Site visit inspection report on compliance with HTA licensing standards
Inspection date: **30/31 January 2020**

Broomfield Hospital

HTA licensing number 12441

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
Broomfield Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology laboratory	-	-	*Carried out*
Maternity department	-	*Carried out*	-
Accident and Emergency (A&E) department	-	*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 Broomfield Hospital (the establishment) had met the majority of the HTA's standards, eight major and 11 minor shortfalls were found against standards for Consent, Governance and Quality, 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		
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	The establishment's policy for seeking consent for adult post-mortem (PM) examinations refers to the 'Next of Kin' (NOK) giving consent. However, the policy does not reference seeking consent from a nominated representative, the person themselves in life or those in a qualifying relationship. This means that the policy does not reflect the requirements of the HT Act or the HTA's Codes of Practice.	**Major (cumulative)**
b) There is a documented standard operating procedure (SOP) detailing the consent process	There is no SOP for seeking consent for an adult hospital consented PM examination.	

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	Staff seeking consent for PM examination do not have up-to-date training records. Staff are not required to undergo refresher training.	**Major (cumulative)**
d) Competency is assessed and maintained	Staff are not competency assessed for seeking consent for PM examination. A number of consent forms reviewed by the inspection team had been completed incorrectly.	
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 do not include sufficient details of procedures. • The SOPs for viewings, release of bodies from the mortuary and PM examination do not include sufficient details of what identifiers could be used to identify the deceased and how identification checks should be performed. • The SOP 'control of human tissue' does not describe the process of transfer between the mortuary and maternity department. It does not include sufficient details of what identification checks are done each time. • The SOP 'post mortem specimens' does not include sufficient details for how specimen pots are labelled for whole organs and if confirmation is received for receipt of these specimens. The SOP does not describe the procedure for identification of bodies requiring repatriation of organs or tissues and how this is recorded as completed.	**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 all licensed activities or the risks associated with these activities. For example, the transfer of bodies into the mortuary has not been risk assessed. This presents a risk that staff may not be aware of the risks associated with the activities they undertake.	**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's procedures for identification of bodies do not use a minimum of three identifiers of the deceased. • For release of bodies, the name of the deceased is provided verbally by those wishing to collect the body. This is the only identifier checked against the identification bands on the body prior to release taking place. • For viewings of bodies, only the name of the deceased is requested from families when they arrive at the mortuary. No further crosscheck against the identification bands on the body is carried out prior to the viewing taking place.	**Major**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	The inspection team's audits found that in some cases, tissue has not been disposed of as soon as reasonably possible. This means that some tissue taken at PM examination has been retained without consent from the family. (Refer to audit section of the report for details of these cases.)	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The mortuary does not have freezer storage facilities or arrangements with other establishments to meet the need for long-term storage of bariatric bodies.	**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 for the PM room has not been tested. Staff cannot be assured it works to the required specification and provides the necessary ten air changes per hour.	**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		
f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds	The consent form for an adult hospital consented PM examination does not provide contact details or the date and time by which withdrawal of consent can occur.	**Minor**

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	Activities related to licensed activities in the maternity, A&E and neonatal unit departments are not included in the establishment's governance framework for the licence. There are no Persons Designated nominated to help oversee activities related to the licence in these departments. The DI does not have regular contact with staff undertaking licensed activities in these departments.	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	There are no HTA governance meetings involving staff who perform licensed activities or activities related to licensed activities in the various departments at the establishment.	**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).	Records are not kept of transfer and receipt of tissue samples from the mortuary to the histology laboratory.	**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	The floor of the PM room is showing signs of wear. • Some of the seals around the sink and the access panels in the floor are damaged. • One area of the floor is peeling away from the wall. This means that the floor surface is difficult to clean and disinfect adequately.	**Minor**
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	Bodies are transferred into a temporary storage unit located in the PM room using the body store hydraulic trolley. This poses a risk of contamination of the body store area. The body store area is classified as a transitional area but no personal protective equipment (PPE) is used by staff and visitors to this area to protect against potential contamination.	**Minor**

c) There are documented cleaning and decontamination procedures and a schedule of cleaning	There are no cleaning schedules or cleaning records for the PM room or the contingency storage suite.	**Minor**
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 intercom at the visitor's entrance to the mortuary building and no other way for staff to identify who is visiting without opening the door.	**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	There are some areas of rust on the hydraulic trolleys. This means they cannot be cleaned and disinfected adequately. The trolleys do not lower to the bottom fridge spaces. This poses a health and safety risk to staff and risk of accidental damage to bodies.	**Minor**
d) Staff have access to necessary PPE	Although staff have access to face masks for use in the PM room, they have not been fit-tested for these masks and they have not been trained in the use of the vented hoods available.	**Minor**
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	There are no maintenance records for the fridge and freezer body storage units.	**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)	The DI may wish to consider introducing a procedure to record that bodies have been returned to storage following a viewing.
2.	PFE1(a)	The DI is advised to review the temperature of the viewing room. Staff reported that the viewing room temperature is highly dependent upon the outside temperature and that this is a problem for the integrity of bodies being viewed during the summer months.
3.	PFE1(d)	The DI is advised to keep under review the security arrangements of all entrances to the mortuary building.

Background

Broomfield Hospital has been licensed by the HTA since March 2007. This was the fourth site visit inspection of the establishment; the most recent previous inspection took place in March 2017.

Since the previous inspection, an onsite contingency storage suite has been built and the establishment has been identified as the regional Disaster Victim Identification (DVI) site. The establishment has been used twice for this purpose since the last inspection.

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 policies and procedural documents relating to licensed activities, cleaning records for the mortuary, contracts for servicing of equipment and records of servicing, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training records.

Visual inspection

The inspection team carried out a visual inspection of the body storage areas, PM room, viewing room, contingency storage suite and histology department where PM tissue is stored. The A&E department and maternity department were not inspected as it was reported no storage of relevant material takes place in these areas. During the visual inspection of the body storage area of the main mortuary, release of a body was observed.

Audit of records

The inspection team performed traceability audits of four bodies in storage. Identification details were crosschecked between the identification band on the body and the electronic mortuary register. For one body, there was a minor discrepancy in the surname on the identification band compared to the mortuary register.

Audits were conducted of tissue taken at PM examination for twelve cases. Information was crosschecked between the mortuary documentation and database, Coroner's paperwork, family wishes forms and the histology database. For six cases, disposal of tissue had been completed in line with the wishes of the family. For the other six cases, the following discrepancies were identified:

- In one case, the tissue had been retained but the consent form had been completed to both retain for future use and dispose of tissue.
- For one case, the tissue had been retained but there was no family consent wishes form. No evidence could be provided to demonstrate whether the Coroner's authority was still ongoing for this case.
- For four hospital consented PM examination cases, the tissue had been retained but the family consent wishes forms stated tissue was to be disposed of. The establishment stated the reason for the retention was either the PM report had not been completed or due to the findings at PM examination. However, no evidence was provided for follow up on these cases. The PM examinations were conducted between one and five years ago.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including mortuary staff, staff in the A&E department responsible for Sudden Unexpected Deaths in Infants and Children (SUDIC) sample collection, porters who admit bodies into the mortuary, consent seekers for adult and perinatal PM examinations, a pathologist who conducts PM examinations and the DI.

Report sent to DI for factual accuracy: 26 February 2020

Report returned from DI: 9 March 2020

Final report issued: 10 March 2020

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 site visit 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 site visit.

   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 site visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.