Site visit inspection report on compliance with HTA licensing standards
Inspection date: **26 September 2019**

Rotherham General Hospital

HTA licensing number 12288

Licensed under the Human Tissue Act 2004

Licensed activities

The table below denotes whether the site is licensed to carry out an activity and whether or not the activity is currently carried out in that area.

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
Rotherham General Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology laboratory	-	-	*Carried out*
Maternity department	-	*Carried out*	-
Accident and Emergency (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 Rotherham General Hospital (the establishment) had met the majority of the HTA's standards, five major and nine 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		
b) There is a documented standard operating procedure (SOP) detailing the consent process	The SOP for seeking consent for PM examination does not include details of: • Who can give consent, including determining whether if, prior to their death, the deceased person had indicated their consent (or refusal) to PM examination or had appointed a nominated representative; • The requirement that the individual seeking consent must be trained in seeking consent and if untrained staff are involved in seeking consent, they should be accompanied by a trained individual; and • The timeframe in which consent can be withdrawn.	**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.	Standard operating procedures (SOPs) describing procedures for identification of bodies do not include sufficient details of procedures. The SOPs for viewings, release of bodies from the mortuary and post-mortem (PM) examination do not include sufficient details of the minimum number of identifiers of the deceased that should be used and how identification checks should be performed.	**Major**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	The inspection team's audit identified one body in freezer storage that had not been reconstructed appropriately following PM examination. This poses a risk to the dignity of the deceased. The establishment had not documented a reason for this deviation from the expected standard of practice.	**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	Procedures for identification of bodies do not always use a minimum of three identifiers of the deceased. • The establishment's identification procedures consider the deceased's name (forename and surname) to be two separate identifiers instead of one. The inspection team's traceability audit identified that one patient was labelled with only two identifiers (full name and date of birth). • Identification of bodies for release from the mortuary to funeral directors may be performed using only one or two identifiers provided by the funeral directors. • Identification of bodies for viewings may be based on only one identifier of the deceased (full name) provided by the family at the time of arranging a viewing and upon arrival at the mortuary.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	At times of peak storage activity, bodies may be stored directly on the base of the refrigeration units and not on trays. The mortuary trolley cannot be used to transfer bodies in these circumstances and the procedure for manual transfer of bodies presents health and safety risks to staff and a risk of accidental damage to bodies. This practice does not ensure the dignity of the deceased. These procedures have not been documented or risk assessed.	**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	The policy for seeking consent for PM examination does not include details of: • Who can give consent, including determining whether if, prior to their death, the deceased person had indicated their consent (or refusal) to PM examination or had appointed a nominated representative; and; • The timeframe in which consent can be withdrawn.	**Minor**
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 training materials for seeking consent do not contain sufficient details of: • An explanation of PM examination, including information on types of material that may be removed at PM examination and how this may be stored; • Options available for continued storage or disposal of material removed during PM examination; and • Alternatives to full PM examination.	**Minor**

b) Records demonstrate up-to-date staff training	The establishment does not have a process to identify which staff have received consent training and when refresher training is due.	**Minor**
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual	The establishment's procedures do not make it clear that if untrained staff are involved in seeking consent for PM examination, they should be accompanied by a trained individual.	**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	Not all staff have been competency assessed for the activities they perform. Competency assessments of some staff have not been reviewed regularly to ensure that competency has been maintained. This includes competency assessments of Anatomical Pathology Technologists, portering staff and site manager staff covering out-of-hours release of bodies from the mortuary and viewing of bodies.	**Minor**
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 assessment of HTA reportable incidents (HTARI) does not cover all HTARI categories and risks of incidents occurring.	**Minor**
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	Risk assessments do not contain sufficient detail of the risks related to licensed activities and mitigating actions.	**Minor**

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's body traceability audit identified a discrepancy in the storage location of a body recorded in the mortuary register.	**Minor**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The inspection team's tissue traceability audit identified discrepancies in the number and types of tissue samples recorded on the mortuary paperwork, laboratory database and the paperwork completed at the time of the PM examination, for two cases.	**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.	GQ5(a)	The DI is advised to review the HTARI summary document (L1-MORT-023) displayed in the mortuary to ensure it includes sufficient detail of the reporting procedure outlined in the HTARI SOP.
2.	T1(a)	The DI is advised to consider adding the unique mortuary identification number allocated upon receipt of bodies to the mortuary to the identification bands attached to the deceased. This may help to further strengthen the procedures for traceability of bodies.
3.	T2(c)	The DI is advised to ensure that clear viscera bags are used for the return of organs and tissue to the body following PM examination.

4.	T1(g)	The DI is advised to review the processes to link the information received from the Coroner's office about the consent wishes from the family for the fate of tissues taken at PM examination. The current process uses two identifiers of the deceased (name and date of death) to link this information to the laboratory records.
5.	PFE1(d)	The DI is advised to ensure the audio-visual entry system for entry to the mortuary for hospital staff is repaired. This will help to ensure that the security procedures for the mortuary are robust.

Background

Rotherham General Hospital has been licensed by the HTA since June 2007. This was the third site visit inspection of the establishment; the most recent previous inspection took place in June 2015.

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 assessed during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection team undertook a review of policies and procedural documents relating to licensed activities, cleaning records for the mortuary and PM room, records of servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, incident reports, staff training records and consent training information.

Visual inspection

The inspection team carried out visual inspection of the body storage area, PM room, viewing room, the laboratory tissue storage area, and the maternity department.

Audit of records

The inspection team undertook audits of traceability for four bodies in storage, including one body in long-term storage. Traceability details were crosschecked between the identification band on the body, information on the door of the storage unit, mortuary register and paperwork. For one body, there was a discrepancy in the storage location recorded in the mortuary register.

Audits were conducted of tissue taken at PM examination for four cases. Information was crosschecked between the mortuary documentation, Coroner's paperwork, family wishes forms, laboratory database, and tissue blocks being stored. One of these cases reviewed disposal of tissue had been completed in line with the wishes of the family. Full traceability of tissues was demonstrated for all four cases; however, minor discrepancies were found between the mortuary records and the laboratory database for two cases.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including mortuary staff, portering staff, laboratory staff, individuals involved in the consent seeking process, and staff involved in the Sudden Unexpected Death in Infancy and Childhood protocol.

Report sent to DI for factual accuracy: 24 October 2019

Report returned from DI: 04 November 2019

Final report issued: 12 November 2019

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 the 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.