AGENDA ITEM
2.2.12

QUALITY & SAFETY COMMITTEE

HUMAN TISSUE ACT (HTA) (2004) COMPLIANCE UPDATE REPORT

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 (HTAuth) who 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 This paper provides an update on current compliance and assurances looking ahead to further inspections.

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

HTA Codes of Practice

2.1 Our Health Board HTA plans, service delivery and checks on compliance are driven by seven specific HTAct Codes, available on the HTAuth website at www.hta.gov.uk

2.2 These Codes are as follows;

- **Consent Code A** offers professionals guidance about how to inform people and their families about their options and seek consent for the use of organs, tissue and cells.
- **Post Mortem Code B** offers professionals guidance about how to meet HTA requirements relating to post-mortem examination and the storage of bodies and tissue.
- **Anatomical examination Code C** of Practice and Standards offer professionals guidance about how to meet HTA requirements relating to the use of human bodies and tissue for education and training.
- **Public Display Code D** of Practice and Standards offer professionals guidance about how to meet HTA requirements relating to the display of bodies and body parts in museums and exhibitions.
- **Research Code E** provides guidance on the type of research regulated by the HTA under the HT Act usually takes the form of 'laboratory bench' research. HTA ensures that tissue for this type of research is removed and stored in an appropriate and well managed way.

- **Donation of solid organs and tissue for transplantation Code F** offers guidance to practitioners working in the field of living organ donation, and deceased organ and tissue donation.
- **The Donation of allogeneic bone marrow and peripheral blood stem cells (PBSCs) for transplantation Code G** provides supplementary guidance to clinicians working in the field of allogeneic bone marrow and PBSC transplantation and HTA Accredited Assessors (AAs).

2.3 In addition to the above there is a specific Code of Practice on Human Transplantation for Wales Act 2013. This Code of Practice is primarily intended for use by Specialist Nurses for Organ Donation (SNODs), other clinicians and professionals working in the transplantation sector in Wales. It may also be of assistance to clinicians in other areas and specialities, as well as the public.

2.4 In terms of Cwm Taf Morgannwg University Health Board Codes A and B are the main reference documents in working practice.

2.5 We also work in partnership with the specialist team for organ donation. The Licence for organ donation and transplantation are managed centrally by the South Wales Organ Donation team.

The 2018/19 HTA inspection

2.6 Cwm Taf Morgannwg University Health Board was last inspected in 2018 and major shortfalls were identified across a wide range of areas.

2.7 At that time the Pathology team managed the HTA inspection findings and the subsequent Corrective and Preventative Plans (CAPAs) over 2018/19 to recover to a position of compliance.

2.8 It was not until July 2019 when the Health Board finally received a sign-off from the HTA that we were compliant to retain our Licence.

Providing on-going assurance of compliance

2.9 Since the 2018/19 HTA inspection our continued HTA compliance checks is embedded within the Pathology quality assurance system led by a small dedicated team of quality and service managers.

2.10 In order to ensure continued compliance with Code B HTA standards, there are four scheduled HTA compliance audits conducted within the quality Pathology audit calendar.

2.11 These audits cover the breadth of all the relevant standards. Findings from these audits are highlighted to managers and also recorded in the non-conformity spreadsheet which is centrally located on the Mortuary document centre on SharePoint.

2.12 The non-conformity spreadsheet facilitates the Root Cause Analysis (RCA) Process, allowing any necessary actions to be assigned to appropriate individuals with accompanying timeframes.

2.13 On completion of actions there is also a section for the CAPA (Corrective and Preventative Action) review, to ensure any actions have been effective in addressing findings from HTA compliance audits.

2.14 The Quality Team have also undertaken a gap analysis for the revised HTA Code B standards (August 2020) and this did not highlight any significant concerns for Pathology.

2.15 Of course, these Pathology systems are exclusive to the department and do not predominantly extend to other clinical areas however Maternity Services have their own audit system which regularly checks adherence to standards for Pregnancy Loss Remains.

2.16 This is reassuring as our management of Pregnancy Loss Remains was a significant concern within the original inspection. Maternity services have also developed a competency-based learning package for Pregnancy Loss Remains which will be adapted and adopted by other Departments such as Emergency Department (ED), Theatres, Early Pregnancy Unit (EPU) and Gynaecology.

Actions by the Designated Individual

2.17 Whilst services are operationally responsible for ensuring compliance with the standards set within the HTAct (2004), the Designated Individual also has a key lead role.

2.18 The Designated Individual is the person under whose supervision the licenced activity is authorised to be carried out. The Designated Individual has the primary (legal) responsibility under Section 18 of the Human Tissue Act to secure;

- that suitable practices are used in undertaking the licenced activity;
- that other persons working under the licence are suitable and;
- that the conditions of the licence are complied with.

2.19 As well as reporting formally to the Licence Holder at the HTA Board on a quarterly basis, the Designated Individual has implemented the following systems since his appointment in November 2021;

- A revision of the Persons Designated list to include the Princess of Wales Hospital and notification the HTA
- Frequent analysis, follow-up and reporting of lessons learnt from reported Datix incidents where tissue and the deceased are involved
- A HTA Internal Inspection schedule **(Appendix 1)** which plans to visit every relevant Directorate/clinical area at least twice a year.

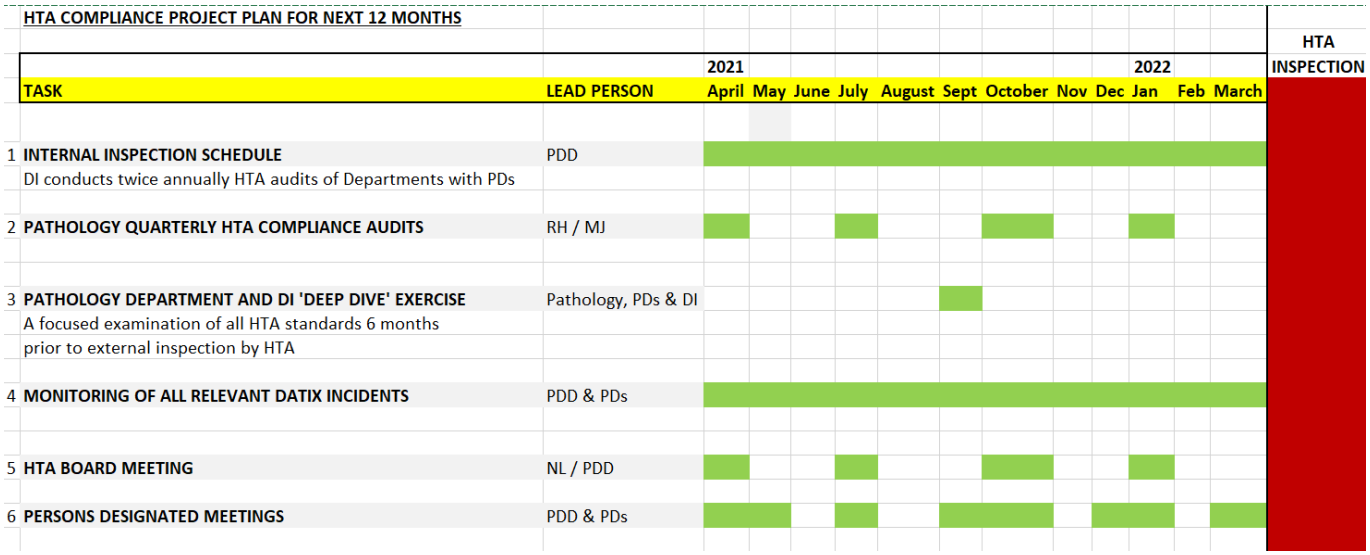
2.20 The Designated Individual has conducted 10 such audits to date and it is proving to be helpful in terms of assurance compliance outside the Pathology and Mortuary departments and importantly shared learning.

2.21 The aim is to ensure we have a visible audit system outside the Pathology Department and offer departments support, many of whom do not frequently deal with the handling and disposal of tissue.

2.22 The Designated Individual and Pathology managers are planning to undertake a *deep dive* of compliance by returning to the current HTA standards at least 6 months beforehand in September/October this year. This *deep dive*, in parallel with the above audit systems, will provide a pre-inspection robust check to ensure we are on track and remain so for inspection.

2.23 Through the implementation of our concurrent audit systems, there should be no surprises with this deep dive.

2.24 A summary plan for work to be conducted over the next 12 months is attached below:



HTA COMPLIANCE PROJECT PLAN FOR NEXT 12 MONTHS														HTA INSPECTION
		2021										2022		
TASK	LEAD PERSON	April	May	June	July	August	Sept	October	Nov	Dec	Jan	Feb	March	
1 INTERNAL INSPECTION SCHEDULE DI conducts twice annually HTA audits of Departments with PDs	PDD													
2 PATHOLOGY QUARTERLY HTA COMPLIANCE AUDITS	RH / MJ													
3 PATHOLOGY DEPARTMENT AND DI 'DEEP DIVE' EXERCISE A focused examination of all HTA standards 6 months prior to external inspection by HTA	Pathology, PDs & DI													
4 MONITORING OF ALL RELEVANT DATIX INCIDENTS	PDD & PDs													
5 HTA BOARD MEETING	NL / PDD													
6 PERSONS DESIGNATED MEETINGS	PDD & PDs													

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

3.1 An emerging risk is being considered with ILG colleagues to continued compliance is 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. This is a risk to continued compliance and currently around half of all HTA related incidents within the Health Board relate to tissue traceability.

3.3 The need for a more robust tissue traceability 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)
	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.
	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** the HTA compliance assurance for the Health Board

5.2 To **NOTE** 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.

5.3 To **NOTE** 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.