HTA (Follow Up)

Final Internal Audit Report

2025/26

Hywel Dda University Health Board

Contents

Review Reference	HDU-2526-12
Fieldwork	February-March 2026
Executive Sign Off	April 2026
Audit Committee	April 2026
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Executive Summary

Purpose

The overall objective of this follow-up review was to assess the progress in implementing the actions agreed with management to address the issues identified in the previous Human Tissue Act audit (HDU-2526-21). This review focuses on progress made on the implementation of actions and is not a full re-audit of the topic area; therefore, an assurance rating has not been assigned.

Overview

The agreed management actions raised in the original Human Tissue Authority report were reviewed and a summary of their status is noted in the table below:

Ref.	Matter Arising	Priority Rating	Implemented	Partially Implemented	Not Implemented
1	Standardisation of SOPs and Forms	Medium	✓		
2	Staff Training	Medium	✓		
3	Central Record of Tissue Samples	Medium	✓		
4	Missing/Incomplete Traceability Documentation	High	✓		
5	Delayed Disposals/Prolonged Retention of Tissue	High	✓		
6	Mortuary Services Risk Register	Medium	✓		

Our follow-up review confirms that significant progress has been made in addressing the issues identified in the previous Human Tissue Act audit, with all actions now fully implemented. The standardisation of SOPs and Forms is considered implemented, and duplications and discrepancies have been identified and an action plan with timescales developed, however it should be noted that amendments to the documents are not due to be completed until the end of 2026.

Further details on each recommendation are provided below.

Status of Previously Agreed Management Actions

Ref	Original Key Finding	Original Responsibility & Timescale	Priority Rating	Status
1	**Standardisation of SOPs and Forms** A legacy of site-specific SOPs and documentation has resulted in multiple versions and inconsistencies. Now that all postmortems are undertaken on one site a review to consolidate and standardise SOPs, forms and documents needs to be completed to simplify naming and referencing and remove duplication and also standardise processes where practicable as part of the regional mortuary with SBUHB. This will be a significant undertaking and there is no plan in place setting out how and when this will be achieved.	Hannah Albery, Pathology Quality Manager 31 December 2025	**Medium Priority**	**Implemented** An action plan with timescales for achievement and an initial review of documents has been done to identify those that can be merged or are obsolete, however amendments to the documents are not due for completion until 31/12/26.
2	**Staff Training** Training records for a sample of six (of 16) mortuary staff were reviewed to ensure completion of training competency forms had and accurate recording on the Q-Pulse system. Five competencies were reviewed for each employee – a total sample of 30 competencies. We identified: • Seven instances where the employee had not signed and dated the competency form. • Three instances where the assessor had not signed or dated the competency form to confirm achievement of competency. • Eight instances where there was a significant period (more than two months) between the employee and assessor signed dates, including four instances of 12 months+	Cathy Cenayko, Mortuary Manager 31 December 2025	**Medium Priority**	**Implemented** We verified that a gap analysis has been undertaken to identify where records have not been uploaded to the QMS and where records have not been fully completed. Training and competence plans in Q-Pulse have been refreshed with target dates for all outstanding training and competences completed so that ongoing compliance can be monitored. We confirmed that a competency compliance target has been set at 85% (in line with the HB's target for mandatory training compliance) and saw evidence that this is being monitored via the Quality Management meetings, the HTA operational group and the HTA assurance group. A review of papers highlighted that compliance has improved month on month and achieved 69% in December 2025.

Ref	Original Key Finding	Original Responsibility & Timescale	Priority Rating	Status
	• Eight instances where the competency had not been recorded on the individual's training history record on Q-Pulse. • Inconsistency in the use of the employee and assessor signed date as the competency completion date on Q-Pulse which, given the time lapse between the two, could impact on competency renewal dates. The overall compliance position for mortuary staff training was 51% as at 22 August 2025.			
3	**Central Record of Tissue Samples** The central tracking spreadsheet does not provide oversight of tissue location, and it was not always clear at what stage of the process the active cases were. Sample testing also identified instances where the data held in the spreadsheet was incomplete or inaccurate including incorrect PM date, incorrect number of slides recorded as disposed, items recorded as disposed but still retained.	Yasmin Brown, Regional Mortuary Manager 31 December 2025	**Medium Priority**	**Implemented** We confirmed that a flowchart of the traceability process has been created and the central tracker spreadsheet has been reviewed and updated to ensure full traceability of all samples. We noted that columns have also been added to record details and dates of contact with HMC/other external stakeholders to facilitate chasing outstanding paperwork. We reviewed the new template for the tissue traceability audit and verified that it has been updated to include reconciliation of case records to the central tracker which will enable the identification and correction of discrepancies.

Ref	Original Key Finding	Original Responsibility & Timescale	Priority Rating	Status
4	**Missing/Incomplete Traceability Documentation** Sample testing of 15 active and 15 closed (disposed) cases identified: • Five instances where form LFMOR613 Tissue Blocks Retained Record was not on file, so there was no itemised list of tissue blocks retained (although the total number of blocks is documented elsewhere). • Two instances where form LFMOR416 Mortuary Specimen Transfer Record was not on file, so there was no record of the transfer of tissue from the mortuary to histology. • Five instances where form LFMOR415/13 Retained Histology Block Transfer Log was incomplete so there was no record of the transfer of tissue from histology to the mortuary. • One instance where form LFMOR409 Release & Disposal of Tissue was incomplete with details of disposal missing (although high level disposal information was recorded elsewhere), and one instance where form LFMOR640 Disposal Form did not record the pathologist details.	Hannah Albery, Pathology Quality Manager 31 December 2025	**High Priority**	**Implemented** Mortuary staff are required to acknowledge that they have received and read any newly issued procedures via the QMS system. Although we verified that the 'Standards of record keeping and good documentation practice' instructions document has been recirculated to all staff via Q-Pulse, the Pathology Quality Manager advised us that staff have confirmed that they have read them, noting the exception of staff off work at the time. We reviewed the audit template for the HTA Standards: Traceability Horizontal audit and verified that it has been updated and understand that the audit frequency will be increased to twice yearly for all sites. A review of Monthly Quality Management Meeting papers confirmed that audit findings and non-conformances are discussed at the meetings.

Ref	Original Key Finding	Original Responsibility & Timescale	Priority Rating	Status
5	**Delayed Disposals / Prolonged Retention of Tissue** Sample testing of 15 active and 15 closed cases identified: One active case (i.e. tissue samples held in the mortuary) where the Coroner's investigation had concluded in March 2024 and therefore the tissue should have been disposed of in June 2024. • One closed case (i.e. tissue samples disposed) where tissues had been recorded as disposed but some of the samples were still present in the mortuary. • Six instances where the Coroner's expiry date (i.e. disposal due date) had been miscalculated, posing a risk of premature or delayed disposal. • Ten instances of delayed disposal (for the purpose of this test we have deemed this to be more than one month after the 14-week expiry date), with one case disposed of three years after closure of the Coroner's investigation. The delayed disposals and instances of retained tissue identified have not been reported as incidents, either internally via Datix or externally to the HTA as reportable incidents (HTARIs). We were advised that confirmation of investigation closure is often not received from the Coroner in a timely manner and although the team will request updates from the Coroner's Office where capacity allows, this is outside the role of the mortuary and not documented.	Craig Baker, Cellular Pathology Service Delivery Manager 31 December 2025	**High Priority**	**Implemented** We obtained evidence that the tissues being held without consent have been disposed of correctly and that these incidents have been reported via Datix. It was determined by the Designated Individual however that these instances don't constitute HTARI's (HTARI Guidance for Establishments stating that discovery of an organ or tissue, including tissue blocks and slides, retained following post-mortem examination when they should have been disposed of are classed as HTARI's) and a professional judgement was taken to report internally and to discuss this issue at the next HTA visit. We reviewed the central tracker spreadsheet to confirm it has been updated to auto calculate the retention expiry date based on the Coroner's investigation closed date. A review of a sample of case files confirmed that the date of receipt of correspondence from HMC is now being recorded and details of follow up correspondence and updates are being noted on an action log. We confirmed that the central tracker spreadsheet now contains a column to record the date that the confirmation of investigation closure was received by the mortuary. Work is currently underway to review the tissue traceability system in collaboration with HM Coroner. The Regional Mortuary Manager engaged with key personnel at the Coroner's Office in October 2025 and has held several follow-up meetings since. These discussions have resulted in progress and an agreement to revise existing processes. Implementation of the revised processes is pending the return of key HMC staff who are currently absent. The Mortuary Service deems that inadequate communication from the understaffed Coroner's office presents a risk of breaching the HTA licence and we verified that this has been added to the operational risk register.

Ref	Original Key Finding	Original Responsibility & Timescale	Priority Rating	Status
6	**Mortuary Services Risk Register** Risks on the operational risk register require review (due June/July 2025) and updating to record progress in implementing the identified actions, any consequent impact on the risk scores and any further action required.	Craig Baker, Cellular Pathology Service Delivery Manager 31 December 2025	**Medium Priority**	**Implemented** We obtained the latest risk register and confirmed that risks have been reviewed, and the risk register updated accordingly. The Mortuary Manager has been provided with training by the DATIX risk team so that she can now access and update the risk register. We also evidenced that risks are being reported to and reviewed at the HTA assurance group.

Appendix A

Assurance Opinion

 **Substantial**	Few matters require attention and are compliance or advisory in nature. **Low impact** on residual risk exposure.
 **Reasonable**	Some matters require management attention in control design or compliance. **Low to moderate impact** on residual risk exposure until resolved.
 **Limited**	More significant matters require management attention. **Moderate impact** on residual risk exposure until resolved.
 **Unsatisfactory**	Action is required to address the whole control framework in this area. **High impact** on residual risk exposure until resolved.
 **Advisory**	Given to reviews and support provided to management which form part of the internal audit plan, to which the assurance definitions are not appropriate. These reviews are still relevant to the evidence base upon which the overall opinion is formed.

Prioritisation of Findings

Priority	Explanation
High	Significant risk to achievement of a system objective OR evidence present of material loss, error, or misstatement. Poor system design OR widespread non-compliance.
Medium	Some risk to achievement of a system objective. Minor weakness in system design OR limited non-compliance.

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Website: [Audit & Assurance Services - NHS Wales Shared Services Partnership]

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