Reference Number: *UHB 509* Version Number: 2	Date of Next Review: Oct 2029 Previous Trust/LHB Reference Number:

Clinical Audit Policy

Policy Commitment

Cardiff and Vale University Health Board commits to a systematic, prioritised programme of clinical audit that provides assurance against evidence-based standards and drives measurable improvement. All clinical audits will be appropriately approved, registered and monitored; findings will be reported through established governance routes; identified shortfalls will result in clear improvement actions, escalation of material risks where required, and re-audit or ongoing monitoring to evidence sustained improvement. Clinical audit will support the Health Board's Duty of Quality and its wider quality management, learning and assurance arrangements.

Supporting Procedures and Written Control Documents

This policy is supported by the following documents

- Cardiff and Vale UHB Information Governance Poli**cy -** CAV IT Security & IG - CV IG policy v0.7.pdf - All Documents (sharepoint.com)
- Cardiff and Vale UHB Clinical Audit Strategy

Other supporting documents are:

- The Eight Caldicott Principles – National Data Guardian The Eight Caldicott Principles
- UK GDPR Principles – Information Commissioners office Guide to the UK GDPR Regulation
- HQIP (Healthcare Quality Improvement Document) Guide to Ensuring Data Quality in Clinical Audits HQIP CA PD 028 - Guide to Ensuring Data Quality in Clinical Audits 220212:Layout 1.qxd

Scope

This policy applies to all staff in all locations including those with honorary contracts.

In addition to the responsibilities detailed within the procedure, staff have a responsibility for making sure they meet the requirements of their role profiles and any other responsibilities delegated to them.

Equality and Health Impact Assessment (EHIA)

Part 1 - Equality Impact Assessment - The Equality and Health Impact Assessment has been considered and deemed not to be required. Equality and Diversity aspects are addressed within the policy.

Part 2 – Health Impact Assessment (HIA) - A Health Impact Assessment (HIA) is not required for this policy.

Group with authority to approve procedures written to explain how this policy will be implemented	Quality Committee
Accountable Executive or Clinical Board Director	Executive Medical Director

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments

Version Number	Date Review Approved	Date Published	Summary of Amendments
1	Approved by QSE on 18.07.2023	23.04.2024	*New policy*
2	16/10/2026	Nov 2026	No amendments, reworded paragraphs to make it easier to read.

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1. Introduction

A Healthier Wales (2018) established quality and safety as central to the future of health and social care in Wales, with an emphasis on person-centred, evidence-based care, continuous improvement and the reduction of harm, waste and unwarranted variation.

This commitment has been strengthened through the Health and Social Care (Quality and Engagement) (Wales) Act 2020 and the statutory Duty of Quality, which require NHS organisations to secure continuous improvement in the quality of services they provide. The Health and Care Quality Standards 2023 provide the supporting framework for delivering safe, effective, timely, efficient, equitable and person-centred care.

Clinical audit is an integral part of this quality management approach. It enables services to measure care against evidence-based standards, identify variation and areas for improvement, and demonstrate that actions result in improved quality and outcomes. Participation in the NHS Wales National Clinical Audit and Outcome Review Plan, where applicable, further supports organisational assurance, learning and continuous improvement.

2. Policy Statement

Cardiff and Vale University Health Board is committed to using clinical audit as an integral component of its quality management system to provide assurance, identify unwarranted variation, support learning and drive measurable and sustained improvement in the safety, effectiveness and

experience of care. Clinical audit will be used to systematically review practice against explicit, evidence-based standards and to ensure that, where standards are not met, proportionate improvement actions are agreed, implemented, monitored and re-audited to demonstrate impact and sustained compliance.

Clinical audit activity will be prioritised according to organisational and Clinical Board quality and patient safety priorities, statutory and regulatory requirements, national clinical audit and outcome review programmes, national guidance and standards, identified risks, patient safety intelligence and opportunities to reduce variation and inequalities. The Health Board will support full participation in relevant national clinical audits and will maintain robust arrangements for the timely review and escalation of results, including outlier notifications.

All clinical audits undertaken within, or on behalf of, the Health Board must have appropriate clinical and managerial oversight, be registered and managed through the approved corporate clinical audit system, use proportionate and robust methodology, comply with information governance and confidentiality requirements, and report findings through the relevant governance route. Results must be translated into clear, measurable actions with named leads and timescales, with risks escalated where necessary and learning shared across services.

Through these arrangements, the Health Board will use clinical audit to support its Duty of Quality by strengthening evidence-based decision-making, organisational learning, accountability and continuous improvement, and by providing clear assurance from service level through the Clinical Effectiveness Committee and the Health Board's quality governance structure.

3. Purpose

The purpose of this policy is to set out the rationale for clinical audit and provide a framework to support a prudent clinical audit programme designed to provide assurance and to drive improvement around quality and safety priorities:

- Patient safety priorities
- Recommendations resulting from external inspection and peer reviews

- Increased mortality rates
- Implementation of new NICE/HTW/AWMSG guidelines
- National Clinical Audit and Outcome Review Programme

4. Aims and Objectives

The policy aims to:

- Ensure full and appropriate participation in relevant national clinical audits, outcome reviews, national confidential inquiries, and national service reviews relevant to the services provided.

- Ensure all clinical audit activity within the UHB, or conducted in partnership with external bodies, is registered both locally and nationally as appropriate, and conforms to nationally agreed best practice standards (HQIP's guide, best practice in clinical audit).

- Maintain an annual audit forward plan that meets Board assurance framework objectives and includes all the clinical audits necessary to meet the requirements of regulators and commissioners.

- Maintain robust records of clinical audit activity, including reviews of the annual clinical audit plan, individual clinical audit projects, as well as the results of national clinical audits, national confidential inquiries and national service reviews, ensuing findings, recommendations, actions and evidence of improvement are documented and available to provide assurance.

- Support the development of a Health Board clinical audit forward plan aligned to key Clinical Board Quality and Patient Safety risks and priorities.

- Ensure health professionals engage in meaningful audits as part of their ongoing development.

- Ensure service evaluation activity within the UHB is registered locally along with the monitoring and reporting arrangements at the time of registration.

- Promote participation in clinical audit and service evaluation as evidence of professional development for revalidation and re-registration.

5. Scope

This policy applies to anyone engaged in clinical audit projects within the health board, including:

- All staff, including management, senior management, and Health Board members, both clinical and non-clinical, and those on short-term or honorary contracts.
- Students and trainees in any discipline.

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

The Health Board 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 of patient, carer, and members of the public on clinical audit project steering groups or quality improvement patient panels (QSE Framework, 2021)

6. Roles and Responsibilities

Lead	Responsibilities

Chief Executive Officer	The Chief Executive is accountable for the statutory duty of quality, and takes overall responsibility for this policy, for effective prioritisation to participate in national clinical audit, and for decisions about local clinical audit and service evaluation
Executive Medical Director	The Executive/Board lead for clinical audit is the Medical Director. Their responsibilities in respect of clinical audit are: • To ensure that the Health Board's clinical audit strategy and audit forward plan are aligned to the Board's strategic interests and concerns. • To ensure clinical audit is used appropriately to support the Board's assurance framework. • To ensure this policy is implemented across all clinical areas. • To be aware of any investigative projects and give formal approval where required. For example, larger scale projects which do not constitute research, but which may impact on other departments or involve an element of risk. • To ensure any serious concerns regarding the UHB'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 Board.

Associate Medical Director of Patient Safety and Clinical Effectivenss	The Associate Medical Director of Quality and Safety has responsibility for Clinical Effectiveness and is the Chair of the Clinical Effectiveness Committee which oversees the implementation and monitoring of clinical standards including NICE guidance and the outcomes of clinical audits, service evaluations and associated improvement plans.

Assistant Director of Patient Safety and Quality	The Assistant Director of Patient Safety and Quality is responsible for leading the development of Health Board Clinical Audit Policy and Strategy in relation to supporting the development of a clinical audit programme that provides assurance and supports meaningful programmes of quality improvement
Head of Patient Safety and Quality Assurance	The Head of Patient Safety and Quality Assurance is the Health Board's professional lead on specific aspects of quality governance and quality assurance ensuring compliance with quality related statutory and regulatory requirements, national and local policy, ensuring that quality governance and assurance processes are embedded throughout the Health Board. The Head of Patient Safety and Quality Assurance leads on the development of the Clinical Audit Policy and Strategy
Clinical Board Directors	Clinical Board Directors are responsible for ensuring the provision of safe, effective and high-quality care within their Clinical Board. They should ensure that clinical audit is used as an integral component of the Clinical Board's quality management system, supporting quality assurance, improvement and learning.
Clinical Directors	All Clinical Directors must ensure that a senior clinician within their directorate is nominated as the directorate lead for clinical audit, they may choose to take on this role themselves. The responsibilities of the directorate lead for clinical audit are: • To ensure this policy is implemented throughout their directorate. • To ensure all clinical audit activity within their directorate is registered on AMaT and complies with nationally accepted best practice standards. • To ensure their directorate 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, service managers, directorate/clinical board governance and quality managers, and clinical audit staff, to ensure the clinical audit programme meets all clinical, statutory, regulatory, commissioning, and health board requirements Clinical Directors are responsible for coordinating and prioritising clinical audit and service evaluation activity, avoiding unnecessary duplication, and ensuring findings are used effectively to drive improvement in patient care and service delivery.
Clinical Leads for National Clinical Audits	Clinical Directors who act as National Audit Leads are responsible for facilitating national audits, sharing findings with relevant teams, escalating barriers to audit completion, presenting results through appropriate governance forums, and ensuring audit outcomes are translated into service improvements .
Clinical Audit Leads /Quality & Patient Safety Lead for Clinical Audit	The QPS Lead for clinical audit is responsible for the operational management of the Clinical Audit Programme and facilitation of the AMaT system.
Clinical Effectiveness Committee (CEC)	The Clinical Effectiveness Committee supports the UHB's quality and safety agenda by providing oversight and assurance of clinical effectiveness activity and promoting continuous improvement in the quality and safety of care. The Committee monitors performance against relevant national standards, regulatory requirements, Welsh Risk Pool Standards and other applicable quality measures, ensuring that areas of concern and opportunities for improvement are identified and acted upon.
Quality Committee	The Quality Committee provides assurance to the Board that robust arrangements are in place to deliver high-quality, safe, effective, timely and dignified care.

Clinical Board Quality and Safety Forums	Clinical Board Quality and Safety Forums are responsible for reviewing and disseminating learning from national and local audits, ensuring findings, recommendations, and examples of good practice are shared across services to support continuous quality improvement and enhance patient care. They will provide oversight and assurance that effective systems and processes are in place to support the delivery of high-quality, safe, effective, timely and dignified care
Healthcare professional/Teams	All staff employed by the Health Board have a responsibility for the continual improvement of the quality of the service they provide. 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 within this policy. Healthcare professionals undertaking clinical audit or service evaluation must work within their professional competence and appropriate supervisory arrangements. All projects must be appropriately registered, relevant stakeholders engaged, and findings and learning shared to support service improvement. Advice should be sought from the Clinical Audit Team where required.

7. Clinical Audit

7.1 Definition of Clinical Audit

Clinical audit is a quality improvement process that seeks to improve practice and outcomes through systematic review of practice against explicit criteria and the implementation of change. (Healthcare Quality Improvement Partnership (HQIP) 2010).

Clinical audit measures against evidence-based standards as part of an ongoing, planned annual quality assurance programme that ensures that high quality care is always delivered. . Further information is available in 'Best Practice in Clinical Audit' (HQIP, 2020).

Types of audits

Tier 1 - National audits and outcome reviews mandated by Welsh Government

Tier 2 – Audits relating to patient safety priorities within the Health Board

Tier 3 – audits that are of interest to a specific clinician to support learning and professional development.

7.2 Clinical Audit process

Clinical audit involves measuring clinical practice against explicit standards of best practice. Standards may already exist locally or nationally in the form of guidelines or protocols. National standards are available for certain treatments and conditions in the form of NICE/HTW/AWMSG/Royal College/Professional body guidelines.

7.3 Definition of Service Evaluation

Service evaluation does not require systematic comparison against a predetermined standard, but by evaluating current care delivered can generate useful information to aid local decision making. Service evaluation can be a stand-alone project or may be used as a baseline for future audits, research or benchmarking.

Service evaluation and research are often used to describe similar activities. Both use systematic investigation to increase knowledge, both include the

collection and analysis of data, and may share similar data gathering methods. However, an evaluation is different from pure scientific research by its practical nature. Service evaluation is intended to be of use to those needing information to decide an action and involves judging value.

All service evaluation projects should be reviewed and approved by the clinical directors for the relevant specialty area, to ensure the project aligns with service priorities and satisfies the health board governance arrangements. All service evaluation projects will require local registration on AMaT (CAV AMaT), where the research team will have oversight to ensure the projects meets all ethical requirements.

Please refer to the Service Evaluation Procedure for more information.

8.Quality Management System

Clinical audit has an important function in the implementation of a quality management system, supporting the measurement of care against an explicit set of standards and informing quality improvement.

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.

Clinical audit is fundamentally a quality improvement process that provides the opportunity for ongoing review and service development, clinical audit also plays an important role in providing assurance on the quality of services.

Service evaluation can act as a significant contributor to the healthcare provision and determines the quality and effectiveness of a service. An evaluation can ensure that a service provider is continuously improving the delivery of services for patients.

Diagram 3 below illustrates the four components of quality management systems, Quality Planning, Quality Control, Quality Assurance and Quality Improvement.

Diagram 4 illustrates tools within those four components of quality management systems.

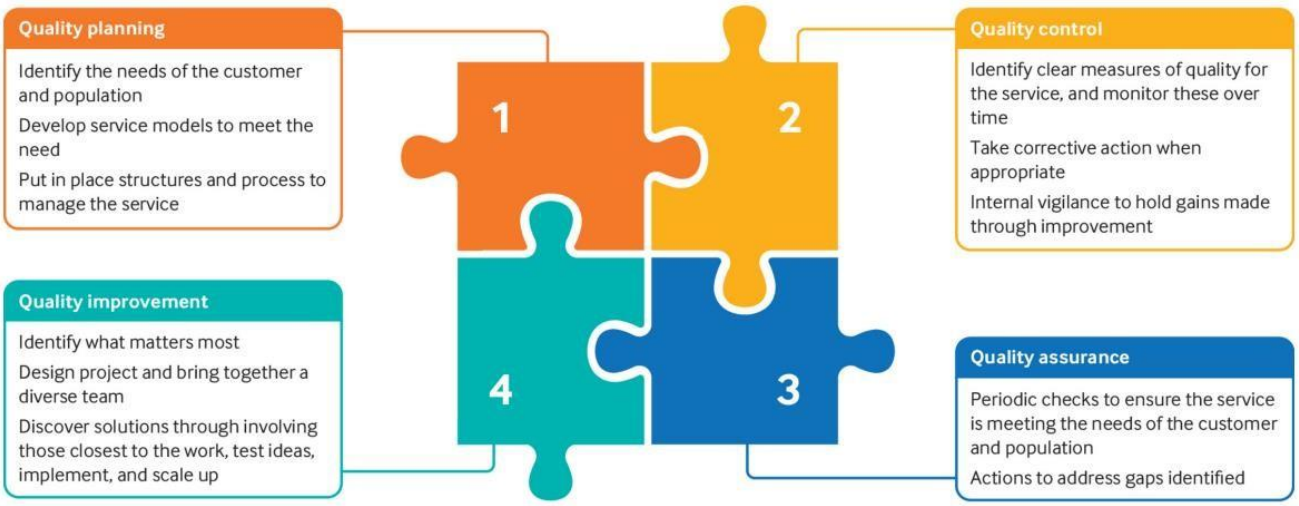

Diagram 3 (ShaH, 2020)

Tools Within the Quality Management Systems

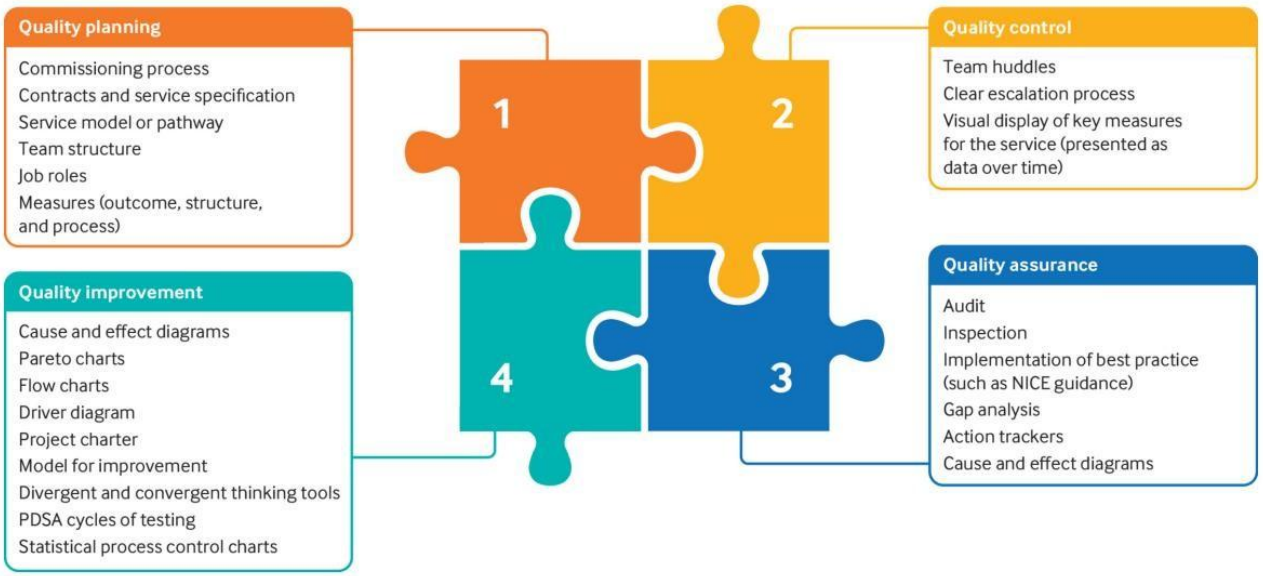

Diagram 4 (ShaH, 2020)

9. Clinical Audit Programme

The Health Board will agree an annual Clinical Audit Forward Plan that supports corporate assurance requirements and organisational priorities, while ensuring that clinical audit activity is clinically led and owned by the relevant service.

The Health Board is committed to supporting locally determined clinical audit activity to significantly contribute to the process of continuous service quality improvement.

9.1 Clinical Boards Clinical Audit Activity

A programme of Clinical Audit should be developed by each Clinical Board to provide assurance and where required to inform the necessary improvements associated with directorate quality and patient safety priorities (Tier 2 audits).

It is acknowledged that individual clinicians may initiate a clinical audit project on the basis of personal interest or personal development (Tier 3 audit). Where a clinician wishes to undertake a clinical audit for the purpose of CPD, or as part of an educational or training programme, a discussion must take place with the clinical director to ensure that wherever possible the directorate's quality and patient safety priorities and assurance requirements are considered in the first instance.

For each clinical audit project:

- The audit must be approved by the clinical director and directorate clinical audit lead.

- The audit must be registered with the Clinical Audit Department on AMaT.

- All audit findings should be reported through the appropriate Clinical Board Quality and Safety meetings with oversight of the requisite improvement plans and regular monitoring for quality assurance purposes to ensure that they are progressed appropriately.

- Inclusion on the Clinical Board Risk Register should be undertaken if the audit demonstrates that care provision falls below the required standard.

9.2 Process for National Clinical Audits

The Welsh Government publishes a National Clinical Audit and Outcome Review Programme on an annual basis. Health Organisations is Wales are expected to fully participate in the programme and ensure the necessary resources are allocated to ensure appropriate levels of case ascertainment and data completeness.

In line with the Duty of Quality Health Boards will be required to develop an Annual Quality Report and National Clinical Audit Performance and Progress Report to ensure that improvement plans have been completed and implemented.

Where a Health Board's performance in any of the national clinical audits falls outside two standard deviations from the target the organisation is deemed to be at Alert level and three standard deviations from the target then they are deemed to be at Alarm level. In this situation the Health Board will receive formal notification of outlier status from the collegiate body if at Alarm level and in many cases when at Alert level.

A National Clinical Audit Outlier Standard Operating Procedure (appendix 2) ensures a standardised approach to investigating and responding to Outlier Notifications and the development and monitoring of an improvement plan.

9.3 Clinical Audit Annual Report

A bi-annual clinical audit report will be presented to the Clinical Standards and Effectiveness Group and a bi-annual clinical audit report encompassing national, local and corporate clinical audits will be presented to the Quality Committee.

9.4 Database - AMaT (Audit Monitoring and Tracking CAV AMaT)

The Audit Monitoring and Tracking (AMaT) is the Health Board's system for registering and monitoring clinical audits and service evaluations, including progress, findings, learning, actions and supporting evidence

9.5 Clinical Audit and Service Evaluation Registration

All clinical audit and service evaluation activity must be registered and managed on the AMaT system (CAV AMaT).

The Clinical Audit Team will provide training on the use of AMaT for staff and host the system.

Once the clinical audit project registration process has been completed, the Clinical Audit Team will receive a notification, and the team will review the project to ensure it meets the relevant criteria before approval.

Service evaluation will have a slightly different approval process; submissions will be shared with the Research Team and Shaping Change for approval to ensure that any governance issues can be addressed prior to project commencement.

AMaT is a live system and should be updated regularly by the appropriate quality leads/managers to inform directorates, Clinical Boards and the Clinical Effectiveness Committee about the progress and outcome of projects undertaken.

9.6 Clinical Audit and Service Evaluation Results

All clinical audit and service evaluation results must be entered onto the AMaT system (CAV AMaT) either by undertaking data collection on AMaT or by uploading the results to the AMaT system on completion of the project. The individual directorates are responsible for quality control of the clinical audits and service evaluation projects that are conducted in their area and must ensure there is a mechanism in place for this e.g. Safety and Quality Sessions (Audit session) or Quality and Safety forums.

9.7 Dissemination and Sharing Learning

Clinical audit findings and recommendations should be shared with relevant services and governance forums to support organisational learning and improvement. Completed audits should be recorded on AMaT, enabling findings and learning to be identified and, where appropriate, shared across the UHB.

Following data collection and analysis, results should be presented at the relevant Safety and Quality Session or audit meeting to agree actions, responsibilities and timescales for improvement. Where required, re-audit should be undertaken within an agreed timeframe to demonstrate that actions have resulted in improvement and to complete the audit cycle. Completed clinical audit reports and associated action plans should be shared with the relevant clinical area.

9.8 Action Plans and Improvement

The primary purpose of clinical audit is to improve the quality and effectiveness of clinical practice. Where an audit identifies that standards are not being met, a SMART improvement plan must be developed, identifying clear actions, responsible leads and timescales for completion.

Improvement plans must be agreed with the relevant service lead or manager and recorded on AMaT, where progress and supporting evidence will be monitored. Directorates and Clinical Boards are responsible for ensuring that agreed actions are implemented and, where appropriate, reflected in business plans and/or risk registers. Progress should be monitored through the relevant quality and patient safety governance arrangements, with the Clinical

Effectiveness Committee providing oversight and assurance of clinical audit activity and associated improvement plans.

Where required, re-audit should be undertaken following implementation of the agreed actions to demonstrate that improvement has been achieved and sustained, thereby completing the audit cycle.

Where an audit demonstrates that standards are being met and no improvement action is required, the audit report should clearly record this conclusion and the supporting rationale.

9.8 Repeating Audit Cycles

The clinical audit cycle is complete only when agreed actions have been implemented and their impact on compliance has been evaluated through re-audit or ongoing monitoring. Repeated audit cycles should be undertaken where necessary to demonstrate that improvements are sustained.

10 Governance and Ethics

10.1 Ethics and Consent

The Clinical Director is responsible for approving all clinical audits and service evaluation that take place within their directorate. The Clinical Effectiveness Committee will have ethical oversight of clinical audit across the organisation to ensure the following:

- The programme of clinical audits is managed efficiently to make best use of resources, and to ensure that 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 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 with robust action plans, which are implemented effectively

Any person who has concerns regarding the ethics of a clinical audit should refer them to the Chair of the Clinical Effectiveness Committee.

10.2 Equality and Diversity

The UHB aims to ensure that its healthcare services and facilities are not discriminatory and, wherever possible, attend to the physical, psychological, spiritual, social, and communication needs of any patient or visitor, 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 the 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 clinical audit activity within the Health Board should refer them in the first instance to the Clinical Effectiveness Committee, 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.

10.3 Information governance: Collection, Storage and Retention of Data and Confidentiality

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

• Adequate, relevant, and not excessive

• Accurate
• Processed for limited purposes
• Held securely
• Not kept for longer than is necessary

11 Overall Organisational Approach

11.1 Training and Development

Clinical audit requires appropriate knowledge and skills to ensure the correct methodology is applied, and audit cycles are completed effectively. The UHB will support staff involved in undertaking or managing clinical audit to access appropriate training and protected time to develop and maintain these competencies.

Clinical audit education and training will support consistent application of best practice, build organisational capability, promote reflective practice and enable healthcare professionals to use audit findings to drive quality improvement.

Training raises the profile of clinical audit and best practice standards, builds capacity and capability for the reflective practice of all those involved, and acts as a driver for quality improvement.

11.2 Provision of Clinical Audit Training

The UHB will make available suitable training, awareness and support programmes to all relevant staff regarding the systems and arrangements for participating in clinical audit. This will ensure:

- An introductory clinical audit training session is available to any member of staff
- An ongoing programme of clinical audit training is available to all staff to enable them to undertake clinical audit
- Educational resources on clinical audit processes will be available on the Quality Assurance and Clinical Effectiveness page of the Patient Safety and Quality SharePoint page.

11.3 Employment and development of clinical audit staff

The UHB will employ a team of suitably skilled clinical audit staff to support the programme of clinical audit activity.

The UHB will ensure staff have access to further relevant training where possible, in order to maintain and develop their knowledge and skills.

9 Monitoring

9.1 Monitoring the effectiveness of clinical audit activity

The implementation of AMaT will support the UHB to ensure that:

- The Clinical Board Quality and Safety forum is discharging its responsibilities.
- Staff are receiving clinical audit training
- There is a rigorous system for determining what is represented in the annual clinical audit programme
- Stakeholders are being involved
- 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 provided to the Clinical Effectiveness Committee, Quality committee and the Management Executive Team as appropriate

13. Resources

All national clinical audits should be resourced from the clinical board in which they sit.

Where a new service is being commissioned by the Health Board consideration should be given to whether it is subject to a mandated national audit and how this will be resourced.

14. Implementation

A copy of this policy is available on the Health Board's SharePoint site.

Evidence of audit outcomes and associated improvement plans will be considered at Clinical Board performance reviews.

15. References

CAV Clinical Audit Strategy

Wales National Clinical Audit and Outcome Review Plan 2022

Quality and Safety Framework: learning and improving Welsh Government https://gov.wales/sites/default/files/publications/2021-09/quality-and-safetyframework-learning-and-improving_0.pdf

Best practice in Clinical Audit Healthcare Quality Improvement Partnership 2020 https://www.hqip.org.uk/resource/best-practice-in-clinical-audit/