Inspection report on compliance with HTA licensing standards
Inspection date: **18 and 20 April 2023**

Colchester General Hospital

HTA licensing number 11104

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
Colchester General Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 Colchester General Hospital (“the establishment”) had met the majority of the HTA’s standards, three major and four 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

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	The establishment was not able to provide evidence that all staff who seek consent for perinatal PM examinations are trained in line with the requirements of the HT Act and the HTA's codes of practice.	**Major (cumulative)**
b) Records demonstrate up-to-date staff training	The establishment was unable to provide training records for all staff who seek perinatal consent.	

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The current audit schedule does not include the following: • Security audits of access to the mortuary and checking of CCTV footage • Completed consent forms for adult and perinatal PM examinations • Horizontal audits of mortuary processes	**Major (cumulative)**

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	Regular audits of tissue traceability are conducted, however the inspection team discovered two slides that should have been disposed of in 2017.	

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 do not cover all HTARI categories or the risk to the areas of the mortuary that lack CCTV coverage.	**Major**

Minor shortfalls

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 quantity of tissue samples is recorded when taken for histology, however records do not indicate type of tissue sample taken.	**Minor**

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)	Some areas of the mortuary are lacking CCTV coverage.	**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 contingency fridge temperatures are not monitored out of hours.	**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 mortuary trolleys and equipment have some areas of rust. The fridge doors are also damaged from where the trolley has come in contact with the doors causing several dents.	**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.

The HTA advises the DI to consider the following to further improve practice:

Number	Standard	Advice
1.	C1 (a)	For contingency purposes, the DI may wish to consider having staff cover seeking consent at another establishment which is under the same Trust. The establishment is also advised to continue with their plans to upload the e-learning module for consent training.
2.	GQ5 (a)	The DI is advised to put signage up in the mortuary for awareness of incidents that need to be reported to the HTA. The DI is also advised to record incidents where ward staff have not informed porters that a bariatric patient is to be collected from the mortuary as there is a risk of accidental damage to a deceased if portering staff are under time pressure by not returning to the mortuary to collect the correct size trolley.
3.	GQ1 (h)	The establishment communicates with portering staff regularly and the DI is advised to formalise this process by including portering managers to the regular governance meetings.
4.	T1 (c)	The DI is advised to consider the following to make traceability procedures more robust: • ensure that all information on body tags is reflected in the electronic system • put a whiteboard on the paediatric fridge door to ensure the same procedures as admission for adult cases • additional visual cues to highlight organs and tissue for repatriation (e.g. wristband on the body, sticker on the fridge door)
5.	PFE2 (a)	The contingency chiller units are not secured and there is a risk that the units could be accidently switched off from the outside of the unit. The DI is advised to take appropriate measures to mitigate this risk.

Background

Colchester General Hospital has been licensed by the HTA since October 2008 This was the fifth inspection of the establishment; the most recent previous inspection took place in January 2018.

Since the previous inspection, there has been a change of DI and four Persons Designated added to the licence. The establishment has also added additional capacity in May 2020.

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 assessment 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 for the mortuary were reviewed. Traceability audits, risk assessments, meeting minutes, incidents, consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection

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

Audit of records

Audits were conducted for three bodies in refrigerated storage and two in freezer storage. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and relevant documentation. Some of the information on the body tags was not recorded on the electronic system (see advice item 4).

Forward and reverse audits of traceability were conducted for tissue blocks and slides from coronial and hospital consented PM cases, including audits of the consent documentation for the retention and disposal of these tissues (see shortfall against GQ2 (c) and T1 (g)).

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including the DI, Anatomical Pathology Technologists, a porter, and consent seekers for PM examinations.

Report sent to DI for factual accuracy: 17 May 2023

Report returned from DI: 05 June 2023

Final report issued: 13 June 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: 4 September 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.