- Attach any of the reports you have been able to find – general national report and any local reports/spreadsheets etc
- Attach the meeting report template
- Copy email to CE Manager
- Save the email in the individual national audit’s folder and in the CEG folder
- Update the national audit publication tracker as appropriate
- If the resulting paper is sent to you save it both in the national audit’s folder and the CEG meeting folder and update the tracker.
    - Check the paper when it is sent back to see if it needs any formatting and to
    - check the SMART actions table has been completed
- When the date for submission of papers is near check with Richard about the status, if he has had any responses and who will be chasing up.

4) After CEG:

- Update the publication tracker
- Add any actions from the papers to the clinical audit database (use the new option for publication of report without closing the audit)
- You may need to do some work with the leads to make the actions/recommendations listed in their report SMART so they can be added to the database