Inspection report on compliance with HTA licensing standards
Inspection date: **12 – 13 April 2023**

North Middlesex University Hospital

HTA licensing number 12562

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 **North Middlesex University Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
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 North Middlesex University Hospital ('the establishment') had met the majority of the HTA's standards, three critical, four major and three 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

Critical 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) focus on office administrative processes, and do not include practical tasks undertaken within the mortuary. These include, but are not limited to, SOPs detailing the process for: • admission of bodies; • preparing bodies for viewings; • transfer and release of bodies to funeral services; • transfer of bodies to freezers; • transfer of bodies to other licensed establishments for post mortems; and • checking identification against wristbands (*Refer to shortfall T1c)* This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail to reflect current practice.	**Critical (Cumulative)**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	There is no formal documented process for checking and recording the condition of bodies. The inspection team identified bodies that were not checked until the time they were transferred to the funeral service. This poses a risk of deterioration to the bodies not being known to mortuary staff. Furthermore, on conducting the body audit the inspection team identified two bodies that were showing signs of deterioration and had not been transferred to the freezer within the recommended 30-day timeframe following death.	**Critical (Cumulative)**

e) There is a system for recording that staff have read and understood the latest versions of these documents	Whilst a document management system has recently been introduced, the function for recording that staff have read and understood the latest versions of documents has not been completed. The inspection team are therefore not assured that staff have read, acknowledged and understood mortuary documented procedures.	**Critical (Cumulative)**
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	There is currently no one within the establishment that has mortuary related qualifications, and staff working within the mortuary do not have documented training. The inspection team were therefore not assured that suitable training was available, and staff lone working have appropriate supervision. *(See advice GQ3a)*	**Critical (Cumulative)**
c) Staff are assessed as competent for the tasks they perform	There is no process for assessing that staff are competent for the tasks they perform.	**Critical (Cumulative)**
f) There is a documented induction and training programme for new mortuary staff	There is no induction or training programme for new mortuary staff which includes regulated activities.	**Critical (Cumulative)**
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	Whilst porters receive an induction to the mortuary, this does not include training for mortuary specific duties or regulated activities. This poses the risk of accidental damage to the body, and release of the wrong body, when they are assigned this task unsupervised.	**Critical (Cumulative)**
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	Three identifiers of the deceased are not routinely used to identify bodies for the following procedures: **Admission** Identification bands are not checked on the body when they are admitted to the mortuary. The inspection team identified occasions where a bodies' identification would not be checked until transfer to the funeral service. This poses a risk of misidentification of the body, or issues of identification not being observed and corrected in a timely manner. **Viewings** Three points of identification are not taken when viewings are booked or checked against wristbands when preparing the body. This poses the risk of a viewing of the wrong body. No additional checks take place when the family arrive, other than a verbal confirmation of the patient's name. This further increases the risk of a viewing of the wrong body. **Release** The establishment could not provide evidence that funeral services produced three points of identification when collecting bodies. Furthermore, the SOP states bodies are released on sight of the green disposal certificate, which does not have three unique points of identification. The inspection team was therefore not assured that three points of identification were routinely checked when releasing bodies. This poses a risk to the wrong body being released. *Following the site visit, the establishment submitted a HTA reportable incident under the category of 'release of the wrong body'. The initial investigation report from the establishment has identified that the root cause was not checking three points of identification provided by the funeral service against the wristbands on the body.*	**Critical**

	The lack of identification checks, absence of staff training, competency assessments or documented procedures together constitutes a significant risk to the reoccurrence of a HTA reportable incident.	

Major shortfalls

Standard	Inspection findings	Level of shortfall
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 all incidents are fully investigated internally, staff interviewed were unaware of the classifications of incident that must be reported to the HTA. Furthermore, whilst on site the inspection team identified incidents in the classification of 'accidental damage to a body' that had not been reported. *(Refer to shortfall GQ1c)*	**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	During the body audit the inspection team identified a body that required transfer to the freezer. At the time of inspection, no freezer spaces were available, and there are no documented contingency plans, if freezers are full.	**Major**

d) Fridge and freezer units are in good working condition and well maintained	The inspection team identified one block of fridges where the rollers for the trays were not correctly aligned. This caused four of the trays to slide forwards when the fridge doors are opened. Whilst these have been temporary secured, these actions do not fully mitigate against the risk to both staff safety and accidental damage to bodies.	**Major**
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	There is one single unit fridge within the maternity ward used for storing relevant material. Whilst temperature monitoring is in place, this fridge is not connected to an alarm system.	**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	There is no process in place to assess the competency of those trained in seeking adult post mortem consent. (*See advice C2b)*	**Minor**
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	Whilst a schedule is in place for future audits. No previous audits were available. The inspection team were therefore not assured that any previous audit findings had been documented, or any follow up actions had taken place.	**Minor**
GQ4 There is a systematic and planned approach to the management of records		

a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record	The mortuary has recently introduced a new document management system, however staff were unaware of how to login, access documents, and relied on printed versions of SOPs. Functions of the software such as document distribution, acknowledgement and version control were not being utilised.	**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.	C2b	The DI and mortuary manager are advised to use the recently attended consent training course to implement a competency assessment process for those already trained.
2.	GQ1h	Governance meetings are currently ad hoc, the DI is advised to schedule future HTA governance meetings on a regular basis.
3.	GQ3a	The DI and mortuary manager are advised to contact other licensed establishments, and the APT professional body, to explore training options that may be delivered by already trained staff.
4.	GQ6b	Risk assessments are in place for relevant HTA reportable incidents, The DI and mortuary manager are advised to review all risk assessments to ensure they encompass these inspection findings.

5.	T1d	Whilst processes are in place to identify bodies with a same or similar name the DI is advised to explore options, so this alert takes place at the point of release.
6.	PFE1d	The DI is advised to add swipe card access and a signing in sheet to the schedule of audits. This will further strengthen oversight of who enters the mortuary and for what reason.
7.	PFE2e	Whilst a post mortem service is currently not offered, the DI is advised to introduce a documented procedure for preparing the post mortem room, either for tissue donation or recommencement of a post mortem service.

Background

North Middlesex University Hospital has been licensed by the HTA since April 2010. This was the third inspection of the establishment; the most recent previous inspection took place in April 2018.

Since the previous inspection, there has been a recent change to both the designated individual and mortuary management staff. The licensed activity of *'making of a post mortem examination'* remains on the licence. However, procedures were introduced in 2019 to transfer deceased patients, requiring a post mortem, to alternative licensed establishments due to staffing constraints.

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

67 of the 72 HTA licensing standards were covered during the inspection (standards published 22 September 2022). Standards T1(g), T2 (a, b, c & d) were not applicable as post mortem tissue is not stored on site.

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, cleaning records for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, and reported incidents. Training and competency assessment documentation was requested, but unavailable.

Visual inspection
The inspection included a visual assessment of mortuary fridge rooms, the viewing facilities, post mortem room and the maternity storage area.

Audit of records
Audits were conducted for four bodies from refrigerated storage and one from freezer storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified. However, two bodies were in a state of deterioration. *See shortfall GQ1c.*

A tissue audit was not conducted, as all retained tissue is stored at the referral licensed establishments.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, mortuary manager, mortuary assistant, mortuary porter, and bereavement midwife.

Report sent to DI for factual accuracy: 15 May 2023

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

Final report issued: 07 June 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: 18 January 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.