Inspection report on compliance with HTA licensing standards
Inspection date: **14 September 2023**

Kettering General Hospital

HTA licensing number 12096

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
Kettering General 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 Kettering General Hospital ('the establishment') had met the majority of the HTA's standards, ten major and three minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and

Premises, facilities and equipment. These related to insufficient documentation, storage capacity, erroneous transcription of information and fabric of the building in need of repair.

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
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		
c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	Whilst the Establishment has an information pack for those giving consent for perinatal post mortem examinations, no information for adult consented post mortem examinations is available. (See *advice* item 2)	**Major (cumulative)**

d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives	As the Establishment does not have written information available for adult consented post mortem examinations this standard has not been met. (See *Shortfall* against standard C1(c)).	
e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained	As the Establishment does not have written information available for adult consented post mortem examinations this standard has not been met. (See *Shortfall* against standard C1(c)).	
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	Training for consent taking is undertaken every 5 years. This represents a risk of taking consent that is not in line with the latest standards. Furthermore, some Perinatal consent takers could not provide evidence of their latest training although assurance was given that they have been trained historically. (see *Shortfall* against standard C2(d))	**Major (cumulative)**
d) Competency is assessed and maintained	The Establishment does not have a system to monitor the competence of staff undertaking consent for post mortem examination.	
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	A security audit reviewing swipe card access is undertaken monthly however CCTV is not reviewed against swipe card access. (See *Shortfall* against standard PFE1(e)).	**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	Whilst the Establishment has temporary measures in place to manage capacity for body storage, which is captured on the Trust Risk register, risk mitigations to ensure sufficient capacity long-term are not captured.	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records)	Multiple handwritten records are completed relating to bodies and tissues in storage in addition to electronic records. This creates a risk of errors relating to traceability of bodies. Two errors were noted during traceability audits carried out by the inspection team. Furthermore, whiteboards on fridge doors are not formatted in a way the clearly that separates information for each body. This causes a risk of information becoming confused with other bodies in the same fridge unit. The perinatal fridge does not have whiteboards on the doors. The inspection team noted information is written directly onto doors. It was evident that although old information has been removed, elements were still visible. This carries a risk of confusion when new information is added. (see *Advice* item 9)	**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	Whilst the premises were clean at the time of the inspection, the inspection team identified the following which require maintenance: • Vinyl floors in the body store are split in multiple locations, this prevents effective decontamination. • Within the body store, ceilings had not been repaired following maintenance. Holes were present exposing pipework. • Areas of damage were noted on skirting between the floor and body store walls. Furthermore, plastic trims around whiteboards in the body store were noted to be damaged in several areas. • The Perinatal fridge was powered with a trailing extension lead with multiple power cords attached. This may present of a risk of overload and failure of the fridge unit as well as potential a trip hazard. • There are small areas of exposed plaster in the PM room ceiling and an area of water damage on the wall. These areas are permeable and could prevent effective decontamination.	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Monthly security audits reviewing swipe card access is undertaken however CCTV is not reviewed against swipe card records. This method does not give assurance that there is effective oversight of persons entering the Mortuary out of hours. (See *Shortfall* against standard GQ2(a)).	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

a) Storage arrangements ensure the dignity of the deceased	The inspection team identified during the inspection a bank of fridges running at 2 degrees Celsius above the upper temperature set point. The delay time of alarms is set to two hours. This delay presents a risk of deterioration to bodies. (See *advice* item 13)	**Major**
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	There is insufficient capacity within the Mortuary. The Establishment relies on the use of four temporary store units, of which most are permanently erected and in use. At times of high activity two units are also deployed into the Post Mortem room which presents a risk of cross contamination. (see *Shortfall* against standard PFE2(c))	**Major**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	Whilst the Establishment have systems in place to facilitate the storage of bariatric bodies there are no bariatric fridges or freezers on site. The Establishment is reliant on the use of other HTA premises storing deceased. These premises may not be able to assist in times of high activity.	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
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	Whilst bodies are checked and their condition is recorded upon arrival, and it was evident that staff are monitoring condition, there is no documented procedure in place for this process.	**Minor**

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	The Establishment holds meetings that include discussions relating to licensed activities. These meetings do not incorporate all staff groups working under the license, for example Bereavement midwives. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements	The Establishment do not have an SOP in place relating to transfer of bodies and tissues off site or to internal storage locations. The Establishment have identified this in a gap analysis undertaken and it is currently in the process of being addressed.	**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.	C1b	The Maternity SOP for consent taking lacks detail. The DI is advised to review the SOP and consider rewriting to give greater clarity of the steps required for the process.
2.	C1c	The Establishment have not undertaken an adult consented post mortem for a number of years. The DI may wish to consider if this is a service that the Establishment want to continue offering.

3.	C2b	Perinatal consent forms are reviewed by a member of Maternity before sending to reference centres. The DI is advised to introduce a formal audit of Perinatal consent to measure competence of consent takers.
4.	GQ1a	The DI is advised to review and update the following SOPs: SOP ‘Coroners Legal Requirements’ uses a quote from HTA Code 5 which is out of date. This should be updated to reflect it is now Code B para 133 onwards. SOP ‘Long term storage of the deceased’ does not outline the required identification prior to transfer to Long term storage.
5.	GQ1c	Whilst the Funeral Directors’ entrance is not on a public thoroughfare and collection vehicles obscure the view into the Mortuary the privacy screen is in disrepair. The DI is advised to repair or replace this screen.
6.	GQ4a	The DI is advised to review the period of retention for various mortuary records and their storage location.
7.	GQ6c	The DI is advised to review long term staffing arrangements for provision of mortuary services as some staff are considering retirement shortly. This may pose a risk to the continued provision of mortuary service therefore succession planning could be considered before the risk manifests.
8.	T1a	The DI may wish to consider how the use of the ‘Patient identification card’ taped to shroud can be protected from soiling.
9.	T1b	The DI should review mortuary body traceability systems and consider condensing the number of paper records to reduce the risk of errors. Furthermore, the DI may wish to consider the use of an electronic system for traceability.
10.	T1c	A process for same and similar names exists in the Mortuary. The DI is advised to consider how this can be enhanced with the use of colour alerts, magnets or other mechanisms.

11.	T2d	The DI should investigate gaining permanent access to historic records of tissue retention and disposal.
12.	PFE1c	Records of cleaning for various areas of the Mortuary are completed weekly. The DI is advised to review the format of these records to reflect what tasks are undertaken
13.	PFE1d	The DI is advised to consider replacing the overhead manual lock between the viewing room and fridge to ensure usability needs of all staff.
14.	PFE2e	The fridge alarms are challenged on a regular basis. The method currently employed does not ensure probes are subject to testing. The DI is advised to consider different methods of testing to ensure all elements of the fridge are subject to challenge.
15.	PFE2f	The DI is advised to consider introducing a trend analysis audit of fridge temperatures. This process will help with the early detection of faults.

Background

Kettering General Hospital has been licensed by the HTA since August 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in May 2018.

Since the previous inspection, there has been a change of Corporate Licence Holder contact (June 2023) and Designated Individual (July 2023).

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 undertook a review of the Establishment's self-assessment document provided by the DI in advance of the inspection. A further review included governance documents, policies and procedural documents, records of servicing of equipment, audits and risk assessments. In addition, departmental meeting minutes, reported incidents and training records for staff employed by the Establishment were inspected.

Visual inspection
The inspection included a visual assessment of the body storage areas in the mortuary, PM room, viewing room and tissue storage areas. The inspection team observed the processes for release of bodies within the mortuary.

Audit of records
A traceability audit of six bodies in storage was undertaken. This included bodies from both the community and hospital including those with same and similar names and one in long term storage. Details were cross checked against identity bands, mortuary register and an electronic database. Two discrepancies were found.

Audits were conducted of tissue taken at PM examination for six cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the laboratory database, and tissue blocks and slides being stored. One minor discrepancy was noted which was rectified immediately following the inspection.

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including the DI, the Mortuary Manager, Anatomical Pathology Technologist (APT), a porter, and midwifery staff involved in the consent seeking processes.

Report sent to DI for factual accuracy: 05 October 2023

Report returned from DI: 16 October 2023

Final report issued: 20 October 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: 22 December 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.