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Bwrdd Iechyd Prifysgol  
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Swansea Bay University  
Health Board



<b>Meeting Date</b>	<b>05 June 2019</b>	<b>Agenda Item</b>	<b>5.2</b>
<b>Report Title</b>	<b>Mortuary Human Tissue Authority (HTA) Inspection Preparedness</b>		
<b>Report Author</b>	Chris Bowden, Cellular Pathology Service Manager		
<b>Report Sponsor</b>	Chris White, Deputy Chief Executive/Director of Therapies and Health Science		
<b>Presented by</b>	Christine Morrell, Deputy Director of Therapies and Health Science		
<b>Freedom of Information</b>	Closed		
<b>Purpose of the Report</b>	<p>The mortuary is due to have an inspection by the HTA on 26<sup>th</sup> 27<sup>th</sup> and 28<sup>th</sup> of June 2019. This covers mortuary at Morriston and satellite at Princess of Wales Hospital.</p> <p>This paper will outline the readiness of the mortuary and highlight areas of shortfall identified and actions being taken to address these.</p>		
<b>Key Issues</b>	<p>The mortuary has been successful in previous inspections however these were against the previous HTA standards.</p> <p>The HTA published new standards in April 2017, these are far more rigorous and prescriptive. The mortuary has performed a gap analysis and there are a number of shortfalls which are being addressed.</p> <p>The satellite mortuary at Princess of Wales Hospital is managed on behalf of Cwm Taf Morgannwg UHB under a Service Level Agreement.</p>		
<b>Specific Action Required (please choose one only)</b>	<b>Information</b>	<b>Discussion</b>	<b>Assurance</b>
	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<b>Recommendations</b>	<p>Members are asked to:</p> <ul style="list-style-type: none"> <li><b>CONSIDER /ENDORSE</b></li> </ul> <p><b><u>Items for information will not be allocated time for consideration within the Board/Committee meeting</u></b></p>		

## **Mortuary HTA Readiness Report**

### **1. INTRODUCTION**

- 1.1. The aim of this report is to highlight to Executive team the current Human Tissue Authority(HTA) compliance status of the mortuaries of Swansea Bay Health Board.
- 1.2. The Human Tissue Authority is an Executive Non-Departmental Public Body (ENDPB) sponsored by the Department of Health (DH). As a statutory body the core of what the HTA does is laid down in legislation including the The Human Tissue Act 2004 (HT Act) and associated Regulations which are relevant to the mortuary sector.
- 1.3. The [Human Tissue Act 2004](#) (link is external) covers England, Wales and Northern Ireland. It established the HTA to regulate activities concerning the removal, storage, use and disposal of human tissue. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living. The Human Tissue Act 2004 lists the purposes for which consent is required (these are called [Scheduled Purposes](#) (link is external)).  
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- 1.4. The HTA operate under criminal law and reports of inspections are available in the public domain. If the standards are not being met the HTA may take regulatory action against a licensed establishment and/or the Designated Individual, for example by:
  - i) proposing additional conditions to the HTA licence, which the licensed establishment will be required to comply with by a certain date (subject to a statutory 28-day period in which they can notify the HTA that it intends to make representations)
  - ii) issuing special directions that impose requirements on a licensed establishment, with immediate effect
  - iii) suspending or revoking a licence
  - iv) providing written and oral advice and guidance or advice and warning;
  - v) refer the matter to the police under its protocol for managing potential breaches of human tissue legislation after considering HTA-POL-023 if any offences are suspected of being or have been committed under the applicable legislation.

### **2. BACKGROUND**

- 2.1. The Post Mortem Mortuary license (30015) lists Morriston Hospital as the Licence Holder site (Post Mortem); Princess of Wales Hospital is a satellite site. The mortuary at Princess of Wales continues to be covered by Swansea Bay under Service Level Agreement after Boundary Change at the request of Cwm

Taf. This is due to the issues raised by the HTA at their mortuary inspection on 28 and 29 March 2018.

- 2.2. The Designated Individual under the license is a Consultant Pathologist and the Corporate License Holder is Christine Morrell, Deputy Director of Therapies and Health Science
- 2.3. The Health Board has a HTA Assurance group in place, which is Chaired by the Corporate License Holder and attended by the Designated Individual, key Unit and Mortuary Staff and others with key responsibilities under the Act. This group reports to the Quality and Safety Forum and provides exception reports and an Annual Report to the Quality and Safety Committee.
- 2.4. Swansea Bay sites will be inspected by the HTA, on 26<sup>th</sup>, 27<sup>th</sup> June and 28<sup>th</sup> June 2019. As well as Morriston and Princess of Wales mortuaries the HTA may inspect body store facilities (Neath and Singleton Hospitals) and areas related to storage of foetal remains (obstetrics, Gynaecology, and Emergency Departments).
- 2.5. As well as mortuary sites other areas and staff can expect to be involved in inspection. The areas include body stores at Singleton hospital and Neath Port Talbot Hospitals and Maternity, gynaecology and Emergency department areas department fridges where foetal remains may be stored across Swansea Bay and Princess of Wales Hospital. Each of these specialties will have a nominated Person who is responsible for overseeing standards are maintained in that area. Ward staff and portering staff also must be aware of procedures for dealing with the deceased and may be required to provide information during the inspection .
- 2.6. The last inspection for post mortem was in Princess of Wales Hospital in 2016 The Health Board had two minor findings in that inspection. Morriston was last inspected in 2015. Both of these were inspections against old standards and there were no major issues highlighted against these licenses. All issues raised have been addressed and closed.

### **3. ASSESSMENT**

- 3.1 A self-assessment audit has been undertaken against new standards and a gap analysis and action plan developed. A series of gaps have been identified and a SMART action plan is in place to address these. Latest update is provided at HTA assurance meetings. Meetings are currently being held at 2-3 week intervals to support progress and to highlight risks and mitigation. The mortuary is working through each of the new standards with the aim of addressing all of the shortfalls before the inspection.
- 3.2. Cwm Taf University Health Board (March 2018), Cardiff and Vale University Health Board (August 2017) and Aneurin Bevan University Health Board (March 2019) have been inspected under the new standards. The HTA found that Royal Glamorgan Hospital had a total of 19 major and 13 minor shortfalls, Cardiff and Vale University Hospital, had three critical shortfalls, fourteen major

shortfalls and nine minor shortfalls found across the range of standards.. Both of these Health Boards had adverse media from these inspections and are still working through the Corrective and Preventative actions (CAPA) highlighted. Aneurin Bevan had eight minor shortfalls. Learning from these inspections has been considered within the self- assessment undertaken in Swansea Bay UHB.

- 3.3. Internal audit have undertaken a review against the self- assessment audit and made a series of recommendations, which have been accepted. (Appendix 1) The assessment indicates that there is currently a limited level of management assurance currently. Whilst compliance is noted in some areas, there are several key areas of non-compliance and many more indicated as requiring improvement or further review. Some of these are in areas the HTA have considered critical or major at other establishments. It has been agreed that these Internal Audit recommendations will form part of the action plan for mortuary going forward.
- 3.4 Internal audit have now agreed dates for an Internal Audit Review in October 2019. In considering a suitable date, the Health Board has considered the timescales within the improvement plan, and the point at which it is anticipated management's own self-assessment will provide a substantial level of assurance regarding arrangements in place. This would be subject to independent review within the scope of the internal audit. This has been agreed and will be scheduled post HTA audit dependent on report.
- 3.5. The Internal audit team mapped the self-assessment audit against the outcome of HTA inspections in C&VUHB and CTUHB, and added note of these to the mortuary self-assessment audit for consideration in the action plan.
- 3.6. Additional staff have been allocated to the mortuary to support progress. Corporate teams are supporting and escalating actions to ensure they are promptly actioned where appropriate. Additional meetings are scheduled and terms of reference of HTA Oversight group have been revised to strengthen arrangements including frequency of meetings. An additional recommendation has been added to ensure there are effective mechanism for oversight due to recent cancellation of the Quality and Safety Forum.
- 3.7. Actions are being taken forwards across all domains of the HTA standards (Consent, Governance and Quality, Traceability, Premises, facilities and equipment, and documentation) to ensure compliance with the Act and to assure the Board via the Executive team that the necessary actions are being taken.

#### **4. FINANCIAL IMPLICATIONS**

- 4.1 There are current and ongoing financial implications; currently around £50k has been spent. This does not take into account additional staff hour. There has been a staffing shortage highlighted at band 2 which would require an ongoing revenue investment.

- 4.2. All costs are currently being picked up through the Cellular Pathology J301 budget, although some will relate to ward areas and portering. A tally of all expenditure is being kept. Most of the costs will be associated with one off purchases such as autopsy saws, mortuary trolleys, alarmed fridges, bariatric bed covers, respirators and storage cupboards. This has been informed by shortfalls identified in other local inspections.

## **5. RECOMMENDATION**

- 5.1. The Executive Team Forum note the report and the actions taken to comply with the Human Tissue Act and to prepare for Inspection in June 2019.

Governance and Assurance		
Link to Enabling Objectives (please choose)	<b>Supporting better health and wellbeing by actively promoting and empowering people to live well in resilient communities</b>	
	Partnerships for Improving Health and Wellbeing	<input type="checkbox"/>
	Co-Production and Health Literacy	<input type="checkbox"/>
	Digitally Enabled Health and Wellbeing	<input type="checkbox"/>
	<b>Deliver better care through excellent health and care services achieving the outcomes that matter most to people</b>	
	Best Value Outcomes and High Quality Care	x <input type="checkbox"/>
	Partnerships for Care	<input type="checkbox"/>
	Excellent Staff	<input type="checkbox"/>
	Digitally Enabled Care	<input type="checkbox"/>
	Outstanding Research, Innovation, Education and Learning	<input type="checkbox"/>
Health and Care Standards		
(please choose)	Staying Healthy	<input type="checkbox"/>
	Safe Care	x <input type="checkbox"/>
	Effective Care	x <input type="checkbox"/>
	Dignified Care	x <input type="checkbox"/>
	Timely Care	x <input type="checkbox"/>
	Individual Care	x <input type="checkbox"/>
	Staff and Resources	x <input type="checkbox"/>
Quality, Safety and Patient Experience		
<p>Meeting all of the HTA standards will ensure that the patients are cared for in a dignified and respectful manner. Appropriate staffing and skill mix will enable a timely and efficient care pathway.</p>		
Financial Implications		
<p>Short term there is a requirement to replace some old equipment and refurbish other equipment. Longer term in order to maintain the standards an investment in a band 2 support workers will be required.</p> <p>There is currently no budget for this work or staffing requirement.</p>		
Legal Implications (including equality and diversity assessment)		
<p>Failure to comply with HTA regulations can have a major detrimental effect on the public perception of the Health Board.</p> <p>Adverse publicity with regards to mortuaries causes loss of public confidence and this damage is difficult to repair.</p> <p>Breaches of the standards can result in Police intervention under criminal law.</p>		

<b>Staffing Implications</b>	
<p>It has become evident that in order to reach and maintain the standard's there will need to an investment in support staff. Currently band 5 Anatomical Pathology Technicians are required to complete the documentation plus receive and release deceased patients. This compromises their capacity to perform the post mortems. To modernise the workforce we would need to invest in Anatomical Pathology Support Workers at band 2.</p>	
<b>Long Term Implications (including the impact of the Well-being of Future Generations (Wales) Act 2015)</b>	
<b>Report History</b>	Refer to previous reports presented on the same issue/item including any patient and public engagement. If this paper has been considered by other committees, the dates and the name of the committee that considered it should be detailed here.
<b>Appendices</b>	Appendix 1: Internal Audit Report