Inspection report on compliance with HTA licensing standards
Inspection date: **8 May 2024**

Dorset County Hospital

HTA licensing number 12449

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 **Dorset County Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab			*Carried out*
Maternity			*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 Dorset County Hospital ('the establishment') had met the majority of the HTA's standards, one cumulative major, five major and seven 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
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 standard operating procedures (SOPs) do not accurately reflect current practice and some do not contain sufficient detail for staff regarding the procedures that must be followed. Particular examples include but are not limited to: • Receipt and release; • Mortuary security; • Storage of deceased; and • Viewing of deceased. 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 of the procedures.	**Major**
GQ2 There is a documented system of audit		

a) There is a documented schedule of audits	Although a schedule of audits is in place, the scope for licensed activities conducted under the licence is limited. The audit schedule does not include sufficient vertical or horizontal audits to check compliance with documented procedures, the completion of records and traceability of bodies or tissues.	**Major**
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	The establishment cannot provide assurance that tissue is being disposed of as soon as reasonably possible. The establishment is currently auditing tissue every two years. *See shortfall against T2(b) for further detail.*	**Cumulative Major**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	A number of cases were identified where tissue was being retained for a relatively long time after PM examination. Although staff have communicated with the Coroner's office this is done infrequently and notification of completion of the Coroner's authority or the families wishes as to the fate of the tissue has not been received for a number of cases dating back to 2017. When conducting the tissue traceability audit there were four cases where paperwork relating to tissue taken at PM examination could not be found. There is a risk that the establishment is storing tissue without appropriate authority or consent under the HT Act.	
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	The inspection team identified incidents and near-misses since the previous inspection which have not been reported to the HTA. *See advice item 5.*	**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	Risk assessments of procedures related to licensable activities do not identify all the associated risks; examples include, but are not limited to: • Major equipment failure; • Viewing of the wrong body; • Disposal or retention of a foetus under and over 24 weeks; • PM conducted not in line with families wishes; and • PM conducted on the wrong body.	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
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)	There is no CCTV coverage of the external body store door by the existing CCTV camera, or swipe card access to this unit The external body store is also used by medical engineering to store equipment when not in use by the mortuary who access the store using a separate second door. There is no CCTV or swipe card access to this door and the key is held by medical engineering. There is a risk of unauthorised access to the external body store when in use by the mortuary as part of the contingency plans.	**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	A draft consent policy is currently waiting for approval however, at the time of the inspection there is no consent policy in place which reflects the requirements of the HT Act and the HTA's codes of practice.	**Minor**
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	Staff involved in the consent seeking process for adult consented post mortem (PM) examinations have not received refresher training.	**Minor**
d) Competency is assessed and maintained	Competency in seeking consent for adult consented PM examinations has not been assessed.	**Minor**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	Deviations from documented SOPs are not recorded or monitored via audit activity.	**Minor**
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).	The establishment do not receive confirmation of receipt of tissue slides sent to and from the laboratory to the pathologist undertaking the analysis. This poses a risk that traceability of tissue slides may be lost when being transferred.	**Minor**
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	The lone working alarm used by staff when conducting out of hours viewings does not link to an appropriate area in the hospital if required.	**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	The mortuary staff do not manually challenge the lower temperature alarm of the fridges on a regular basis in both the body store and maternity unit. This does not provide assurance that the alarm will trigger when temperature deviates from the expected range.	**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(g)	While reviewing the perinatal consent documents which is used by staff to seek consent, it was noted that the document was last reviewed prior to 2017 when the HTA updated the codes of practice. The DI was made aware and contacted the referral centre for the updated guidance package which was in place when the inspectors were

		on site. The DI is advised to ensure that documents relating to seeking consent are up to date to enable those giving consent are fully informed of the options available.
2.	GQ2(a)	The DI is advised to ask for a list of staff with access to the mortuary as part of the security audit.
3.	GQ3(a)	The DI is advised to ensure that training and competency forms are fully completed.
4.	GQ4(b)	The DI is advised to include in the record keeping SOP how to correct written errors.
5.	GQ5(a)	The DI is advised to place signage in the mortuary and maternity unit to raise awareness amongst all staff working there of the importance of reporting any incidents, including a list of all the appropriate HTA Reportable Incident (HTARI) categories.
6.	T1(c)	The DI is advised to ensure that the transfer of foetuses from maternity SOP also includes the procedure for release of a baby and recording of identifiers.
7.	PFE1(d)	The DI is advised to ensure that the mortuary doors are on the essential generator power in case of a power failure and the magnetic locks disengage.
8.	PFE2(e)	The DI is advised to have the same temperature monitoring and alarm system in the external body store to provide assurance that temperatures are not deviating from the expected range.

Background

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

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

All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

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, cleaning records for the mortuary and post-mortem room, records servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, reported incidents and staff training records.

Visual inspection

The inspection included a visual inspection of the mortuary body store, PM room and viewing room.

Audit of records

Audits were conducted for four bodies in refrigerated storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic system. Whilst two minor discrepancies were found, these were not sufficient to amount to a shortfall but oral advice was given to the establishment at the time of the inspection.

Audits of traceability were conducted for tissue blocks and slides from five PM cases, including audits of the consent documentation for the retention of these tissues. Four discrepancies found (see shortfall against T2(b)).

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, Anatomical Pathology Technologists (APT), mortuary assistant, medical examiner officer, quality lead, laboratory personnel, portering staff and mortuary manager.

Report sent to DI for factual accuracy: 28 May 2024

Report returned from DI: 10 June 2024

Final report issued: 1 August 2024

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: 20 January 2025

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.