



AGENDA ITEM

3.2.4

QUALITY & SAFETY COMMITTEE

HUMAN TISSUE ACT (2004) PROGRESS REPORT

Date of meeting	24/05/2023
FOI Status	Open/Public
Prepared by	Dr Paul D Davies, Assistant Director (Operational Support), HTA DI
Presented by	Dr Paul D Davies, Assistant Director (Operational Support), HTA DI
Approving Executive Sponsor	Executive Medical Director
Report purpose	FOR NOTING

Engagement (internal/external) undertaken to date (including receipt/consideration at Committee/group)

Committee/Group/Individuals	Date	Outcome
1. Executive Medical Director 2. Chief Operating Officer 3. Head of Cellular Pathology	(20/4/23)	SUPPORTED

ACRONYMS

CTMUHB	Cwm Taf Morgannwg University Health Board
DI	Designated Individual
HTA	Human Tissue Act
HTAuth	Human Tissue Authority
HTARI	Human Tissue Act Reportable Incident
PLR	Pregnancy Loss Remains

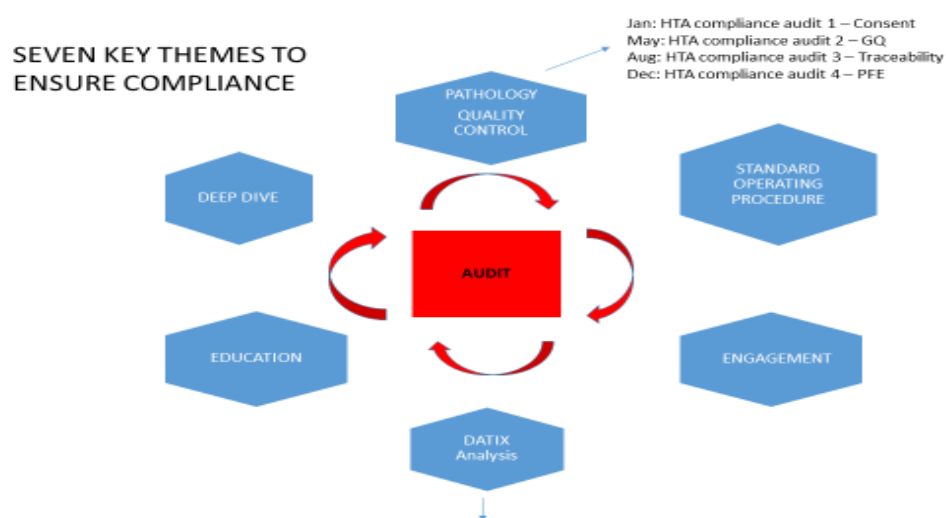
1. SITUATION/BACKGROUND

- 1.1 CTMUHB manage a range of clinical and support services which are involved in the removal, storage, use and disposal of human tissue in the Post Mortem sector across the three main hospital sites.
- 1.2 CTMUHB is thus subject to the legal requirements of the HTA (2004) and regulated by the HTAuth.
- 1.3 The purpose of this progress report is to present the progressive work toward HTA compliance and provide assurance to the Health Board that services are legally compliant.
- 1.4 Whilst within CTMUHB the main focus of the relevant HTAuth standards and guidance is the Post Mortem sector, there is also specific guidance around the management of pregnancy loss (< 24 weeks) in a number of services which is subject to regulation.
- 1.5 CTMUHB is licensed by the HTAuth through compliance inspections which are undertaken every four years or as required.
- 1.6 This report presents the findings of the most recent HTA Inspection in February 2023.

2. SPECIFIC MATTERS FOR CONSIDERATION BY THIS MEETING (ASSESSMENT)

Quality Control

- 2.1 The DI was appointed by the Health Board and HTAuth in November 2020 and has worked toward strengthening the governance of compliance with the standards set out within the HTA. The focus of the DI has predominantly focused upon seven key themes;





- 2.2 The Quality Control Department within Pathology also have a specific role in terms of ensuring there is an annual and cyclic programme of audit around the specific standards with the HTAuth Codes, predominantly Code A (Consent) and Code B (Post Mortem).
- 2.3 This quality system is augmented through regular inspections of a range of services by the DI including Mortuary Departments, Maternity Services, Emergency Departments, Theatres, Early Pregnancy Units and Gynaecology Wards.
- 2.4 For those departments outside Pathology, the focus is mainly upon compliance with guidance regarding the sensitive disposal of PLR under 24 weeks and dignity of the deceased.
- 2.5 During 2021 the DI conducted 31 inspections and 39 in 2022.
- 2.6 The frequency of inspections at all three Mortuary departments was increased in preparedness for HTAuth inspection in February 2023.
- 2.7 The outcomes of each local inspection is reported to the Persons Designated for the clinical area and corrective actions put in place.
- 2.8 Shared learning arising from all inspections is reported widely to clinical teams and the HTA Board.
- 2.9 The inspection process, coupled with the quality control programme and staff training ensures the Health Board is HTA compliant.

Engagement

- 2.10 Engagement is key to ensuring there is compliance with the HTA and making sure there is effective communication on a number of issues such as audit findings, incident outcomes, standard operating procedure reviews, improvements in standards and seeking ideas on the development of services.
- 2.11 To assist this goal the Designated Individual has introduced a network of 14 Persons Designated across a wide range of services and specialities within the Health Board, focused mainly at the three HTA licenced sites; Prince Charles Hospital, Royal Glamorgan Hospital and Princess of Wales Hospital.
- 2.12 Persons Designated appointed by the DI are able to directly influence services in relation to licensable activities.
- 2.13 The HTA recommend that the role is supplementary within the governance framework, although the DI remains responsible for supervising the activities to be authorised by the licence.
- 2.14 The DI meets with the Persons Designated group every six weeks to share learning and provide support where needed.
- 2.15 Establishing such a wide ranging network ensures that there is support across departments. To date this has been received well.
- 2.16 One key area of development for engagement has been the introduction of an *Office 365* Sharepoint page specifically to support Persons Designated and relevant clinicians/ managers in relation to the HTA.

- 2.17 With the support of the Assistant Director of ICT this intranet portal is now operational and has been helpful as a *one stop* site for all matters related to the HTA to support departments throughout the Health Board.
- 2.18 For example, the following information can be found at this site for shared learning by Persons Designated and for prospective inspection by the HTA;
- Outcomes of local inspections and audit
 - HTA newsletters
 - Incident Trend Analysis
 - Shared Learning log
 - Educational Powerpoint presentations
 - Estate reports on service records for the ventilation systems within the Mortuary Department
- 2.19 This new sharepoint page continues to be improved and developed.

Legal Compliance

- 2.20 The HTAuth have completed their full inspection of CTMUHB and the full report can be perused at Appendix 1.
- 2.21 The inspection process was undertaken in three stages;
- A Self-Assessment led by the DI in November 2022, mainly focused upon the uploading of Policies, Standards Operating Procedures, Risk Assessments and data to a secure HTA Portal
 - A Teams meeting led by the HTAuth with a range of clinicians and managers focused upon assessing Consent, Tissue Traceability and Governance (February 2023)
 - A two day inspection visit to all three HTA Licenced sites including Maternity Services at the Princess of Wales Hospital.
- 2.22 The outcome of the inspection concluded that the Designated Individual (DI) and the Licence Holder (LH) are suitable in accordance with the requirements of the legislation.
- 2.23 The HTA found that the Health Board had met the majority of the HTA's standards and only two minor shortfalls were found against standards for Consent and Governance and quality systems.
- 2.24 These related to the consent policy, recording of competency assessment for consent seekers and mortuary standard operating procedures regarding condition monitoring.
- 2.25 The DI and operational team resolved these matters in short order and thus the Corrective and Preventative Action Plan accompanying the final inspection report had both these minor shortfalls 'closed' at publication (Appendix 2).

- 2.26 The HTA also fed back 15 advisory items for the Health Board to consider within the final report.
- 2.27 Whilst advisory items are not classed as shortfalls against the current standards, they are important suggestions for quality improvements to service delivery.
- 2.28 It was indicated by HTAuth that in time some of these advisories are likely to inform future changes to statutory standards, thus it is important to consider their value in practice.
- 2.29 Most of the advisories are relatively practical to implement with a moderate cost impact to the Mortuary department.
- 2.30 Where there is a cost element to the estate it is estimated that this will cost up to 25k (Advisory Items 9, 10, 14 & 15) and potential funding is being discussed at Care Group level.
- 2.31 Some advisories are more strategic and will be discussed at the HTA Board for consideration on next steps. For example, Advisory Item 12 and the suggestion to consider relocating the Hub site for Post Mortems to reduce inter hospital transfers due to limited storage at the Royal Glamorgan Hospital.

Good Practice

- 2.32 The HTA do not publish areas of good practice within the formal inspection reports, however they did highlight a number of areas within their verbal feedback, which included;
- The dignified care provided by the Mortuary staff
 - The overall governance arrangements
 - The Tissue Traceability set up and work of the HTA Compliance department
 - Clear and well documented follow-up of actions between HTA Board meetings
 - The overall cleanliness and maintenance of the estate
 - The Maternity service compliance with the HTA standards at the Princess of Wales Hospital
 - The quality of the Porter staff and the overarching training manual which drives their practice
 - The HTA Sharepoint Portal to support Persons Designated and their role
 - The proactive and transparent engagement with the regarding service changes as well as incidents, potential incidents and corrective actions taken.
- 2.33 The Licence Holder and Executive Director of Therapies & Health Sciences have written to staff to thank and congratulate the team on such a successful outcome.



Annual Incident Analysis

- 2.34 All Datix reports which have indicated that an incident involved a deceased person and/or have key words such as "Pregnancy Loss Remains", "Death" or "Mortuary" are automatically copied to the DI.
- 2.35 This provides an 'early warning' system so that the DI can quickly follow-up such incidents, alert Persons Designated and support corrective actions.
- 2.36 All HTA related incidents are collated by the DI and presented on a quarterly basis to the HTA Board and Persons Designated and Table 1 presents data collated over the last 2 years.
- 2.37 The importance of collating such data is primarily to analyse trends and seek improvements in clinical / service areas which may be experiencing issues with training compliance and high staff turnover.

Table 1 HTA related incidents reported via DATIX from April 2021 to March 2023, by type and hospital site.

		PLR	Deceased	Equipment	Security	PCH	RGH	POW	Other	TOTAL	HTARI	Near-Miss
2021/22	Q1	3	9	0	0	0	2	10	0	12	1	0
	Q2	7	14	1	0	8	7	6	1	22	1	0
	Q3	11	15	2	0	10	10	8	0	28	0	1
	Q4	4	5	0	0	4	1	3	0	9	0	0
2022/23	Q1	4	4	0	3	6	0	4	1	11	0	1
	Q2	3	5	0	0	3	3	2	0	8	1	0
	Q3	6	6	0	1	5	2	6	0	13	0	1
	Q4	7	3	0	0	8	1	1	0	10	1	0

- 2.38 For 2021/22 there were **71** HTA related incidents including 2 HTARIs and 1 near-miss HTARI.
- 2.39 In 2022/23 there were **42** HTA related incidents including 2 HTARIs and 2 near-miss HTARI.
- 2.40 The overall reduction can be attributed to diligent follow-up and learning post incidents, general awareness raising and regular inspection and audit.
- 2.41 As with the audit programme, any shared learning from the outcomes of the incidents is communicated and discussed within the Persons Designated group and HTA Board.



3. KEY RISKS/MATTERS FOR ESCALATION TO BOARD/COMMITTEE

- 3.1 The mortuary team and relevant clinical services have demonstrated excellent leadership and great aplomb to achieve the successful HTA inspection report for 2023.
- 3.2 The overall mortuary space capacity has improved since the commissioning of a new 85 space Unit at Prince Charles Hospital in January however the waiting list for Post Mortems continues to be challenging due to the increased volume of referrals to the Coroner.
- 3.3 This is currently being managed through extra Pathology sessions procured by the Coroner's Office. However this additional demand continues to pose a risk to capacity (in particular long term storage).
- 3.4 The Mortuary Department at the Royal Glamorgan Hospital is the main centre for Post Mortems and the storage and general post mortem room space is limited. The Pathology Directorate will be leading plans to examine the advisory item 12 from the HTA inspection and its feasibility looking ahead.
- 3.5 Within the two Gynaecology clinical pathways at both the Princess of Wales Hospital and Prince Charles Hospital for women experiencing early pregnancy loss it is important that the ring-fenced beds at ward level are maintained to ensure there is a 'fast-track' from Emergency Departments on presentation. This is essential to maintain dignity and safety but has been challenging to maintain over the winter pressures at the Princess of Wales Hospital.

4. IMPACT ASSESSMENT

Quality/Safety/Patient Experience implications	Yes (Please see detail below)
Related Health and Care standard(s)	Individual Care If more than one Healthcare Standard applies please list below: Governance, Leadership & Accountability Safe Care
Equality Impact Assessment (EIA) completed - Please note EIAs are required for <u>all</u> new, changed or withdrawn policies and services.	No (Include further detail below) No changes reported to services or new policies to consider
Legal implications / impact	Yes (Include further detail below) The Human Tissue Act is a legal requirement
Resource (Capital/Revenue £/Workforce) implications / Impact	Yes (Include further detail below) Potentially up to 25k to address advisory items such as enhanced security and new



	PLR/Infant fridge to enable the release of 4 adult fridge spaces. This is currently being discussed at Care Group level.
Link to Strategic Goals	Improving Care

5. RECOMMENDATION

- 5.1 The Quality & Safety Committee are requested to **NOTE** the on-going work to assure compliance with HTA standards. The continuing need to maintain our high standards is essential to ensure the Health Board is ready for an inspection from the HTAuth at any time.
- 5.2 The Quality & Safety Committee are requested to **NOTE** the highlighted key risks looking ahead, which may adversely impact upon HTA compliance.