Inspection report on compliance with HTA licensing standards
Inspection date: **24 November 2022**

Wythenshawe Hospital

HTA licensing number 12203

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
Wythenshawe Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology laboratory	-	-	*Carried out*
Maternity department	-	-	*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 Wythenshawe Hospital ('the establishment') had met the majority of the HTA's standards, two major and six minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment. These related to the harmonisation of documentation across the different post mortem (PM) licences at this multi-site Trust (Manchester University NHS Foundation Trust, "MFT"), long stay procedures, condition checking, release procedure and the body store flooring.

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
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.	The establishment do not receive bodies from the community and therefore formalised condition checking of bodies does not take place prior to 21 days in storage. However, one body that was audited during the site visit had extensive purging and stained shrouding. The current procedure increases the risk of this not being identified for a significant period of time, and in turn could compromise the dignity of the deceased. Bodies are not considered for transfer to frozen storage until they start to show signs of decomposition. In order to preserve the dignity of the deceased, bodies should be considered for freezing at 30 days or sooner if there is no indication they are soon to be released or further examined.	**Major**

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.	The inspection team observed the release of a body to funeral directors. During the release, only two points of identification were checked against the body and release documentation. Once highlighted, three points of ID were subsequently identified, and the release was carried out in line with procedures.	**Major**

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		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue, and which reflects the requirements of the HT Act and the HTA's Codes of Practice.	The policy *'The taking of consent for a hospital post mortem examination of an adult or child',* is an overarching MFT policy which covers the requirements of the Human Tissue Act 2004 (HT Act). The policy however does not detail the specific arrangements at each of the establishments within MFT. For example, the policy fails to detail that adult hospital PMs are not consented for at Wythenshawe Hospital and, as such, families are referred to another establishment within the Trust. To fully address this shortfall the establishment should review all MFT documents to ensure that they are reflective of current practice at each of the sites they cover.	**Minor**

b) There is a documented standard operating procedure (SOP) detailing the consent process.	The SOP for the perinatal PM consent seeking process is an overarching MFT document entitled- *Taking of Consent for a hospital post mortem examination after an early pregnancy, perinatal loss or neonatal loss (Saint Mary's Oxford Road Campus site only).* Although it details a procedure that covers the requirements of the HT Act, it is not clear that it relates to Wythenshawe Hospital in addition to Saint Mary's Oxford Road Campus. To fully address this shortfall the establishment should review all MFT documents to ensure that they are reflective of current practice at each of the sites they cover.	**Minor**
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.	Some of the SOPs for mortuary activities are overarching MFT documents however it is not always clear that they relate to Wythenshawe Hospital. For example, the opening times are included for other MFT mortuaries in the viewing of deceased SOP, however Wythenshawe Hospital is not mentioned. To fully address this shortfall the establishment should review all MFT documents to ensure that they are reflective of current practice at each of the sites they cover. Furthermore, the SOP *'Conducting an Adult Post Mortem Examination – ORC and Wythenshawe sites (Examination Procedures)'* states that consent for retention of tissue should be sought from the next of kin. The HTA did not find evidence that the establishment had removed or used relevant material without the consent of the appropriate person under the Human Tissue Act 2004 (HT Act), namely the person highest in the hierarchy of qualifying relationships, as set out in the legislation. However, if "next of kin" is used instead of the statutory hierarchy of relationships, it could result in a breach of the HT Act. References to next of kin was picked up during the previous inspection in November 2018 and has not yet been addressed.	**Minor**

g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.	Licensable activities are taking place within the mortuary, the pathology department and on the maternity ward however there are no up-to-date Persons Designate (PDs) named on the licence. PDs assist DIs in maintaining oversight of areas, ensure compliance with the HTAs standards and have the ability to report incidents to the HTA if required to do so. *Prior to the final report being published the DI submitted evidence of the actions taken in relation to the shortfall. The HTA has assessed this evidence as satisfactory and considers this standard to be met.*	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
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.	Mortuary staff have identified that some areas of the body store flooring are not slip-resistant and, when wet, detailed that it poses a significant risk to staff and the deceased (when being moved around the facility). Although identified as a risk there is nothing being actioned to mitigate this risk. In addition, many of the Risk Assessments (RAs) for mortuary activities are overarching MFT documents, however it is not always clear that they relate to Wythenshawe Hospital as the mitigating factors are not reflective of current practices being carried out. For example, to mitigate the risk of accidental damage, the risk assessment refers to the use of head blocks. However, head blocks are not used at Wythenshawe Hospital. To fully address this shortfall the establishment should review all MFT documents to ensure that they are reflective of current practice at each of the sites they cover.	**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.	The flooring of the body store has not been maintained to a sufficient standard. This was identified as a shortfall in the previous inspection in November 2017 and was corrected, however areas of grouting have deteriorated again. The poor condition makes the floor uneven which increases the risk of obstruction when using the trolleys to move the deceased to and from the refrigerated storage. It is also difficult to fully clean and decontaminate. There is a small area of damage on the PM suite door that requires maintenance.	**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.	C1(e)	The establishment gives the option to families for retention of PM material for research. Currently the establishment does not conduct research. The DI is advised to consider providing this information to families to set expectations and ensure that informed consent is obtained.

2.	GQ1(h)	Although governance meetings are held by all departments and staff engaged in licensed activities, the DI rarely attends. The DI is advised to either prioritise attendance or organise separate meetings with PDs to ensure full oversight of the areas.
3.	GQ6(a)	Risk assessments reference the next of kin determining the fate of the tissue taken at PM. The next of kin may not be the person highest in the list of qualifying relationships under the Section 27 (4) of the HT Act and therefore the DI is advised to correct this reference.
4.	PFE1(a)	As part of the corrective and preventative actions to address the shortfall against standard PFE1(a), the DI should keep the suitability of the body store floor under regular review to ensure that it is fit for purpose, clean and well maintained.
5.	PFE2(a)	The Funeral Directors entrance is overlooked by operating theatres. The DI may wish to consider the use of frosted glass on these windows to maintain dignity of the deceased during admission and release.
6.	PFE3(f)	The ventilation system within the PM room is subject to regular testing and servicing however records are not kept within the mortuary and only available upon request. The DI is advised to request copies of all maintenance, servicing and repair reports so that they are easily accessible to the Mortuary Supervisor for review and monitoring purposes.

Background

Wythenshawe Hospital has been licensed by the HTA since December 2007. This was the fourth inspection of the establishment; the most recent inspection took place in November 2017.

Since the previous inspection, there has been significant changes to the licence arrangements including changes to the Designated Individual and the Corporate Licence Holder contact. Wythenshawe Hospital has also undergone a Trust merger and is now part of the Manchester University NHS Foundation Trust (MFT). As part of the merger, adult consented PMs are no longer provided at Wythenshawe Hospital and, if requested, are organised and provided by another licensed establishment which is part of MFT. Wythenshawe Hospital also do not receive bodies from the community.

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, ventilation reports, training and competency assessment documents. Consent seeking procedures and information for relatives giving consent for perinatal PMs was also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the mortuary body storage areas, the PM suite, storage arrangements for relevant material held within the histology department and the storage facility on the maternity department.

Audit of records

The inspection team undertook audits of traceability for six bodies in storage. This included adult and perinatal cases. Traceability details were crosschecked between the identification band on the body and information on the mortuaries electronic database and paper records. No discrepancies were identified.

The inspection team undertook observations of the establishments booking-in and release procedures. One discrepancy was identified in that the release of a body was taking place after only two identifiers were checked (see shortfall under T1(c)). This was identified by the Regulation Manager and subsequently rectified prior to the release of the body, on three identifiers as per the establishment's SOP.

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

Meetings with establishment staff
The assessment team met with staff carrying out activities under the licence, including mortuary staff, a trainee APT, a senior APT, the pathology services manager, a senior portering staff member, the bereavement midwife, the midwifery matron and a consultant histopathologist who is also the DI.

Report sent to DI for factual accuracy: 16 December 2022

Report returned from DI: 4 January 2023

Final report issued 4 January 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 August 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.