Site visit inspection report on compliance with HTA minimum standards

Sheffield Children's Hospital

HTA licensing number 12001

Licensed under the Human Tissue Act 2004 for the

- **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; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

07 October 2016

Summary of inspection findings

The HTA found the Designated Individual (DI), the Licence Holder, and the premises to be suitable in accordance with the requirements of the legislation.

One minor shortfall was found in relation to governance and quality systems. Before this report was issued, the DI took appropriate steps to address the shortfall.

Particular examples of good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the DI, Licence Holder, premises and practices are suitable.

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.

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. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

This report refers to the activities carried out at Sheffield Children's Hospital (the establishment). This was the third routine site visit inspection of the establishment (the previous inspections having taken place in 2009 and 2013). The inspection included a visual inspection of the body store, post mortem (PM) suite, viewing area, and histology department. The Intensive Care Unit (ICU) and Accident and Emergency (A&E) departments, where removal of tissue may take place in cases of Sudden Unexpected Death in Infancy (SUDI), were also visited. Interviews with members of staff and a review of governance and quality documentation were also undertaken.

The mortuary is staffed by a Mortuary Manager and two Anatomical Pathology Technologists (APTs). There are three Paediatric/Perinatal Consultant Pathologists employed by the hospital, who conduct PM examinations; one of these is the DI for the purposes of HTA licensing. The Corporate Licence Holder (CLH) is Sheffield Children's NHS Foundation Trust.

Approximately 450 paediatric/perinatal PM examinations are conducted each year, the majority of which are from referring hospitals under a formal agreement. The cases range from fetuses of 12 weeks gestation up to children aged 16 years. The number includes coroners' cases from a number of coronial districts, forensic cases and a small number of defence cases. High risk cases are sent to other licensed establishments.

The hospital rarely conducts PM examinations on infants or children who have died within the hospital. Therefore, they rarely need to seek consent. However, when the need arises, consent is sought by trained staff who may also support clinicians in seeking consent.

Mortuary staff from the establishment regularly deliver consent training sessions for staff from referring hospitals. Referring staff are trained to use standardised consent forms, which they are required to use when seeking consent.

The body store has 12 purpose-built refrigerated spaces for paediatric bodies. There is a separate fridge for products of conception (POCs) and fetal tissue. Fridges are temperature monitored and there is an alarm that is linked to the switchboard during the day if

temperatures go out of range. Out of hours, the system is linked to a mobile phone which on call staff keep in case of emergency. This system can also be accessed remotely to check the temperatures of the fridges. In the event that the mortuary reaches body storage capacity, the establishment has agreements with other hospitals for contingency storage.

Only a small number of staff have access to the mortuary, which is via secure swipe card. There is CCTV monitoring outside the building covering the area where bodies are brought into the mortuary.

During working hours, an APT admits bodies, writing the identification details in the mortuary register. They then complete a card recording the name, date of birth, hospital number and NHS number of the deceased, as well as the mother's details, which are usually known. The card is then placed on the corresponding fridge door and the deceased's name is written on the mortuary whiteboard, indicating the space in which the body has been placed. The ID details are also entered into the mortuary computer system.

Out of hours, porters and nursing staff, who are trained by mortuary staff, admit bodies to the mortuary. They record the date, ward, name of the child, their age, time of death and date of death in the mortuary register and the body is placed in the fridge. Both the porter and the nurse must sign the mortuary register after entering the ID details. A fridge door label with the ID details is then completed and placed on the relevant fridge. When the APT is next on duty, they perform dignity and identification checks on the body and paperwork. If there are any discrepancies, the APT contacts the ward to resolve the matter.

Before a body is released, mortuary staff must confirm the identity of the deceased with the funeral director, by checking at least three identifiers against release paperwork. If there are any discrepancies, mortuary staff will not release the body until the correct identification details are confirmed.

Viewings are arranged directly with the mortuary and there are panic alarms for staff who conduct out-of-hours viewings, that ring to security.

The PM suite has two down-draft tables for PM examinations to be carried out. Consent forms are always checked and signed off by the Pathologist and the APT before the PM examination can take place.

Tissue retained during the PM examination is cassetted in the mortuary and sent directly to histology for processing and analysis via a purpose-built service elevator. Tissue is then stored or disposed of according to the wishes of the family. A red identifier is placed on a body and on the outside of the fridge to identify cases where tissue is waiting to be returned to that body before release.

The HTA conducted audit trails on three bodies stored in the refrigerators. Body location and identification details on body tags were cross referenced against the information card on the fridge doors, whiteboard, paper records and the computer system. No discrepancies were found.

An audit trail was also conducted on two coronial cases where histology samples had been retained during the PM examination. Relevant paper records, computer records, consent forms and locations of samples in the Histology storage area were checked. No discrepancies were found.

Materials held for the police

Under s39 of the Human Tissue Act 2004, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored in the fridge were reviewed by the HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

One minor shortfall was found in relation to governance and quality systems.

Governance and Quality Systems

Standard	Inspection findings	Level of shortfall
GQ7 There are systems to ensure that all adverse events, reactions and /or incidents are investigated promptly	Although there is a procedure that staff follow to report incidents, there is no standard operating procedure (SOP) relating specifically to HTA reportable incidents (see advice item 2). *Satisfactory information has been received from the establishment and the HTA considers the shortfall to have been met.*	**Minor**

Advice

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

No	Standard	Advice
1.	GQ1	The process for reviewing risk assessments is unclear and many documents are overdue for review. The DI is advised to update and review risk assessments as soon as possible so that they remain current.
2.	GQ7	In relation to the minor shortfall identified, the DI is advised to include in the SOP: the categories of HTA reportable incidents; the individual(s) responsible for reporting incidents; and the requirement to report incidents to the HTA within five days of discovery. This will ensure that all staff are aware of the requirements for reporting HTA incidents and help mitigate the risk of failing to report an incident. *Satisfactory information has been received from the establishment and the HTA*

		considers the shortfall to have been met.
3.		The DI is advised to display staff contact details in the mortuary so porters know immediately whom to contact in case an incident occurs out of hours, and how to contact them, mitigating the risk of a delay in notifying mortuary staff. *Following the inspection, the establishment informed the HTA that a document identifying whom to contact in an emergency is on display in the mortuary.*

Concluding comments

Despite one minor shortfall, many areas of good practice were observed. These included:

- the DI and the Mortuary Manager run training sessions for other hospitals in seeking consent, to ensure they are aware of their responsibilities under the HT Act. The DI also extends this training to Police Liaison Officers;

- the use of red and green tags on the bodies, so staff immediately know if they can or cannot release a body; and

- the use of colour coded cards on fridge doors to highlight cases such as same/similar names, 'do not release' bodies and forensic cases, so that staff have a visual reminder.

Advice was given to the DI regarding governance and quality systems and premises, facilities and equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 27 October 2016

Report returned from DI: 07 November 2016

Final report issued: 10 November 2016

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

GQ4 There is a systematic and planned approach to the management of records

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- 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.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's

family.

- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

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 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 Human Tissue Act 2004 (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:

(1) A notice of proposal being issued to revoke the licence

(2) 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.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) 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 CoPs, 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 or 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. You 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 desk-based or site-visit inspection.

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