

AGENDA ITEM

2.2.13

QUALITY & SAFETY COMMITTEE

**HUMAN TISSUE ACT (2004)
ANNUAL UPDATE REPORT
1 NOVEMBER – 31 MARCH**

Date of meeting

18/05/2021

FOI Status

Open/Public

If closed please indicate reason

Not Applicable - Public Report

Prepared by

Dr Paul D Davies, HTA Designated Individual & Assistant Director (Operational Support)

Presented by

Dr Nick Lyons, HTA Licence Holder & Executive Medical Director

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

ACRONYMS

HTAct

Human Tissue Act

HTAuth

Human Tissue Authority



1. SITUATION/BACKGROUND

- 1.1 Cwm Taf Morgannwg University Health Board manage a range of clinical and support services which are involved in the removal, storage, use and the disposal of human tissue, as well as caring for the deceased. This responsibility also includes the Mortuary and associated services at the Princess of Wales Hospital which were transferred to the Health Board in April 2020.
- 1.2 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 activities concerning the removal, storage, use and disposal of human tissue across a number of sectors in health care, education and research.
- 1.3 Other associated legislation includes Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) and the Quality and Safety of Organs Intended for Transplantation Regulations 2012. The Health Board do not hold a license for activities under these laws but has associated partnership working. For example, clinical specialists for Organ Donation from the South Wales Organ Donation Team assisted the Health Board in facilitating 11 solid organ donations resulting in 29 patients receiving a life-saving or life-changing transplant during 2019/20.
- 1.4 Consent is the fundamental principle of the legislation and different consent requirements apply when dealing with tissue from the deceased and the living.
- 1.5 Offences under the HTA 2004 include;
 - Removing, storing or using human tissue for Scheduled Purposes without appropriate consent.
 - Storing or using human tissue donated for a Scheduled Purpose for another purpose.
 - Trafficking in human tissue for transplantation purposes.
 - Carrying out licensable activities without holding a license from the HTA (with lower penalties for related lesser offences such as failing to produce records or obstructing the HTA in carrying out its power or responsibilities).
 - Having human tissue, including hair, nail, and gametes (i.e. cells connected with sexual reproduction), with the intention of its DNA being analysed without the consent of the person from whom the tissue came or of those close to them if they have died. (Medical diagnosis and treatment, criminal investigations, etc., are excluded).

- 1.6 It is important to note that whilst the Mortuary and Cellular Pathology departments across Cwm Taf Morgannwg University Health Board (including the Princess of Wales Hospital) are the main focus for regulation, other areas such as Maternity services, Early Pregnancy Units, Operating Theatres, Emergency Departments and Hospital Wards are also required to comply with the HTAct (2004). For example, issues can arise in terms of removal of tissue in theatres, consent regarding Pregnancy Loss Remains and care of the deceased.

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

Roles & Responsibilities

- 2.1 The License Holder, Designated Individual and Persons Designated are the main key roles for implementing the HTAct (2004) within the Health Board.
- 2.2 The License Holder represents the Health Board but does not impose the duties that are expected of the Designated Individual. It is important to note that they have the right to apply to the HTAuth to vary the license and thus the role is more senior than the Designated Individual.
- 2.3 The License Holder chairs a HTAct Board quarterly and reports to the Health Board annually.
- 2.4 A Designated Individual has the key role for implementing the requirements of the HTAct (2004). They are the person under whose supervision the licensed activity is authorised to be carried out. They have the primary (legal) responsibility under Section 18 of the Human Tissue Act to secure:
- that suitable practices are used in undertaking the licensed activity;
 - that other persons working under the license are suitable and;
 - that the conditions of the license are complied with.
- 2.5 The Designated Individual must ensure that activities are conducted properly, by people who are suitable to carry out those activities, and that all the necessary requirements are complied with.
- 2.6 The Person Designated appointed by the Designated Individual is able to directly influence services in relation to licensable activities. The role is supplementary within the governance framework, although the Designated Individual remains responsible for supervising the activities to be authorised by the license.

- 2.7 Within Cwm Taf Morgannwg University Health Board there are **23** Persons Designated who act at a local level to support the Designated Individual (**Appendix 1**). This list has been recently updated with new appointees by the Designated Individual to include the Princess of Wales Hospital and changes through new appointments at the Royal Glamorgan Hospital and Prince Charles Hospital.
- 2.8 Regular meetings (every 6 weeks) have been held with Persons Designated both as a group and individually to assist with updating requirements and local inspection audits, ensuring the Health Board is ready at anytime for a HTAct inspection.

Tissue Traceability

- 2.9 Tissue traceability is a critical component of the HTAct (2004) and is one of the main reasons where Trusts and Health Boards are found to have shortfalls during inspections. It covers the systems and records for the traceability of bodies and tissue for disposal.
- 2.10 For many years the Health Board has managed traceability through a paper-based process and strategically there is an expectation that it will put in place an electronic system.
- 2.11 Discussions are currently being held on a number of options looking ahead on systems such as EDEN and LIMS / LINC.

Learning resources

- 2.12 To ensure the compliance of standards, the Designated Individual will support the development and implementation of a range of competency-based learning material for managers and clinicians across the service.
- 2.13 The Designated Individual intends to utilise the ESR Learning Resource and enable competency-based learning on Sharepoint, however this work is currently on hold due to the redirection of resources from the Training Department to the vaccine programme.
- 2.14 An excellent development by the Persons Designated within Maternity Services is currently being rolled out to the Directorate
- 2.15 It is planned to adapt this competency based learning resource for the management of Pregnancy Loss Remains to Theatres, Emergency Departments, Early Pregnancy Units and Gynaecology.

Audit

2.16 Audit is key to compliance and the Designated Individual is implementing cyclic internal audit inspections in the following areas of Cwm Taf Morgannwg University Health Board, with the support of the Persons Designated for Quality in Pathology;

- Maternity Services
- Mortuary Services (including SW02)
- Emergency Departments
- Theatre departments
- Early Pregnancy Units

Outcomes of the audits are immediately reported to departmental teams and corrective actions followed-up.

2.17 An Audit Schedule can be seen at **Appendix 2** and those completed to date are highlighted in green.

2.18 All local action plans are up to date for the 8 audits conducted since the commencement in 2021.

2.19 A Persons Designated with responsibility for a Department are also requested to conduct their own monthly audits.

2.20 In addition to local actions for follow-up, a number of matters arising for shared learning are communicated via the Persons Designated group. Shared learning include;

- The need to use the formal Pregnancy Loss Registers supplied by the Mortuary Department and not have ad hoc books/paperwork
- The need to ensure Estates are immediately informed when there is a need for repairs and maintenance
- The need to ensure local training records are available
- The need to follow-up in a timely manner Datix incident investigations

Incidents

- 2.21 All Datix reports which reference an incident involving a deceased person and/or have key words such as "Pregnancy Loss remains" or "Mortuary" are automatically copied to the Designated Individual.
- 2.22 This provides an 'early warning' system so that the Designated Individual can quickly follow-up such incidents, alert Persons Designated and support corrective actions.
- 2.23 Importantly, an assessment can be made to determine if such a report is a HTA Reportable Incident (HTARI) which will demand a higher level of scrutiny and corrective actions.
- 2.24 Since appointment on 1 November 2020 the Designated Individual is aware of **22** such incidents (see Table 1).
- 2.25 One incident was reported as an HTARI as it caused 'Harm' however the HTA stepped it down from being reportable as it considered a Placenta as maternal and not fetal tissue. It was noted by the HTA that it was right to report as it concerned tissue traceability.
- 2.26 One further incident was reported as an HTARI 'near-miss' as it involved an unsecured Mortuary door out of hours at the Princess of Wales site.
- 2.27 It is intended to examine trends of incident reporting on a quarterly and annual basis.

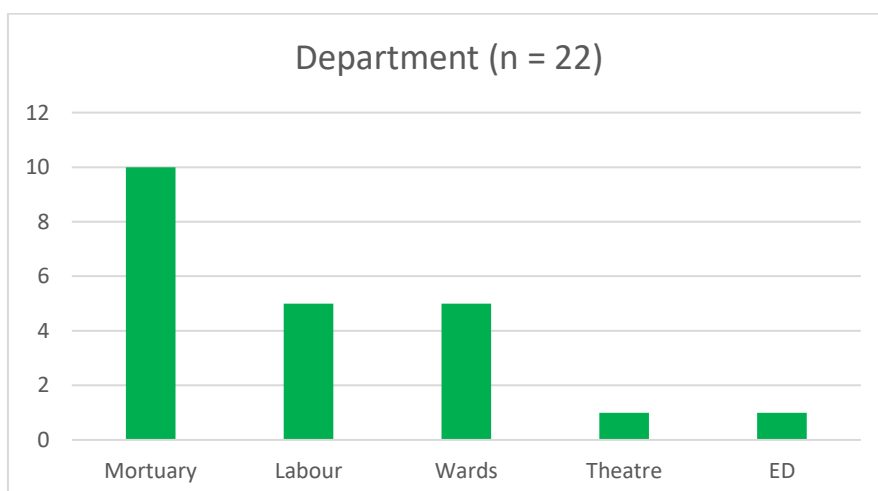
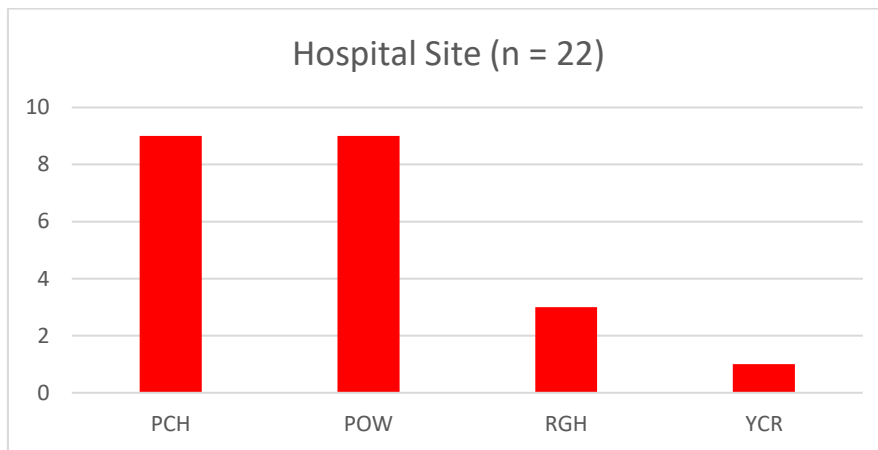
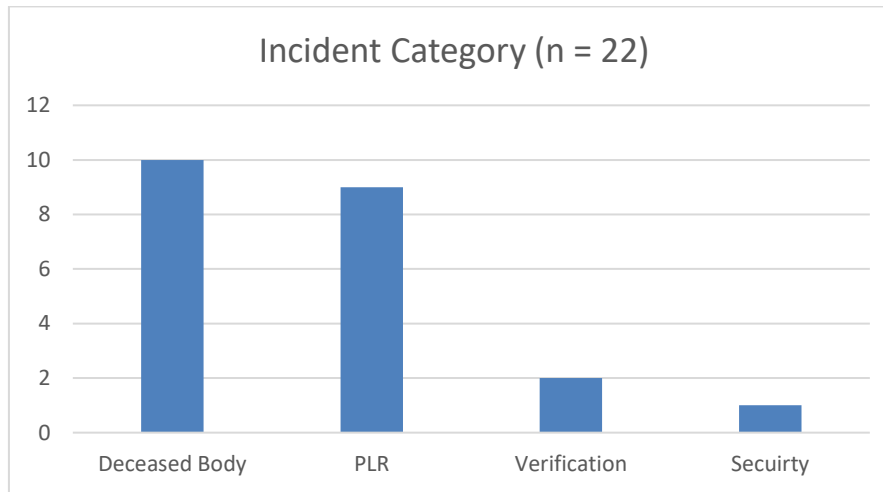


TABLE 1 A summary of 22 Datix Incidents relating to HTA standards (November 1st 2020 to March 31st 2021)

ref.	DATIX	CATEGORY	DATE REPORTED	SITE	DEPT	OUTCOME	Traceability Issue?
1	W154516	Verification	11/11/2020	POW	Ward 8	No Harm	✓
2	W155851	PLR	18/11/2020	PCH	Labour	No Harm	✓
3	W155492	PLR	24/11/2020	POW	Labour	HTARI	✓
4	W155607	Deceased Body	26/11/2020	POW	Ward 9	No Harm	
5	W155617	PLR	19/11/2020	PCH	Labour	No Harm	✓
6	W156091	PLR	23/10/2020	PCH	Labour	No Harm	✓
7	W156184	Security	04/12/2020	POW	Mortuary	HTARI near miss	
8	W157149	Verification	18.12/20	PCH	Ward 3	No Harm	✓
9	W157548	PLR	23/12/2020	PCH	Theatres	No Harm	✓
10	W157830	Deceased Body	28/12/2020	PCH	Mortuary	No Harm	
11	W158284	Deceased Body	04/01/2021	PCH	Mortuary	No Harm	
12	W158540	PLR	08/01/2021	POW	Mortuary	No Harm	✓
13	W159139	Deceased Body	15/12/2020	RGH	Mortuary	No Harm	
14	W159202	Deceased Body	19/01/2021	POW	Mortuary	No Harm	
15	W159523	PLR	22/01/2021	PCH	ED	No Harm	
16	W160727	PLR	05/02/2021	PCH	Ward 5, Gynae	No Harm	
17	W161845	PLR	26/02/2021	POW	Labour	No Harm	✓
18	W162521	Deceased Body	09/03/2021	POW	Mortuary	No Harm	✓
19	W162557	Deceased Body (FD)	08/03/2021	POW	Mortuary	No Harm	✓
20	W163003	Deceased Body (FD)	15/03/2021	RGH	Mortuary	No Harm	
21	W163735	Deceased Body	26/03/2021	RGH	Ward 20	No Harm	✓
22	W163926	Deceased Body	27/03/2021	YCR	Mortuary	No Harm	



TABLE 2 A summary of 22 Datix Incident Trends relating to HTA standards (November 1st 2020 to March 31st 2021)



2.28 As with the audit programme, any shared learning from the outcomes of the incidents are communicated and discussed with the Persons Designated group. Shared Learning include;

- The importance of following up incidents in a timely manner, in particular where there is a potential competency issue
- The importance of identifying and correcting areas of potential weakness within Standard Operating Procedures
- Tissue traceability being a theme throughout a number of incidents and the need for vigilance and further training

Mass Fatalities Plan

2.29 South Wales Local Resilience Forum is responsible for the multi-agency Mass Fatalities Plan which came into force in April 2020 as a response to the COVID-19 pandemic.

2.30 As part of this plan, additional body storage was commissioned in the South Wales Region. Firstly at Cardiff (stepped down in March 2021) and now at Prince Charles Hospital, namely SW02.

2.31 SW02 is a temporary body store and became operational on 22 March 2021 following a local HTA inspection process by the License Holder, Designated Individual, Persons Designated (Estates, Facilities, Mortuary and Quality) and Pathology Management.

2.32 SW02 is managed by the Mortuary Department at Prince Charles Hospital to ensure compliance with HTAct standards.

2.33 This service is aimed at assisting any potential surge in demand beyond current capacity within Cwm Taf Morgannwg, Cardiff & Vale, Aneurin Bevan and Swansea Bay University Health Boards and is currently planned for a 12 month period.

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

3.1 An emerging risk is being considered with ILG colleagues in relation to the sustainability of the Royal Glamorgan Hospital Mortuary Department. As a building it is very challenging to remain *fit for purpose* and is our greatest risk of non-compliance with standards. It is in clear need of a major refurbishment or rebuild, particularly in light of its role as the main centre for Coroner autopsies. The

Pathology Department is currently working on an options appraisal with a view to bid for capital monies.

- 3.2 The Health Board is currently reliant upon a mainly paper-based system for the traceability of the deceased and tissue. The need for a more robust system where there are less steps in the process and the potential for human error is eliminated is paramount. It is thus important that the current options appraisal led by the Pathology Department is completed and decisions made on future direction.

4. IMPACT ASSESSMENT

Quality/Safety/Patient Experience implications	Yes (Please see detail below)
Related Health and Care standard(s)	Governance, Leadership and Accountability
	Individual Care Effective Care
Equality Impact Assessment (EIA) completed - Please note EIAs are required for <u>all</u> new, changed or withdrawn policies and services.	No
	This is a well established Legislative requirement and no significant new changes introduced
Legal implications / impact	Yes (Include further detail below)
	<ol style="list-style-type: none"> 1. The Human Tissue Act 2004 (HT Act) and associated Regulations. 2. Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended). 3. Quality and Safety of Organs Intended for Transplantation Regulations 2012.
Resource (Capital/Revenue £/Workforce) implications / Impact	Yes (Include further detail below)
	The requirement for a replacement Mortuary Department at RGH has been identified as a key priority in the RTE ILG IMTP (2021/22)



Link to Strategic Well-being Objectives

Provide high quality, evidence based, and accessible care

5. RECOMMENDATION

- 5.1 To **NOTE** that the emerging risk of the Royal Glamorgan Hospital Mortuary Department not remaining *fit for purpose* and the need to secure Capital funding is being explored and will be considered in accordance with the Health Board's Risk Management Strategy and escalated as appropriate.
- 5.2 To **NOTE** that the emerging risk of continuing with a paper-based tissue traceability system and the need for an electronic solution is being explored and will be considered in accordance with the Health Board's Risk Management Strategy and escalated as appropriate.