Inspection report on compliance with HTA licensing standards
Inspection date: **22 and 23 January 2024**

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	*Carried out*	*Carried out*	*Carried out*

Summary of inspection findings

This was a targeted unannounced site visit inspection. The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

The site visit of William Harvey Hospital ('the establishment') found three major shortfalls and one minor shortfall against standards for Consent, Governance and quality systems and Premises, facilities and equipment.

One of the Major cumulative shortfalls relates to findings from the last inspection. The HTA is concerned that adequate steps were not taken to address these findings in the intervening period and to embed suitable practices at the establishment. A similar issue was identified in standards GQ3(a) and GQ3(c) during the last previous inspection carried out in August 2023.

Concerns were discussed with the establishment as part of this inspection and escalated to the Corporate Licence Holder Contact (CLHc). The current DI has provided assurance that key personnel have been appointed to manage the activities under the licence and that the establishment is committed to meeting the regulatory requirements. Based on this assurance, 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. However, in light of the establishment's lack of progress with addressing shortfalls from previous inspections, the HTA will consider the need for regulatory action if appropriate action is not taken to meet the regulatory requirements in accordance with the timeframes detailed in Appendix 2.

Major 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	Records do not demonstrate up to date training in HTA requirements when seeking consent. There are no records available to review indicating which staff have received training in obtaining consent for perinatal PMs. *(as a result, standard C2(c) cannot be met)*	**Major (cumulative)**
d) Competency is assessed and maintained	There were no documents available for review assessing staff as competent with the HTA requirements when seeking consent for perinatal PM's. This includes those who have received consent training	
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	Porters have not yet received the updated training package written in response to the shortfall identified during the remote offsite inspection undertaken in August 2023, as a result the inspection team are not assured that staff carrying out licensed activities are appropriately trained	**Major (cumulative)**
c) Staff are assessed as competent for the tasks they perform	The inspection team are not assured all staff who carry out licensed activities have been assessed as competent. Members of the midwifery team have not received a competency assessment for the checking of identification. An assessment of competency was developed in support of the training package written in response to a serious incident and subsequent shortfall identified in August 2023. This has not been completed by all staff.	
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	Whilst the HTA saw evidence of processes to restrict and actively manage swipe card access. The internal door between the viewing suite and main mortuary corridor at Queen Elizabeth the Queen Mother Hospital can be unlocked from the family viewing area. This poses the risk of unauthorised access to restricted areas including the body store, by family members attending the mortuary for viewings.	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies	Whilst there is separate storage available for infants across both sites. There is no identified location in the main body store for the storage of babies at Queen Elizabeth the Queen Mother Hospital.	**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(c)	Although the establishment undertakes documented condition checks these are limited to on admission, after a Post Mortem Examination (PM) and on release. The DI should consider implementing regular body condition checks to ensure that the dignity of deceased is upheld throughout the time in their care.
2.	GQ1(h)	Whilst there is a bereavement midwife identified as a Persons Designate (PD) the DI should consider adding an additional bereavement midwife as a PD to ensure there is oversight across the hub and satellite sites.
3.	T1(a)	Whilst bodies are fully traceable, the DI should consider an alternative to the paper identity labels currently used as there is a risk of these becoming illegible or misplaced.
4.	PFE2(d)	There are some areas of minor rust on the base of the fridges at the hub site. This should be monitored and rectified as any further deterioration could pose the risk of ineffective decontamination.

Background

William Harvey Hospital has been licensed by the HTA since 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in August 2023. During this inspection we identified two shortfalls that have not been addressed in standards GQ3(a) and GQ3(c) which were identified during the last previous inspection.

Since the previous inspection, there has been a change to the CLHc in 2023. There have been no changes to the activity undertaken under the licence.

A decision to undertake an unannounced visit was made by the HTA's Director of Regulation at a Regulatory Decision-Making meeting on 4 December 2023. This followed concerns relating to an increase in incidents relating to mortuary security and the

training and competency of non-mortuary staff undertaking activities under the licence, which could have an impact on the safety and dignity of the deceased.

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

20 out of the HTA's 72 standards were covered during the targeted unannounced inspection. Standards covered at this inspection are listed in Appendix 3. The inspection focussed on areas of concern; the remaining 52 standards will be assessed during the next routine inspection.

Review of governance documentation

A review of governance documents was not undertaken as part of this inspection. A full review of governance documentation will be undertaken at the next routine inspection.

Visual inspection

The inspection included a visual assessment of the establishment including body storage areas and viewing rooms. The PM suite was not assessed as part of this inspection. A full review of the PM suite will be undertaken at the next routine inspection.

Audit of records

Audits were conducted onsite of four bodies from refrigerated storage across the hub and satellite sites, including adults and perinatal bodies. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork, in addition to information held on the mortuary whiteboard and in the electronic patient record system. No discrepancies were identified.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence at the hub and satellite sites. This included the DI, Senior APT, bereavement midwives, APT, the mortuary quality officer and the Pathology Manager.

Report sent to DI for factual accuracy: 14/02/2024

Report returned from DI: 20/02/2024

Final report issued: 20/02/2024

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.

Appendix 3: Standards Assessed during onsite Inspection

Consent
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice.
b) Records demonstrate up-to-date staff training
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.
d) Competency is assessed and maintained.
Governance and Quality systems
GQ1 All aspects of the establishment's work are governed by documented policies and procedures
c) Procedures on body storage prevent practices that disregard the dignity of the deceased.

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. c) Staff are assessed as competent for the tasks they perform.
Traceabiliy
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail
a) Bodies are tagged/labelled upon arrival at the mortuary.
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).
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.
d) There is system for flagging up same or similar names of the deceased.
e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.
Premises,facilities and equipment

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).
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
a) Storage arrangements ensure the dignity of the deceased.
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.
g) Bodies are shrouded or in body bags whilst in storage.
h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.