



AGENDA ITEM

3.2.13

QUALITY & SAFETY COMMITTEE

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

Date of meeting	24/5/2022
FOI Status	Open/Public
If closed please indicate reason	Not Applicable - Public Report
Prepared by	Dr Paul D Davies , Assistant Director (Operational Support) and Designated Individual for the Human Tissue Act
Presented by	Dr Paul D Davies , Assistant Director (Operational Support) and Designated Individual for the Human Tissue Act
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
(Insert Name)	(DD/MM/YYYY)	Choose an item.

ACRONYMS

HTA	Human Tissue Act
HTAuth	Human Tissue Authority
HTARI	Human Tissue Act Reportable Incidents



1. SITUATION/BACKGROUND

- 1.1 The purpose of this progress report is to present the on-going work of the Designated Individual for the Human Tissue Act (2004) and provide assurance to the Health Board that services are ready for inspection and compliant.
- 1.2 Cwm Taf Morgannwg University Health Board manage a range of clinical and support services which are involved in the removal, storage, use and disposal of human tissue.
- 1.3 The Health Board is thus subject to the legal requirements of the Human Tissue Act 2004. This Act established the Human Tissue Authority (HTA) who then regulate such activities. The main focus is the Post Mortem sector within our Health Board.
- 1.4 The Health Board is licensed by the HTA who inspect services 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 (HTA) in November 2020 and has since worked toward strengthening the governance of compliance with the standards set out within the HTA.
- 2.2 The focus has predominantly been on six key themes;
 1. Quality Control
 2. Engagement
 3. Deep Dive events
 4. Standard Operating Procedures
 5. Education
 6. Trend analysis
- 2.3 To ensure transparency these six key themes are the basis of the Designated Individual reporting quarterly to the HTA Board chaired by the Licence Holder, Dr Dom Hurford Executive Medical Director.

Quality Control

- 2.4 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 HTA Codes, predominantly Code A (Consent) and Code B (Post Mortem). These standards can be perused at the following links;

[Code A \(hta.gov.uk\)](https://www.hta.gov.uk/code-a)

[Post Mortem Standards and Guidance \(hta.gov.uk\)](https://www.hta.gov.uk/post-mortem)

- 2.5 This system is augmented through regular inspections of a range of services by the Designated Individual including Mortuary Departments, Maternity Services, Emergency Departments, Theatres, Early Pregnancy Units and Gynaecology Wards.
- 2.6 For those departments outside Pathology, the focus is mainly upon compliance with guidance set by the HTA with regard to the sensitive disposal of pregnancy loss remains;

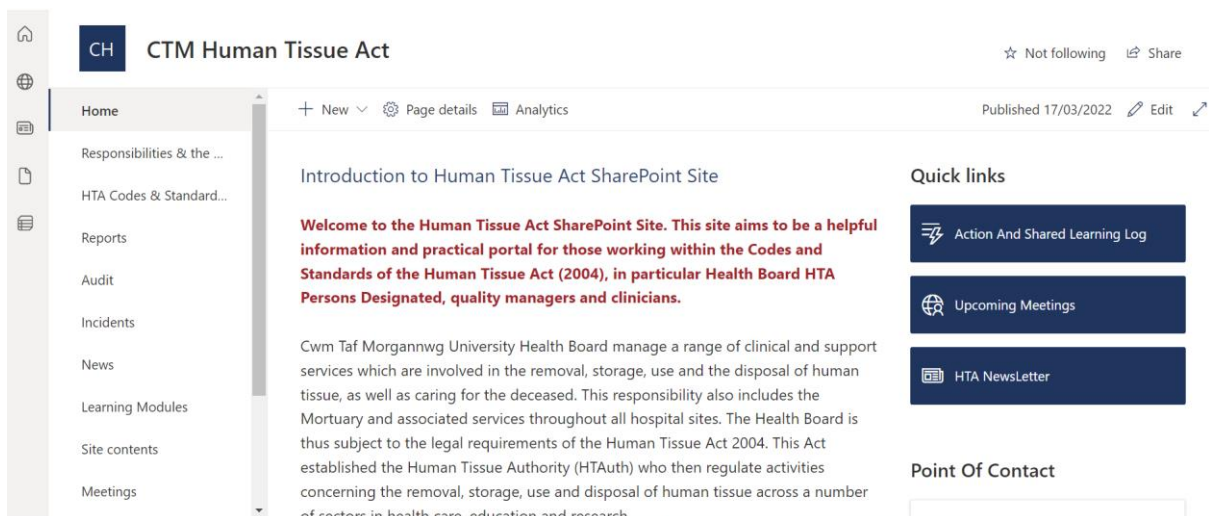
[Guidance on the disposal of pregnancy remains \(hta.gov.uk\)](https://www.hta.gov.uk)

- 2.7 During 2021 the Designated Individual conducted 31 inspections. From January to April 2022 a total number of 21 inspections have been conducted. The frequency of inspections at all three Mortuary departments have been increased in preparedness for inspection.
- 2.8 The outcomes of each local inspection is reported to the Persons Designated for the clinical area and corrective actions put in place.
- 2.9 Shared learning arising from all inspections is reported widely to clinical teams and the HTA Board.
- 2.10 Within the last 18 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
- 2.11 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

- 2.12 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.
- 2.13 To assist this goal the Designated Individual has introduced a network of 26 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.

- 2.14 Person's Designated appointed by the Designated Individual are able to directly influence services in relation to licensable activities.
- 2.15 The HTA recommend that the role is supplementary within the governance framework, although the Designated Individual remains responsible for supervising the activities to be authorised by the licence.
- 2.16 The Designated Individual meets with the Person's Designated group every six weeks to share learning, discuss developments and provide support where needed.
- 2.17 Establishing such a wide ranging network ensures that there is support across departments. To date this has been received well.
- 2.18 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.
- 2.19 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.
- 2.20 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
- 2.21 This new sharepoint page continues to be improved and developed.





Deep Dive events

- 2.22 During the months of October to December 2021 the Designated Individual has led a number of *Deep Dive* sessions to examine in detail each of the HTAct standards within Code A, B and E; further sessions have been conducted in 2022 focusing upon Post Mortem tissue traceability.
- 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 currently the Designated Individual is leading a review of PATH 02, our Policy for the sensitive disposal of pregnancy remains.

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 Designated Individual recently participated in the Health Board Development programme on 9th March 2022 to update members with regards to our legal requirements in relation to the HTA and progress to date. The presentation was well received.



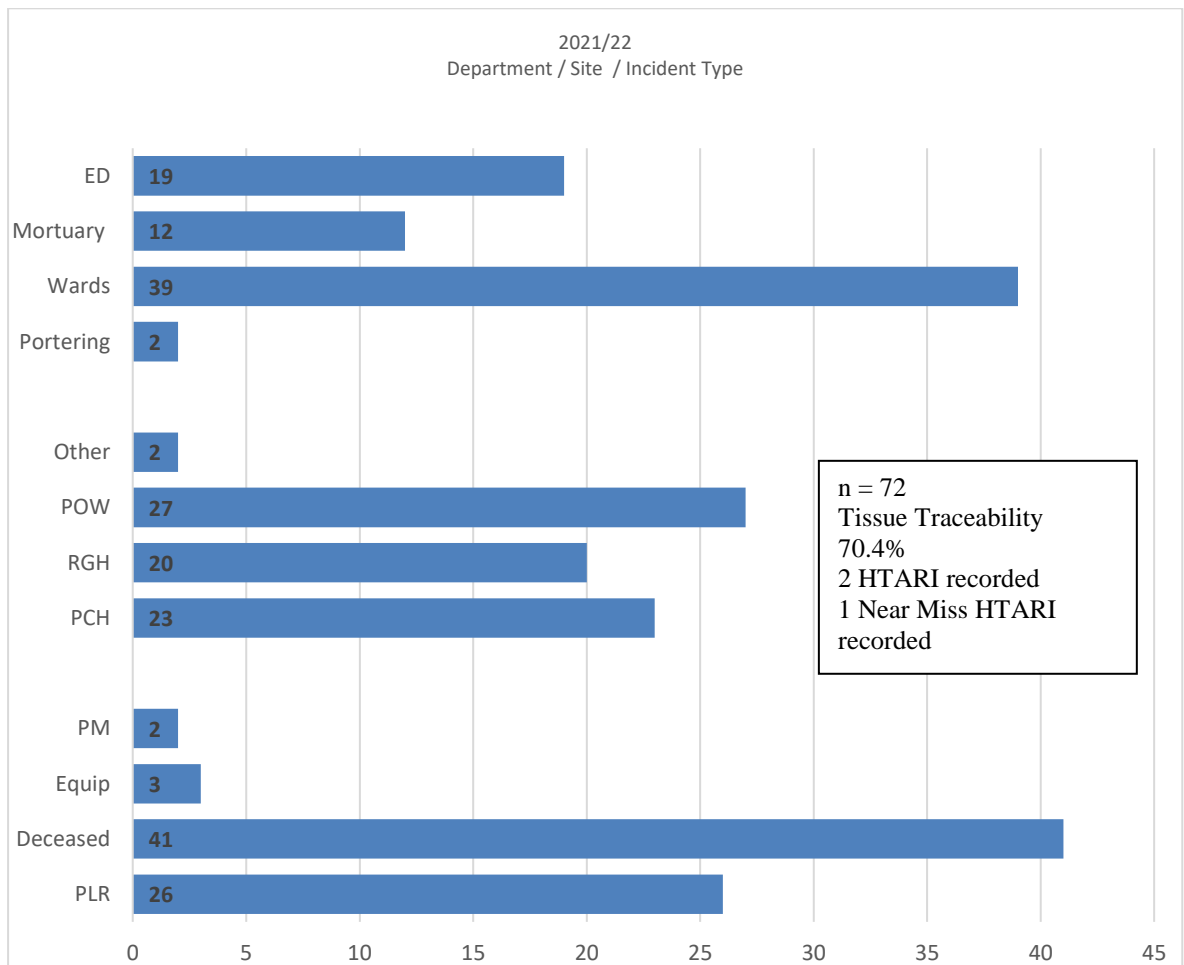
Incident Trend Analysis

- 2.31 Up until April 2022 all Datix reports which indicated an incident involved a deceased person and/or have key words such as "Pregnancy Loss Remains", "Death" or "Mortuary" were automatically copied to the Designated Individual.
- 2.32 This provided an 'early warning' system so that the Designated Individual could quickly follow-up such incidents, alert Persons Designated and support corrective actions.
- 2.33 This system however has changed through the introduction of a new all-Wales Datix system and only a limited number of sub-type categories of incidents include reference to the HTA.
- 2.34 The Designated Individual has raised concerns with the Datix lead as this has significantly altered the early warning system put in place.
- 2.35 To assist, the Datix team are conducting weekly audits of incidents to look for 'key words' and also Persons Designated have been requested to share any HTA related incidents with the Designated Individual.
- 2.36 All HTAct related incidents are compared and presented on a quarterly basis to the HTA Board and persons Designated and Graph 1 (page 7) presents the four quarters of this financial year.
- 2.37 There were 72 HTAct related incidents in 2021/22, including 2 HTARIs and one Near-Miss HTARI.
- 2.38 Tissue Traceability (TT) continues to be a trend and represents 70.4% of all incidents reported.
- 2.40 In the last 12 months the number of incidents reported doubled in the first 3 quarters and it is concluded that this was due to;
- A strengthened Persons Designated network, in particular at the Princess of Wales Hospital
 - Heightened awareness of the requirements for reporting through the Persons Designated and education
- 2.41 As with the audit programme, any shared learning from the outcomes of the incidents is communicated and discussed with the Persons Designated group.



GRAPH 1

**A summary of 72 Datix Incidents relating to HTAct standards
(April 2021– March 2022)**



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

- 3.1 There is on-going support required to the Gynaecology services at both the Princess of Wales Hospital and Prince Charles Hospital in relation to the pathway for patients attending Emergency Departments.
- 3.2 The tissue traceability system for Pregnancy Loss Remains is mainly a paper-based system and requires an electronic solution within the current all-Wales strategic objective to improve the Laboratory Information systems in the next 2-3 years.
- 3.3 SW02, the temporary body store at Prince Charles Hospital commissioned by the Local Resilience Forum, has now been decommissioned. The Pathology Department will be assessing its capacity plans looking ahead to the winter this year in light of this.



4. IMPACT ASSESSMENT

Quality/Safety/Patient Experience implications	There are no specific quality and safety implications related to the activity outlined in this report.
Related Health and Care standard(s)	Choose an item. If more than one Healthcare Standard applies please list below:
Equality Impact Assessment (EIA) completed - Please note EIAs are required for <u>all</u> new, changed or withdrawn policies and services.	Choose an item. If yes, please provide a hyperlink to the location of the completed EIA or who it would be available from in the box below. If no, please provide reasons why an EIA was not considered to be required in the box below.
Legal implications / impact	Yes (Include further detail below) HTA is a legal requirement
Resource (Capital/Revenue £/Workforce) implications / Impact	Yes (Include further detail below) Capacity planning looking ahead may have an impact upon Capital Budget
Link to Strategic Goals	Improving Care

5. RECOMMENDATION

- 5.1 The Health Board Quality & Safety Committee are requested to **NOTE** the on-going work undertaken to assure compliance with HTA standards.
- 5.2 The Health Board Quality & Safety Committee are requested to **NOTE** the highlighted key risks looking ahead, although presently these are not significant to adversely impact upon compliance.