Inspection report on compliance with HTA licensing standards
Inspection date: **11 July 2023**

Countess of Chester Hospital

HTA licensing number 12049

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 **Countess of Chester Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*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 Countess of Chester Hospital ('the establishment') had met the majority of the HTA's standards, four major and four minor shortfalls were found against standards for consent, audits, risk assessments, traceability and premises.

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		
b) There is a documented standard operating procedure (SOP) detailing the consent process	The SOP for seeking adult post mortem consent has not been reviewed since 2021 and does not reflect current practice. This includes, but is not limited, to: • Incorrectly stating that the patient's clinician can take consent; • Instructing the completion of a different consent form to that being used; and • Referring to the 'Next of Kin' giving consent for a post mortem examination. For consent to be valid under the Human Tissue Act 2004, consent must be obtained in accordance with the 'hierarchy of qualifying relationships'.	**Major (Cumulative)**
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	Whilst valid, the consent form used for taking adult post mortem consent is not that agreed by the establishment, and is not referenced in the adult post mortem consent SOP.	
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	Current arrangements for adult post mortem consent training is acknowledgement of the document *'Refresher Training – Consent for Hospital Post Mortems.'* This alone is not sufficient to be considered as training for taking post mortem consent. The establishment were unable to provide evidence in relation to when initial training had been completed.	**Major (Cumulative)**
d) Competency is assessed and maintained	There is no competency assessment for those responsible for taking adult post mortem consent. Furthermore, a review of a recently completed adult post mortem consent form identified areas that were incomplete, including contact numbers and the withdrawal period in which consent givers may change their mind. *The establishment provided evidence that whilst not documented, a consent withdrawal period was given to the consent giver and the consent was therefore valid.* *See Advice C2(d)*	
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	Contingency fridge spaces are situated away from the main mortuary building. The transfer and use of this unit has not been risk assessed. The inspection team identified risks to accidental damage to bodies without suitable documented mitigations. These include but are not limited to: • Transfer over a misaligned, removable ramp; • Alignment of fridge rollers, causing trays to roll forwards; • Depth of space between trays and the ceiling; and • Protective covering on trays, posing a risk to ineffective decontamination. This is not an exhaustive list of risks requiring review. To fully address this shortfall the establishment should fully risk assess all procedures relating to the use of the contingency unit.	**Major**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The ventilation system in the post mortem room does not provide the necessary ten air changes per hour. The most recent ventilation report from November 2022 states the air changes per hour were 7.79 and failed the compliance test. *See advice PFE3(c)*	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Whilst there is a documented schedule of audits, this does not contain sufficient vertical, horizontal or observational audits covering all regulated activities.	**Minor**
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	Whilst mortuary staff gain assurances of preparing the right body, via a third identifier from the mortuary register, three identifiers supplied by the family are not checked directly against the deceased's wristband. This does not fully mitigate against the risk of the viewing of a wrong body.	**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	Although the mortuary premises are subject to regular cleaning, the age and subsequent deterioration of some areas means there is a risk that they cannot be cleaned or decontaminated effectively. Examples include: • Minor areas of exposed plaster within the fridge room; • Minor chipped door frames with exposed, splinted wood; and • Uplift covering around a post mortem table, allowing water to enter under the flooring. *See advice PFE1(a)*	**Minor**

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	There are no bariatric-sized freezers and no formal contingency plan in place if one was required.	**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.	C2(d)	The DI is advised to review the embedded processes for consent training and competency assessment within maternity services and consider using the same practices for the adult post mortem consent taking process.
2.	GQ3(c)	The DI is advised to continue the planned competency assessments for locum staff, who at the time of inspection were new to the role.
3.	T1(g)	Whilst a process is in place, the DI is advised to formalise and document the procedure for following up tissue slides that have left the site. This will mitigate against the risk of tissue being stored on an unlicensed premises once the coroner's jurisdiction has ended.
4.	PFE1(a)	The post mortem room floor is showing signs or wear. The DI is advised to take this into consideration when addressing shortfall PFE1(a) to ensure there are no further areas of water entering under the flooring, and that it can be decontaminated effectively.

5.	PFE3(a)	The DI is advised to monitor the minor rust on the mortuary trolleys, as any further deterioration may result in a shortfall of standard PFE3(a).
6.	PFE3(c)	The ceiling within the post mortem room is in a poor condition, with holes from previous works and gaps between ceiling tiles. The DI is advised to take this into consideration when addressing shortfall PFE3(c) and gain assurance that this does not affect the post mortem room ventilation.

Background

Countess of Chester Hospital has been licensed by the HTA since May 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in September 2018.

Since the previous inspection, there has been a change to the Designated Individual, in May 2019, and Corporate Licence Holder contact, in April 2023. The mortuary has had upgrades to CCTV and security systems, and introduced a contingency unit of an additional 52 spaces.

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 27 September 2022).

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, cleaning records for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents and training records for staff.

Visual inspection
The inspection included a visual assessment of the mortuary fridge room, post mortem room, tissue storage areas and the viewing facilities. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted for three bodies from refrigerated storage and one from frozen storage. Identification details on bodies were crosschecked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from three coronial consented cases. These included audits of the consent documentation for the retention or disposal of these tissues. No discrepancies were identified.

Audits were conducted on stored material, for five cases, that were collected by a third party as part of Research Ethics Committee approved studies. These included audits for consent documentation and correct storage. No discrepancies were identified.

Meetings with establishment staff
Staff carrying out processes under the licence were interviewed including the DI, APT, Mortuary Porter, Pathologist, Bereavement Midwife, consent seekers and the Quality Manager.

Report sent to DI for factual accuracy: 01 August 2023

Report returned from DI: 14 August 2023

Final report issued: 08 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: 5 March 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.