Inspection report on compliance with HTA licensing standards
Inspection date: **13 and 16 March 2023**

Royal Preston Hospital

HTA licensing number 12037

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
Royal Preston Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*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 Preston Royal Hospital ('the establishment') had met the majority of the HTA's standards, ten 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
All applicable HTA standards have been assessed as fully met.

Major shortfalls

Standard	Inspection findings	Level of shortfall
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.	Not all mortuary procedures had a documented policy in place. There was no Standard Operating Procedure (SOP) in place for the following activity: • Procedures for the identity checking of bodies for staff to follow whilst supporting and undertaking the retrieval of organs by third party agencies. • Procedures for staff to follow to minimise the risk of a serious incident during a Post Mortem Examination (PM) Some SOPs lack detail and do not reflect staff practice. At the time of inspection, some procedures observed by the inspection team were not consistent with that of the SOPs. These include, but are not limited to, SOPs detailing the process for: • Viewings and formal ID's • Release/transfer SOP This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall, the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail to reflect current practice.	**Major**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Audit reports reviewed do not clearly document actions taken to rectify non-conformances, who is responsible and the timeframe for completing any follow up actions. This means there may be a risk that corrective and preventative actions to address non-conformances may not be completed or closed in an appropriate timeframe.	**Major**
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	Whilst an audit schedule is in place and audits have been completed, the audits do not contain a sufficient sample size for the establishment to assure themselves that any non-conformances are identified and robust follow-up action is completed. *Refer to standard T2(a) for more detail.*	**Major**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	The Inspection team are not assured all staff who carry out licensed activities are appropriately trained. Porters and members of the bereavement team who undertake licensed activities have not received training from the mortuary team. This poses the risk of a serious incident.	**Major**

c) Staff are assessed as competent for the tasks they perform	The Inspection team are not assured all staff who carry out licensed activities receive regular competency assessments. Assessments of competency are not carried out for members of the bereavement team who are involved in tissue retrieval out of hours. This poses the risk of bodies being incorrectly identified, and accidental damage to a body.	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
a) Bodies are tagged/labelled upon arrival at the mortuary	Whilst bodies are tagged on arrival at the mortuary, the Inspection team were not assured ID bands were checked by staff as per procedure. During the inspection, discrepancies were identified between identification bands for two of the bodies audited. This poses the risk of a serious incident relating to the viewing of the wrong body and release of the wrong body.	**Major** **(cumulative)**
b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records)	Whilst there is a system in place to track each body, fridge location numbers are not recorded in the mortuary register and the electronic system is not updated to reflect movement of the deceased.	
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	During the inspection, cases were identified where paper records of slides taken and the number of slides physically held did not match the number recorded on the laboratory information management system and consent paperwork had not been scanned to the case as per the SOP. These discrepancies had not been identified by the establishment's audits. This poses the risk of tissue blocks and slides being retained when no longer needed.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained	There are significant areas of damage to the structure of the building and equipment in use: • There are areas of exposed plaster and cracked ceiling tiles, in an annex off the isolation PM room following a flood. • There is evidence of mould in the annex off the isolation PM room following a flood. • The cover of the drain in the isolation PM room could not be lifted for staff to clean effectively. • Cracking of the floor tiles in the main PM suite and failure of the grouting. • The sealant around the floor and base of the PM tables in the main PM suite is failing. • There is exposed wood around the door frames in the PM suite. This poses the risk of ineffective cleaning and decontamination.	**Major**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Whilst there is a system in place for tissue retrieval teams to sign in and out of the mortuary out of hours, the staff supporting these teams do not always follow the procedure of the visitors log being completed. There is a visitors book for the use of family members attending the mortuary for a viewing, the inspection team noted the log is not always fully completed. This means mortuary staff are not always aware when the bereavement team and tissue retrieval teams have entered the mortuary for an authorised purpose out of hours .	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	There is insufficient freezer storage capacity to meet establishment needs. Due to the limited freezer storage facilities, bodies were identified as being held in refrigerated storage for longer than the HTA's recommended 30 days. The establishment has no long-term storage for bariatric bodies.	**Major (cumulative)**
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	The fridge used for the storage of toxicology samples awaiting transfer to the pathology lab is not attached to the central alarm system. Whilst the fridge does have an audible local alarm, it would not be heard out of hours. This poses the risk of damage to the tissue samples. Whilst fridge alarms were regularly tested. Systems in place for contacting staff out of hours are not challenged. Temperature trend analysis is not routinely undertaken to identify trends and the extent of any variations in storage temperatures.	

i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	Whilst there are mutual aid agreements in place, there are no documented service level agreements with local establishments available for review.	

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	There is no Persons Designate for every area that carries out HTA licensed activity. The inspection team were therefore not assured the DI has oversight of regulated activities on the maternity and gynaecology wards.	**Minor**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Whilst staff report incidents internally the inspection team are not assured all incidents and near miss incidents were appropriately reported to the HTA. The establishment was asked to report an incident meeting the threshold for an HTA reportable incident (HTARI) identified by the inspection team during the inspection process.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		

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	Whilst risks are assessed on a regular basis, the mitigating controls in place are not reflected in the risk assessments.	**Minor**
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	Whilst significant risks are entered into the Trust risk register and there is a process for escalation, the inspection team are not assured measures in place are robust and effective at mitigating risks to the deceased. *Refer to standard PFE2(i) for more detail.*	**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	There was significant rusting to three hydraulic trolleys, three mortuary trolleys and two autopsy saws. This poses the risk of ineffective cleaning and decontamination. *The inspection team received assurance from the establishment action was underway to replace rust damaged hydraulic trolleys.*	**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(a)	The DI is advised to use colour coded evisceration bowls for PM examinations
2.	GQ2(c)	The DI is advised to undertake a tissue traceability audit of all holdings removed and stored before 2021.
3.	GQ5(a)	The DI is advised to display a list of HTA reportable incidents to all areas of the establishment undertaking licensed activity.
4.	GQ6(a)	The DI is advised to separate risk assessments to HTARI risks and staff risks, the lone working risk assessment should be reviewed, and consideration given to the use of a “man down” alarm for staff use whilst supporting viewings.
5.	T1(b)	The DI is advised to add an additional external whiteboard to reflect the capacity within the overflow body store. The racking system within both the overflow body stores should be labelled to reflect the whiteboard.
6.	T1(d)	The DI is advised to further develop the existing database used in the mortuary to flag similar sounding names and to include the date and outcomes of body condition checks.
7.	PFE1(a)	The DI is advised to progress existing plans to repair the flooring affected by water damage
8.	PFE1(b)	The DI is advised to replace the worn transition tape in the body store, and to add tape between the PM room and the CT scanning room.

9.	PFE1(c)	The DI is advised to introduce a sign sheet to indicate the date and member of staff who has undertaken scheduled cleaning and decontamination activity.
10.	PFE1(e)	The DI is advised to remove the lock between the maintenance storage room and the Funeral Directors entrance to the mortuary. Consideration should be given to adding a sign to remind staff to lock the adjoining door between the viewing room and body store.
11.	PFE2(e)	The DI is advised to ensure fridges used to provide additional temporary storage can be added into the central alarm monitoring system before it is used.

Background

Royal Preston 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 December 2017.
There have been changes to the named personnel on the licence with a change of Corporate Licence Holder Contact (CLHc) in April 2018 and the DI in February 2019.

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:
The inspection included a visual assessment of the establishment including, body storage areas in the mortuary, PM room, viewing room and tissue storage areas. The inspection teams observed the processes for admission, release and viewing of bodies within the mortuary.

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 mortuary, records of servicing of

equipment, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary staff, porters and consent seekers.

Visual inspection
The inspection included a visual assessment of the establishment including the PM room. body storage areas and viewing rooms. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted onsite of five bodies from refrigerated storage, and one body in frozen storage. Identification details on bodies were crosschecked against the information recorded in the register, associated paperwork and electronic records. The inspection team identified a discrepancy between the post code information on the identification bands for two bodies.

Audits of visitors signing in log for viewings were conducted. Three records reviewed were incomplete with no sign out time recorded.

Audits of traceability were conducted for tissue blocks and slides from five coronial consented cases. The inspection team identified one case did not have a electronically held copy of the families wishes. One case found a discrepancy in the number of slides stored against the number recorded in the laboratory information management system.

Meetings with establishment staff
Staff carrying out processes under the license were interviewed including the DI, mortuary manager, pathologist, SUDIC lead, APT, mortuary porter, bereavement midwife and consent seekers.

Report sent to DI for factual accuracy: 30 March 2023

Report returned from DI: 24 April 2023

Final report issued: 04 May 2023

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: 18 October 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.