

Pinderfields Hospital
 HTA licensing number 12086

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 Pinderfields Hospital	Licensed	Licensed	Licensed
Mortuary	<i>Carried out</i>	<i>Carried out</i>	<i>Carried out</i>
Satellite site Dewsbury District Hospital	Not licensed	Licensed	Licensed
Mortuary (satellite site)	-	<i>Carried out</i>	<i>Carried out</i>
Pathology lab	-	-	<i>Carried out</i>

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 Pinderfields Hospital ('the establishment') had met the majority of the HTA's standards, nine major and four minor shortfalls were found against standards for Consent, Governance and quality systems, 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.

Major shortfalls

Standard	Inspection findings	Level of shortfall
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GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPATH.	The current SOP relating to release of bodies to funeral directors creates a risk of accidental damage to bodies.	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	There is no risk assessment for the transfer of patients to the external body store at Dewsbury relating to use of the ramp and for staff working in extreme low temperatures.	Major
b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed	The risk assessment relating to lone working does not adequately mitigate the risk of accidental damage to bodies or injury to staff.	Major

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).	There is currently no formal system to separate organs and tissues for samples taken at post mortem (PM) examination. There is a risk that sample traceability may be lost. <i>See advice item 2.</i>	Major
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PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.

<p>a) The premises are clean and well maintained</p>	<p><u>Pinderfields Hospital</u></p> <ul style="list-style-type: none"> • In the post mortem (PM) room, the seals that join the floor and sink units to the walls are failing in areas. • There was a leak to one post mortem table producing pooling of water on the floor. • An area of rust was noted to the external area of the Cold room door frame on PM room side. • Two painted metal tables used in the PM room had paint peeling away <p>These areas cannot be fully decontaminated.</p> <ul style="list-style-type: none"> • There was powder like debris noted on the floors of some of the fridges. <p><u>Dewsbury District Hospital</u></p> <ul style="list-style-type: none"> • The entrance doors to the body store are damaged and have some exposed wooden surfaces which are porous and cannot be fully decontaminated. 	<p>Major</p>
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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)	<p>At Dewsbury District Hospital, the external controls and power supply for the additional body storage unit are accessible. This leaves a risk of the external controls being tampered with.</p> <p>The door to the funeral director's entrance is not included in the electronic swipe card system and is a single key lock. The doors at this entrance are loose when closed and don't lock into frame.</p>	Major
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	There are no panic alarms in the viewing rooms on both sites. Lone working staff have no means to raise the alarm in the event of an emergency.	Major

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	<p>The funeral director's entrance is visible from local housing and a service road with public access.</p> <p>The external storage unit is currently sited in a service area which is in full view of a service road and is within an area frequented by multiple Trust staff, meaning the transfer of patients, albeit on a covered trolley, is visible.</p>	Major
d) Fridge and freezer units are in good working condition and well maintained	<p>Fridge seals at both the hub and satellite site are defective.</p> <p>The internal metal framework, rollers and trays at both the hub and satellite site are showing signs of corrosion making it difficult to adequately decontaminate this area.</p> <p>The internal metal framework and some trays within the fridges at Dewsbury District Hospital are showing signs of corrosion and cannot be fully decontaminated</p>	Major

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
d) Competency is assessed and maintained	Whilst full training is provided and recorded, there is currently no competency assessment in place for staff seeking adult consented post mortem examination.	Minor

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	A security audit is not included in the audit schedule.	Minor

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	Whilst fridge alarm testing is taking place regularly and being recorded, the lower temperature alarm is not currently tested. There is a risk that the lower alarm will not trigger when temperatures deviate from expected ranges.	Minor

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
d) Staff have access to necessary PPE	Staff have access to PPE for general duties but do not currently have access to additional protective clothing whilst working in extremely low temperatures in the external freezer unit.	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.	PFE1a	The DI is advised to add the baby viewing cot to the maintenance schedule at Pinderfields Hospital. This has a height adjustable mechanism that requires maintenance.
2.	T1g	The DI is advised to adopt a colour coded system in the PM room to differentiate between cases of tissue taken at PM examination.
3.	T1b	<p>The DI is advised to add recording of condition checking and transfer of deceased to freezer to the electronic progress notes.</p> <p>The DI is also advised to add the same or similar name to this system to provide an alert to staff releasing patients.</p> <p>The DI is advised to review the release process paperwork as currently multiple signatures and paperwork are required and this may lead to an administrative error occurring.</p>
4.	GQ1a	The DI is advised to consider developing a formal procedure for de-escalating services in the event of

		reduced capacity or staff absence.
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Background

Pinderfields Hospital has been licensed by the HTA since 27 May 2008. This was the fourth inspection of the establishment; the most recent inspection took place in February 2018.

There have been no significant changes to the licence arrangements since the last inspection.

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

Visual inspection

The inspection team undertook a visual inspection of the hub and satellite premises which included the mortuary body storage areas, the PM suite at Pinderfields Hospital as well as the storage arrangements for relevant material held at Dewsbury District Hospital.

Audit of records

The inspection team undertook audits of traceability for eleven bodies in storage. This included community and hospital cases. Traceability details were crosschecked between the identification band on the body and information in the mortuary register and electronic records. One minor discrepancy was noted. This was corrected by staff immediately.

Audits were conducted of stored tissue taken at PM examination for five cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, the mortuary electronic database, and tissue being stored. No discrepancies were identified.

Meetings with establishment staff

The assessment team met with staff carrying out activities under the licence, including the DI, the Mortuary Manager, an Anatomical Pathology Technologist (APT), laboratory staff, porters and staff involved in the consent seeking processes.

Report sent to DI for factual accuracy: 7 June 2023

Report returned from DI: 28 June 2023

Final report issued: 28 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: 25 September 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.