Clinical audit

Internal Audit Report

Cwm Taf Morgannwg University Health Board

2020/21

June 2021

NHS Wales Shared Services Partnership

Audit and Assurance Services

Contents **Page**

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Auditors:	Lucy Jugessur, Internal Audit Manager Emma Samways, Deputy Head of Internal Audit
Executive sign off:	Nick Lyons, Medical Director
Distribution:	Dom Hurford, Interim Deputy Medical Director Mark Townsend, Head of Clinical Audit & Quality Informatics

Natalie Morgan-Thomas, Deputy Head and lead Nurse for Clinical Effectiveness

Committee: Audit & Risk Committee

Audit and Assurance Services conform with all Public Sector Internal Audit Standards as validated through the external quality assessment undertaken by the Institute of Internal Auditors.

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NHS Wales Audit & Assurance Services would like to acknowledge the time and co-operation given by management and staff during the course of this review.

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1. Introduction and Background

Our review of Clinical Audit was completed in line with the 2020/21 Internal Audit Plan for Cwm Taf Morgannwg University Health Board (the 'Health Board'). The relevant lead for the review is the Medical Director.

The Healthcare Quality Improvement Partnership (HQIP) defines clinical audit as *"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 so as to improve the quality of care and health outcomes."*

Its purpose is to engage all healthcare professionals in systematic evaluation of their clinical practice against standards and to support and encourage improvement in the quality of treatment and care. Additionally, it provides information for patients and the public on the quality of specific healthcare services being provided locally and nationally.

Each year the Health Board produces a Clinical Audit Forward Plan that sets out the national audits from the National Clinical Audit and Outcome Review Plan (NCAORP) in which they must participate. As stated in the annual plan, it is essential that these audits are treated as priorities and that appropriate resource is provided to support them. Clinical audit outcomes are an integral part of the Health Board's continuous improvement programme of work and assurance framework.

The clinical audit process within the Health Board operates on a tiered system:

- Tier 1– National audits – set out in the NCAORP
- Tier 2 – Organisation Priority audits – identified though incidents or Patient Safety Alerts
- Tier 3 & Tier 4 – local speciality clinical audits

In December 2019 the Health Board approved a number of funding bids aimed at strengthening the Clinical Audit and Quality Informatics department's ability to monitor compliance against the forward plan and improve data quality across all national audits. Funding was used to support a number of new posts, which have all been recruited to, and procure the Clinical Audit & NICE (National Institute for Health and Care Excellence) management system.

At the onset of the Covid-19 pandemic, Welsh Government advise was that all clinical audit data collection should be suspended to allow clinically qualified staff to be mobilised to the frontline. The Welsh Government later revised this guidance as they acknowledged that a blanket ban on all clinical audit work may have unintended consequences. The delayed 2020/21 plan has had one national audit removed and a national Covid-19 audit included. We understand that the clinical audit plan for 2021/22 will be taken to a committee for approval in the summer of 2021.

2. Scope and Objectives

The overall objective of this audit was to evaluate and determine the adequacy of the systems and controls in place within the Health Board in relation to Clinical Audit. Our review sought to provide assurance to the Health Board's Audit and Risk Committee that risk material to the system's objectives are managed appropriately.

The areas that the review sought to provide assurance on are:

Roles, Responsibilities and Resources

- There is a nominated lead clinician with responsibility for clinical audit across the whole organisation.
- Clinical leads for clinical audit and quality improvement are in place at an ILG level, with dedicated time for this activity.
- There are resources in place for the management and administration of the audit programme both at corporate and ILG levels.
- Relevant staff have been appropriately trained in both undertaking audits and the information governance requirements and in the use of the clinical audit system and using it to monitor data in real time.

Programme Planning

- There is a Health Board agreed approach to clinical audit that links to its strategic aims.
- There is a planned programme of clinical audit, which has been appropriately approved and in line with the Health Board's clinical audit approach.
- Arrangements are in place to engage clinicians, managers and service users/patients during the development of the programme, and to ensure Health Board priorities and risks are considered alongside national requirements.
- Audit proposals are registered, reviewed and approved in accordance with the Health Board's approach to ensure that each has clear improvement aims and objectives and a named lead responsible for delivery.
- Documented procedures are in place to ensure a consistent approach to clinical audit activity and achievement of the audit criteria.

Programme Delivery & Board Assurance

- Progress against the planned programme is reported and monitored effectively at both a corporate and ILG level, with use made of real time data from the system.
- Arrangements are in place to ensure that the outcomes of all planned audits are appropriately reported, providing assurance or identifying action where improvement is required.

- Arrangements are in place to ensure action is agreed and implemented, and improved outcomes achieved.
- Identified risks are given consideration as to where they are recorded and monitored.

3. Associated Risks

The risks considered in the review were as follows:

- Financial penalties are imposed on the Health Board where there are failed targets for 'must do' national audits.
- Clinical audit plan is not completed as resources are not available.
- Clinical issues materialise if risks are not identified due to monitoring and governance arrangements not being in place.
- Patient harm due to healthcare not meeting quality standards.
- Quality issues with service delivery not identified.

OPINION AND KEY FINDINGS

4. Overall Assurance Opinion

We are required to provide an opinion as to the adequacy and effectiveness of the system of internal control under review. The opinion is based on the work performed as set out in the scope and objectives within this report. An overall assurance rating is provided describing the effectiveness of the system of internal control in place to manage the identified risks associated with the objectives covered in this review.

The overall level of assurance that can be assigned to a review is dependent on the severity of the findings as applied against the specific review objectives and should therefore be considered in that context. The level of assurance given as to the effectiveness of the system of internal control in place to manage the risks associated with established controls within the Clinical Audit is **Reasonable assurance**.

RATING	INDICATOR	DEFINITION
Reasonable assurance		The Board can take **reasonable assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. Some matters require management attention in control design or compliance with **low to moderate impact on residual risk** exposure until resolved.

Since our previous audit review in 2017/18, significant developments have taken place within the Clinical Audit Department that have contributed to a greatly improved control environment. Changes include the purchasing of a clinical audit & NICE compliance monitoring system (AMaT), the recruitment of additional staff, restructuring around the new Integrated Locality Group (ILG) model, and producing a Clinical Audit & Effectiveness Policy & Strategy.

Roll out of the AMaT system started in April 2020, with 2020/21 seen as a transition year. All clinical audits should be recorded on the AMaT system from April 2021. Despite the pandemic, some training has been provided to staff on the use of the AMaT system. However, we found that there are a considerable number of staff that are registered on the system, that have yet to be trained. Whilst the system appears intuitive, and a number of documented procedures are in place, training is likely to be needed for some of those already registered to use the system.

Roles and responsibilities in relation to clinical audit are clearly defined, with the Executive Medical Director having overall responsibility. A Deputy Assistant Medical Director for Clinical Audit was appointed in January 2021 to oversee the clinical audit and clinical effectiveness functions. There are Clinical Auditor Manager roles to provide direct support to the ILGs.

While there is a draft Clinical Audit & Effectiveness Policy & Strategy (the 'policy'), which has been used since April 2020, at the time of our fieldwork it had not been approved by the Audit & Risk Committee.

The Health Board Clinical Audit Forward Plan 2020/21 lists the tier 1 national and tier 2 priority audits. The plan identifies all of the clinical audit projects from the National Clinical Audit and Outcome Review Plan for 2020/21. All tier 3 and tier 4 clinician speciality audits form part of the ILG clinical audit programmes. These local audits are held electronically on the AMaT system to ensure consistency in the format and recording of the clinical audit data. Although there has been a Health Board wide plan and ILG plans in place for 2020/21, these plans had either not been approved at the start of the 2020/21 year, or at all. We understand that the impact of the pandemic on clinician time and relevant meetings being able to take place has had a direct impact on the approval of plans.

Similarly, the delay in setting up governance meetings within the new ILG structure and the lack of regular meetings due to the pandemic, has meant the monitoring and performance reporting of progress against the national and local clinical audit plans has not happened in line with the draft policy. However, weekly update reports have been circulated to key individuals in the ILGs on the national audits and where monitoring reports have been presented at Board committees, these show that the majority of national audits have had data gathered in line with required timescales. We acknowledge that there has been less activity in relation to local audits over the past year as priority was given to the national audits. Furthermore,

many of the groups where these would have been monitored were stood down or met less frequently.

The draft policy that we were provided with during our fieldwork required the outcomes and actions of national and local audits to be reported to a number of forums ranging from a department's or speciality's clinical audit meetings, through to the Quality & Safety Committee. However, we did not see evidence of the outcome and actions of specific audits being reported in line with the draft policy.

Audit proposals are required to be completed prior to undertaking a clinical audit detailing the objectives, rationale and Audit Lead. We reviewed a sample of completed clinical audits and confirmed that the audit proposals were available for all of the audits in the sample.

We made one high priority recommendation in relation to the Clinical Audit and Effectiveness risk register which had previously been used to log all risks in relation to Clinical Audit Department operational and staffing issues. Going forward the register should include outlier related issues such as where the audit results show the Health Board as being an outlier in comparison to other Health Boards, or the clinical audits where there are delays or issues in collecting data and there is a risk in being able to complete the audit. At the time of our review the risk register it was not being consistently used to record these risks.

5. Assurance Summary

The summary of assurance given against the individual objectives is described in the table below:

Assurance Summary					
1	Roles, Responsibilities and Resources			✓	
2	Programme Planning			✓	
3	Programme Delivery & Board Assurance		✓		

** The above ratings are not necessarily given equal weighting when generating the audit opinion.*

Design of Systems/Controls

We did not identify any findings that are classified as a weakness in the system control/design for Clinical Audit.

Operation of System/Controls

The findings from the review highlighted six issues that are classified as weaknesses in the operation of the designed system/control for Clinical Audit.

6. Summary of Audit Findings

In this section, we highlight areas of good practice that we identified during our review. We also summarise the findings made during our audit fieldwork. The detailed findings are reported in the Management Action Plan (Appendix A).

Roles, Responsibilities and Resources

Objective: There is a nominated lead clinician with responsibility for clinical audit across the whole organisation.

We identified the following area of good practice:

- The Clinical Audit & Effectiveness Policy & Strategy confirms that the Executive Medical Director has overall responsibility for clinical audit, with delegated responsibility given to the Deputy Assistant Medical Director for Clinical Audit who oversees the clinical audit and clinical effectiveness functions.

We did not identify any findings under this objective.

Objective: Clinical leads for clinical audit and quality improvement are in place at an ILG level, with dedicated time for this activity.

We note the following:

- The Health Board are in the process of recruiting into posts that will be the clinical audit lead in each of the three ILGs. Each post holder will have dedicated time for clinical audit on their job plans.
- There are named audit leads for the national audits within each ILG. Audit leads either have dedicated sessions to fulfil their audit role or use their agreed Supporting Professional Activity (SPA) time for clinical audit and effectiveness duties. The national audit leads will report to ILG audit leads once appointed.

We did not identify any findings under this objective.

Objective: There are resources in place for the management and administration of the audit programme both at corporate and ILG levels.

We identified the following areas of good practice:

- In recent years, there has been an increase in investment within the clinical audit service that has resulted in resources to cover the TARN national trauma audit, the transition of Bridgend, NICE compliance monitoring with the appointment of a NICE Coordinator and Lead Nurse for Clinical Effectiveness and there are greater development opportunities for all staff.
- A revised Clinical Audit & Quality Informatics team structure has been put in place with dedicated staff assisting and acting as the primary contact for each ILG if required.
- There are a number of Senior Clinical Audit Facilitators within the Clinical Audit Department who along with the Interim Clinical Audit Manager and Effectiveness Mangers undertake quality assurance checks of the clinical audits and assist the Clinicians in carrying out clinical audits.

We did not identify any findings under this objective.

Objective: Relevant staff have been appropriately trained in both undertaking audits and the information governance requirements and in the use of the clinical audit system and using it to monitor data in real time.

We identified the following areas of good practice:

- From April 2021, all staff that are undertaking clinical audits and newly registered on the AMaT system are required to have user training. Following the training, we understand that a trainer will check that staff are using the system appropriately.

- The AMaT system prompts the user to do tasks at certain times to progress the clinical audit. In addition, each of the clinical audits are allocated a Clinical Audit Facilitator who undertake quality assurance checks of the work being undertaken.
- The Clinical Audit Department have a structured training programme for departments delivered over a number of sessions as and when required.

We identified the following finding:

- Since the introduction of the AMaT system in April 2020, while many staff are registered to use the system, due to the pandemic and clinical pressures, not all have received training. (Finding 2 - Medium)

Programme planning

Objective: There is a Health Board agreed approach to clinical audit that links to its strategic aims.

We identified the following:

- Since our previous audit review a draft Clinical Audit & Effectiveness Policy & Strategy has been produced. This confirms that the Executive Medical Director is responsible for ensuring the Clinical Audit Strategy is allied to the Board's strategic interests. This document has been circulated for comment to ensure that it is appropriate and has been updated in line with the observations made.

We identified the following finding:

- At the time of our review, the draft Clinical Audit & Effectiveness Policy & Strategy has been in use for over a year but has not been approved by the Audit & Risk Committee. (Finding 3 - Medium)

Objective: There is a planned programme of clinical audit, which has been appropriately approved and in line with the Health Board's clinical audit approach.

We identified the following areas of good practice:

- There is a Clinical Audit Forward Plan 2020/21 that lists the tier 1 national and tier 2 priority audits. The plan identifies all of the clinical audit projects from the National Clinical Audit and Outcome Review Plan for 2020/21.
- All tier 3 and tier 4 clinician speciality audits form part of the local ILG Clinical Audit Programmes and these are held electronically on the AMaT system for all specialities to ensure consistency in the format and recording of the clinical audit data. There is one *pro forma* on the AMaT system so that the ILGs can share learning across the three areas.

- We understand that during the pandemic the national audits were given priority and have continued, but a number of the local audits have stopped as there has not been the staff resource to continue with them. Management will review plans to see what was initially agreed and ascertain which audits can start again and archive the ones that are no longer applicable.
- Speciality and clinical audit forward plans were available for all the departments that we sampled.

We identified the following finding:

- The approval of the Clinical Audit Forward Plan for 2020/21 was delayed due to the pandemic. The ILG Clinical Audit Programme was not approved by the ILG governance groups mainly due to the ILG governance arrangements not being fully established at the time. In addition, a number of the specialities' forward plans were not approved, as the relevant meetings had ceased during the first wave of the pandemic. (Finding 4 - Medium)

Objective: Arrangements are in place to engage clinicians, managers and service users/patients during the development of the programme, and to ensure Health Board priorities and risks are considered alongside national requirements.

We identified the following areas of good practice:

- There are named clinicians for national audits as they are responsible for undertaking these audits.
- Staff that have specific interests may request to undertake local clinical audits in these areas, must obtain prior approval to ensure that they are appropriate.

We did not identify any findings under this objective.

Objective: Audit proposals are registered, reviewed and approved in accordance with the Health Board's approach to ensure that each has clear improvement aims and objectives and a named lead responsible for delivery.

We identified the following area of good practice:

- There are assurance *pro formas* for national audits that are completed by the Clinicians. A clinical audit registration form is completed for all local audits on the AMaT system detailing the rationale and objectives of the clinical audit. Our sample of forms confirmed they had been completed appropriately and included the audit rationale and objectives as well as the audit lead for the review.

We did not identify any findings under this objective.

Objective: Documented procedures are in place to ensure a consistent approach to clinical audit activity and achievement of the audit criteria

We identified the following areas of good practice:

- Tailored standard operating procedures for each of the clinical audits that are undertaken are in place for the Clinical Audit Facilitators to support and guide staff through the process for the specific audits being undertaken.
- There are documented procedures for using the AMaT system.

We did not identify any findings under this objective.

Programme delivery and Board assurance

Objective: Progress against the planned programme is reported and monitored effectively at both a corporate and ILG level, with use made of real time data from the system.

We identified the following area of good practice:

- The national audit plan is reviewed and monitored on a weekly basis by Clinical Audit Management.

We identified the following finding:

- Due to the pandemic, reports on progress of the Health Board's 2020/21 Clinical Audit Programme were not taken to the Quality & Safety Committee as set out in the draft Clinical Audit & Effectiveness Policy & Strategy that we reviewed during our fieldwork. We understand that an earlier version of the policy had a different reporting requirement, but we have not seen the document to confirm this.

  Furthermore, progress reports on the ILG Clinical Audit Programme were not taken to the Clinical Audit & Effectiveness Group and could not be taken to the ILG Governance Groups as they have only recently become fully established. In addition, as many meetings were suspended during the pandemic progress against the department, speciality or ward clinical audits were not being discussed within these forums, though we acknowledge that these local audits were not deemed a priority. (Finding 5 - Medium)

Objective: Arrangements are in place to ensure that the outcomes of all planned audits are appropriately reported, providing assurance or identifying action where improvement is required

We identified the following areas of good practice:

- We selected a sample of local clinical audits that had been completed and confirmed that the outcome of these had been presented to the speciality groups.

We identified the following finding:

- The national clinical audits outcomes and actions were not being reported to the Quality & Safety Committee as detailed within the draft policy document, although management have indicated that this was not a requirement of the previous version of the policy. There was limited reporting to the Clinical Audit and Effectiveness Group.

  In addition, local audits and recommendations should be reported to the Quality & Safety Committee and the Clinical Audit & Effectiveness Group, but at the time of our review this was not happening. We have recommended that management consider the need for the Quality & Safety Committee's to receive reports on local audits. (Finding 6 - Medium)

Objective: Arrangements are in place to ensure action is agreed and implemented, and improved outcomes achieved.

We identified the following area of good practice:

- From the sample of completed clinical audits that we reviewed, presentations were undertaken at the speciality groups and these included recommendations to address any issues identified.

We have reported the finding within the above objective (Finding 6 - Medium).

Objective: Identified clinical risks are given consideration as to where they are recorded and monitored

We identified the following area of good practice:

- The Clinical Audit and Effectiveness risk log has been expanded beyond clinical audit operational and staffing issues and will now include outlier related risks such as where the audit results show the Health Board as being an outlier in comparison to other Health Boards, or clinical audits that have delays and there is a risk in being able to complete them.

We identified the following finding:

- There were some inconsistencies with the outliers related issues being recorded on the Clinical Audit and Effectiveness risk log. In addition, the log has not been reported to the Clinical Audit & Effectiveness Group. (Finding 1 - High)

7. Summary of Recommendations

The audit findings and recommendations are detailed in Appendix A together with the management action plan and implementation timetable.

A summary of these recommendations by priority is outlined below.

Priority	H	M	L	Total
Number of recommendations	**1**	**5**	**0**	**6**

Finding 1 – Capturing, monitoring and reporting risks (Operating effectiveness)	Risk
We understand that the clinical audit and effectiveness risk register has been used for recording risks relating to the Clinical Audit Department. Following the roll out of the Health Board's updated risk management strategy, the department has been advised by management to also capture risks associated with clinical audit reviews. For example, where the outcomes of the Health Board's clinical audits are not in line with other health organisations, or where there is a risk in being able to complete the audit. While the department have agreed to record these 'outlier' risks, responsibility for monitoring and mitigation actions rests with the relevant clinician and department that have the responsibility for delivery of the service to which the clinical audit relates. At the time of our fieldwork the risk register showed two open risks and seven closed risks. As such, it did not appear to capture all of the risks that could relate to clinical audit. In addition, there did not appear to be consistency as to what was being recorded on the register in relation to audits that are at risk of not being completed. For example, when we compared the register to the clinical audit report taken to the March 2021 Quality & Safety Committee, not all of the 'amber' audits in the report were on the risk register. Furthermore, while the risk register is a standing agenda item at the Clinical Audit & Effectiveness Group meeting, we did not see evidence of its review in the meeting minutes that we reviewed.	Clinical issues materialise if risks are not identified due to monitoring and governance arrangements not being in place. Quality issues with service delivery not identified.

Recommendation	Priority level
1. Management should discuss with the Health Board's Governance Team the process to follow to ensure that risks logged in Datix, relating to clinical audits, can be allocated to clinicians to manage. 2. Management need to ensure that all clinical audit related risks are recorded consistently on the risk register, including audits that are delayed or where there has been issues with collecting the data. A wider review of risks should be undertaken to ensure that other risks, such as the reliance on the AMaT system and the current level of training uptake on the system, have been considered for inclusion on the register. 3. The Clinical Audit and Effectiveness risk register should be a standing agenda item on the Clinical Audit & Effectiveness Group and reviewed at each meeting.	**High**
Management Response	**Responsible Officer/ Deadline**
1. Meetings schedule to review the risk log arrangements and agree ILG governance arrangements for logging risks linked to clinical audit outcomes.	Head of Clinical Audit & Quality Informatics & Deputy Head CA&QI and Lead Nurse for Clinical Effectiveness - 31/08/2021
2. Management review of Clinical Audit Risk Log management and development of standard operating procedure for this process.	Head of Clinical Audit & Quality Informatics - 31/08/2021

3. The revised Clinical Audit and Effectiveness risk register has been added as a standard agenda item for the inaugural Clinical Audit & Effectiveness Group meeting in June 2021 and then as a standing agenda item.	Deputy Head CA&QI and Lead Nurse for Clinical Effectiveness - 30/06/2021

Finding 2 - Training (Operating effectiveness)	Risk
Clinical audit training within the Health Board comprises of two elements: • The clinical audit process, which includes data collection, analysing and presenting findings, benchmarking and re-auditing. • Training on the Audit Management and Tracking (AMaT) system that was implemented in April 2020. At the time of our fieldwork 1,142 users were registered on the AMaT system. While approximately 250 clinicians have had training, this has been inhibited by the pandemic. More recently 35 midwives and outreach staff have received training as part of the rollout of the ward audit module. Over the last year, some clinicians chose to continue using paper records for their audits, even though they had been registered on AMaT. Their work was subsequently input onto AMaT by the Clinical Audit Facilitators who had capacity at that time. However, from 1 April 2021 it has been agreed that all clinical audits should be undertaken directly on the AMaT system and therefore staff will need to be trained on the use of the system as will any new users. In terms of wider clinical audit training, a training programme was previously in place but there was poor uptake. As such a decision was made to not have a training programme with fixed training dates for people to enrol onto. Instead structured training is provided by a dedicated lead trainer to specific departments as and when required, with some sessions booked for June 2021.	Clinical issues materialise if risks are not identified due to monitoring and governance arrangements not being in place. Quality issues with service delivery not identified

Recommendation	Priority level
Management should ensure that departments undertaking clinical audits are provided with training on the AMaT system. In addition, the clinical audit department could target staff / departments to be trained on the AMaT system and general clinical audit principles whereby the quality reviews highlight potential problems with how their audits are being undertaken.	**Medium**
Management Response	**Responsible Officer/ Deadline**
A plan has been formalised to address the training backlog for 2021-22, caused by the pandemic, with the Deputy Assistant Medical Director for Clinical Audit that will include: • A regular training session following each monthly / bi-monthly specialty clinical audit meeting. • Formal classroom based departmental training courses booked on a monthly basis. • 1:1 Adhoc training for individual provided by their clinical audit facilitator in person or over Teams	Head of Clinical Audit & Quality Informatics - Training plan in place by 31/07/2021

Finding 3 - Clinical audit policy (Operating effectiveness)	Risk
The Health Board has a draft Clinical Audit & Effectiveness Policy & Strategy that has been used since April 2020. While the Audit & Risk Committee are responsible for approving the policy, it appears that this has not happened. We understand that the policy will be discussed at the Clinical Policy Group in May 2021, and the Quality & Safety Committee in July, before seeking approval at the August 2021 Audit & Risk Committee.	Clinical issues materialise if risks are not identified due to monitoring and governance arrangements not being in place.
Recommendation	**Priority level**
Management should ensure that the Clinical Audit & Effectiveness Policy & Strategy is approved by the correct committee as detailed within the document. Going forward, it should be reviewed on a regular basis to ensure it remains current.	**Medium**
Management Response	**Responsible Officer/ Deadline**
After consideration it was deemed inappropriate for review by the Clinical Policy Group and instead the Policy & Strategy document was approved at the Audit and Risk Committee on the 18/05/2021, Equality Impact Assessment approved on the 20/05/2021 and has been submitted for final approval at the July 2021 Quality and Safety Committee.	Executive Medical Director & Head of Clinical Audit & Quality Informatics - 31/07/2021

Finding 4 - Planned programme of clinical audits (Operating effectiveness)	Risk
The Clinical Audit & Effectiveness Policy & Strategy states that the Audit & Risk Committee has responsibility for approving the Health Board's Clinical Audit Programme and Annual Clinical Audit Forward Plan. At the start of 2020/21 Welsh Government advised that clinical audit work should be stood down due to the pandemic. Following an update to that decision, the Forward Plan was 'noted' at the October 2020 Audit & Risk committee, with approval obtained at the April 2021 committee. Whilst there was a delay in approving the 2020/21 plan, the clinical audits listed were still undertaken. We understand that the Forward Plan for 2021/22 will be presented for approval at the June 2021 committee. ILG governance groups should approve ILG clinical local audit programmes. However, the 2020/21 programmes were not approved due to the pandemic and the ILG governance groups had not been fully established at the time when the programmes should have been approved. We understand that the local programmes for 2021/22 will be approved in accordance with the requirements of the policy. We tested a sample of specialities to ensure that there were clinical audit forward plans in place. Our sample included Therapies, Obstetrics & Gynaecology, Anaesthetics, Medicine including Cardiology and Paediatrics. In all cases the forward plans were available. Therapies and Obstetrics & Gynaecology forward plans had been appropriately approved within their speciality meetings, but the	Clinical audit activity is not undertaken within the Health Board if an approved clinical audit plan is not in place.

other areas did not have their plans approved due to the relevant meetings being stood down during the height of the first wave of the pandemic.	
Recommendation	**Priority level**
Due to the Covid-19 pandemic and the pausing of committees and groups, clinical audit plans were not able to be approved as outlined in the Clinical Audit & Effectiveness Policy & Strategy. Going forward: 1. The Health Board's Clinical Audit Programme and Annual Clinical Audit Forward Plan should be appropriately approved. 2. The ILG Governance Groups, in compliance with the Clinical Audit & Effectiveness Policy & Strategy should approve their ILG clinical audit programmes. 3. The speciality groups should approve the forward work plans for each of their specialities.	**Medium**
Management Response	**Responsible Officer/ Deadline**
1. The Clinical Audit Programme and Annual Clinical Audit Forward Plan has been scheduled for approval in the July 2021 Quality & Safety Committee and dates set for quarterly updates through to March 2022. Due to purdah and the transfer of responsibilities for the NHS Wales National Clinical Audit & Outcome Review Plan (NCA&ORP) from Welsh Government to Digital Health and Care Wales (formerly known as NWIS) there is currently no date set for release of the NCA&ORP for 2021-22.	Head of Clinical Audit & Quality Informatics – 31/07/21

Therefore, the CTMUHB Clinical Audit Plan will be rolled over from the 2020-21 programme of national audits and reviewed once the NCA&ORP is released later this year.	
2. After the Clinical Audit & Effectiveness Policy & Strategy has been approved by the Quality and Safety Committee, in July 2021. The 2021-22 ILG plans will be signed off for their tier 1-4 clinical audits in accordance with the approach defined in the policy and strategy.	Head of Clinical Audit & Quality Informatics - 30/09/2021
3. The specialty group 2021-22 forward plans are on the agendas for the June – August clinical audit meetings for discussion and sign off across all specialities. In accordance with the pre-pandemic process, that was suspended during the pandemic due to restrictions placed by the Health Board on the organisation of clinical meetings.	Deputy Head CA&QI and Lead Nurse for Clinical Effectiveness - 31/08/2021

Finding 5 - Progress against the planned programme (Operating effectiveness)	Risk
The current version of the Clinical Audit & Effectiveness Policy & Strategy states that the Audit & Risk Committee should receive a bi-monthly performance report in relation to the national audits. Clinical audit reports were presented at the October 2020, February and April 2021 meetings. While the October and April reports related to approval of the 2020/21 plan, the February report provided performance and compliance information. The Quality & Safety Committee should receive a more detailed bi-monthly performance and monitoring report, including the progress against the clinical audit programme. Our review of committee papers identified an update report in May 2020, but no further reports presented until March 2021, despite the committee continuing during the pandemic. Following the audit debrief meeting we have been informed by management that the requirement to report bi-monthly was introduced in January 2021 and was not a requirement of the previous version of the policy, although we have not seen the iteration to confirm this. We understand that during the height of the pandemic the national audit plan (tier 1 & 2) was reviewed and monitored on a weekly basis by the Clinical Audit Manager to ensure progress and allow identification of potential issues. Weekly updates were also provided to key staff within the ILGs. The Clinical Audit & Effectiveness Group is responsible for reviewing progress of the local ILG clinical audit programme (tier 3 & 4). However, within the group's minutes, there was no evidence of progress against the ILG clinical audit	Clinical issues materialise if risks are not identified due to monitoring and governance arrangements not being in place.

programmes being discussed, though we did see summaries of national audits discussed at the group. We acknowledge that local audit activity was not a priority at this time. The policy further states that the ILG Governance Groups are responsible for reviewing progress of the local clinical audit programme for their areas. However, as detailed earlier, the ILG Governance groups were only set up recently and therefore the programmes were not being reviewed as anticipated. At a department and ward level, the policy states that the department, speciality or ward clinical audit meetings are responsible for monitoring progress of their own clinical audits. As earlier confirmed, meetings were suspended for a number of the specialities during the pandemic and therefore the progress against the plans were not always being discussed.	
Recommendation	**Priority level**
As the Health Board moves out of the pandemic, clarity should be sought around the role and remit of the Audit & Risk Committee and the Quality & Safety Committee to ensure there is no overlap or duplication of reporting. The Clinical Audit Department should seek advice from the governance team and consider the frequency of providing performance reports on the progress against the Health Board Clinical Audit Programme to the relevant committee. In line the Clinical Audit & Effectiveness Policy & Strategy, the Clinical Audit & Effectiveness Group, ILG Governance Groups and the department / speciality /	**Medium**

ward clinical audit meetings should review the progress of the clinical audit programmes within their areas.	
Management Response	**Responsible Officer/ Deadline**
The CTMUHB Clinical Audit Forward Plan 2021-22 will go to the July Quality & Safety Committee, subsequent update reports will then go to the QSC on a quarterly basis. Submission timetable agree with corporate team. A review of the Terms of Reference for all groups will be undertaken to ensure incorporation of the requirement to regularly review progress against the Health Board, ILG and Specialty audit plans.	Head of Clinical Audit & Quality Informatics – 31/07/2021 Deputy Assistant Medical Director for Clinical Audit & Deputy Head CA&QI and Lead Nurse for Clinical Effectiveness - 30/09/2021

Finding 6 - Outcomes and actions of all planned audits (Operating effectiveness)	Risk
The current version of the Clinical Audit & Effectiveness Policy & Strategy states that the Quality & Safety Committee is responsible for receiving a bi-monthly performance and monitoring reports which consider findings, outcomes and recommendations of national and local clinical audits. The committee is also responsible for ensuring that actions to address the risks identified through clinical audit are implemented. Our review of the two most recent clinical audit papers taken to the committee in May 2020 and March 2021, did not identify any evidence of the committee receiving the details of findings, recommendations and actions of national and local clinical audits. The clinical audit management team have since questioned if taking local audit reports to the Quality & Safety Committee is appropriate and plan to change the policy. The policy states that the Clinical Audit & Effectiveness Group is responsible for receiving summaries of national clinical audit reports and completed baseline assessments to agree recommendations and actions and completed local clinical audit reports and recommendations. Our review of the minutes of this group identified that there were updates provided on some of the national audits, but nothing relating to completed local clinical audit reports. In addition, there was no evidence of the group monitoring clinical audit action plans. We did see evidence of the outcomes of local audits (tier 3 & tier 4) being presented in relevant speciality groups.	Quality issues with service delivery not identified.

Recommendation	Priority level
Management should ensure that the Quality & Safety Committee receive, in line with agreed timescales, a performance and monitoring report which considers the findings of national and local clinical audits, including outcomes and actions to address risks identified. A decision should be made as to whether the findings of local audits should be presented at the Quality & Safety Committee or if there is a more appropriate committee or group to receive these reports. The policy should be updated to reflect any changes. In addition, the Clinical Audit & Effectiveness Group should receive summaries of national clinical audit reports and completed local clinical audit reports with recommendations and action plans.	**Medium**
Management Response	**Responsible Officer/ Deadline**
As part of the review of the Risk Log arrangements in consultation with the Deputy Assistant Medical Director for Clinical Audit and ILGs and agree the approach to considers the findings of national clinical audits, including outcomes and actions to address risks identified. We have already reviewed the policy and saw the mistake in reporting requirements and have notified for changes to made to the policy.	Head of Clinical Audit & Quality Informatics & Deputy Head CA&QI and Lead Nurse for Clinical Effectiveness - 31/08/2021 Executive Medical Director & Head of Clinical Audit & Quality Informatics – 31/07/2021

A review of the Terms of Reference for Clinical Audit & Effectiveness Group will be undertaken to ensure incorporation of the requirement to receive summaries of national clinical audit reports and completed local clinical audit reports with recommendations and action plans.	Deputy Assistant Medical Director for Clinical Audit & Deputy Head CA&QI and Lead Nurse for Clinical Effectiveness - 30/09/2021

Appendix B - Assurance opinion and action plan risk rating

Audit Assurance Ratings

 **Substantial assurance** - The Board can take **substantial assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. Few matters require attention and are compliance or advisory in nature with **low impact on residual risk** exposure.

 **Reasonable assurance** - The Board can take **reasonable assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. Some matters require management attention in control design or compliance with low to **moderate impact on residual risk** exposure until resolved.

 **Limited assurance -** The Board can take **limited assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. More significant matters require management attention with **moderate impact on residual risk** exposure until resolved.

 **No assurance** - The Board can take **no assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. More significant matters require management attention with **high impact on residual risk** exposure until resolved.

Prioritisation of Recommendations

In order to assist management in using our reports, we categorise our recommendations according to their level of priority as follows.

Priority Level	Explanation	Management action
High	Poor key control design OR widespread non-compliance with key controls. PLUS Significant risk to achievement of a system objective OR evidence present of material loss, error or misstatement.	Immediate*
Medium	Minor weakness in control design OR limited non-compliance with established controls. PLUS Some risk to achievement of a system objective.	Within One Month*
Low	Potential to enhance system design to improve efficiency or effectiveness of controls. These are generally issues of good practice for management consideration.	Within Three Months*

* Unless a more appropriate timescale is identified/agreed at the assignment.