Inspection report on compliance with HTA licensing standards
Inspection date: **7-8 September 2021**

Salisbury District Hospital
HTA licensing number 12047

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 **Salisbury District Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab			*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 Salisbury District Hospital ('the establishment') had met the majority of the HTA's standards, 10 major and six 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.

Compliance with HTA standards

Major 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	The Standard Operating Procedure (SOP) does not include detail on the consent seeking process for perinatal/paediatric post-mortem examination (PM examination). It does not detail who can seek consent or the training they must receive.	**Major**
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	Not all staff involved in the consent seeking process for perinatal/paediatric PM examination have received training which addresses the requirements of the HT Act and the HTA's codes of practice.	**Major (Cumulative)**

b) Records demonstrate up-to-date staff training	*Perinatal/Paediatric PM examinations:* The establishment does not have a process to identify which staff have received consent training and when refresher training is due for those who are trained. There are no accessible records held for staff to determine who is appropriately trained to seek consent.	
d) Competency is assessed and maintained	Staff competency in seeking consent for perinatal/paediatric PM examination is not assessed.	
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	SOPs lack sufficient detail. Key steps are included but these do not specify the individual actions that need to be undertaken to accomplish each step. These include, but are not limited to, SOPs detailing the process for: • admitting, storing and release of bodies; • post-mortem examination; • identification of deceased for viewing of bodies; and • reporting incidents. This is not an exhaustive list of the SOPs requiring amendment. To fully address this shortfall the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail to reflect current practice.	**Major**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	The scope of the audit schedule for activities conducted under the licence is limited. The audit schedule does not include sufficient audits to check compliance with documented procedures, the completion of records, and traceability of bodies and samples.	**Major**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	Although staff have been initially 'signed off' on completion of training, there is no on-going competency assessments.	**Major**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	There is no assurance that all staff undertaking licensable activities know how to identify and report HTA Reportable Incidents (HTARIs). The inspection team identified an incident in the establishment's incident log that should have been reported to the HTA (this has been retrospectively reported to the HTA).	**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	The risk assessments do not cover the risks of incidents in relation to HTA licensable activities and licensing standards.	**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	Procedures for identification of bodies do not always use a minimum of three identifiers of the deceased. • The procedure for conducting viewings does not include steps to check a minimum of three identifiers of the deceased provided by relatives against the identification on the body before a viewing takes place. • Unidentified bodies admitted to the mortuary are only labelled with two identifiers. • The procedure for checking identification prior to retrieval of organs and tissue in the mortuary by NHSBT staff only uses two identifiers.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The establishment does not check the condition of bodies during the length of stay in the mortuary. (The condition of bodies are checked on arrival but not subsequently.)	**Major**
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	Temperature monitoring and alarm testing is carried out remotely by an external supplier. The mortuary staff are not actively involved in testing of the fridge and freezer temperature alarms to ensure call-out procedures work and are followed. The temperature alarm trigger points for the fridges and freezers are not set at appropriate temperatures to ensure that the alarms will trigger when storage temperatures deviate from acceptable ranges.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Governance meetings that discuss HTA-licensed activities are not held.	**Minor**
GQ2 There is a documented system of audit		
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Records of audits do not document who is responsible for follow-up actions and the timeframe for completing the actions.	**Minor**
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	Although the establishment undertakes an annual rolling tissue audit, this is restricted to auditing tissue samples collected in the previous year, rather than encompassing all the holdings potentially on site. The DI cannot be assured of what tissue is being held and that tissue is disposed of in a timely manner.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	The establishment does not have an induction process in place to document that newly employed pathologists or external visitors, such as observers of post-mortem examinations, have read and understood local policies and procedures.	**Minor**

GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
d) Information about incidents is shared with all staff to avoid repeat errors	There is no mechanism or practice of sharing information about incidents with the portering and maternity teams.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	The establishment could not provide the servicing and maintenance records for key items of equipment.	**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.	C1a	The DI is advised to review the adult post mortem consent form to remove references to Next of Kin.
2.	C1a	The DI is advised to contact the Coroner to assure themselves that Coronial authority is still in place for Sudden Unexpected Death in Childhood (SUDIC) removal in the Emergency Department.
3.	C1c	The DI is advised to check that the patient information document ‘consent information for PM examination’ contains the most up to date information on the HTA website.

4.	GQ5b	The DI is advised to ensure that incident follow-up actions are completed in a timely manner.
5.	T1c	The DI is advised to phase out the use of the ‘green disposal form’ and to only accept the establishment’s release form for releasing bodies to funeral directors.
6.	T1g	The DI is advised to contact the brain bank establishment to ensure that there have been no changes in procedure since the establishment previously transported a brain.
7.	PFE1d	The DI is advised to check that the establishment funeral director entrance has CCTV coverage.
8.	PFE2c	The DI is advised to ensure that contingency arrangements are in place if a bariatric body requires moving to long term storage.
9.	PFE2c	The DI is advised to include bariatric freezer storage in the business plan for the refurbishment of the mortuary.
10.	PFE2e	The DI is advised to liaise with the bereavement midwife on the future installation of a fridge for storage of bodies in the maternity bereavement suite. This is to ensure that the appropriate HTA standards are complied with.
11.	PFE2f	The DI is advised to record and review trends in storage temperatures. This may help to identify trends and the extent of any variations in storage temperatures.

Background

Salisbury District Hospital (SDH) is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

SDH has been licensed by the HTA since 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in August 2016.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

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

Standard C2a was not assessed as it is not applicable to the activities undertaken. Standards PFE2d, PFE3a and PFE3e are applicable but were not assessed as this was a virtual regulatory assessment. The remaining 68 HTA licensing standards (standards published 3 April 2017) were assessed.

Review of governance documentation

The inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, records of equipment servicing, audits, risk assessments and reported incidents.

Visual inspection

No visual inspection was undertaken as part of this inspection.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, CLHc, Mortuary Manager, an Anatomical Pathologist Technician, a Pathologist, portering staff, SUDIC representative and maternity and adult consent seeker representative.

Report sent to DI for factual accuracy: 17 September 2021

Report returned from DI: 20 September 2021

Final report issued: 7 October 2021

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 Virtual Regulatory Assessment Report.

Date: 27 April 2022

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.