Inspection report on compliance with HTA licensing standards
Inspection date: **15th November 2022**

Torbay Hospital
HTA licensing number 12181

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
Torbay 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 Torbay Hospital ('the establishment') had met the majority of the HTA's standards, 5 major and 3 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
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	The establishment has a comprehensive programme of competency assessment for mortuary staff but this does not include regular reassessment of competency. The inspection team were not assured that all porters were familiar with current procedures and noted that some porters had not carried out a competency assessment on mortuary procedures for a considerable amount of time.	**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 points of identification are checked prior to the movement of bodies for viewing within the maternity department. The current location of the fridge is not a suitable environment for staff to carry out these checks (see below shortfall under PFE2a).	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	The fridge for storage of human tissue within the maternity department is housed within the sluice room/waste storage area. This area is subject to a high footfall and swipe-card access to this area is open to a large number of staff from across different divisions of the hospital. Although there is CCTV covering the entrance to the maternity department there is no CCTV coverage of the door to the room containing the fridge. The fridge itself is secured by a manual keylock held by the lead midwife. These arrangements do not constitute a secure environment for the storage of human tissue.	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Due to the number of people requiring access to the sluice and waste storage area, the establishment's bereavement midwifery team have not been able to monitor or audit access to this room. Whilst the key to the fridge is held by the senior midwife on duty, it is not signed out upon each use, meaning it is not possible to audit who has accessed the fridge in any given time period. These arrangements do not provide the DI with the necessary oversight of access to the premises where human tissue is stored within the maternity department.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

a) Storage arrangements ensure the dignity of the deceased	The position of the fridge in the maternity department means that human tissue could be viewed unintentionally and at close proximity by a wide range of staff passing through the area to use the sluice/refuse bins. This environment, particularly at time of waste bin removal, does not ensure the dignity of the human tissue being stored.	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	The establishment has recently carried out an audit of stored tissue and introduced an effective system for following up with the Coroner to establish, and act on, family wishes with regards to disposal or retention of tissue. However, there are a small number of outstanding cases from which blocks and slides are held in storage and for which the family wishes are either not known or have not yet been actioned.	**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	The fridge room has sustained a small area of damage to the flooring, which was covered in tape on the day of the inspection, this means the area cannot be cleaned and decontaminated effectively.	**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(e)	The DI is advised to consider reviewing the options given to families regarding tissue taken at post mortem, to ensure that the options presented reflect the potential uses for which the establishment can store the tissue.
2.	T2(b)	The DI is advised to continue to work with the Coroner's office to strengthen existing systems and processes to ensure tissue is not retained longer than necessary.
3.	PFE2(a)	The DI is advised to consider the addition of a seal to cover the gap between the double doors within the viewing room. Although this door is covered by a curtain, a seal would prevent visitors from attempting to see inside the body store area.

Background

Torbay Hospital has been licensed by the HTA since 20th June 2007. This was the third inspection of the establishment; the most recent previous inspection took place in May 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
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, postmortem/preparation rooms, viewing room and tissue storage areas. The inspection teams observed the processes for admission and release of bodies within the mortuary.

Audit of records
Audits were conducted onsite of three bodies from refrigerated, and one from 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 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, pathologist and mortuary porter.

Report sent to DI for factual accuracy: 21st of December 2022

Report returned from DI: 4th of January 2023

Final report issued: 5th of January 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: 4 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.