Inspection report on compliance with HTA licensing standards
Inspection date: **01 August 2023**

William Harvey Hospital
HTA licensing number 30011

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 **William Harvey Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
A&E	-	*Carried out*	-
Satellite site **Queen Elizabeth the Queen Mother Hospital**	Licensed	Licensed	Licensed

Mortuary (satellite site)	*Carried out*	*Carried out*	*Carried out*

Summary of inspection findings

This was a targeted announced Virtual Regulatory Assessment. The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

The targeted Virtual Regulatory Assessment found that William Harvey Hospital ('the establishment') had met the majority of the HTA's standards. However, three major and two minor shortfalls were found against standards for Governance and quality systems.

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.

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		

a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	The Inspection team is not assured all staff involved in mortuary duties have been appropriately trained. There were no records available to review indicating contracted Funeral Directors working for the Coroner have received mortuary training. *During the inspection, assurance was received that a training package for contracted funeral directors is being developed.* Whilst a 'train the trainer' system is in place for porters there has been no refresher training provided by the mortuary for at least four years. Porter training is focussed on the use of lifting equipment and safe transfer of bodies. However, the inspection team are not assured porters and other staff groups undertaking mortuary activity receive training relating to the completion of mortuary paperwork or ID checking. (Refer to advice point 3 below) Following the site visit, the establishment submitted an HTA reportable incident under the category of viewing of the wrong body. The initial investigation report from the establishment has identified the Standard Operating Procedure (SOP) for ID checking was not followed by the ward staff and porters transferring the body from the mortuary to the ward.	**Major**

c) Staff are assessed as competent for the tasks they perform	Whilst porters undertake an annual assessment of competency this is assessed through questions and a professional discussion with team leaders. There is no documented practical assessment of competency undertaken. Porters team leaders who carry out the training do not receive regular competency assessments from mortuary staff. Additionally, Maternity staff involved in facilitating ward-based viewings and direct release have not been assessed as competent in completing the mortuary visitors register and release paperwork. This poses the risk to bodies of a reportable incident- Refer to standard GQ3(a) above.	**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	The Inspection team are not assured all risks are assessed on a regular basis. The risk assessment relating to the use of hydraulic trolleys had not been reviewed annually in line with establishment policy. Additionally, not all risks have been identified and mitigated. The accidental damage to a body risk assessment did not identify the risk of deterioration to bodies in storage. This means there is insufficient mitigation in place to minimise the risk to bodies of a reportable incident.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
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 the DI has oversight of regulated activities undertaken within Maternity and in the Emergency Department.	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Whilst matters relating to HTA licensed activities are discussed in monthly meetings, there is no representation from staff working outside the mortuary who undertake activities under the licence. Maternity, Emergency Department staff and Porters do not attend or receive the minutes of governance meetings discussing matters relating to HTA activity.	**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)	To provide consistency across teams of staff. The DI should consider working with the third party provider of portering services to ensure SOP's used by mortuary staff and porters include the same information. The DI should consider providing a copy of relevant SOPs to the Coroners contracted Funeral Directors. Additionally, some SOPs outline practices relating to similar activities such as admission to the mortuary. These should be reviewed, and consideration given to combining the information into a single document. SOPs in place do not always provide procedural information for staff working within the unlicensed body store. Whilst unlicensed body stores do not fall under the remit of the HTA. The DI should review and add information to instruct staff to ensure working practices protect the dignity of the deceased.
2.	GQ1(c)	Although the establishment undertakes documented condition checks these are limited to on admission, after a Post Mortem Examination and on release. The DI should consider implementing regular body condition checks to prevent incidents relating to accidental damage to a body.
3.	GQ3(a)	Currently there is limited mortuary staff input into training. The DI should consider working with non-mortuary based teams undertaking mortuary duties to produce a training package and reference guides. Consideration should be given to the re-introduction of the mortuary led 'train the trainer' programme and expansion to include regular refresher training.
4.	T1(c)	The DI should review systems and processes in place for the obtaining and checking of identifiers on bodies before a viewing and on release. Information on ID bands should reflect identifiers provided by families and Funeral Directors, and three identifiers should be checked.

Background

William Harvey Hospital has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in March 2022.

Since the previous inspection there have been no significant changes to the licensed activities undertaken. However, there has been an alteration in key personnel with a change of the DI in July 2022.

A decision to undertake a targeted Virtual Regulatory Assessment was made by the HTA's Head of Regulation for the Post Mortem Sector at a Case Review Meeting on 20 April 2023. This followed concerns relating to access to the mortuary by authorised staff for non mortuary activities which may impact the dignity of the deceased. This inspection focussed on the following standards: GQ1(a)(e)(g)(h), GQ2(a)(b), GQ3(a)(b)(c)(d)(e)(f)(g), GQ5(a)(b)(c)(d)(e), GQ6(a)(b)(c) and PFE1(e).

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:

Review of governance documentation

The inspection included a review of the establishment's governance documentation relating to licensed activities. This included procedural documents relating to licensed activities, audits, risk assessments, meeting minutes, documents used for training and competency assessments and mortuary access lists. The review of documents was limited to those relating to the standards being inspected.

Visual inspection

The Inspection team did not undertake a visual inspection of the establishment- the inspection was carried out virtually. A full visual inspection of the premises will be undertaken during the next scheduled routine inspection.

Audit of records

Audits of traceability were not undertaken during this Inspection. A full traceability audit of bodies and tissue in storage will be carried out during the next routine inspection to be scheduled.

Meetings with establishment staff

Staff carrying out processes under the license at the Hub and satellite sites were interviewed including the DI, Mortuary Manager, APT (Anatomical Pathology Technician), Porter Manager, Porter Team Leader, and Quality Lead for the mortuary.

Report sent to DI for factual accuracy: 07 August 2023

Report returned from DI: 16 August 2023

Final report issued: 05 September 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: 20 May 2024

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.