Human Tissue Authority

Final Internal Audit Report

2025/26

Hywel Dda University Health Board

Limited Assurance

Contents

Review Reference	HDU-2526-21
Fieldwork	August – September 2025
Executive Sign Off	2 October 2025
Audit Committee	October 2025
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Executive Summary

Purpose

To provide assurance over the systems and controls in place for the management and monitoring of activities under the scope of the *Human Tissue Act 2004*.

The Human Tissue Authority (HTA) is a UK government regulatory body established under the *Human Tissue Act 2004* ('the Act') to oversee the legal and ethical framework governing the removal, storage, use, and disposal of human tissue and organs in England, Wales and Northern Ireland. NHS organisations are required to obtain a licence from the HTA to undertake post-mortem examinations and to store human tissue. Organisations must maintain comprehensive and accurate records of consent, storage conditions and the use and disposal of tissue. Compliance with the Act is essential to ensure ethical and lawful handling of human tissue and to maintain HTA licences required for mortuary services.

Overview

Our review confirmed compliance with key HTA standards in relation to the secure storage of tissue and adherence to family wishes regarding disposal. Tissue samples for all active cases reviewed could be physically located and verified, although we identified instances of missing and incomplete forms and records for both active and closed (disposed) cases, compromising full traceability. We also identified instances of delayed disposals resulting in tissue being held without consent, these had not been reported to the HTA as 'reportable incidents' (HTARIs). The mortuary service undertakes a programme of compliance audits although there is no evidence that action is taken to address areas of non-compliance. We confirmed that HTA regulations compliance matters are regularly reviewed via the internal reporting structure with significant matters escalated through the governance groups and committees. We have concluded **Limited** assurance on this area. Matters requiring management attention include:

- Procedures and associated documentation require review and updating to reflect existing working arrangements under one site (GGH) and remove duplication
- Low compliance with competency requirements and discrepancies in competency records
- Central record of tissue samples requires enhancement to provide oversight of tissue location and case progress tracking
- Missing and incomplete traceability documentation
- Delays in tissue disposal and inappropriate retention of tissue without consent
- Risks in the risk register are overdue for review

Full details of matters arising are detailed within the Findings & Agreed Action Plan.

Scope & Assurance Summary

Objectives (The objectives and associated assurance ratings are not necessarily given equal weighting when formulating the overall audit opinion.)		Related Findings	Assurance
1	Comprehensive and accurate records of consent, storage conditions and the use and disposal of human tissue are maintained, ensuring full traceability from donor to final use or disposal	1, 2, 3, 4, 5	**Limited**
2	There is oversight and monitoring of compliance with the Act, with regular assurance reporting via Health Board governance structures	4, 5, 6	**Reasonable**

Management Actions

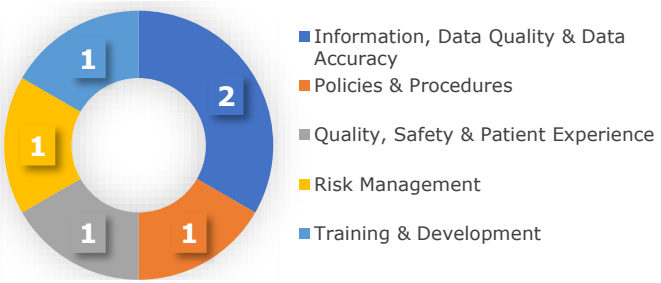
2

High Priority

4

Medium Priority

Themes



Risk Types

Legal & Regulatory Non-Compliance

Public Perception & Reputational Risk

Quality or Safety Issues

Findings & Agreed Action Plan

Objective 1: Comprehensive and accurate records of consent, storage conditions and the use and disposal of human tissue are maintained, ensuring full traceability from donor to final use or disposal	Limited

Overview / Summary of Observations

Glangwili General Hospital (GGH) is the sole licensed facility for the Health Board for undertaking postmortems (PMs), following the removal of Withybush General Hospital as a back-up facility. The Health Board's HTA licence authorises the removal and storage of human tissue for a range of scheduled purposes including determining cause of death. The licence is displayed within the mortuary at GGH.

Historically each hospital site has operated with its own set of Standard Operating Procedures (SOPs) for licensed activities, resulting in multiple versions and site-specific forms, and we observed examples of information duplicated across multiple forms. The intention is that SOPs will be updated as part of the standardisation for the regional mortuary with Swansea Bay UHB. This will be a significant undertaking and there is no plan in place setting out how and when it will be achieved. **[Finding 1]**

Review of staff training records revealed gaps in competency training for a number of staff. **[Finding 2]** Training compliance is discussed at the HTA Operational Group and the HTA Assurance Group, which reports to the Quality, Safety & Experience Sub-Committee (QSESC). The Regional HTA Assurance Group Update Report (September 2025) reported that the overall compliance position for mortuary staff training was 52% as of 22 August 2025, an improvement on the 34% in July 2025.

Tissue samples removed during PMs and retained as blocks and slides were found to be securely stored under appropriate conditions with access restricted. A central record of PMs and related tissue samples is maintained in the form of a spreadsheet. However, it 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. **[Finding 3]**

Sample review of active and closed PM cases to assess tissue traceability from donor to use and disposal identified several instances of missing or incomplete forms, although we were able to trace and physically verify the tissue samples for active cases. **[Finding 4]**

The tissue retention period as per the HTA standards is 14 weeks after the Closure of Investigation (COI) date notified by the Coroner. Sample testing identified errors in calculating the retention expiry date, delayed disposals and instances where tissue was being inappropriately retained. We were advised that in some cases these may be due to delayed notification of COI from the Coroner although there was no means of verifying this. HTA standards state that discovery of retained tissue blocks or slides that should have been disposed of and instances of unnecessary delays in disposal are 'HTA reportable incidents' (HTARIs) – the instances identified had not been reported. **[Finding 5]**

	Key Findings	Risk & Impact	Agreed Management Action
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	Outdated and inefficient SOPs and forms that don't reflect the current arrangements and/or best practice.	**Agreed Action:** Hywel Dda SOPS and forms will be reviewed and consolidated to ensure all Hywel Dda mortuaries work to the same standardisation of practice and consistency of information. An action plan will be developed to achieve this.

	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.		**Expected Evidence of Implementation:** Document review identifying duplication/discrepancies. Documented action plan with timescales for achievement.
		Medium Priority	**Officer:** Hannah Albery, Pathology Quality Manager **Target Implementation Date:** 31/12/2025 (for the action plan to be put in place)
	Theme: Policies & Procedures	Control Design	
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+ • 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.	Staff are not competent to perform their role which could impact on service capacity and quality and compliance with the Act	**Agreed Action:** Gap analysis to be undertaken to identify where records have not been uploaded to the QMS and where records have not been fully completed. Review recent audit undertaken (September 2025) of compliance with training and competences and assign target dates for completion – target dates to be updated in the QMS so ongoing compliance can be monitored. Ensure renewal period is defined in the QMS so that automatic reminders are sent to staff when training/competences are due for renewal. A competency compliance target will be determined and monitored at the HTA Operational Group.
			Expected Evidence of Implementation: Output from gap analysis. Agreed competency compliance target. Improving trend in the competency compliance rate.
		Medium Priority	**Officer:** Cathy Cenayko, Mortuary Manager **Target Implementation Date:** 31/12/2025
	Theme: Training & Development	Control Operation	
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	Tissue samples are not traceable from donor to disposal. Non-compliance with the Human Tissue Act, potentially resulting in sanction	**Agreed Action:** The central tracker will be further enhanced to ensure full traceability of tissue samples. Flowchart of the tissue traceability process to be created. Robust process to be implemented to proactively chase outstanding paperwork from external stakeholders.

	PM date, incorrect number of slides recorded as disposed, items recorded as disposed but still retained.	imposed by the HTA (e.g. loss of licence) causing service disruption and reputational damage.	The existing programme of audits will be further enhanced to include reconciliation of case records to the central tracker to identify and correct any discrepancies. **Expected Evidence of Implementation:** Updated central tracker spreadsheet. Flowchart of Traceability Process Audits evidence reconciliation of case records to central tracker.
		Medium Priority	**Officer:** Yasmin Brown, Regional Mortuary Manager
	Theme: Information, Data Quality & Data Accuracy	Control Design	**Target Implementation Date:** 31/12/2025
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.	Tissue samples are not traceable from donor to disposal. Non-compliance with the Human Tissue Act, potentially resulting in sanction imposed by the HTA (e.g. loss of licence) causing service disruption and reputational damage.	**Agreed Action:** Compliance with SOPs and completion of required documentation to ensure full traceability of tissue samples will be monitored via the existing audit programme. Standards of record keeping document to be recirculated to staff. Audit template and frequency of audit to be reviewed. Monthly Quality meetings to be established to enable more in-depth discussion of audits and audit findings. **Expected Evidence of Implementation:** Minutes of monthly quality meetings demonstrating discussion of completed audits and non-compliances discussed Standards of record keeping disseminated to staff Updated audit template (where applicable)
		High Priority	**Officer:** Hannah Albery, Pathology Quality Manager
	Theme: Information, Data Quality & Data Accuracy	Control Operation	**Target Implementation Date:** 31/12/2025
5	**Delayed Disposals / Prolonged Retention of Tissue** Sample testing of 15 active and 15 closed cases identified:	Unlawful retention of tissue samples without consent, in	**Agreed Action:** The tissue being held without consent has been disposed of immediately and in accordance with SOPs.

	• 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.	breach of the Human Tissue Act, potentially resulting in sanction imposed by the HTA (e.g. loss of licence) causing service disruption and reputational damage.	The individual cases identified will be reviewed and reported to HTA as a HTARI if appropriate. The central tracker spreadsheet will be enhanced to auto-calculate the retention expiry date based on the Coroner's investigation closed date. Paper correspondence from the Coroner will be date stamped on receipt and the central tracker spreadsheet will be enhanced to record the date that the confirmation of investigation closure is received by the mortuary. Follow-up correspondence with the Coroner's Office will be documented on the case file. If this demonstrates recurring issues with the timeliness of correspondence from the Coroner the issue will be formally escalated to the Coroner's Office by the Mortuary and then via the HTA governance structure if the issue isn't resolved. Meeting was held with HM Coroner on the 26/09/25 and a review of whole tissue traceability system is to be scheduled for October 2025. **Expected Evidence of Implementation:** Disposal forms for the tissue held without consent. Updated central tracker spreadsheet. For the individual cases identified - evidence of HTARI reporting, or justification as to why it is not applicable. Output of review of tissue traceability system. If applicable, evidence of correspondence with the Coroner's Officer re delayed communication.
		High Priority	**Officer:** Craig Baker, Cellular Pathology Service Delivery Manager
	Theme: Quality, Safety & Patient Experience	Control Design	**Target Implementation Date:** 31/12/2025

Objective 2: There is oversight and monitoring of compliance with the Act, with regular assurance reporting via Health Board governance structures	Reasonable

Overview / Summary of Observations

We reviewed mortuary related incidents recorded in Datix over the past 12 months to establish whether incidents are recorded, reviewed and corrective actions taken. There were 14 incidents recorded in Datix, although none relate to tissue samples. All but three incidents are closed. We confirmed that incidents are a standing agenda item for the HTA Operational Group and HTA Assurance Group, which evidence discussion and action taken. Datix incidents and HTARIs have also been considered at the Clinical Care Group Integrated Governance Group and escalated to the IQFPD via the Alert, Advise, Assure templates. As highlighted under objective one, our sample testing identified instances of delayed disposal and retained tissue which had not been reported as incidents either internally via Datix or externally to the HTA. **[Finding 5]**

Mortuary Services undertake a programme of audits to monitor HTA compliance of tissue blocks and slides held by the Health Board. A schedule of monthly audits is maintained in the QMS. Review of a sample of completed Tissue Traceability, Blocks and Slides and Tissue/Organs audits noted that a number of non-compliances had been identified in the audits, however there is no evidence that audit findings were followed up or addressed. An action to address this has been raised at **Finding 4**.

Risks associated with the mortuary service and compliance with Human Tissue Authority (HTA) standards are documented within the organisational risk register. Mitigating actions have been identified and are subject to ongoing monitoring through the HTA Assurance Group. Evidence was observed of risk escalation through the Clinical Care Group (CCG) governance structure, with reporting to the Quality, Safety and Experience Sub-Committee (QSESC). Risk 1552 is also scheduled for presentation to the Formal Executive Team in September for approval to escalate to the Corporate Risk Register. The current review dates for risk actions are June/July 2025, therefore, a review of progress and updates to risks and associated actions are now required. **[Finding 6]**

We confirmed that HTA compliance matters are regularly reported internally via the HD HTA Operational Group and HD HTA Assurance Group. The HTA Assurance Group provides oversight and assurance to the QSESC regarding the Health Board's responsibilities under the HTA licence and we saw evidence that QSESC receives updates from the HTA Assurance Group.

Pathology is part of the Allied Health and Health Sciences Clinical Care Group (CCG) and its IGG meets fortnightly to discuss planning, performance and people, and quality and safety maters. We observed HTA compliance updates being provided to these meetings, including assurance that findings from the 2024 HTA inspection have been addressed. However, our sample testing contradicts this and indicates that some of the issues identified in the HTA inspection have not been addressed – findings have been raised under objective 1 to address these.

Key Findings		Risk & Impact	Agreed Management Action
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.	Risks in relation to HTA compliance are not identified and mitigated	**Agreed Action:** The risk register will be reviewed and updated and reported to the HTA Assurance Group. Mortuary manager to receive risk register training to increase the number of staff able to provide updates on risks. **Expected Evidence of Implementation:**

			Updated risk register. Evidence of reporting to/discussion at HTA Assurance Group
		Medium Priority	**Officer:** Craig Baker, Cellular Pathology Service Delivery Manager
	Theme: Risk Management	Control Operation	**Target Implementation Date:** 31/12/2025

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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