Inspection report on compliance with HTA licensing standards
Inspection date: **07 - 10 June 2022**

Tunbridge Wells Hospital at Pembury
HTA licensing number 12616

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 **Tunbridge Wells Hospital at Pembury**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity	-	*Carried out*	-
Satellite site **Maidstone Hospital**	Not Licensed	Licensed	Licensed

Mortuary (satellite site)	-	*Carried out*	*Carried out*
Pathology lab (satellite site)	-	-	*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 Tunbridge Wells Hospital at Pembury ('the establishment') had met the majority of the HTA's standards, eight major and seven minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment. These related to the consent policy and consent training and competency assessment, standard operating procedures and risk assessments, bariatric freezer storage arrangements, capacity management, mortuary maintenance and mortuary equipment in use.

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		

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	The establishment's consent policy for post mortem (PM) examination does not fully reflect the requirements of the HT Act 2004 and the HTA's codes of practice. This includes, but is not limited to, the following: • The policy does not detail that a person can consent in life or that consent can be given by a nominated representative before approaching appropriate persons in the list of highest qualifying relationships. • The timeframe in which consent can be withdrawn and who should be contacted to ensure withdrawal wishes are complied with. • The policy states consent should be sought by someone trained in the consent seeking process. However, it does not provide detail that the person should also be assessed as competent. • There is no detail of information that should be provided to those giving consent.	**Major**
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) do not always include sufficient detail of procedures or reflect current practice. These include but are not limited to: • Condition checking of bodies – whilst a system has been developed to complete this regularly, it is not documented in a SOP. • RWF-CP-MORT-SOP37 Release of bodies from the mortuary: This SOP does not detail the requirement for three points of identification on the body to be crosschecked against information brought by the funeral director. • RWF-CP-MORT-SOP1 Retention and disposal of tissues: This SOP does not detail how whole organs taken at PM examination should be labelled. To fully address this shortfall the establishment should review all SOPs to ensure they contain sufficient detail, are reflective of current practice and cover all mortuary and laboratory procedures relevant to licensed activity.	**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	The establishment are currently using the base of the refrigerated storage units at the satellite site to increase storage capacity. Furthermore, a temporary unit at the hub site is due to be removed from the premises despite having been in frequent use. Whilst the establishment appeared to have sufficient space for bodies at the time of the inspection, there is a risk that storage capacity may not be sufficient long-term which is not captured on the Trust risk register.	**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)	The system to track bodies through the mortuary relies heavily on paper tracking forms in patient files. The tracking forms do not contain sufficient space for staff to record all necessary updates relating to bodies in storage. The inspection team identified a lot of tracking information being written into margins and header and footer spaces on the documents leaving forms difficult to interpret.	**Major**
d) There is a system for flagging up same or similar names of the deceased	The system to flag up bodies with a same or similar name is not robust. The inspection team identified two bodies in storage with the same or similar name that had not been flagged either on paperwork in the patient files, on the body itself or on the fridge door whiteboards.	**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)	Whilst access to the mortuaries is secure, some of the external components of the fridge and freezer units across both the hub and satellite sites are accessible outside of the mortuary. This leaves a risk of the external components being tampered with. Furthermore, the satellite site has no audio or visual entry systems to the doors. This means staff must open doors to assess who is requesting access. This poses a risk to safety of staff when lone working.	**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	Whilst the establishment currently have a temporary storage unit that has the ability to hold bariatric bodies in freezer storage, this unit is due to be removed within a month from the date of the inspection which means the establishment will be without freezer storage for bariatric bodies going forward.	**Major**
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	Hydraulic body trolleys used in the post mortem room do not reach the upper trays of the body storage units. Furthermore, the trays are at a height in which staff found it difficult to manage the admission and removal of bodies safely. This poses a risk of accidental damage to bodies and a risk to safety of staff. Furthermore, the establishment are using the body trolleys frequently as makeshift post mortem tables as they currently only have two post mortem tables in place. The body trolleys are showing signs of rust meaning they cannot be effectively decontaminated following post mortem examination.	**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	Not all staff listed in the training record have up-to-date training in the consent seeking procedure.	**Minor**
d) Competency is assessed and maintained	Competency of some staff involved in the consent seeking procedure has not been assessed or maintained.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Whilst the establishment have a documented schedule of audits, which includes auditing of body traceability records, there are no audits undertaken on bodies in storage.	**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 sufficiently detail how identified risks are mitigated. Furthermore, not all risk assessments consider risks to the deceased in procedures undertaken.	**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).	Whilst the establishment have a system to track receipt of tissue and organs sent off site for analysis, this is not detailed in an SOP. Furthermore, the procedure undertaken for returning tissue or organ to the body prior to release of the deceased does not include detail of identification checks performed.	**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	Whilst the premises were clean at the time of the inspection there are some areas which require maintenance including: • There are some areas of damage to walls and door frames at the satellite site. • The rear entrance of the satellite site where funeral directors arrive is located close to other services and at the time of the inspection was cluttered with various pieces of hospital equipment either waiting disposal or collection.	**Minor**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The establishment have visitor logs to the mortuary in operation for all staff accessing the facility including the porters. The inspection team identified that in some instances porters were only entering their forename in the visitor log or not ensuring the time out of the department is recorded upon departure.	**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)	Consent SOPs, crib sheets and other relevant consent paperwork should be reviewed and language used standardised by the DI. The terminology used for those giving consent differs from document to document. There are a few occasions when the term ‘Next of Kin’ is used or ‘nominated representative’ when meaning an appropriate person in the list of highest qualifying relationships.
2.	C1(g)	The DI is advised to review the consent form used for adult PM examination. Whilst the form includes options for those giving consent for retention and disposal of tissue, there is a possibility that both options could be chosen due to lack of clarity and distinction between options.
3.	C2(b)	The DI is advised to centralise oversight of training and competency records for those seeking consent as some records are held by the training department and some by the mortuary.
4.	GQ1(a)	The DI is advised to review the viewing of the deceased procedure to ensure persons booking appointments have appropriate permission in place to visit the deceased in the mortuary.

5.	GQ2(c)	Whilst regular audits are undertaken of tissue held in storage and no discrepancies with traceability were identified during the tissue audit, the DI is advised to standardise how traceability records are stored. Currently some records are held in paper files, whilst some have been uploaded electronically.
6.	GQ5(a)	Whilst the porters interviewed were aware of internal incident reporting and the types of incidents to be reported, they were unaware that some incidents in which they may be involved are reported to the HTA. The DI is advised to include this in the training provided to both porters and maternity staff.
7.	PFE1(a)	Whilst store cupboards leading off the PM room were neat and well organised; some stock is stored on the floor in cardboard boxes. The DI is advised to review this arrangement to prevent boxes becoming contaminated with water from the PM room.
8.	PFE1(b)	The DI is advised to review demarcation signage in use at the hub site. This will ensure areas are clearly identified between clean, transition and dirty areas of the facility.
9.	PFE1(d)	Whilst the premises are secure, the DI is advised to consider additional steps to minimise the possible risk of oversight of activities to the funeral director entrances at both the hub and satellite site.
10.	PFE1(e)	Intruder alarms have been recently installed at both the hub and satellite site, however, at the time of the inspection these were not yet live. The DI is advised to maintain oversight of this work to ensure the systems are operational soon. Some internal doors still use key code pads to secure them, there are also some external wall mounted key safes in use across the hub and satellite site. The DI is advised to change codes on this equipment regularly.
11.	PFE2(g)	The establishment place all bodies into sealed body bags. The DI is advised to review the type of body bags used as the seams of some had split due to being slightly too small for some of the bodies. Furthermore, the bags appear to cause condensation to build up within them which has led to some bodies being damp. This could risk accelerating deterioration of the deceased if stored for a long periods within the mortuary fridge units.

Background

Tunbridge Wells Hospital at Pembury has been licensed by the HTA since March 2014. This was the third inspection of the establishment; the most recent previous inspection took place in November 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 team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities for the mortuary were reviewed. Evidence of staff training, and competency assessment were reviewed as well as the qualification certificates of mortuary staff. Traceability audits, risk assessments, meeting minutes, incidents, consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises at the hub site which included the mortuary body storage area, the temporary body storage area, the PM room, viewing room and the bereavement suite in the maternity department. The visual inspection at the satellite site included the mortuary body storage area, viewing room and the storage arrangements for relevant material held within the pathology department.

Audit of records

The inspection team undertook audits of traceability for five bodies in storage at the hub site. This included bodies with same / similar names, a body in long term storage and a perinatal body. Traceability details were crosschecked between the identification

band on the body, information on the door of the storage unit, the electronic mortuary register and associated patient tracking files. No discrepancies with traceability were identified.

The inspection team undertook audits of traceability for four bodies in storage at the satellite site. This included a body in long term storage. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, the electronic mortuary register and associated ‘patient tracking’ paperwork. No discrepancies with traceability were identified

Whilst no discrepancies were identified with the identification and traceability of bodies, the inspection team identified that the system for recording bodies with a same or similar name is not robust as the two bodies audited had not been flagged sufficiently. It was also identified that patient tracking files used for recording of information, such as body location changes, do not provide sufficient space to record all changes that can be made in a consistent manner. Mortuary staff are writing details ad-hoc in document margins.

Audits were conducted of tissue taken at PM examination for six cases. Information was crosschecked between the mortuary documentation, family wishes forms, and tissue blocks, and slides being stored. Two cases reviewed demonstrated disposal of tissue had been completed in line with the wishes of the family. The further four cases were being stored for a scheduled purpose and consent was in place for this storage. No discrepancies were identified.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including mortuary staff, portering staff, staff involved in the consent seeking process for adult PM examination, and the DI who is also a pathologist undertaking PM examination. The inspection team also met with the quality manager, the mortuary manager, and the pathology service manager as part of roundtable discussions

Report sent to DI for factual accuracy: 13 July 2022

Report returned from DI: 25 July 2022

Final report issued: 03 August 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: 13 April 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.