Inspection report on compliance with HTA licensing standards
Inspection date: **8 November 2022**

The County Hospital

HTA licensing number 12409

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 **The County Hospital**	Licensed/Not licensed	Licensed/Not licensed	Licensed/Not 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 The County Hospital ('the establishment') had met the majority of the HTA's standards, 13 major and nine 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
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	*Perinatal/paediatric consent training* Consent for post mortem examination is sought by clinicians, who have undertaken basic clinical consent training. Consent training for staff seeking consent for perinatal PM examinations does not address the requirements of the HT Act.	**Major**
d) Competency is assessed and maintained	*Perinatal/paediatric consent training* Competency assessments are not in place for those seeking consent for PM examinations.	**Major**
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 Standard Operating Procedures (SOPs) relating to mortuary activities are not reflective of current practice. These include, but are not limited to, SOPs detailing the process for: • admission of hospital and community bodies; • viewing of deceased; • release of bodies; • Post Mortem Histology; and • tissue tracking. This is not an exhaustive list of the amendments required to all the SOPs and, to fully address this shortfall, the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate, are cross referenced to the appropriate SOPs and contain sufficient detail of procedures.	**Major**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although the establishment have a schedule of audits, the schedule does not include vertical audits and a number of audits in the schedule for 2022 have not been undertaken. *See advice item 3.*	**Cumulative Major**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Whilst the establishment has a checklist for audits conducted in the mortuary, the checklists contain little detail or comment on what was looked at on the audit, or have a written report to identify non-compliances and an action plan to complete follow-up actions. There are no formal checklists in place for completed audits undertaken in histology on post mortem tissue. The inspection team found that follow-up actions for non-compliances had not been investigated sufficiently.	
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 a number of incidents since the previous inspection which have not been reported to the HTA.	**Major**
c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed	The HTARI SOP does not include any detail of reporting incidents through the Trust incident system and does not refer to all relevant HTARI categories. Although follow-up actions were identified the inspection team found that some actions were not investigated sufficiently. This presents the risk that incidents may not be identified, reported and followed up appropriately.	**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	All procedures relating to licensed activities have not been risk assessed.	**Major**
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	The establishment's risk assessments lack sufficient detail for what control measures have been implemented to reduce the risk score.	**Major**

c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register	Contingency storage was provided for the mortuary in 2020 by the local authority and was risk assessed at that time, however; the storage facility has not been regularly risk assessed and does not identify or mitigate all risks associated with transfer of deceased or security to the off-site premises for storage. The establishment is currently using a temporary storage unit for the majority of the year which is situated in the garage area of the mortuary. This means that funeral directors are unable to enter the garage area to collect deceased and are required to park outside the garage and use a locked side entrance gate which is overlooked by a ward, staff offices and Trust staff members. At the time of the inspection there was no evidence that a risk assessment had been conducted of the risks associated with transfers of the deceased. *See shortfall PFE2(i) for further detail.*	**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 establishment only require relatives to provide one identifier of the deceased when they attend the mortuary for a viewing. The maternity department can release babies from the maternity wards. There is no SOP in place requiring relatives to provide three identifiers or training of staff in release procedures. These practices pose a risk of releasing or viewing a 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)	Although all access to the mortuary had swipe card access and had CCTV in the office areas, there is no mortuary or hospital CCTV in the body store or at the access point to the mortuary from the hospital corridor. There is no audio-visual intercom system, so staff are only able to verify who has arrived by opening the entrance doors to the mortuary. This poses a risk of the doors being opened to inappropriate persons, potentially causing a security and safety issue for staff.	**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	The mortuary staff do not manually challenge the body store alarms on a regular basis. This does not provide assurance that the alarms will trigger when temperatures deviate from the expected range and that the call out procedure works.	**Major**
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	The establishment have a business continuity plan in place which identifies when contingency arrangements should be activated. At the time of the inspection there were no written agreements in place with funeral directors to facilitate the transfer of deceased in the event of a power failure or storage capacity being reached. There are no SOPs in place for staff to follow to arrange for the transfer of the deceased.	**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 for post mortem (PM) examination has been created however, this has not yet been ratified and distributed to staff involved in consent seeking for PM examinations.	**Minor**
b) There is a documented standard operating procedure (SOP) detailing the consent process	At the time of the inspection the establishment had not submitted an adult consent seeking standard operating procedure (SOP). *See advice item 1.*	**Minor**
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	At the time of inspection there was no evidence provided that porters have been competency assessed for the tasks they perform. *See advice item 4*	**Minor**
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures	Although an induction is provided to visiting pathologists there is no training programme and subsequent sign off against procedures in place.	**Minor**
GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected	In the histology laboratory correction fluid has been used on the receipt of tissue paperwork. The use of correction fluid does not allow for full auditability of any changes to a record.	**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	Relevant information about incidents is not always shared with portering staff who undertake activities in the mortuary. The portering team is not represented at governance meetings relating to the HTA licence.	**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	Issues were identified with the maintenance of the establishment, making it difficult to adequately clean or decontaminate this area, posing a potential health and safety risk to mortuary staff and visitors. Issues include but are not limited to: • Minor areas of exposed wood on the doorframes; • Rust along the drains in the post mortem room; and • The floor of the body store has areas of cracking.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		

f) Temperatures of fridges and freezers are monitored on a regular basis	The temporary fridge unit and products of conception fridge are monitored once a day however, the temperatures are not monitored at the weekends or over bank holidays.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	The trolleys have multiple areas of rust. This means that it is difficult for staff to adequately clean and disinfect this 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.	C1b	The DI is advised to add more detail on who takes consent and the training required in the guidelines for maternity staff seeking consent for PM examination.
2.	C1g	Staff seeking consent for perinatal/paediatric PM examinations are using an old version of Birmingham and Women's Childrens Hospital (BWCH) consent form. The DI is advised to contact BWCH to have the most recent version of the consent form sent to them.
3.	GQ2a	The DI is advised to introduce a vertical audit of post mortem paperwork in histology to ensure that all tissue taken at PM examination matches the paperwork received from the mortuary and Coroner's office.
4.	GQ3c	The DI is advised review the competency assessment template to record what type of competency has been assessed e.g., observation or discussion.
5.	GQ3e	The DI is advised to look at offering external training to mortuary staff to support wider mortuary activities.

6.	T1d	The DI is advised to increase the robustness of the same/similar name process by highlighting on the paperwork those with same and/or similar names.

Background

County Hospital 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.

County Hospital 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 2018.

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, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, 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 three bodies in refrigerated storage and one in long term storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and electronic database. No discrepancies found.

Audits of traceability were conducted for tissue blocks and slides from four PM cases, including audits of the consent documentation for the retention of these tissues. No discrepancies found.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, anatomical pathology technician (APT), pathologist, portering staff, maternity staff, and adult consent seeker.

Report sent to DI for factual accuracy: 9 December 2022

Report returned from DI: 20 December 2022

Final report issued: 16 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: 5 July 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.