



**AGENDA ITEM**

3.2.11

**QUALITY & SAFETY COMMITTEE**

**HUMAN TISSUE ACT (2004)  
COMPLIANCE AND PROGRESS REPORT**

**Date of meeting**

15/11/2022

**FOI Status**

Open/Public

**If closed please indicate reason**

Not Applicable - Public Report

**Prepared by**

Dr Paul D Davies, AD & HTA Designated Individual

**Presented by**

Mr Gethin Hughes, Chief Operating Officer

**Approving Executive Sponsor**

Chief Operating Officer

**Report purpose**

FOR NOTING

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

**Committee/Group/Individuals**

**Date**

**Outcome**

Executive Medical Director &  
Chief Operating Officer

26/10/22

NOTED

**ACRONYMS**

CTMUHB

Cwm Taf Morgannwg University Health Board

HTA

Human Tissue Act

HTAuth

Human Tissue Authority

DI

Designated Individual

HTARI

Human Tissue Act Reportable Incident

## 1. SITUATION/BACKGROUND

- 1.1 The purpose of this progress report is to present the progressive work of the Designated Individual for the Human Tissue Act (2004) and provide assurance to the Health Board that services are compliant and prepared for inspection.
- 1.2 CTMUHB manage a range of clinical and support services which are involved in the removal, storage, use and disposal of human tissue.
- 1.3 CTMUHB is thus subject to the legal requirements of the HTA (2004) which subsequently established the Human Tissue Authority (HTAuth) who then regulate relevant sectors.
- 1.4 Within CTMUHB the main focus of the relevant HTAuth standards and guidance is the Post Mortem sector, although specific guidance around the management of pregnancy loss (< 24 weeks) in a number of services (i.e. Maternity, Theatres, Gynaecology) also apply.
- 1.5 CTMUHB is licensed by the HTAuth at our three main District General Hospital sites and compliance inspections take place every four years or as required (last inspection 2018).

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

- 2.1 The Designated Individual was appointed by the Health Board and Human Tissue Authority (HTAuth) in November 2020 and has worked toward strengthening the governance of compliance with the standards set out within the HTA. The focus has predominantly been focused upon six key themes;

- 2.1.1 Quality Control
- 2.1.2 Engagement
- 2.1.3 Deep Dive events
- 2.1.4 Standard Operating Procedures
- 2.1.5 Education
- 2.1.6 Trend analysis

- 2.2 To ensure transparency these six key themes are the basis of the Designated Individual reporting to the HTA Board chaired by the Licence Holder, Dr Dom Hurford Executive Medical Director.

### Quality Control

- 2.3 The Quality Control Department within Pathology 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 the recently updated Code B (Post Mortem). These standards can be perused at [Home | Human Tissue Authority \(hta.gov.uk\)](https://www.hta.gov.uk)

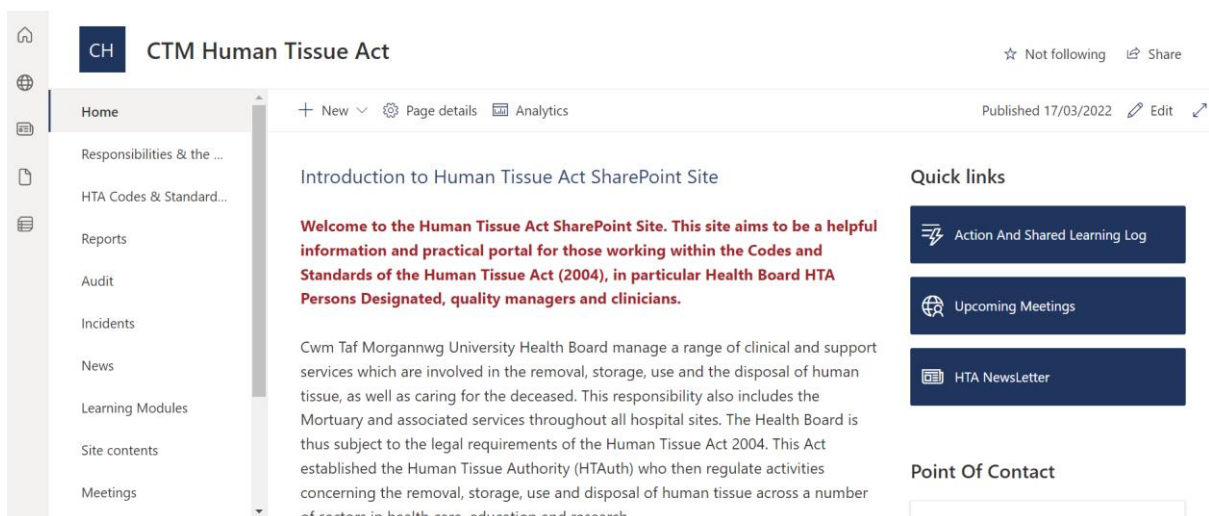


- 2.4 This quality system is augmented through regular inspections of a range of services by the DI including Mortuary Departments, Maternity Services, Emergency Departments, Theatres, Early Pregnancy Units and Gynaecology Wards.
- 2.5 For those departments outside Pathology, the focus is mainly upon compliance with guidance regarding the sensitive disposal of pregnancy loss remains under 24 weeks and dignity of the deceased.
- 2.6 During 2021 the DI conducted 31 inspections. From January to September 2022 a total number of 33 inspections have been conducted. The frequency of inspections at all three Mortuary departments have been increased in preparedness for HTA inspection.
- 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 Within the last 24 months the Designated Individual has observed significant improvements through inspections and shared learning, including the following examples;
- New flooring at the Royal Glamorgan Hospital Mortuary Department body store and a number of improvements in the general estate
  - Replacement of equipment to maintain health and safety
  - Introduction of a checklist at Ward level for improving care and dignity for the deceased prior to transfer to the Mortuary Department
  - Improvements in the clinical pathway for patients attending Emergency Departments and requiring Gynaecology services
  - Revisions in Policies and Standard Operating Procedures
  - Improvements in security and controlled access to Mortuary Departments.
- 2.10 The inspection process, coupled with the quality control programme within Pathology will continue and indeed intensify to ensure the Health Board is HTA compliant and ready for inspection.

### **Engagement**

- 2.11 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.
- 2.12 To assist this goal the Designated Individual has introduced a network of 15 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.

- 2.13 Person's Designated appointed by the DI are able to directly influence services in relation to licensable activities.
- 2.14 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.
- 2.15 The DI meets with the Person's Designated group every six weeks to share learning, discuss developments and provide support where needed.
- 2.16 Establishing such a wide ranging network ensures that there is support across departments. To date this has been received well.
- 2.17 One key area of development for engagement is the introduction of an Office360 Sharepoint page specifically to support Persons Designated and relevant clinicians/ managers in relation to the HTA.
- 2.18 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.
- 2.19 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
- 2.20 This new sharepoint page continues to be improved and developed.



### **Deep Dive events**

- 2.21 Since October 2021 the DI has led a number of *Deep Dive* sessions to examine in detail each of the HTAct standards within Code A and B to undertake a gap analysis and subsequent corrective actions.
- 2.22 Further sessions have been conducted in 2022 focusing upon Post Mortem tissue traceability and Post Mortem examination.
- 2.23 Such *Deep Dive* events have ensured there is a detailed review of compliance and preparedness for the next HTAuth inspection. In particular, an analysis of any outstanding Standard Operating Procedures for review.
- 2.24 These events will continue as needed to ensure compliance with the HTA standards.

### **Standard Operating Procedures**

- 2.25 Contemporary, evidence-based Policies and Standard Operating Procedures are the bedrock to compliance.
- 2.26 Through the method of *Deep Dive* events all Policies and Standard Operating Procedures have been reviewed for relevancy and whether they remain contemporary.
- 2.27 There are no significant outstanding reviews and recently the DI has led a review of PATH 02, our Policy for the sensitive disposal of pregnancy remains. The newly revised policy is now operational and update sessions are available to clinical staff.

### **Education**

- 2.28 The Mortuary Department have an on-going training programme with regards to HTA standards which is checked on a regular basis for compliance.
- 2.29 A PATH 02 training Powerpoint presentation with a competency checklist has been rolled out beyond Maternity services to Emergency Departments, Theatres, Early Pregnancy Units and Gynaecology services.
- 2.30 The DI has been leading teaching sessions in Gynaecology regarding PATH 02 for new staff and an essential update for existing staff members.

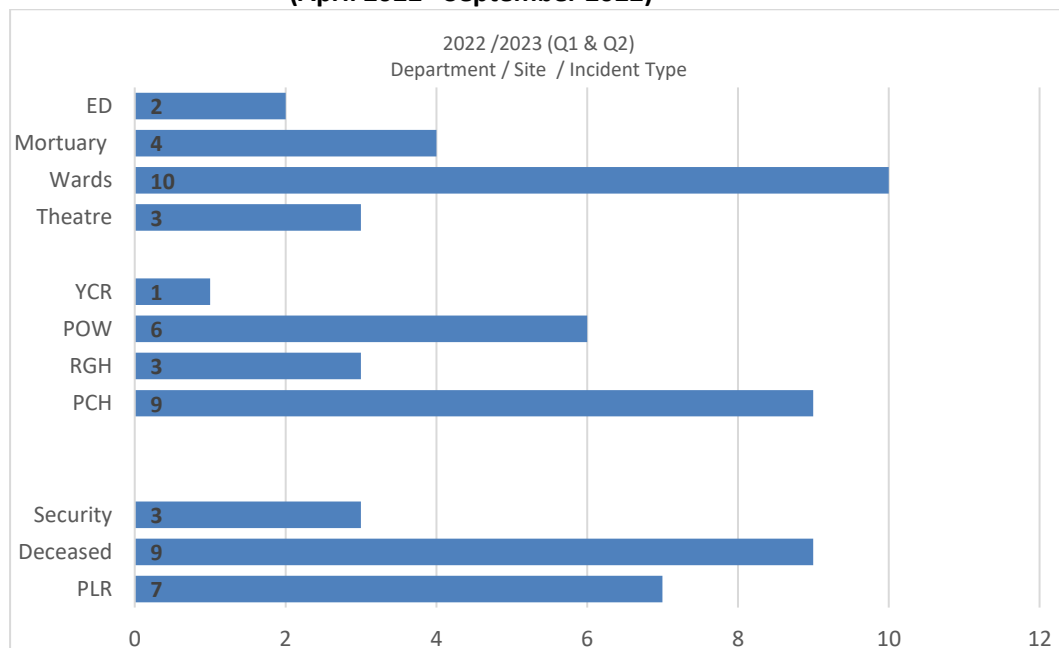
### **Incident Trend Analysis**



- 2.31 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.
- 2.32 This provides an 'early warning' system so that the DI can quickly follow-up such incidents, alert Persons Designated and support corrective actions.
- 2.33 All HTA related incidents are compared and presented on a quarterly basis to the HTA Board and Persons Designated; Graph 1 presents the first two quarters of this financial year.
- 2.34 There were **19** HTA related incidents in the first two quarters of 2022/23, including 1 HTARI (mortuary) and 1 HTARI near-miss (security).
- 2.35 In 2021/22 there were **34** HTA related incidents in the first two quarters, including 2 HTARIs.
- 2.36 Tissue Traceability continues to be a trend and represents 74 % of all incidents reported.
- 2.37 As with the audit programme, any shared learning from the outcomes of the incidents is communicated and discussed within the Persons Designated group.

**GRAPH 1**

**A summary of 19 Datix Incidents relating to HTAct standards  
(April 2022– September 2022)**



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

- 3.1 The overall Mortuary space capacity will be significantly challenged over the winter months and the Pathology Directorate are leading plans to provide an immediate solution to address this need for



consideration by the Health Board. The plans have been presented to the Executive Capital Planning Group on 26<sup>th</sup> October 2022.

- 3.2 The Mortuary Department at the Royal Glamorgan Hospital is the main centre for Post Mortems and the estate is in need of a major refurbishment to maintain its future compliance with the HTA. The Pathology Directorate will be leading plans to submit an outline case to the Health Board for such work.
- 3.3 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.

#### 4. IMPACT ASSESSMENT

<b>Quality/Safety/Patient Experience implications</b>	Yes (Please see detail below)
<b>Related Health and Care standard(s)</b>	Individual Care
	If more than one Healthcare Standard applies please list below:
<b>Equality Impact Assessment (EIA) completed - Please note EIAs are required for <u>all</u> new, changed or withdrawn policies and services.</b>	No (Include further detail below) If no, please provide reasons why an EIA was not considered to be required in the box below.
	No changes reported to services or new policies to consider
<b>Legal implications / impact</b>	Yes (Include further detail below)
	The Human Tissue Act is a legal requirement
<b>Resource (Capital/Revenue £/Workforce) implications / Impact</b>	Yes (Include further detail below)
	Pathology Directorate are leading business plans for investment in the Mortuary Department estate and to increase resilience with Mortuary Capacity
<b>Link to Strategic Goals</b>	Improving Care

#### 5. RECOMMENDATION

- 5.1 The Quality & Safety Committee are requested to **NOTE** the on-going work undertaken to assure compliance with HTA standards.
- 5.2 The Quality & Safety Committee are requested to **NOTE** the highlighted key risks looking ahead, which may adversely impact upon HTA compliance.