Inspection report on compliance with HTA licensing standards
Inspection date: **8 &9 November 2023**

Sandwell General Hospital
HTA licensing number12131

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 **Sandwell General Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Satellite site **City Hospital**	Not licensed	Licensed	Licensed
Mortuary (satellite site)	-	*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 Sandwell General Hospital ('the establishment') had met the majority of the HTA's standards, six major shortfalls were found against standards for, Governance and quality systems, Traceability and Premises, facilities and equipment.

One of the shortfalls for standard PFE2 e) Major relates to a finding from the last inspection. The HTA is concerned that adequate steps were not taken to address this findings in the intervening period, although there was discussion between the HTA and the contractors to resolve the shortfall and the corrective action agreed and approved, this action remains insufficient. The DI is engaged in communication with contractors to address this issue in line with the HTA recommendation

Concerns were discussed with the establishment as part of this inspection, the current DI has provided assurance that key personnel have been appointed to manage the activities under the license and that the establishment is committed to meeting the regulatory requirements. 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		
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.	Although the establishment has a range of SOPs covering licensed activities, some SOPs do not reflect current practice or do not contain sufficient details of procedures. Examples include, but are not limited to: • The SOP PROC-MORT-S Arrival of bodies to mortuary from wards in-hours (and out of hours)and the SOP PROC-MORT-C Arrival of infected cases, refer to age for identification checks. • The SOP PROC-MORT-Plan Contingency - Winter pressures body storage, lacks sufficient detail regarding the identification of bodies or how temperatures are monitored for contingency storage. Some SOPs do not refer to the latest version of the codes of practice and some links to HTA guidance do not work.	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		

d) There is system for flagging up same or similar names of the deceased	There is a system for flagging up same and similar names of the deceased. However, at the time of the inspection the orange wrist bands designed to highlight same or similar names were being placed into the patient folder with the body rather than being attached to bodies. During the body audit at City Hospital the inspection team noted that some entries in the mortuary register relating to same/similar names had not been marked in red as set out in the SOP. At City Hospital the orange wrist bands had not been placed into the patient folder or attached to the body. This poses a risk of misidentification of bodies.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Staff alarms for use when conducting viewings at Sandwell Hospital are not effective due to connectivity issues. Whilst staff engaged in lone working at City Hospital have access to body worn staff alarms, these are not always used. This presents a risk to staff in the event of a medical emergency, or they require assistance from hospital security.	**Major**
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 all fridge and freezer units are temperature monitored and alarmed, the fridge alarm trigger points at both Sandwell General Hospital and City Hospital are set for High Temperature Alarm at +12°C and Low Temperature Alarm at 0°C. This poses a risk of bodies being frozen or not being stored at an optimum temperature, which may cause deterioration.	**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 at Sandwell does not provide the necessary ten air changes per hour. The establishment have recently contracted a service visit and are instructing corrective maintenance work.	**Major**

Minor 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	In the body store at City hospital some metal drain covers are rusty and cannot be fully decontaminated. In the contingency body store area at City Hospital some areas of racking are rusty and cannot be fully decontaminated.	**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)	Whilst condition checking is taking place, the DI is advised to update SOPs to ensure the condition of bodies on arrival to the mortuary is fully recorded.
2.	GQ1(a)	Portering staff read the HTARI reporting SOP as part of their training. The DI is advised to reshare the HTARI SOP with porter supervisors and consider displaying HTARI categories in the porters' office.
3.	GQ2(a)	The DI is advised to add a review of Fob access and CCTV to the security audit.
4.	GQ4(b)	The DI is advised to remind mortuary staff to follow procedure to score a line through and initial when updating fridge spaces in the written mortuary register.
5.	GQ6(b)	The DI is advised to review risk assessments to include public access to the funeral directors entrance at Sandwell General Hospital to ensure adequate mitigation is documented.

Background

Sandwell General Hospital has been licensed by the HTA since 5 July 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in July 2019.

Since the previous inspection, there has been a change to the Designated Individual. The establishment intends to close the site at City Hospital and transfer activities across to a new site during 2024.

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 PMs were also reviewed.

Visual inspection

The inspection team undertook a visual inspection of the premises which included the mortuary and additional body storage area, viewing facilities, the PM suite and the storage arrangements for relevant material held.

Audit of records

The inspection team undertook audits of traceability for five bodies in storage at Sandwell General Hospital and four bodies in storage at City Hospital. Traceability details were crosschecked between the identification band on the body and information in the mortuary register and electronic records. For one case at Sandwell, the patient passport had not been updated with the fridge position for a body that had been moved into the freezer. This was immediately corrected by staff. No other discrepancies were identified. The inspection team noted that the procedure for same or similar names had not always been followed. (see T1d above)

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), bereavement midwives, porters and staff involved in the consent seeking processes.

Report sent to DI for factual accuracy: 28 November 2023

Report returned from DI: 9 December 2023

Final report issued: 12 December 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: 3 April 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.