nspection report on compliance with HTA licensing standards
Inspection date: **6 March 2024**

Sheffield Children's Hospital
HTA licensing number 12001

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
Sheffield Children's Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 Sheffield Children's Hospital ('the establishment') had met the majority of the HTA's standards, five major and seven 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) lack sufficient detail and require review to ensure they detail each stage of the procedure, reflect practice and are methodical for staff to follow. Examples include but are not limited to: • Releasing a body from the mortuary 350.1.017 states 'the funeral director will bring either a green form and transfer of care form' for ward deaths which is confusing. Staff informed the inspection team that in practice, funeral directors bring documentation stating a minimum of three identifiers of the deceased. In addition, coroner's bodies are only released with a signed copy of a coroner's form. However, it is not clear that the coroner's form is brought by the funeral director to release the body. • Viewing procedures 360.1.027 does not include what three identifiers of the deceased are obtained when booking a viewing in the 'pre-viewing arrangements' section and the SOP is not clear to follow. • Extra body identification 350.1.087 states that when bodies are received from external trusts where they do not have an ID band in place, one is completed using the paperwork brought with the body. In practice, the admission of the body would be refused. Where a procedure refers to checking identification at relevant points of a procedure, what identifers could be used and what they are checked against are not always stated. Examples include but are not limited to: • Accepting a body into the mortuary 350.1.090. • Releasing a body from the mortuary 350.1.017. • Referral or work and transport requirements 326.4.324 • The Coroner's post mortem 350.1.095 This is not an exhaustive list. All SOPs require review to ensure they meet the required standard.	**Major**

GQ2 There is a documented system of audit		
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Although audits are carried out the inspection team reviewed audits with open CAPAs for non-conformances from 2023 and identified audits not closed from 2021 and 2022.	**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	The establishment has identified a significant risk to the delivery of mortuary services due to the current mortuary staffing levels. This risk was placed on the Trust risk register in October 2022. Whilst plans are in place to address this risk, these should be expedited and fully supported to ensure the mortuary service's future.	**Major**
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	Although the SOP for viewings states three identifiers of the deceased are obtained prior to viewings, staff informed the inspection team that in practice two identifiers are usually obtained. This presents a risk of viewing of the wrong body.	**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	The mortuary does not currently have a visitor log for staff or contractors who attend the mortuary directly. Occasionally the porters may be responsible for admitting a body out of hours. The inspection team were informed that a minimum of two porters and nursing staff are involved in the process, however, only one porter will record their name in the mortuary register. This may not be the porter who has used their swipe card to gain access to the mortuary. The attendance of all staff accessing the mortuary out of hours is not documented, therefore not auditable. Mortuary CCTV footage is erased every 28 days meaning the current quarterly security access audit does not include review of CCTV footage for the entire quarter.	**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		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	The Trust Post Mortem consent policy 990-104 refers to doctors seeking consent for PM examination which does not reflect current practice.	**Minor**
b) There is a documented standard operating procedure (SOP) detailing the consent process	The SOP Conducting a PM consent meeting 350.2.009 states consent for PM examination can be obtained by the senior treating consultant who may not have received training in this task and PM consent can be sought by bereavement staff who are no longer in post. The SOP also references HTA Code of Practice 1, which is out of date.	**Minor**
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	Although the porters have received training in mortuary activities, in some cases training has not been completed for sometime. The activities they undertake have also changed and the training documentation needs updating to reflect this.	**Minor**
c) Staff are assessed as competent for the tasks they perform	As training has not been refreshed, competency has not been formally assessed.	**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	The inspection team identified a HTA reportable incident (HTARI) from the documents reviewed during the inspection, relating to the loss of traceability of a PM specimen.	**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	Whilst the transfer of bodies for MRI scanning is risk assessed, the HTARI category 'PM cross-sectional imaging of the body of a deceased person included an invasive procedure for which consent had not been given' has not been risk assessed. Not all risk assessments have been reviewed on an annual basis in-line with the establishments own policy.	**Minor**
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	One item of PM equipment has wooden handles and one item has areas of rust meaning they are porous and cannot be adequately cleaned or disinfected.	**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(a)	The DI is advised to remove reference to the version numbers of the PM consent forms and information booklets from the trust PM consent policy. The version numbers of these documents may change before the policy is reviewed.
2.	C2(d)	The DI is advised to formally record competency for seeking consent for PM examination.
3.	GQ2(a)	The DI is advised to increase the frequency of traceability audits of records and specimens in the annual audit schedule to reflect the number of cases the establishment deals with.
4.	GQ6(b)	The DI is advised to include staff training and competency as a mitigating factor in applicable risk assessments.
5.	PFE1(a)	The DI is advised to ensure the corner in the PM room where the old x-ray machine was housed is repaired and painted when the new machine is in place.
6.	PFE1(d)	The DI is advised to consider the use of CCTV in the body store area to aid in the security access audits. This will help to identify all persons who may access the mortuary, especially out of hours. In addition this would aid in the review of incidents, should any occur.
7.	PFE1(e)	The mortuary manager is advised to update the admission procedure for porters to include the names of all those admitting a body into the mortuary, including any nursing staff who may accompany the body. When a visitor log is implemented, the DI should include checking CCTV and swipe card access against the visitor log as part of security access audits.
8.	PFE3(c)	The DI is advised to ensure investigations in to the mortuary ventilation system continue to help assess the level of risk presented by the findings in the system report.

Background

Sheffield Children's has been licensed by the HTA since May 2008. This was the fifth inspection of the establishment; the most recent previous inspection took place in November 2021.

Since the previous inspection, the establishment's PM examination workload has continued to increase. As a specialist paediatric service, the establishment carries out both hospital consented and coroner's post mortem examinations for numerous hospitals and coroners. Whilst workload has increased staffing levels have decreased (see shortfall against GQ6(c)) above.

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 for the mortuary 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 paediatric and perinatal PM examinations were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the mortuary body storage area, PM room, viewing room, histopathology laboratory and storage areas.

Audit of records

The inspection team undertook audits of traceability for four bodies in 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 electronic system. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for four cases. Information was crosschecked between the mortuary paperwork, Coroner's paperwork, mortuary and laboratory electronic systems, family wishes forms and tissue being stored. No discrepancies were identified.

Meetings with establishment staff
The assessment team met with staff carrying out processes under the licence, including cellular pathology and mortuary staff, quality manager, a portering staff member, pathologist, staff involved in the consent seeking process for paediatric 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: 2 April 2024

Report returned from DI: 16 April 2024

Final report issued: 24 April 2024

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: 11 September 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.