Inspection report on compliance with HTA licensing standards
Inspection date: **12 January 2023**

Barnsley Hospital

HTA licensing number 12346

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
Barnsley Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Maternity	-	*Carried out*	-
Accident & Emergency	-	*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 Barnsley Hospital ('the establishment') had met the majority of the HTA's standards, seven major and six minor shortfalls were found against standards for Consent, Governance and Quality systems, Traceability and Premises, Facilities and Equipment. These related to staff training and competencies, Standard Operating Procedures, incident reporting, traceability systems, security arrangements, equipment suitability, maintenance of premise and storage capacity.

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 consent SOP in place does not include the requirement for staff taking consent to have HTA compliant training and hold an up-to-date competency assessment. Furthermore, it does not detail the withdrawal of consent process including how withdrawal is communicated to the mortuary.	**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	The establishment were not able to demonstrate that all staff seeking consent for perinatal post mortem (PM) examination have HTA compliant training in this procedure.	**Cumulative Major**
b) Records demonstrate up-to-date staff training	The establishment were not able to supply training records for all staff seeking consent for perinatal PM examination.	
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual	It was not possible to assess this standard as records relating to C2(b) were not available for the inspection team.	
d) Competency is assessed and maintained	The establishment were not able to supply competency assessment records for staff seeking consent for perinatal PM examination.	
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 the Royal College of Pathologists	Whilst documented policies and SOPs covering all mortuary and laboratory procedures are in place, the current versions lack sufficient detail and do not consistently reflect current practice. These include but are not limited to: • Mortuary-Receipt and Release of Deceased Patients • Mortuary-General Procedures • Standard Operating Procedure for the care, storage and transfer of a fetus or still born baby To address this shortfall the establishment should review all SOPs relating to mortuary activities, ensuring that they are up to date, accurate, cross referenced to the appropriate codes of practice and guidance, and contain sufficient and clear detail of procedures.	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		

b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records)	The inspection team were not assured that a robust system is in place which tracks bodies adequately from admission to release. During the inspection the following issues were identified: • Several perinatal deceased had not been signed back into the relevant mortuary register after a viewing being conducted on the ward. • Several perinatal cases had initially been entered in the wrong mortuary register, subsequently an entry was made in the correct register however the incorrect entry had not been updated. The deceased had been released however the initial register showed the body as still being in the care of the mortuary. • Several of the entries in the perinatal register in Maternity were incomplete. The frequency of moving the deceased, and the mortuary registers not being maintained as expected poses a risk of loss of traceability of bodies in storage.	**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)	During the external inspection of the premise, the inspection team found that access to the condenser units, which maintain the power supply to the refrigeration units for “Mortuary 2”, was not controlled. Uncontrolled access to the main electrical breaker switches poses a risk of access by unauthorised personnel and the power supply to Mortuary 2 being interrupted.	**Cumulative Major**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The inspection team identified the following risks to the security arrangements of the mortuaries: • The viewing room does not have systems in place for staff to be able to raise an alarm should this be required. This may pose a risk of visitors accessing the rest of the mortuary if staff security is compromised.	
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The freezer storage is set to a maximum temperature of −5.8ºC, this does not comply with the optimal operating temperature of −20ºC documented in the HTA standards and guidance, Code B. The maximum temperature of the freezer has increased by 4.2ºC since the last inspection when it was set at −10ºC. Furthermore, during the site visit the inspection team noted that the temperature increased further due to the practice currently being deployed to manage freezer capacity issues. (See shortfall against HTA standard PFE2(c)) At the time of the inspection, the PM room housed a temporary storage unit which was in use, and the room was also stocked with numerous hospital beds which were not in use, to be utilised as a further contingency storage measure should this be required. This arrangement poses a risk to contamination of the deceased stored in this area as it is actively in use for post mortem examination, including high risk PM activity.	**Cumulative Major**

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	During the site visit the inspection team noted that deceased who required low temperature storage were being rotated through the freezers rather than being stored in them. This was as a result of insufficient capacity to meet the demand for long term storage. Long term storage capacity is insufficient, it does not ensure the dignity of the deceased and poses a significant risk of deterioration of the deceased that could otherwise be preventable and increases risks related to traceability of the deceased.	
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 concealment trolleys in use are not appropriate for the task or suitably maintained. They present an impediment to the staff using them and a risk of accidental damage to the deceased. The trolleys are not a commercially available, industry standard or Health and Safety approved moving and handling aid. Lateral transfer techniques are not possible as one side is fixed. This poses a manual handling risk to staff and risk of accidental damage to the deceased being transferred. Furthermore, the trolleys are showing areas of rust and do not appear to form part of a routine cleaning schedule to ensure they are effectively decontaminated prior to being used in clinical areas. A risk assessment from Infection Control was not available for the inspection team. An alternative trolley had been purchased however it had not been approved by the health and Safety team and was therefore not in use. The Trust should be aware that this is a stretcher trolley rather a concealment trolley.	**Cumulative** **Major**

b) Equipment is appropriate for the management of bariatric bodies	The bariatric concealment trolley in use is not appropriate for the task or suitably maintained. It presents an impediment to the staff using it and a risk of accidental damage to the deceased. The trolley is not a commercially available, industry standard or Health and Safety approved moving and handling unit. Lateral transfer techniques are not possible as one side is fixed. This poses a manual handling risk to staff and risk of accidental damage to the deceased being transferred. Furthermore, the trolleys are showing areas of rust and do not appear to form part of a routine cleaning schedule to ensure they are effectively decontaminated prior to being used in clinical areas. A risk assessment from Infection Control was not available for the inspection team. In the event that a bariatric patient cannot be transferred to the mortuary using a concealment trolley, the deceased is conveyed on a hospital bed and in a manner which does not provide assurance that the dignity of the deceased is being fully preserved and that the Health and Safety of the staff performing this procedure is protected.	

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		
d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives	The information provided to families during the consent seeking process for both adult and perinatal PMs does not include what steps will be taken if no decision is made, by the relatives, in relation to how tissue will be handled after the post mortem examination is concluded.	**Minor**
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 documentation used during the consent seeking process for perinatal post mortem examination (consent form and information leaflet) does not include information on the process of withdrawing consent.	**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	During the site visit the inspection team noted that white stickers were used to cover errors in written registers. This practice does not comply with HTA guidance and with the establishments SOP for record management.	**Minor**
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	Staff involved in licensable activities, including staff working outside of the mortuary, such as in Maternity, Accident and Emergency departments and the porting staff, are not aware of the HTARI reporting requirements and the procedure for reporting HTA reportable incidents.	**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	Areas of the mortuary premises are showing signs of wear and require maintenance to ensure decontamination procedures are effective: • The doors between the PM suite and body store are damaged exposing porous wood. • There is damage to the wall of the PM suite exposing bare plaster • There is rust damage to the flooring adjacent to the base of the PM tables	**Minor**
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors	The doors which act as demarcation between the clean, dirty, and transitional areas of the mortuary (PM suite and body store), did not provide a watertight seal. Therefore, contamination of the body store during cleaning of the PM suite cannot be prevented.	**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(a)	The DI is advised to review the Consent policy to ensure that training requirements for staff seeking consent is clearly articulated.
2.	C1(f)	The DI is advised to review and strengthen the communication of withdrawal of consent for PM examination between the Maternity and Mortuary teams.
3.	GQ1(a)	The DI is advised to add clear guidance relating to condition checking in the relevant SOP.
4.	GQ1(a)	The DI is advised to include clear instruction on which sources of ID should be cross checked during identification of the deceased in all relevant SOPs.
5.	GQ2(a)	The DI is advised to add traceability audits of the records in maternity to the existing audit schedule
6.	PFE1(a)	The DI is advised to refresh the flooring treatment in the Funeral Directors entrance to the Mortuary.
7.	PFE1(e)	The DI is advised to consider alternative security arrangements for the doors between the viewing room and body store, and the visitors' reception and mortuary. These doors are reliant on the deployment of manual locks. This may pose a risk of unauthorised access to the body store if the manual locks are not deployed.
8.	PFE2(a)	The fridge used to store perinatal deceased in the Maternity department is not co-located within the viewing area, therefore the deceased are conveyed through a high traffic area used by patients in labour, their families, and staff. The DI is advised to move the storage facility to a more sensitive location to ensure the dignity of the deceased and prevent oversight from the public and staff.
9.	PFE2(a)	The fridge used to store perinatal deceased in the Maternity department is located in a room named "Dirty Utility". The DI advised to change the name of this room to something more sensitive.

10.	PFE2(b)	The DI is advised to audit the use of the temporary storage unit currently housed in the PM suite to fully understand the capacity challenges of the service.
11.	PFE2(e)	The DI is advised to increase the frequency of testing the out of hours fridge and freezer temperature alert process to ensure the call out procedures work as expected in the event of a unit failure
12.	PFE2(f)	The DI is advised to review the temperature records of the storage facilities in Maternity for trends.
13.	N/A	The DI is advised to display all three HTA certificates in the Mortuary.
14.	N/A	The DI is advised to inform the HTA licensing team to the extension to storage put in place as a result of the Covid 19 pandemic.

Background
Barnsley Hospital has been licensed by the HTA since June 2008. This was the fourth inspection of the establishment; the most recent previous inspection took place in December 2017.

Since the previous inspection capacity has been increased by 48 spaces in response to the Covid 19 pandemic and additional security measures implemented following communication from NHS England in November 2021.

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 the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities were reviewed. This included cleaning records for the mortuary

and post-mortem room, records of servicing of equipment, fridge and freezer alarm testing records, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training and competency records. Consent seeking policies and procedures, information for relatives giving consent and current consent forms in use for both adult and perinatal PM examination were also reviewed.

Visual inspection

The inspection included a visual assessment of the three mortuary body storage areas, PM room, viewing room, tissue storage areas and the Maternity department. The inspection teams observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records

The inspection team undertook audits of traceability for six bodies in storage. This included a paediatric case, bodies with same/similar name and bodies in long term storage. The audit covered deceased stored in all the body stores. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, the mortuary register and paperwork. One minor discrepancy was found relating to a same/similar name not being marked in the mortuary register.

Audits were conducted of tissue taken at PM examination on six cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms and tissue blocks and slides being stored. Retention and disposal of tissue had been completed in line with the wishes of the family and compliant with HTA requirements. Full traceability of tissues was demonstrated for all six cases.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including the DI, Integrated Cellular Pathology Manager, Chief Anatomical Pathology Technician, consent seekers for both adult and perinatal hospital post mortem examinations, Bereavement Midwife, Porter, Pathologist, and the Consultant Paediatrician in charge of the Sudden Unexpected Death in Infants and Children (SUDIC).

Report sent to DI for factual accuracy: 10 February 2023

Report returned from DI: 24 February 2023

Final report issued: 17 April 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: 13 October 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.