Inspection report on compliance with HTA licensing standards
Inspection date: **08 and 09 October 2024**

Royal Shrewsbury Hospital
HTA licensing number 12184

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 **Royal Shrewsbury Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
A&E	-	*Carried out*	-
Satellite site **Princess Royal Hospital**	Not licensed	Licensed	Licensed

Mortuary (satellite site)	-	-	*Carried out*
Maternity	-	-	*Carried out*
A&E	-	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 Royal Shrewsbury Hospital ('the establishment') had met the majority of the HTA's standards, eight major and two minor shortfalls were found against standards for Governance and quality systems, Traceability and Premises, facilities and equipment. Two of the Major cumulative shortfalls relate to findings from the last inspection. At the inspection feedback meeting, the HTA inspectors expressed their concerns that adequate steps had not been taken to address these findings in the intervening period and to embed suitable practices at the establishment. A similar issue was identified in standards GQ3(c) and PFE2(e) at the previous inspection carried out in January 2023.

Compliance with HTA standards

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.	Whilst Standard Operating Procedures (SOPs) cover all mortuary procedures, at the time of inspection some procedures could not follow the relevant SOPs as the underlying systems were not active. Additionally, some procedures described by staff appeared to be better than the documented SOPs. Examples include, but are not limited to, SOPs detailing the process for: • Lone Working • Security • Mortuary Register • Fridges • Lodging and release of bodies. 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 capable of being implemented and reflect current good practice.	**Major**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	Whilst regular documented body condition checks are undertaken, bodies exhibiting signs of deterioration are not always transferred to long term storage in a timely manner. Whilst no bodies had been in refrigerated storage over 30 days, the inspection team identified several bodies starting to show signs of deterioration that had not been transferred to a freezer.	**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	Porters, contracted funeral directors and site teams have not been appropriately trained for all mortuary duties undertaken, this includes the completion of the mortuary register, and the release of bodies out of hours. This poses the risk of release of the wrong body incident.	**Major (cumulative)**

c) Staff are assessed as competent for the tasks they perform	The inspection team are not assured that all staff who carry out licensed activities receive regular competency assessments. No records were available for review relating to the site team, porters and contracted funeral directors being assessed as competent to undertake activities under the licence. This poses the risk of a reportable incident.	
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	Some risk assessments lack detail with not all risks to the dignity and safety of bodies identified. Furthermore, not all mitigating controls identified have been implemented and fully embedded. These include but are not limited to: • Post Mortem (PM)Examinations • Lone working • Security • Transfer of bodies to the bariatric unit at the satellite site This is not an exhaustive list of the risk assessments requiring review. To fully address this shortfall, the establishment should review all risk assessments relating to mortuary activities to ensure that they are accurate and reflect current practice.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	Whilst there is an intruder alarm at the satellite site this does not sound or electronically alert the security team should it be activated. Additionally, at the satellite site, there is no audiovisual device on the door to the mortuary from the main corridor so staff cannot visually identify who is requesting access to the mortuary. This poses a risk of unauthorised access.	**Major (cumulative)**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	There is no visitors signing in/out log for authorised staff who enter the mortuary for a legitimate purpose under the supervision of porters. This includes estates teams, Police Officers and Site staff. *The establishment submitted sufficient evidence to address this element of the shortfall before the report was finalised.* Furthermore, the security audit does not include a check of the mortuary keys in circulation held by mortuary staff, porters and the estates team. This means the DI is unable to have effective oversight of personnel entering the mortuary for a legitimate purpose.	
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	At the satellite site, the courtyard from the mortuary where funeral directors collect bodies and where the bariatric storage unit located is used as a thoroughfare by staff and others accessing the main hospital. This poses a risk to the dignity of the deceased as passersby can oversee the transfer of bodies from the mortuary and see into the bariatric storage unit when it is in use. Staff vehicles were parked in the courtyard in front of the fridge compressor units and the housing for the gas used to cool the fridge had failed leaving the gas bottles exposed. This poses the risk of damage to the fridge cooling system. Additionally, the floor surface of the walkway used to transport bodies is uneven and poses the risk of accidental damage to the deceased. *After the inspection team left the site, evidence was provided by the establishment that action has been taken to prevent staff from accessing the main hospital from the courtyard.*	**Major**

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	Whilst most of the fridges are monitored centrally and there is an alerting system in place, the temporary storage units and toxicology fridge at the hub site and the external unit at the satellite site are not connected to the monitoring system. Furthermore, whilst there is regular alarm testing of the upper set range there is no testing of the lower set range and no Out of Hours (OOH) testing is carried out. The establishment was unable to provide information regarding temperature of the upper and lower set ranges and the time delay for the alarm. Additionally, there is no testing of the upper and lower set range of the storage fridge in maternity.	**Major (cumulative)**
f) Temperatures of fridges and freezers are monitored on a regular basis	Whilst all fridge and freezer units are manually temperature checked, this is not undertaken at weekends or on Bank Holidays. As not all fridge and freezer units are centrally monitored and alarmed, there is a risk of a delay in the identification of a temperature excursion and appropriate action being taken in mitigation.	
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	Not all items of equipment in the mortuary is in good condition and appropriate for use: • The electrical supply in the PM room is incompatible with the saw so staff use an extension cable located in the body store. This also means that staff are leaving an operational PM room in full PPE to access the cable and body store sockets. • There is minor chipping in the enamel of the post mortem tables. • Additionally, there is minor rusting to hydraulic trolleys used to transfer bodies, this poses the risk of ineffective cleaning and decontamination. • There is a wooden measuring stick kept in the body store at the Hub site, this cannot be effectively decontaminated. *(see advice item 3)*	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	There is a process in place for the offsite transfer of samples taken for toxicological analysis. However, the establishment does not obtain confirmation that the tissue has been received by the third party who carries out testing. This poses the risk of a loss of traceability.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	Systems and processes to alert staff in the event of a failure of major equipment lack detail regarding the roles and responsibilities of staff teams, including the process in place for contacting mortuary staff, who do not routinely undertake on call duties. Offsite contingency storage is available but has never been needed. However, information regarding the responsibility for the care of the deceased is not clear, posing the risk of a reportable incident.	**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(c)	To ensure the use of body bags for decomposed bodies and bodies with a known infection risk is reflective of the guidance in the document published by the Health and Safety Executive (HSE). " Managing infection risks when handling the deceased"; Managing infection risks when handling the deceased - HSG283 - HSE. The DI is advised to review staff practice in line with the SOPs and Service Level Agreements (SLA's) in place with the coroners contracted funeral directors and ward staff. This will help mitigate the risk of cross contamination of bodies and the risk of an infestation of bodies already in storage.
2.	GQ4(a)	The DI is advised to consider the expansion of the functionality of the existing electronic mortuary database to include length of stay, and to alert staff of the due date of condition checks. This will reduce the risk of a transcription error due to the use of more than one paper based system.
3.	PFE3(a)	The DI is advised to consider a full refurbishment of the post mortem (PM) suite at the hub site, including an upgrade of the PM tables. This will support the expected increase in activity due to the planned hospital expansion

Background

Royal Shrewsbury Hospital has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in January 2023.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence. However, pathology services including the mortuaries at the Hub and Satellite sites have combined with another NHS Trust to form a pathology network.

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 mortuary, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for both the mortuary staff and porters.

Visual inspection
The inspection included a visual assessment of both establishments including, body storage areas in the mortuaries and in the maternity department, PM room, viewing rooms and tissue storage areas. The inspection teams observed the processes for admission, of bodies within the mortuary.

Audit of records
Hub Site
Audits were conducted onsite of four bodies from refrigerated storage, and one body stored in long term frozen storage. Identification details on bodies were crosschecked against the information recorded in the register, electronic records and associated paperwork. A minor discrepancy relating to the transcription of information from the mortuary register to the mortuary database was identified. This was rectified immediately.

Audits of traceability were conducted for tissue blocks and slides from five coronial cases, these included audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

Satellite Site

Audits were conducted onsite of three bodies from refrigerated and one body stored in long term frozen storage. The admission of one body by porters was observed. Identification details on bodies were crosschecked against the information recorded in the register, electronic records and associated paperwork. No discrepancies were identified.

Meetings with establishment staff
Staff carrying out processes under the license were interviewed including the DI, mortuary manager, APT, adult consent seeker, mortuary porter, and bereavement midwives.

Report sent to DI for factual accuracy: 04/11/2024

Report returned from DI: 08/11/2024

Final report issued: 08/11/2024

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.