Inspection report on compliance with HTA licensing standards
Inspection date: **7-8 June 2023**

University Hospitals Coventry and Warwickshire
HTA licensing number 30018

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 **University Hospital Coventry and Warwickshire**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab			*Carried out*
Maternity		*Carried out*	*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.

The targeted unannounced site visit of University Hospitals Coventry and Warwickshire ('the establishment') found four major and one minor shortfalls against standards for Governance and quality systems and Premises, facilities and equipment. These related to condition monitoring and recording of information on condition of bodies in storage and fridge and freezer alarm testing.

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

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	While an informal security audit is in place and these audits have been completed, the scope of the audit should be widened to include viewing CCTV and including this audit on the audit schedule.	**Major**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	Although staffing levels have been included on the Trust risk register and a business case is in place to assess the needs of the mortuary, there is an immediate risk to staffing levels that needs to be considered. *Refer to standard PFE2a for further detail*	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

a) Storage arrangements ensure the dignity of the deceased	During the body audits the inspection team found discrepancies when body condition checks should have been undertaken. Good documentation is in place however staffing levels do not allow the completion of the paperwork and condition checking to be completed effectively over three sites.	**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	Due to a change in service providers monitoring temperatures, external fridge and freezer alarms have not been set up to notify staff of any deviations from expected ranges. The alarm panel is situated in the mortuary administration office which is locked out of hours. This panel will alarm locally, however due to where the panel is situated the alarm is not audible from the body store area. Mortuary staff are unaware of any temperature deviations out of hours. This does not provide assurance that the alarms will trigger when temperatures deviate from the expected range or be audible to staff entering the body store out of hours.	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The external controls and power supply for the external freezer unit are accessible. This leaves a risk of the external controls being tampered with.	**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)	Whilst the inspection did not focus on this standard the DI is advised to inform and record discussions with relevant parties, such as the Coroner's office or family nominated funeral directors as to the condition of bodies starting to show signs of deterioration. This may assist with expediting services outside of the control of the mortuary, especially if relevant parties are aware that a delay to their services could potentially impact the dignity of the deceased by leading to more advanced deterioration in the condition of the body.
2.	T1(a)	Whilst the inspection did not focus on this standard the inspection team identified one case where the shroud on the body was soiled. The DI is advised to ensure clean sheets are used to shroud bodies prior to transferring bodies to the freezer. The DI is also advised to meet with maternity staff to ensure that the Trust DPD form is transferred to the mortuary with the bodies which documents the identifiers which can be checked against the identification bands.
3.	T1(d)	Whilst the inspection did not focus on this standard the inspection team identified three cases where the same similar name procedure was not followed. This will be identified as a shortfall at the next routine inspection if not addressed.
4.	PFE1(a)	Whilst this standard was not covered during this inspection, the DI is advised to address the maintenance requirements of the premises, in particular the body store and funeral director entrance at the unlicensed body store. There are several areas where the walls and ceilings are damaged exposing porous plaster. Wooden door frames and fittings are also showing signs of damage. These areas would be difficult to adequately clean and decontaminate, posing a potential health and safety risk to mortuary staff and visitors.
5.	PFE2(i)	A business plan is in place to increase the number of permanent body store fridge and freezer spaces. The DI is advised to look at Clinical Commissioning Groups (CCG) numbers for bariatric and super-bariatric patients that are within the Trust catchment area. This will help with resilience and future-proofing the mortuary capacity.
6.	PFE3(a)	Whilst this standard was not covered during this inspection, the DI is advised to also address the maintenance requirements of the fridges. Some fridge seals are damaged and in need of repair or replacement. This will be identified as a shortfall at the next routine inspection if not addressed.

Background

University Hospitals Coventry and Warwickshire has been licensed by the HTA since 2009. The most recent previous inspection took place in January 2022. Since the previous inspection, a refurbishment to the unlicensed body store premises took place to increase freezer capacity by a further 12 spaces with the use of fridge to freezer conversion units.

A decision to undertake an unannounced visit was made by the HTA's Director of Regulation at a Regulatory Decision-Making meeting on 9 May 2023. This followed concerns relating to body storage and conditions that may impact dignity of the deceased. Accordingly, this inspection focussed on the following standards: C2a, GQ2a, GQ2c, GQ6a, T2a, PFE1e, PFE2a, PFE2b, PFE2c, PFE2e, PFE2f, PFE2i.

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:

Review of governance documentation

A review of governance documents was not undertaken as part of this inspection. A full review of governance documentation will be undertaken at the next routine inspection to be scheduled.

Visual inspection

The inspection team undertook a visual inspection of the premises and unlicensed body store which included the body storage area, the viewing room, and the temporary freezer storage unit.

Audit of records

The inspection team undertook audits of traceability for eight bodies in storage. This included one body still in refrigerated storage over 30 days and two bodies with a same or similar name. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, the mortuary register and associated paperwork. Whilst all bodes were traceable with the use of three

identifiers, some minor discrepancies were identified with the establishment procedures. The body condition checks had not been completed as per procedure. One body had an identification tag that was not fully legible.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence. This included the mortuary manager, mortuary staff and pathologists undertaking PM examination activity who is the DI.

Report sent to DI for factual accuracy: 7 July 2023

Report returned from DI: 20 July 2023

Final report issued: 7 August 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: 17 April 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.