Inspection report on compliance with HTA licensing standards
Inspection date: **18 October 2023**

Macclesfield District General Hospital

HTA licensing number 12411

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
Macclesfield District General Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 Macclesfield District Hospital ('the establishment') had met the majority of the HTA's standards, three major and three minor shortfalls were found against standards for Governance and quality systems 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.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
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	Some areas of the mortuary are very old and have not been maintained sufficiently. The porous nature of some of the material exposed makes it difficult for staff to fully clean and decontaminate: • There are chips to some walls in the post mortem room exposing plaster. • Protective coverings on drawers in the post mortem room have been chipped exposing wood. • The racking and it's component parts in the fridges have extensive areas of rust. • The floor coverings in the bottom of the fridges are lifting.	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	There is a contingency overflow body store unit outside the Funeral Directors entrance to the main mortuary. The unit is not covered by CCTV and is accessed using a manual key. These security arrangements do not ensure full oversight of access to this storage area. Furthermore, the door at the Funeral Directors entrance is constructed of wood and single pane glass, it also has a manual key locking mechanism which provides low level security in comparison to other entrances that have auditable swipe card access arrangements.	**Major**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		

(a) Items of equipment in the mortuary are in a good condition and appropriate for use	The racking system in the body store fridge units is not appropriate for use. The racking is not fixed to the floor and the integrity of the frames are dependent on unfixed spacers which slot together. When bodies are being transferred to and from the units the instability of the racking is clear and there is lots of movement. The frame within the bariatric fridge unit is also warped. The unstable frames are further compromised by extensive rust.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
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	Lone working at the establishment is commonplace, however there are few formalised arrangements for staff in place. The panic alarm in the viewing room does not work. Lone working has the potential for greater risks to staff and the dignity of the deceased and more careful management and oversight is required.	**Minor**
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	Although the establishment has a suite of risk assessments some risk assessments are overdue for review.	**Minor**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		

(b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	There is a door between the post mortem room and the body store area. This does not provide for effective demarcation between the two areas as there is no transition space. When staff are carrying out multiple port mortems, bodies need to be transferred through the door from the body store to the post mortem room and vice versa. Once the doors are opened there is nothing preventing the post mortem room being in full sight of anyone in the body store. Furthermore it is difficult to transition both staff and bodies hygienically from dirty to clean areas.	**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)	The establishment's SOP for Contingency and Capacity (MORTSOPRR018), is not up to date in relation to the external body store unit. The DI is advised to review this SOP to include the recent change in arrangements.
2.	C2(b)	Staff are trained in consent seeking for perinatal PMs by the establishment for which they are referred. Although there is a centralised record of the training, many clinicians on the list are due to be trained or re-trained. The DI is advised to audit the list, follow up on outstanding training requirements and ensure that consent is not taken by staff that have not met the training requirements.
3.	GQ1(a)	There is a formatting error on the HTARI escalation procedure SOP (MORTSOP045) whereby the contents page is for a different document. The DI is advised to review the document and correct the mistake.
4.	GQ6(a)	There are some duplications of hazards in the establishment's risk assessments relating to licensable activity. As part of the action plan to address the shortfall under GQ6(a), the DI is advised to amalgamate the risk assessments that overlap. This will help to streamline documentation and also reduce the time taken for staff to review the documents.

5.	PFE1(a)	The mortuary facility fluctuates in temperature throughout the year. In the summer months, the lack of air conditioning resulted in post mortems being postponed as it was too hot. The DI is advised to review and risk assess the arrangements to ensure that the premises remain fit for purpose.
6.	PFE2(b)	There is a contingency overflow body store unit outside of the main mortuary. Although the capacity of the unit is 25 spaces, the current trolley is too large for it to access the racking at both ends of the units and so the working capacity is only 15 spaces. The DI is advised to source a new trolley so that the unit can be used to its full potential.
7.	PFE2(e)	The fridge and freezer units are temperature monitored and alarmed. The alarm sounds if there is a deviation from the set ranges for an hour or more. The DI is advised to review this extended delay time to ensure that the condition of bodies is appropriately preserved should there be an issue.

Background

Macclesfield District General Hospital has been licensed by the HTA since February 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in February 2019.

Since the previous inspection, there have not been any significant changes to the licence arrangements, although a contingency overflow body store unit has been erected outside the main mortuary building increasing capacity by 25 spaces (see *advice* item 4).

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 of the 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 and Mortuary Manager. 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 perinatal PM's were also reviewed.

Visual inspection

The inspection team undertook a site visit inspection including the main mortuary body storage area, the contingency overflow body storage unit and the post mortem room.

Audit of records

The inspection team undertook traceability audits for four bodies in storage including one body that was stored in the freezer. Traceability details were crosschecked between the identification band on the body and information on the electronic and paper records. No discrepancies were identified.

Meetings with establishment staff

The assessment team met with staff carrying out activities under the licence, including the Mortuary Manager, trainee APT, porter, the Clinical Lead and Consultant Obstetrician & Gynecologist, a Consultant Paediatrician and the Medical Director who is the establishment's DI.

Report sent to DI for factual accuracy: 6 November 2023

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

Final report issued: 17 November 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: 16 October 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.