Inspection report on compliance with HTA licensing standards
Inspection date: **26th and 30th of September 2022**

Worcestershire Royal Hospital

HTA licensing number 12079

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 **Worcestershire Royal Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Accident and Emergency Department	-	*Carried out*	-
Satellite site **Alexandra Hospital, Redditch.**	Not licensed	Licensed	Licensed
Mortuary (satellite site)		*Carried out*	*Carried out*
Accident and Emergency Department	-	*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 Worcestershire Royal Hospital ('the establishment') had met the majority of the HTA's standards, 3 major and 4 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
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 establishment cannot demonstrate that all staff involved in the consent seeking process for perinatal/paediatric post mortem examination have received training which addresses the requirements of the HT Act and the HTA's codes of practice. (as a result, standards C2 (b), (c) and (d) cannot be assessed in relation to these individuals)	**Major**
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	A swipe card access system has been installed at both sites however it is not yet operational at the hub site due to technical issues. The ongoing use of keys and key code locks does not provide the establishment with the ability to monitor or audit access to the mortuary. As a result, there is currently no system in place to formally review access records to ensure that it is limited to those with legitimate right of access. The use of keys and key code locks has not been risk assessed. The key codes which allow access to the mortuary are not regularly changed.	**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	Although the mortuary actively manages capacity, there is insufficient freezer storage capacity to meet the need for long-term storage of bodies. There are only four standard size freezer spaces for the long-term storage of bodies all of which are located at the satellite site. There have been multiple occasions over the preceding 12 months where frozen storage has not been available in circumstances where transfer to frozen storage was indicated by virtue of the length of time the deceased had been in the mortuary. *[See advice item 7]*	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	Whilst the establishment carries out regular audits of all post mortem tissue stored during the previous three month period, there is no regular audit carried out which includes all archived tissue.	**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	Although the establishment has an extensive training and competency assessment programme it does not include post-mortem practices e.g. reconstruction techniques.	**Minor**

g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	Although visiting/ external mortuary staff (such as locums) receive an induction, they do not have access to the electronic Quality Management System in order to read and acknowledge the establishment's policies and SOPs relating to licensable activities. The inspection team was not assured that all locum staff had read the most recent versions of the establishment's policies and procedures.	**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	**Worcestershire Royal Hospital** The sealant to the post mortem tables and ventilation housing has eroded and is in need of replacement.	**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.	T1(b)	The establishment maintains a paper mortuary register which staff complete to record the deceased's details. No discrepancies were identified in this register. However, the DI is advised to ensure that if supplementary information is subsequently added to the register by way of a note, this is secured to the register to prevent loss and to capture this information in any future audits of the register.
2.	C1(a)	The DI is advised to remove the references within the Post Mortem Consent Policy to "Next of Kin/NOK" as this does not reflect the requirements of the HT Act and the HTA's Codes of Practice.
3.	GQ1(g)	The DI is advised to ensure that when there is a change of Persons Designated, for example in A&E or Maternity, the new postholder is invited to relevant HTA governance meetings.

4.	GQ2a	The DI is advised to include the mortuary access audits into the audit schedule once the swipe card access becomes fully operational.
5.	PFE1(a)	In the event that the former post mortem room at the satellite site is brough back into use for post mortem activity, the DI is advised to ensure that the doors between the body store and the post mortem room are of a non-porous nature to facilitate effective decontamination.
6.	PFE1(e)	The DI is advised to ensure that visitor logs are completed for all mortuary visitors at both sites to enable access to be monitored and audited.
7.	PFE2(c)	In addition to ensuring there is adequate on-site frozen storage capacity (see shortfall under PFE2(c)), the DI is advised to clarify that the written contingency arrangements in place address peaks in demand for frozen storage.

Background

Worcestershire Royal Hospital has been licensed by the HTA since June 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in June 2017.

Since the previous inspection, the following changes have been made to the licensing arrangements: the current Corporate Licence Holder contact (CLHc) was approved in 2019, the current DI was approved in 2022 and Persons Designated (PDs) were added to the licence in 2017, 2019 and 2022. There is a pending application to grant a temporary Licence at the Satellite site to enable continuity of PM activity during works to the hub site PM room currently planned for November 2022.

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 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 were reviewed. Traceability audits, risk assessments, staff training and competency records, meeting minutes, cleaning logs and schedules, alarm testing records, incidents, consent seeking procedures, including completed consent forms and information for relatives giving consent was also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises at the hub site which included the mortuary body storage area, the PM room, the temporary body storage units, and the viewing room. The inspection team also undertook a visual inspection of the satellite site which included the body storage area, the viewing room and the former PM room which is currently used to site contingency storage when the need arises.

Audit of records

The inspection team undertook audits of traceability for four bodies in storage at both the hub and satellite sites. This included bodies with same / similar names, a body housed in the temporary storage unit, a body in frozen storage and a Paediatric case. Traceability details were crosschecked between the identification band on the body, information on the mortuary whiteboard, the mortuary register and associated paperwork. No discrepancies with traceability were identified on either site.

Audits were conducted of tissue taken at PM examination for three cases which had been sent to histology. Samples are stored in a dedicated area of the mortuary. Information was crosschecked between consent forms, information on the mortuary block/slide ledger and tissue blocks and slides being stored. One case reviewed demonstrated disposal of tissue had been completed in line with the wishes of the family. The further two cases demonstrated they were being held with appropriate consent for a scheduled purpose. No discrepancies were identified.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including the mortuary manager and members of mortuary staff, laboratory manager, members of the portering staff and team, staff involved in the consent seeking process for perinatal PM examination, a pathologist who undertakes PM examinations and the DI.

Report sent to DI for factual accuracy: 31st October 2022

Report returned from DI: 4th of November 2022

Final report issued: 21st of November 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: 8 June 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-basedreview 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.