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1. Introduction

The aim of this document is to assist the North West, North Wales and Isle of Man Paediatric Critical Care, Surgery in Children, Long Term Ventilation Operational Delivery Network (NW PCC, SiC, LTV ODN) to ensure statutory and mandatory requirements for clinical audit are embedded into its governance arrangements

When carried out in accordance with best practice clinical audit will:

- Improves quality of care and patient outcomes.
- Provide assurance of compliance with clinical standards.
- Identify and minimise risk, waste, and inefficiencies.

Participation in both national and local clinical audit is a statutory and contractual requirement for healthcare providers. The NHS Standard Contract [2] forms the agreement between commissioners and providers of NHS funded services, who must:

- Participate in national clinical audits within the National Clinical Audit and Patient Outcomes Programme (NCAPOP) relevant to their services.
- Make national clinical audit data available to support publication of consultant-level activity and outcome statistics.
- Implement and/or respond to all relevant recommendations of any appropriate clinical audit.
- Implement an ongoing, proportionate programme of clinical audit of their services in accordance with best practice.
- Provide to the co-ordinating commissioner, on request, the findings of any audits carried out, in particular locally agreed requirements such as Commissioning for Quality and Innovation (CQUIN) audits.

In addition, the regulatory framework of the Care Quality Commission (CQC) requires registered healthcare providers to monitor the quality of their services.

2. Statement of purpose

The purpose of this policy is to set out the rationale for clinical audit across the ODN and provide a framework for such activity, including standards, guidance and procedures, as well as details of the support available from the ODN team:

- For registering and approving clinical audit project proposals.
- For developing and designing clinical audit projects.

This policy aims to support a culture of best practice in the management and delivery of clinical audit across the ODN, and to clarify the roles and responsibilities of all staff involved.

3. Improvement and Assurance

There are three dimensions that set out quality in the NHS as defined in the high-quality care for all: NHS next stage review[4]:

1. Patient experience: quality care is delivered for a positive experience, including being treated according to individual wants or needs, and with compassion, dignity, and respect
2. Clinical effectiveness: quality care is delivered according to the best evidence regarding what is clinically effective in improving an individual's health outcomes
3. Patient safety: quality care is delivered to prevent all avoidable harm and risks to an individual's safety.

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.
Quality assurance in healthcare is the planned and systematic monitoring of activity to ensure that the standards for safe, clinically effective services and positive patient experience are met. Quality assurance aims to provide confidence and certainty in the quality of services.

While clinical audit is fundamentally a quality improvement process that provides the opportunity for ongoing review and service development, it also plays an important role in providing assurance on the quality of services. The prime responsibility for auditing clinical care lies with the clinicians who provide that care.

The ODN is committed to ensuring:

- Participation in all national clinical audits, national confidential enquiries and inquiries, and national service reviews relevant to the PCC SiC LTV service specifications.
- All clinical audit activity is conducted in partnership with external bodies, is registered both locally and nationally as appropriate, and conforms to nationally agreed best practice standards.
- The annual audit programme of clinical audit activity meets ODN Board Assurance framework objectives and includes all of the clinical audits necessary to meet the requirements of regulators and commissioners.
- Reviews of the annual programme of clinical audit, individual clinical audit projects, as well as the results of national clinical audits, national confidential enquiries and inquiries, and national service reviews, are maintained, to:
  - Help facilitate effective clinical audit activity through robust governance systems.
  - Demonstrate compliance with requirements of regulators and commissioners.

4. Definitions

Clinical audit is a quality improvement cycle that involves measurement of the effectiveness of healthcare against agreed and proven standards for high quality care, it develops actions to bring practice in line with standards so as to improve the quality of care and health outcomes.

There are four stages of the clinical audit cycle:

- Stage 1 – Preparation and Planning: to agree required standards and clinical audit methodology.
- Stage 2 – Measuring Performance: data collection in order to evaluate performance against required standards.
- Stage 3 – Implementing Change: using action planning where shortfalls are identified.
- Stage 4 – Sustaining Improvement: through monitoring and service development, with repeated clinical audit cycles as required.

Clinical audits measured against evidence-based standards as part of an ongoing, planned annual quality assurance programme ensures that high quality care is always delivered.

5. Scope

This policy applies to all North West, North Wales and Isle of Man ODN and regional providers of:

- Paediatric critical care
- Surgery in children
- Long term ventilation

This policy also applies when clinical audit is undertaken jointly across organisational boundaries.

6. Multidisciplinary and multi-professional audit, and partnership working with other organisations

The ODN clinical audit programme will be jointly undertaken across professional and organisational boundaries. Partnership working with local and regional organisations will be necessary where improvements to the patient journey may be identified through shared clinical audit activity. The ODN supports collaboration on multiprofessional clinical audits of interest to other parts of the local health and care economy, both within and outside of the NHS, e.g. community/secondary care, local authorities, independent health and social care providers, etc.

7. Patient and Public Voice

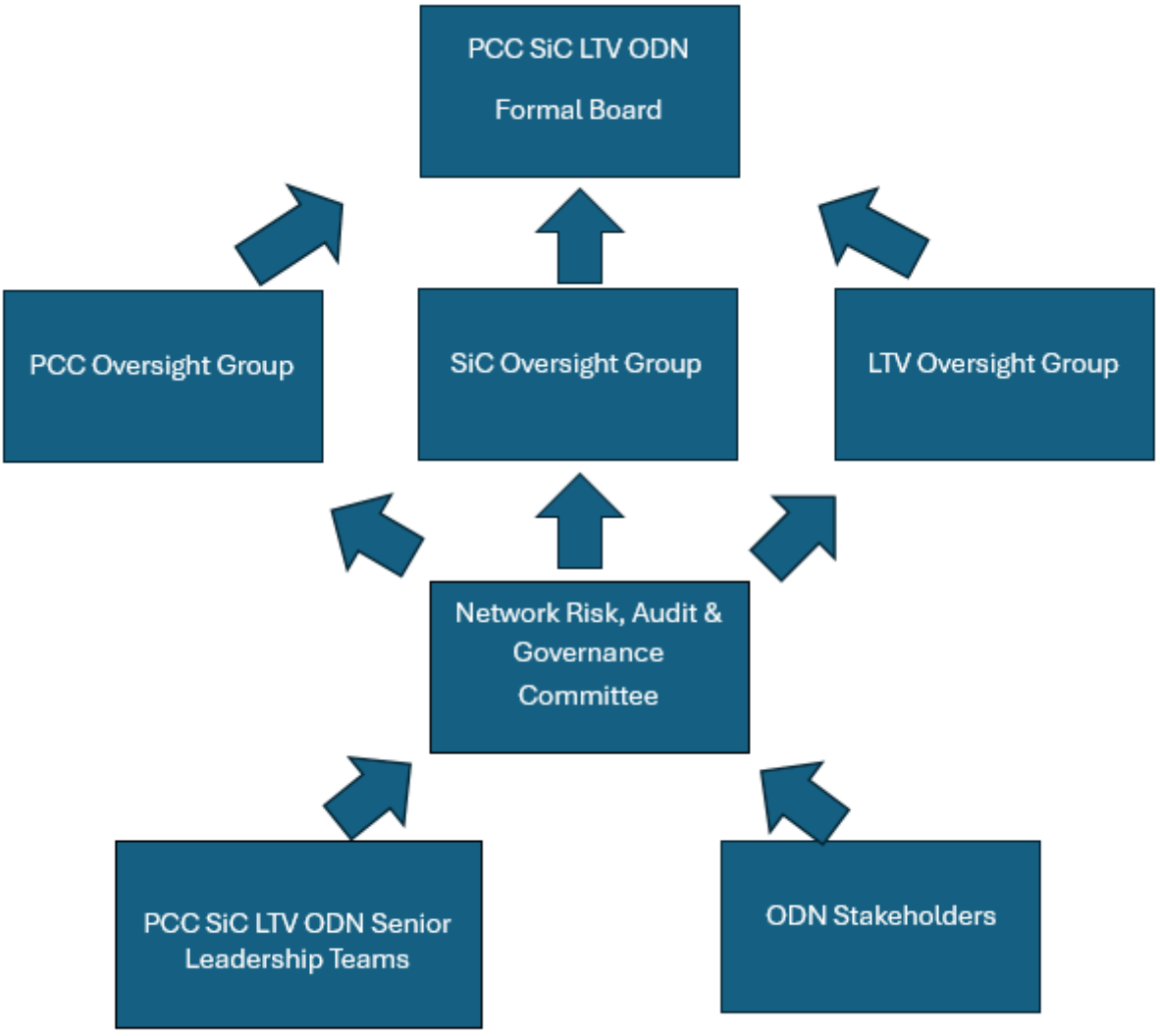
The ODN commits to involving patients, carers, and members of the public in the clinical audit process, either indirectly through the use of patient surveys and questionnaires, or directly through participation of patients, carers, and members of the public on clinical audit project steering groups or quality improvement patient panels.

8. Responsibilities

Overall responsibility for the audit programme will be via the Network Risk, Audit, Governance Committee(NRAG) which will report directly to the ODN Board via the PCC SiC LTV Oversight Committees.

The ODN NRAG will have oversight and scrutiny of the clinical audit activities, prioritisation of participation in national clinical audit and decisions about ODN clinical audit, and the review of audit reports, including progress through repeated clinical audit cycles. The NRAG will provide relevant reports to each of the ODN oversight committees will provide a full report into the ODN Board.

Governance Structure



9.Network Risk Audit Governance Committee (NRAG)

The ODN NRAG senior lead will have the following key responsibilities:

- To ensure that the ODN clinical audit strategy and annual programme of work are aligned to the ODN work programme and clinical risks.

- To ensure that clinical audit is used appropriately to support the ODN workplan and Board Terms of Reference.
- To ensure this policy is implemented across relevant stakeholders.
- To ensure that any serious concerns regarding the ODN's policy and practice in clinical audit, or regarding the results and outcomes of national and local clinical audits, are brought to the attention of the ODN Governance Board.

The Network Manager will be responsible for compiling the annual clinical audit programme supported by the Network Director, Clinical Leads and Lead Nurses for each arm of the ODN.

All providers must ensure that a senior clinician within their organisation is nominated as the lead link for ODN clinical audit. The responsibilities of this lead are:

- To ensure that the ODN audit policy is supported in their organisation.
- To ensure that all ODN clinical audit activity within their organisation is registered on their Trust database and complies with nationally accepted best practice standards.
- To ensure that their organisation participates in ODN clinical audits, that are relevant to the services provided by them.
- To ensure that the clinical audit programme meets all their clinical, statutory, regulatory, commissioning, and Trust requirements.

All members of the ODN 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 code of conduct and in line with their own services standards.

10. Clinical Audit Process

As part of the annual reporting process the NRAG will agree an appropriate planned programme of clinical audit activity. The clinical audit activity will contribute to the process of continuous service quality improvement.

For each clinical audit project:

- An audit proposal form must be completed by the project lead
- The proposal must be approved by the relevant ODN Senior Leadership Team
- All clinical audit activity must be registered with the ODN and the provider organisation, irrespective of the level of facilitation being requested, to ensure project consistency, and to enable progress review and monitoring for quality assurance purposes.
- The Audit Clinical Lead will report into the Host Organisations Audit Commitee the ODN Audit programme.

All clinical audits must involve the measuring of clinical practice against standards of best practice. These may include:

- ODN Guidelines / Standard Operating Pathways
- GIRFT Reports
- Paediatric Critical Care Standards
- Midlands Children's Long Term Ventilation Network (MCLTVN) LTV Quality Standards
- NICE guidance
- NHSE Specialised Services Specifications
- Royal College Standards
- Specialty Association Documents

A database of all clinical audit activity undertaken throughout the ODN will be recorded. This database will be updated regularly by the ODN data analyst and will be used to report to the PCC SiC LTV Oversight Committees on the progress of the annual clinical audit programme. The format and content of the database will be subject to review and approval by the NRAG.

Regular summary clinical audit reports, together with recommendations, will be reviewed by the NRAG. Once completed and the data has been analysed, the results and findings will be presented at the relevant oversight committee, for discussion, agreement of action plans and a commitment to complete another audit cycle within a designated timeframe. The ODN Governance Board will review the annual clinical audit report on completion.

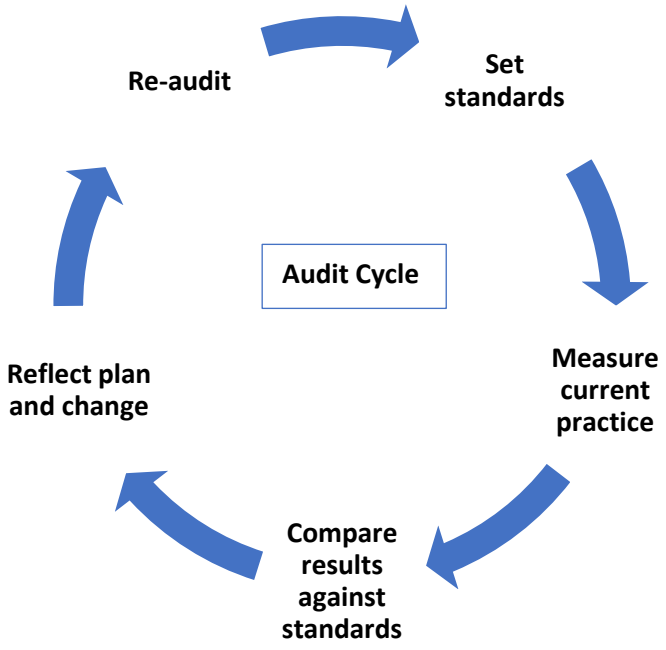
Actions plans should be specific, measurable, achievable and relevant with clear implementation timescales and identified leads for each action. Action plans must be approved by the NRAG. Where an audit shows that standards are consistently and repeatedly being met, and practice is effective an action plan is not required. 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.

The NRAG will monitor the implementation of actions, ensuring that any identified required changes are incorporated into practice and into relevant guidelines and/or risk registers as appropriate.

11. Audit cycles

The clinical audit cycle is not complete until agreed actions are implemented according to the corresponding action plan, and evidence is obtained of the impact of the action plan on compliance with standards. This may be achieved by repeating data collection or by instituting a programme of ongoing monitoring.

Repeated cycles of clinical audit may be carried out to ensure standards and criteria are consistently and repeatedly met, and practice is effective[5]



12. Clinical Audit Annual Report

The Clinical Audit Annual Report will be included in the ODN's annual reporting programme. The annual report will be approved by the ODN Board and regional ICB's. It will be disseminated by the ODN to all stakeholders and uploaded on to the ODN website.

13. Ethics and Consent

The NRAG is responsible for the ethical oversight of clinical audit for the ODN. If concerns are raised regarding the ethics of clinical audit these should be referred to the Chair of the relevant Oversight Committee.

Each audit should consider the following principles:

1. There is a benefit to existing or future patients or others that outweighs potential burdens or risks.
2. Each patient's right to self-determination is respected.
3. Each patient's privacy and confidentiality are preserved.
4. The activity is fairly distributed across patient groups.

The ODNs clinical audit programme will be managed efficiently to ensure it:

- Make best use of resources, and performance management issues associated with poor audit design, poor execution, or failure to deliver improvements in patient care, are addressed.
- Any ethical concerns that arise during the design and planning of individual clinical audits are addressed.
- Any instances of serious shortcomings in patient care that come to light through clinical audit are communicated to the clinical director of the service involved at the earliest opportunity, and appropriate steps are taken to address them.
- Risk management issues identified through clinical audit results are addressed in clinical audit action plans, and those plans are implemented effectively.

14. Equality and Diversity

The ODNs aims to ensure that it does not discriminate and, wherever possible, addresses the physical, psychological, spiritual, social, and communication needs of any patient and their family, showing no discrimination on the grounds of ethnic origin or nationality, disability, gender, gender reassignment, marital status, age, sexual orientation, race, trade union activity, or political or religious beliefs.

The process for determining choice of clinical audit projects, and the manner in which 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 the clinical audit activity within the ODN should refer them in the first instance to the NRAG, who may require equality impact assessments to be undertaken and/or equality data to be collected as part of clinical audit activity, in order to determine whether any particular groups of patients are experiencing variations in practice. If concerns are still present these should be raised to the relevant oversight committee.

15. Information Governance:

All ODN clinical audits must adhere to information governance policies and standards, paying special attention to the Data Protection Act[6] and the Caldicott Principles [7] whereby data should be:

- Adequate, relevant, and not excessive.
- Accurate.
- Processed for limited purposes.
- Held securely.
- Not kept for longer than is necessary.

Each individual organisation should ensure that data shared with the ODN is anonymised. Patient level data will be held at Trust organisation level only.

All data will be stored securely on an NHS approved laptop or computer and data should be held on NHS secured systems and must not be stored on personal devices.

16. Training and education

Staff will be signposted to the most appropriate training and education to support the clinical audit process where required. The ODN will ensure that staff have access to further relevant training in order to maintain and develop their knowledge and skills.

17. Monitoring the effectiveness of clinical audit activity

The ODNs clinical audit activity will be monitored by the Governance Board by the Clinical Audit Annual Report.

18. Monitoring the implementation of the policy

The Network Director alongside the ODN Board will monitor the progress of the ODNs clinical audit programmes and associated outcomes. It will ensure that:

- The NRAG is discharging its responsibilities.
- Staff can access appropriate training and education.
- There is a rigorous system for determining what goes into the annual clinical audit programme.
- Stakeholders are actively involved in the process and those who do not partake are escalated to the medical director for the organisation.
- Clinical audits are approved and registered.
- Clinical audits are based on standards and conducted in line with this policy.
- Projects are meeting data protection and confidentiality guidelines.
- Results are being reported and disseminated.
- Action plans are being agreed and implemented.
- Timely progress reports are being sent to commissioners.

Clinical audit monitoring reports will be provided to the relevant Oversight Committee and will be routinely reviewed by ODN Governance Board and commissioners of services. The report will include:

- Who will perform the monitoring.
- When and how the monitoring will be performed.
- What will happen if any shortfalls are identified.
- Where the results of the monitoring will be reported.
- How the resulting action plan will be progressed and monitored.

19. Appendix

Appendix 1
Clinical Audit Report Template

PCC SIC LTV ODN Clinical Audit Repor

Appendix 2

PCC SIC LTV ODN Clinical Audit Propo **Clinical Audit Proposal Form**

Appendix 3
Clinical Audit Database

PCC SiC LTV ODN Clinical Audit Datab

Appendix 4
Clinical Audit Strategy

Clinical Audit Strategy.pdf

Appendix 5
Network Risk Audit Governance Terms of Reference

PCC SiC LTV ODN
RAG-Terms of Refere

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