Inspection report on compliance with HTA licensing standards
Inspection date: **21, 23 and 24 February 2022**

Worthing Hospital

HTA licensing number 12286

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 Worthing	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	-
Maternity	-	-	-
A&E	-	-	-
Satellite site St Richards	-	-	Licensed
Mortuary (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 Worthing Hospital ('the establishment') had met the majority of the HTA's standards, four major and one minor shortfalls were found against standards for 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
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored.		

a) All procedures related to the licenced activities (as outlined in standard GQ1) are risk assessed on a regular basis.	The route used by funeral directors to reach the mortuary is via a busy service road which is overlooked by a public park on one side and general hospital buildings and car parking on the other. Funeral directors are often unable to reverse their vehicles into the area due to refuge collection vehicles; there is a risk that passers-by at ground level and those in the Trust office buildings could view movement of bodies in and out of the mortuary. This does not ensure the dignity of the deceased and there is an increased risk to accidental damage to the body due to uneven road surfacing. This is not addressed in existing risk assessments.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The establishment have recently started to utilise two secure fridges held at 15 degrees Celsius to store bodies overnight prior to post mortem the following morning. They do so in order to bring bodies to room temperature prior to PM. This is aimed at easing the PM procedure as staff do not have to engage in difficult procedures with cold hands which increases the risk of injury to staff and accidental damage to bodies. This process effectively means bodies are stored outside the required temperature range for up to 16 hours. This risks premature deterioration of bodies.	**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	Equipment in the mortuary at the hub site is showing significant signs of wear and tear and is not fit for purpose. The DI has identified this on the Trust's organisational risk register. Examples include: • Corrosion on the legs of trolleys, pipe work to PM tables and step ladders. • Floors have been repaired with porous material. • Water supplies are inconsistent in temperature making cleaning problematic.	**Major**
b) Equipment is appropriate for the management of bariatric bodies	The three post mortem tables, currently in use, have bent, buckled top plates due to the weight of bodies. These are now uneven which increases the risk of accidental damage to bodies.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	Three points of identification are sought at the time of arranging viewing. However, the procedure for viewing of the deceased does not include a final check using a minimum of three points of identification of the deceased from the family, prior to visitors entering the viewing 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.	GQ1(a)	The establishment have produced SOPs that cover various activities under the licence. The DI is advised to produce an overarching SOP covering all HTARI categories.
2.	GQ3(a)	Whilst SOPs are circulated to staff after periodic review, this only takes place if changes are made. The DI is advised to re-circulate SOPs more regularly, even if they are unchanged, as part of refresher training.
3.	GQ6 (b) and (c)	Following on from the shortfall identified in relation to G6(a), the DI is advised to consider further control measures and mitigations in response to identified risks relating to funeral directors' access to the mortuary and to ensure that any significant risks are escalated accordingly.

Background

Worthing 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 April 2016.

Since the previous inspection, there have been changes to the licence as PM examinations no longer take place at St Richards (satellite site). The second satellite suite at Southlands is no longer used for scheduled purposes and a revocation is pending.

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 establishments self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. The team also undertook a review of records relating to equipment servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units and mortuary, reported incidents, and staff training. Consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the Hub premises which included the mortuary body storage area, PM room and viewing room. The inspectrion team also undertook a visual inspection at the satellite site, St Richards, which included the body storage area and the area for the storage of relevant material.

Audit of records

The inspection team undertook audits of traceability for five bodies in storage. Traceability details were crosschecked between the identification band on the body, information on the digital mortuary register and paperwork. One discrepancy was identified relating to one body with a slight spelling mistake on the computerised system. This was corrected instantly.

Audits were conducted of tissue taken at PM examination for three cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, consent for PM examination forms (where relevant), the laboratory database, and tissue blocks and slides being stored. No discrepancies were identified.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including mortuary staff, staff involved in the consent seeking process, staff from the bereavement team, pathologist, hospital porters and the DI.

Report sent to DI for factual accuracy: 23 March 2022

Report returned from DI: 6 April 2022

Final report issued: 6 April 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: 28 March 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.