Inspection report on compliance with HTA licensing standards
Inspection date(s): **1 June 2023**

Calderdale Royal Hospital

HTA licensing number 12108

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 **Calderdale Royal Hospital**	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*
Accident & Emergency Department	-	*Carried out*	-
Paediatric wards	-	*Carried out*	-
Satellite **Huddesfield Royal Infirmary**	Not licensed	Licensed	Licensed

Mortuary	-	*Carried out*	*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 Calderdale Royal Hospital ('the establishment') had met the majority of the HTA's standards, four minor shortfalls were found against the standards for Consent, Governance and quality systems, and Traceability.

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 shortfall identified during the inspection.

Compliance with HTA standards

Minor 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	Whilst there is a documented process in place for seeking consent for post mortem (PM) examinations, the SOP primarily focuses on training requirements and does not go into detail on the process to follow. The SOP does not include reference to the consent forms, discussions with families or withdrawal procedures that are in place.	**Minor**
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	Although there are condition checks that take place, there are no formalised and documented condition checking procedures.	**Minor**
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 get automatic access to the mortuary at the start of their employment which poses the risk of untrained staff carrying out mortuary duties. Furthermore, refresher training for Porters is overdue.	**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).	The establishment stopped carrying out PMs in 2012, however there is a collection of archived blocks and slides from tissue taken at PM prior to 2012. Although the material is stored in date order, and disposal records are clear, the consent to retain paperwork is not easily accessible and therefore the HTA were unable to audit the material through to the family wishes forms.	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfall 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 practices:

Number	Standard	Advice
1.	C2(b)	Staff are trained in consent seeking for perinatal PMs by the establishment for which they are referred. Although staff had up to date training there are no centralised records which includes trained clinicians. The DI may wish to consider developing a database of consent trained individuals in order to ensure training is kept up-to-date and is auditable.
2.	GQ1(g)	The establishment have documented Service Level Agreements (SLAs) in place with other HTA licenced establishments to carry out PMs. The SLAs are out of date, and the DI is advised to review these to ensure the services continue as expected.
3.	GQ6(c)	There are no bariatric freezers on site, however the establishment do have contingency plans in place. The DI is advised to add the lack of this internal storage to the risk register.
4.	T1(c)	One body that was audited from the freezer had the wrist band facing the wrong way which made it difficult to check. The DI is advised to add to the long stay SOP that the ID bands are to be positioned in an easily viewable way prior to the freezing of bodies.
5.	PFE1(c)	The body store at Calderdale Hospital is very clean however the floors have been laid impeding the ability to lift the drain covers. During the inspection it was noted that there is a build up of dust and debris in the drain that may not be removed just from being washed down. The DI is advised to seek guidance from the estates department for the best way to clean this area.
6.	PFE3(c)	Although the establishment does not carry out PMs, removal of material from the deceased can still take place. The ventilation within the former PM room is only just meeting the necessary requirements. The DI is advised to seek guidance on this to ensure that it continues to meet the requirements.

Background

Calderdale Royal Hospital has been licensed by the HTA since June 2007. This was the fourth inspection of the establishment; the most recent inspection took place in January 2019.

Since the previous inspection, there have been some significant changes to the licence arrangements including the change of Designated Individual (DI) in October 2021, and a change in Corporate Licence Holder contact (CLHc) in April 2023.

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

67 out of 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017). Standards GQ1(b), T2(a), T2(b), T2(c) and PFE3(e) were not applicable as the establishment do not carry out PMs.

Review of governance documentation

The inspection team reviewed the establishment's self-assessment document provided by the DI. Policies and procedural documents relating to licensed activities were reviewed. This included standard operating procedures, risk assessments, audits, incidents, meeting minutes, equipment servicing reports, and training and competency assessment documents. Consent seeking procedures and information for families giving consent for adult and perinatal PM's were also reviewed.

Visual inspection

The inspection team undertook a site visit inspection including the mortuary body storage areas at both the hub and satellite site.

Audit of records

At the hub site, the inspection team undertook audits of traceability for three bodies in storage including one perinatal body. Traceability details were crosschecked between the identification band on the body and information on the electronic and paper records. No discrepancies were identified.

At the satellite site, the inspection team undertook audits of traceability for three bodies in storage including one in long term storage. Traceability details were crosschecked between the identification band on the body and information on the electronic and paper records. No discrepancies were identified.

Audits were conducted of stored tissue taken at PM examination for an archieved collection of PM material (from pre-2012). Although the establishment gave assurance that this material had consent to be retained, the families wishes forms could not be provided (see shortfall under Standard T1(g).

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including the Mortuary Manager, Mortuary Supervisor, Mortuary support assistant, Bereavement Midwife and a Consultant Histopatholigist who is the establishment's DI.

Report sent to DI for factual accuracy: 26 June 2023

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 30 June 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: 1 November 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.