Inspection report on compliance with HTA licensing standards
Inspection date: **07 December 2021**

Alder Hey Children's Hospital
HTA licensing number 12213

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
Alder Hey 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 Alder Hey Children's Hospital ('the establishment') had met the majority of the HTA's standards, two major and six minor shortfalls were found against standards for Governance and quality systems, Traceability and Premises, facilities, and equipment. These related to standard operating procedures, incident reporting, staff competency assessments, tissue traceability and storage of bodies and tissue within the mortuary and mortuary premises.

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) do not include sufficient detail of identification checks performed relating to traceability of bodies. Furthermore, the SOPs do not reflect current practice within the mortuary. These include but are not limited to: • HP SOP-0120: Assisting with post-mortem examination (including high risk cases). This SOP does not sufficiently detail how identification of the deceased is established prior to post mortem (PM) examination. • HP SOP-0042: Specimen reception, management of family visits and the release of deceased children (including high risk cases), fetuses and body parts. This SOP does not sufficiently detail the admission process of bodies to the mortuary and identifiers of the deceased which are present upon arrival for identification checks to be performed adequately. Furthermore, the SOP does not reflect the current practice of receiving three identifiers of the deceased from funeral directors which are crossmatched to the body as observed by the inspection team upon release from the mortuary. The SOP does not sufficiently detail how identification of the deceased is established for viewing and how identification checks are performed during this process. To fully address this shortfall the establishment should review all SOPs relating to traceability of bodies, tissues, and organs to ensure they contain sufficient details of identification checks performed and are reflective of current practice.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	Dissection of placental material for analysis is undertaken in the PM room. Due to insufficient space in tissue storage cabinets, the establishment were using inadequate makeshift shelving, including window ledges, the floor and a body trolley awaiting repair.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	Competency is not assessed or maintained for staff seeking consent for PM examination following initial training and sign off.	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	One body being stored in the long-term body storage unit had not received an adequate condition check. This meant that some soiled sheeting had not been changed as expected.	**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	Bereavement staff involved in viewing and release of bodies from the mortuary have not been competency assessed in the procedures following initial training and sign off.	**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	Whilst staff know how to identify and report incidents internally, an incident falling within the HTA reportable incident (HTARI) categories had not been reported to the HTA. *The establishment reported the incident to the HTA following the inspection for review.*	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	During the tissue traceability audit, two cases were identified where the number of tissue blocks in storage did not match the number indicated in the associated records. Both cases had one tissue block not accounted for in storage at the time of the inspection.	**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 premises were clean at the time of the inspection however, there are a number of porous items in the PM room which would be difficult to clean and disinfect adequately: • Window frames and the large windowsills are constructed from wood. The frames and sills have not been sufficiently sealed to ensure they can be adequately disinfected. • There is a wheeled wooden screen in use in the PM room which is damaged. • Boards used for the dissection of organs and tissues are damaged and require 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.	C1(b)	The DI is advised to ensure that consent seeking SOPs and policies accurately reflect the withdrawal of consent procedure the establishment has in place.
2.	GQ1(c)	The DI is advised to review the shrouding procedure of bodies in storage. All bodies were fully shrouded however, the use of many layers of blankets and sheeting poses a risk that bodies may not be stored appropriately as evidenced in the shortfall against this standard.

3.	GQ1(d)	The DI is advised to review all SOPs to ensure all documents are reviewed by someone other than the author.
4.	GQ1(g)	The DI is advised to nominate a Person Designated based in the mortuary. This will assist the DI in maintaining oversight of activity within the area.
5.	T1(a)	The DI is advised to review how bodies are labelled upon arrival to the mortuary for consistency. Three identifiers of the deceased are present, however, some bodies are tagged with identification bracelets, while others have handwritten identifiers attached directly to the body using 'medical tape'.
6.	PFE1(c)	The DI is advised to add and record the cleaning of the body storage units on the cleaning schedule.
7.	PFE1(e)	The DI is advised to fully frost the glass between the funeral director garage entrance and the mortuary to prevent the risk of oversight of activity when the roller shutter doors are open.
8.	PFE2(c)	The DI is advised to add a sign to the freezer unit to notify staff bringing bodies into the mortuary that this unit is for long-term storage of bodies only. This would reduce the risk of a body being placed into this unit accidentality.
9.	PFE2(g)	The DI is advised to review the 'Guidance on body storage' recently published by the HTA and align the recently introduced body condition checking procedure to the guidance provided.
10.	PFE3(e)	The DI is advised to review the process for the disposal of used formalin. Whilst this is completed in a well-ventilated area, the containers are stored on the floor near to the disposal area which could pose a risk of accidental spillage.

Background

Alder Hey Children's Hospital has been licensed by the HTA since May 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in December 2015.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out 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

All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection team reviewed the establishments self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included cleaning records for the mortuary and post-mortem room, records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training records. 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 and viewing room as well as the area for storage of relevant material held within the pathology department.

Audit of records

The inspection team undertook audits of traceability for four bodies in storage. This included bodies with same / similar name and a body in long term storage. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, the mortuary register, paperwork, and the electronic mortuary database. The surname of one body had a minor spelling error on the nameplate of the storage unit. All other records were correct.

Audits were conducted of tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, consent forms (where applicable), the laboratory database, and tissue

blocks and slides being stored. One case demonstrated disposal of tissue had been completed in line with the wishes of the family. The further three cases demonstrated that tissue was being stored with appropriate consent. One case was found to have a tissue block out of storage for further analysis however, there was no record of this in the system at the time of the inspection. One case was found to have a tissue block unaccounted for. The remaining two cases were fully traceable.

Meetings with establishment staff
The assessment team met with staff carrying out processes under the licence, including mortuary staff, bereavement service staff, laboratory staff, staff involved in the consent seeking process, staff responsible for the removal of relevant material in the Emergency Department and the DI.

Report sent to DI for factual accuracy: 31 January 2022

Report returned from DI: 14 February 2022

Final report issued: 14 February 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: 15 June 2022

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.