Inspection report on compliance with HTA licensing standards
Inspection date: **23 January 2024**

Warwick Hospital

HTA licensing number 12080

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
Warwick Hospital	Not licensed	Licensed	Licensed
Mortuary	-	-	*Carried out*
Pathology lab	-	-	*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 Warwick Hospital ('the establishment') had met the majority of the HTA's standards five major and nine 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

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.	Standard Operating Procedures (SOPs) require review to ensure they are in date, provide sufficient detail, reflect practice and clear for staff to follow. As mortuary staff work across sites in another licensed establishment, it is not always clear in SOPs which site a procedure relates to. Examples include but are not limited to: • MO LPR43 Deceased patient transfer offsite does not consistently state what three points of identification can be used at relevant stages of the procedure, including checking three identifiers with documentation brought by the transferring funeral director. This SOP is also past its review date. • MO LPR74 Procedural overview of the admission of deceased patients does not include the process for out of hours admissions. It refers to checking the identification of the deceased against the Coroner's PM authority and placing on a PM wristband, which is not relevant to this establishment. The grading system used for condition checking of bodies is also not referred to. The SOP does not include how bodies of unknown identity are managed and uniquely identified, until formal identification is completed. • MO LPR41 Deceased patient release does not fully reflect the procedure undertaken by staff to release bodies. The three identifiers provided on the identification checklist brought by funeral directors is checked against the hospital DPD form and the identification on the patient at the point of release. • SWH 05914 Bereavement Operating Process does not include what identifiers are obtained from relatives when they call to book viewings or how these are checked when relatives arrive at the bereavement office. The hospital DPD form is used to check three identifiers with the relatives before viewing but the procedure does not include a physical check of three identifiers on the body before viewing by relatives. • MO LPR44 Identification and viewing of deceased patients does not state the hospital DPD form is left out for bereavement staff to check three identifiers with relatives. However, the SOP does state that three points of	**Major**

	identification should be checked against the identification band before the viewing proceeds, which does not happen.	
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	Most risk assessments in place have not been regularly reviewed in-line with the establishment's own requirements which is determined by the level of risk identified.	**Major (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	Where risk ratings for an activity have been calculated at a level requiring action or escalation this has not been done.	
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	The current procedure for viewings does not include a physical check of a minimum of three identifiers of the deceased before viewing by relatives.	**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)	The mortuary CCTV feed goes directly to the hospital security office. There is a risk that mortuary activities could be viewed by security staff. The mortuary manager can request CCTV footage to review for specific incidents, but it is not readily available for audit purposes and subject to delay. The door between the viewing room and the body store has a thumb lock on the inside meaning that relatives could unlock this door and access the body store.	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Staff are unable to visually verify who is requesting access at the body store door. This is a risk to staff who often work alone and could lead to unauthorised access into the mortuary. The inspection team were informed that hospital security staff allow funeral directors and ambulance staff to access the mortuary to admit bodies out of hours. This is not in-line with standard procedure and their attendance at the mortuary is not documented, therefore not auditable. The DI and the mortuary management team were not aware this is happening. In addition, security staff, funeral directors and ambulance staff are not trained in mortuary practices meaning there is a risk correct procedures are not followed. The mortuary manager does not receive up to date swipe card access records for the mortuary so cannot gain assurance on access. This could mean persons who no longer have authorised access to the mortuary could still gain entry for a period. The current security access audit does not include checking CCTV and swipe card access against the department visitor logs. Hospital estates staff have swipe card access to the mortuary and may enter the mortuary unsupervised to carry out work. The DI cannot be assured of who has access to the mortuary at all times.	**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		
c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	The information leaflet given to relatives who give consent to a post mortem (PM) examination does not fully reflect the HT Act 2004 and the HTA's codes of practice. This includes a reference to the HTA's old code of practice on disposal and implies that consent is only required for large pieces of tissue, whole organs, or body parts.	**Minor**
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	The in-house training document for PM consent seekers refers to limited PM examinations and biopsies. PM examinations do not include taking biopsy samples. There is a risk that staff who seek consent for PM examination may not be correctly informing relatives of the extent of limited PM examinations.	**Minor**
d) Competency is assessed and maintained	Staff who are trained in seeking consent for adult consented PM examinations are not competency assessed.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although there is a documented schedule of mortuary audits for the pathology network, the range of audits are limited for Warwick Hospital and some of these audits were not completed for last year.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		

c) Staff are assessed as competent for the tasks they perform	Competency assessments for staff have inconsistently been carried out and recorded, some have been partially completed.	**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	Although mortuary staff are aware of what HTA Reportable incidents (HTARIs) are, they are not aware there is an SOP in place to follow. Portering staff are not aware of incidents that require reporting to the HTA.	**Minor**
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	The body store floor is cracked in some places, particularly at the edge of the floor drain. Previous repairs have been completed using concrete, which is not sealed therefore porous and cannot be adequately cleaned or disinfected.	**Minor**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	Although there is a cleaning schedule and a record completed by staff, there is no SOP for staff to follow.	**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	Although regular alarm tests are conducted and recorded, the call out procedure for alarm triggers out of hours is not included. On-call staff are sent an email to notify them of alarm triggers out of hours. There is a risk that an email notification may not be seen or heard by staff to act within an appropriate time frame.	**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.	C1(c)	The DI is advised to add a date and version number to the PM examination information leaflet given to relatives.
2.	C2(a)	The DI is advised to add a date and version number to the in-house PM examination consent document to help ensure that staff are trained using the most up to date version.
3.	C2(b)	The DI may wish to consider training more staff to seek consent for PM examination.
4.	GQ1(a)	The mortuary manager is advised to consider ways of documenting procedures in SOPs to clearly differentiate between mortuary sites in the network. This will help to ensure staff are clear on the processes to follow for each site they work at. In addition, references to staff roles and cross references to other SOPs should be checked and updated to avoid confusion.
5.	GQ2 (a)	The DI is advised to include regular audits that cover all activities at the establishment. For example, the viewing procedure, long term body checks, condition checks and storage of PM tissue blocks and slides.
6.	GQ4(a)	To help determine appropriate time scales for the retention of records and tissue, the DI is advised to refer to the RCPath guidance 'The retention and storage of pathological records and specimens' or the NHS England 'Records management code of practice'.
7.	GQ6(a)	The DI is advised to seek training for staff to correctly and competently carry our risk assessments to help ensure appropriate levels of risk are identified, recorded and escalated when required.
8.	T1(b)	The DI is advised to consider using the mortuary register number as another identifier for bodies while in the care of the mortuary, especially when bodies are admitted with unknown identities.
9.	N/A	The DI should ensure that all mortuary staff are aware of lone working procedures, including the requirement to use the lone worker device when working alone at the establishment.

Background

Warwick Hospital has been licensed by the HTA since April 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in November 2021.

Since the previous inspection, the list of Persons Designated under the licence has been updated to reflect changes in staff working 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

Three standards (GQ1(b) and PFE3(c) and PFE3(e)) out of a total of 72 were not covered during the inspection. These standards are not applicable as the establishment does not undertake PM examinations.

Review of governance documentation

The inspection team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities for the mortuary were reviewed. Traceability audits, risk assessments, meeting minutes, incidents, consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the mortuary body storage area, PM room (currently housing temporary body storage units) and viewing room. The storage arrangements for relevant material held within the pathology department was also inspected.

Audit of records

The inspection team undertook audits of traceability for five bodies in storage. This included bodies with same/similar names and a body in long term storage. Traceability details were crosschecked between the identification bands on the bodies, information on the door of the body store, the mortuary register, paperwork and mortuary spreadsheet. No discrepancies were identified.

The inspection team also witnessed a release of a body from the mortuary. Records produced and used to crosscheck with mortuary paperwork and identify the body prior to the activity being undertaken were reviewed. The activity conducted used three identifiers of the deceased crosschecked between paperwork produced and the identification bands on the body. No discrepancies were identified.

An audit of all PM tissue blocks and slides in storage from cases pre-2020 was conducted (when PM examinations ceased at the establishment). It was identified prior to the inspection that the establishment was storing PM tissue blocks and slides that should have been disposed of following the last inspection and they had identified more cases not previously accounted for. In some cases, tissue had been used for a scheduled purpose for which consent was not in place. Minor discrepancies for five cases had already been identified by the establishment and confirmed during this audit. These incidents are being managed through the HTA Reportable Incident (HTARI) process.

Meetings with establishment staff
The assessment team met with staff carrying out processes under the licence, including mortuary staff, quality manager, a portering staff member, staff involved in the consent seeking process for adult and perinatal PM examination, staff responsible for the removal of relevant material in the Emergency Department and the DI.

Report sent to DI for factual accuracy: 07/02/24

Report returned from DI: 21/02/24

Final report issued: 22/02/24

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: 19 December 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.