Inspection report on compliance with HTA licensing standards
Inspection date: **18 - 20 May 2022**

Warrington Hospital

HTA licensing number 12024

Licensed under the Human Tissue Act 2004

Licensed activities

The table below shows the activities this establishment is licensed for and the activities currently undertaken at the establishment.

Area	Making of a post-mortem examination	Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation	Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Hub site **Warrington Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab			*Carried out*
Satellite site **Dataspace**	Not licensed	Not licensed	Licensed
Tissue Store			*Carried out*

Summary of inspection findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Warrington Hospital ('the establishment') had met the majority of the HTA's standards, one critical, five major and five minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities, and equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Compliance with HTA standards

Critical Shortfalls

Standard	Inspection findings	Level of shortfall
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		

a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	During the inspection, the inspection team were not provided with evidence that transfer of bodies internally was being risk assessed. The inspection team identified significant risks to the deceased's safety and dignity whilst being transferred from the hospital wards to the mortuary. These included: • The use of a route which included passage through public car parks and busy traffic areas. • The condition of the roads near the mortuary were in poor condition. These included curb stones and potholes, which poses a risk to patient safety and accidental damage to the bodies. • The inspection team were not assured that lighting on the routes used was sufficient, this further increases the risk of incidents occurring during night hours. Mortuary transfers are not prioritised as they are completed by the hospital security team. This poses a risk of bodies not being admitted to the mortuary or being refrigerated in a timely manner. • The inspection team identified near miss incidents regarding accidental damage to bodies, which were not reported to the HTA. • The main mortuary entrance is on a public road with inadequate shielding to protect oversight of activity. ***Following the regulatory assessment, the establishment provided the inspection team with a risk assessment and documented procedure that described an 'agreed route.' As these documents were not provided nor referenced at the time of the inspection, it is not clear if the route shown to the inspection team is the same route referred to within the documentation. The inspection team are not therefore assured that these procedures are being followed on all internal mortuary transfers.***	**Critical** **(Cumulative)**

b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	As referenced at GQ6(a) above, during the inspection, the inspection team were not provided with evidence that transfer of bodies internally was being risk assessed. Whilst staff were able to demonstrate knowledge of the risks associated with the mortuary transfers, the inspection team did not receive evidence that appropriate mitigations had been identified and/or implemented. ***Following the regulatory assessment, the establishment provided the inspection team with a risk assessment and documented procedure that described an 'agreed route'. As these documents were not provided nor referenced at the time of the inspection, the inspection team were not assured that staff were aware of these documents and that the referenced mitigations were therefore being applied. The inspection team will review the risk assessment and proposed mitigations in respect of transfer of bodies internally as part of a corrective and preventative action plan.***	
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	The significant risks identified are not incorporated on the Trust's organisational risk register.	

Major shortfalls

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		

a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	Whilst a number of consultants had received training in the requirements of the HTA, the inspection team were not assured that this included all consultants that were taking consent.	**Major (Cumulative)**
b) Records demonstrate up-to-date staff training	Records do not demonstrate up to date training in HTA requirements when seeking consent. Consultant training records were last completed in 2014.	
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual	The inspection team were not assured that individuals trained in HTA requirements were always present when consent was sought for paediatric post mortems.	
d) Competency is assessed and maintained	The establishment does not have a formalised system in place for assessing staff as competent on the HTA requirements when seeking consent.	
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	At the time of inspection, procedures observed by the inspection team were not consistent with that of the Standard Operating Procedures (SOPs). • condition checking of the deceased. • visiting and viewing procedures. • release; and • retention and disposal of tissue samples. ***The establishment submitted sufficient evidence to address this shortfall before the report was finalised.***	**Major**
GQ2 There is a documented system of audit		
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	The inspection team were not assured that staff are fully aware of what tissue is being held and why. The establishment does not have electronic records for retained tissue prior to 2021. During the tissue audit the establishment were unable to provide evidence of families wishes for one case.	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	Bodies may be released using fewer than three identifiers of the deceased provided by funeral directors at the time of collection. During the body audit, one body was found to have an incorrect first name. Whilst ID band discrepancies were being followed up, they were not changed in a timely manner as evidenced by the inspection team.	**Major**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	There is no clear demarcation between the body store and the post mortem room. Trolleys used in dirty areas are transferred into the transitional areas without disinfection or adequate precautions for visiting funeral directors and doctors.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
b) There is a documented standard operating procedure (SOP) detailing the consent process	Whilst there is no specific SOP for the consent process, procedures are incorporated in the *guidance for bereavement on the neonatal unit*. However, this does not make clear that a trained individual must always seek consent.	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Matters relating to HTA-licensed activities are only discussed at high level meetings. There are no formalised governance meetings involving the Designated Individual (DI), persons designate (PDs) or staff working under the licence. This means staff do not have the opportunity to attend HTA meetings relevant to them.	**Minor**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		

a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	The establishment could not provide assurance that tissue was disposed of in a timely manner.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	Mortuary fridge alarms are not currently connected to the pathology department system. If the alarm sounds out of hours, this is reliant on the security team hearing this on their patrols of the site. The inspection team were not assured that this was a robust procedure.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	One electric saw in the post mortem room has large areas of rust making it difficult to clean and decontaminate sufficiently.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice
The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	GQ1(g)	The DI is advised to review the persons designates on the licence to ensure all areas undertaking licensed activities are covered. Consideration should be given to making the histology operations manager a PD to ensure a route of escalation and oversight when working remotely.
2.	T2(d)	Whilst method and date of tissue disposal is recorded, this relies on individuals documenting ad-hoc on paperwork. This was not always recorded in the same place. The DI is advised to consider formalising this process of documentation.
3.	PFE1(c)	The DI is advised to extend the daily post mortem cleaning rota to include the body store floor.
4.	PFE1(e)	The DI is advised to review and prioritise the outstanding tasks from the recent refurbishment, such as the malfunctioning audio-visual doorbell and the need for padlocks on the external chiller unit gates.
5.	PFE3(d)	The DI is advised to further risk assess the security arrangements for staff working alone out of hours whilst undertaking viewings.
6.	N/A	The DI is advised to consider adding the Halton Hospital site to the licence so it may be used as part of contingency plans should licensable activities need to be transferred.

Background

Warrington Hospital is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

Warrington Hospital has been licensed by the HTA since 2007. This was the third inspection of the establishment; the most recent previous inspection took place in May 2017.

Since the previous inspection, there has been a change of Designated Individual and a refurbishment of mortuary facilities. There have been no significant changes to the licence arrangements, or the activities carried out under the licence.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017)

Review of governance documentation

The inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the post-mortem room, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for both the mortuary staff and security team.

Visual inspection

The inspection team visited both Warrington Hospital and Database storage facilities. This included a visual inspection of the mortuary body store, PM room, viewing room and tissue storage areas in Warrington, and the tissue storage and traceability arrangements at Dataspace.

Audit of records

Audits were conducted for five bodies in refrigerated and frozen storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. One discrepancy was identified (see shortfall T1c).

Audits of traceability were conducted for tissue blocks and slides from six PM cases, including audits of the consent documentation for the retention of these tissues. On discrepancy was found and the establishment could not provide traceability for slides prior to 2021 (see shortfall GQ2c)

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, satellite manager, security staff, maternity staff, and a consultant pathologist.

Report sent to DI for factual accuracy: 20 June 2022

Report returned from DI: 04 July 2022

Final report issued: 03 August 2022

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 04 January 2023

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004 (HT Act) or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   - A notice of proposal being issued to revoke the licence
   - Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or

- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

   This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

   In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.