Inspection report on compliance with HTA licensing standards
Inspection date: **13th and 15th December 2022**

Tameside General Hospital

HTA licensing number 12067

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 Tameside General Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	-
Maternity	-	-	-
A&E	-	-	-

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 Tameside General Hospital ('the establishment') had met the majority of the HTA's standards, six major and thirteen 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

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.	Some Standard Operating Procedures (SOPs) lack detail and do not reflect staff practice. At the time of inspection, some procedures observed by the inspection team were not consistent with that of the SOPs. These include, but are not limited to, SOPs detailing the process for: - Long term storage and Condition checking - Viewing of bodies 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.	**Major**
GQ2 There is a documented system of audit		

a) There is documented schedule of audits.	Whilst there is a schedule of audits checking compliance with documented procedures, there is no documented schedule of audit to check CCTV against records of mortuary access. This means the establishment cannot be assured that all mortuary access is taking place for a legitimate purpose (see shortfall at PFE1(e) below). Following the inspection, the establishment has introduced a bi-weekly security audit. Evidence will be reviewed by the HTA in line with the corrective and preventative actions (CAPA) process.	**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	During the inspection, the inspection team were not provided with evidence that the following activities had been risk assessed: - Accidental Damage to bodies - Risks to the security of the mortuary - Misidentification of bodies on transfer, release, and viewings - Capacity issues - Inability to provide the service due to a critical failure or staffing issues This is not an exhaustive list of risk assessments required. To fully address this shortfall the establishment should review all risks relating to mortuary activities to ensure that they contain sufficient detail to mitigate and reduce risks to staff and service provision.	**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 establishment only requires relatives to provide one identifier of the deceased when they attend the mortuary for a viewing on more than one occasion. This practice is not reflective of the SOP and poses a risk of viewing the 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	Staff access the mortuary using swipe cards and a coded alarm system is in operation. Whilst, swipe card access lists are reviewed and updated regularly, these are not routinely cross checked against CCTV footage to ensure security arrangements protect against unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access. This means mortuary staff do not have oversight and are not able to effectively audit all individuals accessing the mortuary or their time of entry and exit to the restricted areas. The establishment has an outside storage area which is only partially covered by a roof. Whilst there is some fencing around the area as well as CCTV coverage, the storage is accessible to members of the public. In addition, the stairwell that leads to the outside storage area from the mortuary is not covered by CCTV.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

a) Storage arrangements ensure the dignity of the deceased	In respect of the outside storage area referred to in Standard PFE1(e) above, the Inspection team were not assured that these storage arrangements ensured the dignity of the deceased. The Inspection team noted that that the design of the storage area exposed the deceased to adverse weather conditions, when accessing or removing bodies from these fridges	**Major**

Minor 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		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue, and which reflects the requirements of the HT Act and the HTA's Codes of Practice	At the time of the inspection the establishment had not submitted a consent seeking policy reflecting the HT Act and HTA's Codes of Practice.	**Minor**
b) There is a documented standard operating procedure (SOP) detailing the consent process	At the time of the inspection the establishment had not submitted a perinatal consent seeking SOP. However, it was noted that guidelines were available for staff to follow.	**Minor**

g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	Whilst the consent form used by the establishment has been agreed and ratified, it was due for review in May 2022, and did not reflect current practice regarding documentation for offsite transfer.	**Minor**
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	Records do not demonstrate up to date training in HTA requirements when seeking consent. There are incomplete records available to review indicating which staff have received training in obtaining consent for perinatal post- mortems.	**Minor**
d) Competency is assessed and maintained	The establishment does not have a system in place for assessing staff as competent with the HTA requirements when seeking consent. This includes those who have received consent training.	**Minor**

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	Although SOPs are reviewed regularly and there is a collaborative approach to authorship, the documented author and authoriser is the same person for many of the SOPs.	**Minor**
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	There is no Persons Designate for every area that carries out HTA licensed activity. The inspection team were therefore not assured that the DI has oversight of regulated activities on the maternity ward.	**Minor**

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Whilst scheduled governance meetings do take place. There is no attendance by establishment staff from areas outside the mortuary and governance teams. Maternity staff and porters do not attend or receive the minutes of governance meetings discussing matters relating to HTA activity.	**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	Risk assessments do not identify who is responsible for actions needed to be taken to mitigate risk and the timeframe for actions to be implemented. This means identified risks may not be mitigated in a timely way.	**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).	Although a significant amount of work has been carried out to improve systems and processes to ensure tissue transferred off site is traceable, three records were incomplete. With no record available to review of receipt of tissue by the third party who stores and manages tissue sent by the establishment.	**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	There are small areas of exposed plaster in the post- mortem room. Additionally, there is damage to a plug socket in the fridge room. This presents the risk of ineffective cleaning and decontamination.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	There is significant rust to two hydraulic trolleys, an autopsy saw, and very slight rusting to the shelves in the post -mortem room. This presents the risk of ineffective cleaning and decontamination.	**Minor**
f) Key items of equipment, including fridges/freezers, trolleys and post-mortem tables (if downdraught) are subject to regular maintenance and records are kept	Maintenance checks of the hydraulic trolleys and post -mortem tables were last carried out in 2020. *The inspection team has since received assurance from the establishment that maintenance checks are due to be carried out in January 2023.*	**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.	GQ1(a)	The DI is advised to combine the SOPs detailing the release process for Adults and Perinatal and Children.
2.	GQ5(a)	The DI is advised to display a list of HTA reportable incidents in all areas where licensed activity is undertaken including the porter's office and maternity ward.

3.	PFE2(e)	The DI is advised to review the trigger points for fridge and freezer temperatures to ensure there is no risk of bodies being frozen when in refrigerated storage
4.	T1(c)	The DI should ensure that written procedures for areas in the establishment where the release of bodies is undertaken are aligned to mortuary practice and HTA standards. For example, the maternity ward.

Background

Tameside General Hospital has been licensed by the HTA since 10th May 2007. This was the third inspection of the establishment; the most recent previous inspection took place in September 2017.

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

68 of the 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017), standards GQ2(c), T2 (a), T2(c), and T2(d) are not applicable as the establishment does not store tissue onsite.

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/preparation rooms and viewing rooms The inspection teams observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records

Audits were conducted onsite of five 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 coronial consented cases. These were limited to audits of the documentation relating to transfer of tissue offsite and consent documentation for the family wishes regarding the retention of tissue.

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: 5th January 2023

Report returned from DI: 30th January 2023

Final report issued: 17th March 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 August 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.