Inspection report on compliance with HTA licensing standards
Inspection date: **21 & 26 September 2022**

Royal Blackburn Hospital
HTA licensing number 12309
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 **Royal Blackburn Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	-
Maternity	-	-	-
A&E	-	-	-

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 Royal Blackburn Hospital ('the establishment') had met the majority of the HTA's standards, thirteen major and six minor shortfalls were found against standards for Consent, Governance and quality systems, Traceability and Premises, facilities and equipment. These related to consent policy, Standard operating procedures, traceability and dignity. Some of those shortfalls, detail provided below, relate to findings from the last inspection. The HTA is concerned that adequate steps were not taken to address these findings in the intervening period and to embed suitable practices at the establishment.

Concerns were discussed with the establishment as part of this inspection, the current DI has provided assurance that key personnel have been appointed to manage the activities under the licence and that the establishment is committed to meeting the regulatory requirements. Based on this assurance, 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. The HTA will consider the need for regulatory action if appropriate action is not taken to meet the regulatory requirements in accordance with agreed timescales.

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 do not undertake consented post mortem examination. They do however, retain tissue following coronial post mortem examination. There is no policy in place relating to this retention which reflects the requirements of the HT Act and the HTA's Codes of Practice.	**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.	The standard operating procedure (SOP) for viewing of the deceased does not contain sufficient detail of the identification procedure undertaken to ensure the correct body is prepared for a viewing. Furthermore, it does not adequately detail how three identifiers of the deceased are obtained from visitors at the time of viewing which can be crosschecked against the body to ensure the correct visitors have arrived to view the correct body. The HTA is concerned to note that a minor shortfall was previously implemented in respect of this standard following the HTA inspection in 2018. That shortfall included reference to the SOP for viewing bodies not describing what information is required from families for use by staff to perform identification checks when locating the deceased.	**Major**
b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed	Evisceration sometimes takes place prior to the pathologist's external examination of the body. Whilst staff are trained to complete external examination prior to non-invasive CT scans, this does not apply to invasive procedures where this standard requires an external examination prior to evisceration.	**Major**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	During the body traceability audit, the inspection team identified two bodies in an advanced state of decomposition as a result of not being moved into frozen storage after 30 days. This has subsequently been reported as a HTARI. Two further bodies were found to be in soiled sheets. Items of personal property were seen to be stored in body bags and on trays with the bodies. One bag had mould on it and another had absorbed fluid from the tray.	**Major**

GQ2 There is a documented system of audit		
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	There are no documented audits of tissue in storage.	**Major**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
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	Bodies are also currently stored in an additional unit which is situated outside a service bay area. This means that bodies have to be transferred by covered, wheeled stretcher in view of the public and staff. This transfer process also risks accidental damage as trolleys are wheeled across a parking area before reaching the hospital building. These risks have not been assessed. Low staffing levels indicate a risk to provision of service in the event of sickness or staff absence. There is no evidence that this has been risk assessed or that any contingency is in place.	**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	Risk to delivery of service due to low staffing levels is not incorporated into the trusts organisational risk register.	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		

a) Bodies are tagged/labelled upon arrival at the mortuary	During the traceability audit, the inspection team identified one body to have no identification label attached to the body. A second body was noted to have the identification label in the body bag but not attached to body. This poses a significant risk of misidentification of bodies in storage.	**Major**
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	Viewings are currently conducted using name only. This increases the risk of viewing of the wrong body. The inspection team observed a body release to funeral directors that did not follow the SOP. Staff were about to release a body without confirming three unique identifiers. This was completed correctly after it was pointed out by the inspection team. Failure to follow the SOP increases the risk of releasing the wrong body. The tissue transfer form in use does not include three unique identifiers, this increases the risk of incorrect identification of tissue. The HTA is concerned to note that a minor shortfall was previously implemented in respect of this standard following the HTA inspection in 2018. The risk of misidentification of the deceased was raised at that time.	**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 DI could not provide assurance that retained tissue is being disposed of as soon as reasonably possible. Some records, for retained tissue, do not have supporting documentation relating to families wishes.	**Major**

c) Disposal is in line with the wishes of the deceased's family	As T2 a) above, the DI could not provide assurance that tissue is currently being disposed of in line with the wishes of the deceased family.	**Major**
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 premises is secure with swipe card access and CCTV. However a number of doors have key code locks which have not been regularly changed. Contracted funeral directors have been given swipe cards to access the mortuary out of hours. The DI does not have full oversight on how many cards are in use and there is currently no audit of use or comparison with CCTV footage. There is no visitors log in use.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The inspection team noted two bodies in storage for over 30 days, requiring long term storage, had not been placed into the freezer. Both showed signs of decomposition.	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use	Some SOPs are authored and authorised by the same person. This includes but is not restricted to 'Tissue sampling for HM Coroner' and 'Viewing and identification of deceased'	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.	There are no minuted meetings to discuss HTA licensed activities.	**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	Staff are trained. There is competency assessment, however this was not robust. There was no evidence of how staff are assessed or whether they are assessed against SOPs	**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 know how to escalate general incidents. However, there is no documented training or SOP relating to the reporting of HTA reportable incidents (HTARIs).	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
g) Bodies are shrouded or in body bags whilst in storage	The inspection team noted that some bodies were not fully shrouded.	**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 exposed electrical plug sockers on all PM tables as the covers designed to prevent fluid penetration are not fitted. Towels are used on the sink area for instrument storage. These are porous and stained and a risk to cross contamination.	**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.	GQ2(a)	The DI is advised to add length of stay and condition checks to the body audit.
2.	GQ3(a)	The DI is advised to expand porter/patient service assistant training to include HTA reportable incidents.
3.	T1(d)	There is a system to identify same similar names. The DI is advised to review the printing format for telepath to ensure all bodies are included in the daily printout. This will strengthen the same similar name process.

Royal Blackburn Hospital has been licensed by the HTA since 26 June 2008. This was the fourth inspection of the establishment; the most recent previous inspection took place in December 2017.

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

62 HTA licensing standards were covered during the inspection (standards published 3 April 2017). Standards C1(b),(c),(d),(e), (f),(g) and C2 (a),(b),(c) and d) were not assessed as consent for post mortem examination is not sought. Consented post mortems do not take place at the establishment. Only post mortem examinations authorised by the coroner take place.

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 for the mortuary were reviewed. Evidence of staff training, and competency assessment were reviewed as well as the qualification certificates of mortuary staff. Traceability audits, risk assessments, meeting minutes, incidents, consent procedures relating to retained tissue were also reviewed.

Visual inspection
The inspection team undertook a visual inspection of the premises which included the mortuary body storage areas and the storage arrangements for relevant material held within the mortuary.

Audit of records
The inspection team undertook audits of traceability for five bodies in storage. Traceability details were crosschecked between the identification band on the body, information in the mortuary register and associated patient tracking files. One body was found to have no identity tag and a second body had an identity tag in the storage bag but not attached to the body.

Audits were conducted of tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, family wishes forms, and tissue blocks and slides being stored. One case was identified as having no supporting consent form and a second case had an unsigned consent form. There was also a discrepancy in the record of material stored in this second case when checked against that in storage.

Meetings with establishment staff
The inspection team met with staff carrying out processes under the licence, including mortuary staff, portering staff, and the DI.

Report sent to DI for factual accuracy: 21 October 2022

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI.

Final report issued: 29 November 2022

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: 9 May 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.