Inspection report on compliance with HTA licensing standards
Inspection date: **25 April 2023**

Northern General Hospital

HTA licensing number 12427

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 **Northern General Hospital**	Licensed	Licensed	Licensed
Mortuary		*Carried out*	*Carried out*
Satellite site **Royal Hallamshire Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology Lab			*Carried out*
Maternity (Jessop's wing)		*Carried out*	*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 Northern General Hospital ('the establishment') had met the majority of the HTA's standards, five major and four minor shortfalls were found against standards for 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
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although the establishment have a schedule of audits, the schedule does not include audits of all mortuary activities for example, security audit, and a number of audits in the schedule for 2022-2023 have not been undertaken.	**Major**
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	All procedures relating to licensed activities have not been risk assessed. These include but are not limited to: • major equipment failure • incident leading to unplanned closure of mortuary/inability to deliver services • viewing of the wrong body • release of the wrong body	**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	The maternity department undertakes releases. There are occasions where releases are undertaken using the green form only which does not provide three identifiers. This practice poses a risk of releasing a 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	There is no assurance that mortuary staff are made aware of newly employed porters at the Trust where mortuary access is immediately granted. There is a risk that new porters can access the mortuary without having had the initial training which is in place. The body store door used by mortuary staff to access the viewing room has the lock on the viewing room side. There is a risk that visiting relatives can access the body store from the viewing room. *See advice item 6.*	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
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	The mortuary staff do not manually challenge the body store alarms on a regular basis. This does not provide assurance that the alarms will trigger when temperatures deviate from the expected range and that the call out procedure works.	**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) relating to mortuary activities are not reflective of current practice for example: • Viewing of bodies. • Retention, disposal, donation and repatriation of organs. Not all SOPs include all practices that are undertaken by staff. These include, but are not limited to, SOPs detailing the process for: • Body condition checks of deceased.	**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 an incident since the previous inspection which has not been reported to the HTA. *Following the inspection, this incident has been reported to the HTA for assessment and will be managed accordingly.* *See advice item 4.*	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
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	The risk assessments for the maternity body store do not include all mitigating controls which have been implemented to reduce the risk score.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
d) Fridge and freezer units are in good working condition and well maintained	The fridge seals at both Northern General Hospital (NGH) and Royal Hallamshire Hospital (RHH) are deteriorating.	**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 formalise the Trust consent policy currently in draft format and distribute to appropriate staff.
2.	C2(a)	There are a limited number of staff trained to seek adult consent for post mortem examinations. The DI is advised to implement the agreed plan for APT staff to receive training to seek consent.
3.	GQ4(b)	The DI is advised to add to the control and retention of mortuary records procedure how errors in the mortuary register should be corrected.
4.	GQ5(a)	The DI is advised to include which HTA reportable incident (HTARI) categories are applicable to porters in the training package. The DI is advised to have signage in the mortuary of applicable HTARI categories and personnel to contact as an aide memoire for staff.
5.	PFE1(a)	The DI is advised to check the maintenance of the body stores at both NGH and RHH to ensure that any areas of exposed plaster or wood are repaired to ensure adequate cleaning or decontamination can take place.
6.	PFE1(e)	The DI is advised to look at having a memorandum of understanding with the portering service to set out the requirements for new and existing porters with regards to access to the mortuaries and training. While on the RHH site the inspection team found that the external door to the relatives suite was unlocked. The DI

		is advised to ensure that all external doors to the mortuary are locked to prevent unauthorised access.
7.	PFE2(f)	The DI is advised to complete a trend analysis of fridge and freezer temperatures, including the temporary unit and permanent external unit.
8.	PFE3(a)	The DI is advised to ensure that the hydraulic trolleys used in the mortuaries are free of rust to ensure effective cleaning or decontamination can take place.

Background

Northern General Hospital (NGH) is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

NGH has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in March 2018.

Since the previous inspection, there has been an extension to existing premises for the removal of relevant material on Jessop's wing (NICU).

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 included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary and post-mortem room, records servicing of equipment, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents and staff training records.

Visual inspection

The inspection included a visual inspection of both sites, including the mortuary body stores, PM room and viewing rooms.

Audit of records

Audits were conducted for five bodies in refrigerated storage and one in long term storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic database. No discrepancies were found.

Audits of traceability were conducted for tissue blocks and slides from three PM cases, including audits of the consent documentation for the retention of these tissues. No discrepancies were found.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, anatomical pathology technician (APT), pathologist, portering staff, maternity staff, and an adult consent seeker.

Report sent to DI for factual accuracy: 16 May 2023

Report returned from DI: 30 May 2023

Final report issued: 31 May 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 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.