Inspection report on compliance with HTA licensing standards
Inspection date: **11th October 2022**

Northampton General hospital
HTA licensing number 12253

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 **Northampton General Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	*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 Northampton General Hospital ('the establishment') had met the majority of the HTA's standards, 9 major and 4 minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment.

One of the major shortfalls relates to findings from the last inspection. The HTA is concerned that adequate steps were not taken to address these findings in the intervening period and to embed suitable practices at the establishment.

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.	The establishment has recently updated a large proportion of its procedural documentation to include additional detail and reflect current practice. However, a number of areas of licensed activity are not currently covered by a documented SOP/Policy. For example, the inspection team was not assured that there was an SOP covering the following: - the process for sending tissue taken during post mortem for analysis within the hospital. - the process for removal of samples in cases of sudden unexpected death in infancy. The DI should review all relevant activities to ensure they are covered by a documented procedure.	**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.	The establishment has documented risk assessments for its mortuary procedures. However, some key risks are not covered. For example, the risk of releasing the wrong body or the risk of a serious security breach. In addition, there is insufficient detail in the current range of risk assessments to cover: (i) The risk of accidental damage to the deceased due to the route being taken by porters when transferring the deceased across the hospital site; (ii) the risk to the dignity of the deceased presented by the viewing room being potentially visible to the public; and (iii) the risk to the dignity of the deceased presented by the main entrance to the mortuary (which is used both by Porters and Funeral Directors for the admission and release of the deceased) being overlooked by the Pathology and Histopathology Departments and visible to members of the public walking by. Whilst current practice is to draw the curtain when the mortuary doors are open, this is not a robust method of protecting against oversight into the mortuary. The DI should review all procedures relating to licensed activities to ensure there is an adequate risk assessment in place. *[Please see advice item 3 below]*	**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 Inspection team were not assured that three identifiers are checked upon movement of bodies within the different areas of the maternity department including when bodies are removed from the fridge for viewings.	**Major**
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	There are a number of areas within the mortuary which require maintenance to facilitate effective decontamination. - The post mortem room has wooden doors which are of a porous nature. - There are areas on the walls of the body store and the post mortem room where paintwork has been damaged exposing bare plaster which has started to crack. - The coating of the contingency cold store racking trays shows significant peeling. - The condenser unit in the contingency cold store is coated in black mould or residue. - The post mortem room does not contain adequate enclosed storage facilities for porous items such as towels and inco sheets.	**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	The establishment does not have sufficient permanent fridge space on site to meet levels of activity and employs temporary storage units on a long-term basis to store the deceased. At the time of the inspection one temporary unit was in use on a long-term ongoing basis. A second temporary unit was due to be reinstated in the post mortem room (this unit had been briefly removed to allow work to the floor). The temporary unit in the post-mortem unit is in long term use as indicated by the permanent venting system installed for this unit in the Post mortem room.	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.	The establishment currently has five freezer spaces for the long-term storage of bodies. This is not always adequate to meet the needs of the service. At the time of the inspection, all five freezer spaces were occupied and at least one body was awaiting transfer to the freezer having been in refrigerated storage for 30 days. This was identified as a major shortfall in the previous HTA inspection.	**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.	The fridge within the maternity department is not connected to a remote monitoring alarm system. While the fridge has a local audible alarm, this is not tested regularly and the location of the fridge means that there is a risk the alarm would not be heard promptly by staff if triggered. This could impact on the integrity of the bodies stored in this fridge.	**Major**
f) Temperatures of fridges and freezers are monitored on a regular basis	The establishment procedure is for the fridge within the maternity department to be checked daily. However, the inspection team identified gaps in the daily recording of fridge temperatures. Furthermore, the inspection team noted that a significant temperature excursion had been identified by staff teams but there was no record of action taken in response.	**Major**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The ventilation system was inspected in May 2022. The report concludes that the system does not provide the necessary ten air changes per hour. Furthermore the report identifies a number of required maintenance actions. The inspection team were not assured that these actions has been taken.	**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		
b) Records demonstrate up-to-date staff training	The Inspection team were provided with an example of a clinician's training record relating to perinatal consent training. However, the establishment was unable to provide a register demonstrating that all staff involved in consent seeking had received training. The availability of a register of trained consent seekers is necessary in order for the DI to have oversight of the consent seeking process.	**Minor**
d) Competency is assessed and maintained	The inspection team was not assured that clinician training for perinatal post mortem consent seeking was maintained via the provision of refresher training for permanent staff such as consultants.	**Minor**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
d) The method and date of disposal are recorded	Although the date of tissue disposal is documented, documents do not reflect the method used for disposal.	**Minor**

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	Access to the clinical room in Maternity is by one of three keys held by the maternity team. Although the entrance door to the corridor is monitored by CCTV, the inspection team were not assured that the DI or those acting under their authority could effectively monitor access to this room.	**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 review the SOP's for obtaining consent for post mortem for babies and perinatal deaths to produce a single document.
2.	C1(c)	The DI is advised to explore alternative language options for written information provided to families in support of consent for post mortem examination.
3.	GQ6(a)	The DI is advised to consider carrying out dedicated risk assessments to consider the route of the deceased into and out of the main mortuary doors, including passage across the hospital site. This would include risks to the dignity of the deceased both in terms of risk of accidental damage and visibility to the public. The DI may wish to consider the installation of a canopy/shielding to limit the risk of oversight.

		Although the establishment is not currently facilitating viewings of the deceased, the DI is advised to risk assess the process in detail particularly as the current arrangements present a risk that the deceased may be viewed by passing members of the public. The DI may also wish to consider the privacy of those who come to view the deceased within the waiting area. The DI should also consider installing some form of panic alarm for staff to operate if viewings are recommenced. [Please see major shortfall under GQ6(a).]
4.	T1(c)	The establishment is not currently facilitating viewings of the deceased, and work is being undertaken on the viewing facilities and written procedures. Before recommencing viewings, the DI should ensure that the SOP for viewing includes the necessary identification checks including checking 3 identifiers provided by the family when they arrive for the viewing.
5.	T1(d)	The DI is advised to consider expanding the system for identification of same or similar names to include a second method to flag this to staff (for example, a wristband attached to the deceased).
6.	PFE1(d)	The DI is advised to implement a checking system to ensure the maternity clinical room is secure out of hours (for example, the door and window locks are in place).
7.	PFE2 (c)	The DI is advised to consider the use of a suitable and compatible tray system within fridges used for the storage of babies and foetuses within the mortuary and maternity.
8.	PFE2(f)	The DI is advised to consider linking the fridge in maternity to the central monitoring system used in other areas of the hospital such as the mortuary.

Background

Northampton General Hospital has been licensed by the HTA since 2007. This was the third inspection of the establishment; the most recent previous inspection took place in April 2018.

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 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, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and training records for both the mortuary staff and porters.

Visual inspection

The inspection included a visual assessment of the establishment including, body storage areas, post mortem room, viewing room and block and slide storage area. The inspection teams observed the processes for release of a body within the mortuary.

Audit of records

Audits were conducted onsite of four bodies from refrigerated and frozen storage. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from four post mortem. These included audits of the consent documentation for the retention of these tissues. No discrepancies were identified.

Meetings with establishment staff

Staff carrying out processes under the license were interviewed including the DI, mortuary manager, APT, pathologist, mortuary porter, and bereavement midwife.

Report sent to DI for factual accuracy: 24th of November 2022

Report returned from DI: 6th December 2022

Final report issued: 21st December 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 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.