Inspection report on compliance with HTA licensing standards
Inspection date: **19 July 2023**

Stepping Hill Hospital

HTA licensing number 12031

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
Stepping Hill Hospital	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*
Pathology lab	-	-	-
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.

Although the HTA found that Stepping Hill Hospital ('the establishment') had met the majority of the HTA's standards, two major and four minor shortfalls were found against standards for Governance and quality systems 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
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	There are two areas in the mortuary's forecourt where the semi-permanent overflow fridges are located. One bank of fridges is covered by a wooden frame and although the fridge doors are individually locked the area accommodating the units is open to the public. This poses a risk to the dignity of the deceased when audits or checks are being carried out, such as ID checks or condition checks. One bank of fridges is located in a garage. The entrance to this unit is not covered by CCTV and is accessed using a key which is stored in the mortuary. There is no system in place for recording who has been in this body store, and when they arrived and left.	**Major**
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	The mortuary is not connected to a back-up generator system. In the event of a power failure, although the establishment has an agreement to transfer bodies to another HTA licensed establishment, this arrangement is unlikely to be sufficient due to the extent of storage facilities that would be required. This poses a risk to the dignity of the deceased. Furthermore, during a power outage, there is a possibility that the mortuary access systems would fail posing a security risk.	**Major**

Minor 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.	Some Standard Operating Procedures (SOPs) have not been updated to reflect current practices. These include: ○ The consent for perinatal PM guidance document does not include the updated procedures for sharing paperwork with the receiving establishment prior to the transfer of deceased. ○ The viewing SOP details that families are always accompanied by staff in the viewing room when this is no longer the case. ○ The long term storage of bodies SOP does not refer to the form that is completed for bodies that have been in the mortuary for extended periods of time. ○ The long term storage of bodies SOP does not detail any condition checking of the deceased.	**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	The Mortuary and Bereavement Manager's competency assessments were overdue.	**Minor**
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	Although the establishment has a suite of risk assessments, not all practices and processes relating to licensed activities are included: o there is a lone working risk assessment, however it is not specific to mortuary activities out of hours. o there is an accidental damage risk assessment however it focuses on the risk of an HTA reportable incident, rather than the risk to the dignity and integrity of bodies; o there is a risk assessment which covers failure of the establishment to provide services, however it does not cover equipment breakdown and the use of the semi-permanent overflow body storage units.	**Minor**
(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	Although there are control measures in place to minimise identified risks, some measures have not been documented in the establishment's risk assessments, these include: o the risk assessment relating to the misidentification of the deceased does not detail the robust identification checks that are in place when bodies are admitted, transported and/or released to/from the mortuary. o the risk assessment relating to accidental damage of the deceased does not detail what precautions are considered when storing bariatric or irregular shaped bodies.	**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.	C2(d)	Competency assessments for perinatal PM consent seeking include staff observing the process and being observed carrying out the procedure. As this is infrequent, not all staff have the opportunity to be signed off as competent. The DI may wish to consider a system of simulation training. This will allow additional staff to be trained so that the establishment can offer a seven-day service.
2.	GQ6(a)	There is some duplication of hazards in the establishment's risk assessments relating to licensable activity. The DI may wish to review these and amalgamate those which overlap. This will help to streamline documentation and reduce the time taken for staff to review the documents.
3.	PFE1(a)	During the inspection the mortuary forecourt was littered with rubbish. Electrical units from the hospital had also been left directly outside the overflow fridges, awaiting disposal. The DI is advised to add this area to a cleaning schedule and contact the relevant department to ensure it is kept clear.
4.	PFE2(a)	The semi-permanent overflow fridges are overlooked by hospital wards. The DI may wish to consider a lower canopy to maintain dignity of the deceased during admission and release.

Background

Stepping Hill Hospital has been licensed by the HTA since September 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in May 2019.

Since the previous inspection, there have been significant changes to the licence arrangements including changes to the Designated Individual (DI) and Corporate Licence Holder contact (CLHc) in August 2022. Furthermore, semi-permanent fridges have been erected outside the main mortuary building increasing capacity by 45 spaces.

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
66 out of 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017). Standards GQ1(b), T2(a), T2(b), T2(c) PFE3(c) and PFE3(e) were not applicable as the establishment do not carry out PMs.

Review of governance documentation
The inspection team reviewed the establishment's self-assessment document provided by the DI. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures, risk assessments, audits, incidents, meeting minutes, equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for families giving consent for perinatal PM's were also reviewed.

Visual inspection
The inspection team undertook a site visit inspection including the main mortuary body storage area, the semi-permanent overflow body storage areas and the storage area within the maternity department.

Audit of records
The inspection team undertook traceability audits for five bodies in storage including one perinatal body and one body that was stored in the freezer. Traceability details were crosschecked between the identification band on the body and information on the electronic and paper records. No discrepancies were identified.

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including the Mortuary and Bereavement Manager, trainee APT, porter, Pathology Operations Lead, two Bereavement Midwives and the Technical Head of Cellular Pathology who is the establishment's DI.

Report sent to DI for factual accuracy: 27 July 2023

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 16 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: 21 November 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.