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**

26 November 2013

Summary of inspection findings

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

Sheffield Children's Hospital (the establishment) was found to have met all HTA standards.

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

The HTA's regulatory requirements

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

The statutory duties of the Designated Individual are set down in Paragraph 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

Sheffield Children's Hospital (the establishment) carries out a range of paediatric post mortem activities. It currently undertakes approximately 360 post mortem (PM) examinations each year, most of which are are consented hospital cases. The total includes around 50 coronial cases, of which approximately 20 are forensic cases. The majority of consented hospital post mortem examinations are referrals from other centres.

The main post mortem room has facilities for two PM examinations to be carried out simultaneously and forensic PM examinations may be carried out at the establishment.

Bodies are received into the establishment from referring hospitals, from the wards and, rarely, from the community. The receipt procedures differ slightly depending on whether receipt is during or out of office hours. Referred and community cases are received only during office hours and solely by mortuary staff, while porters deal with transfer of bodies from the wards into storage out of hours. In each case identity details are entered into the mortuary register and each case is subsequently logged onto the various electronic databases used by establishment staff.

The numbering system used within the establishment depends on whether a PM examination is to be carried out. If that is the case, a "P" number is allocated, which follows the body and any organs or tissue samples retained. This numbering system is also used where tissue samples are received into the establishment for specialist examination by one of the staff pathologists.

The body store has refrigerated space for storage of 12 bodies. There are separate storage facilities for products of conception and fetal tissues. The main body store and fetal storage

fridge temperatures are recorded daily by staff for trend analysis. The fridges themselves are alarmed locally and linked to the switchboard, and there is a defined call out procedure in the event of an alarm sounding.

The establishment undertakes PM examinations for 17 coroners, and authority is provided in the main by facsimile. Parental instructions relating to subsequent storage, use or disposal of tissues taken during post mortem examination are obtained either by coroners' officers or by establishment staff.

Referred hospital cases are accompanied by a signed consent form. The establishment provides the standard consent forms and also offers training to those individuals from other hospitals involved in the consent process.

Consent for hospital PM examination of children cared for at the establishment is carried out by clinical staff supported by a member of trained pathology department staff.

Tissue samples retained are either cassetted within the post mortem room (for neonatal cases) or subsequently in the laboratory. In both cases, tissue containers are accompanied by a document detailing which tissues have been removed.

After examination, blocks and slides are placed into store pending receipt of authority from the hospital bereavement office or the coroner for disposal in line with relatives' wishes.

Where any tissues or organs are sent outside the establishment for specialist examination, there are procedures, including the use of a faxback form, to trace delivery. A transport database is searched regularly to highlight cases where confirmation of receipt has not been received and appropriate follow up is carried out.

Electronic records, together with related documents, are updated to trace the passage of tissues through to storage, return or disposal.

Bodies within the store are tagged with a red tag to prevent release until all organs, and if required, tissue blocks and slides, are returned, whereupon a green tag is applied. Release procedures include review of paperwork to ensure that all tissues, where requested, have been repatriated prior to release.

The fetal storage fridge is used for temporary storage of fetuses for disposal by cremation, which takes place every eight weeks. The numbering system used for bodies is also applied to fetal material to maintain traceability.

The establishment has been inspected before, in December 2009, and this was a routine, scheduled, inspection.

The inspection comprised a visual inspection, review of a selection of governance documentation, both in hard copy and by accessing the electronic document management system, and interviews with key staff from the mortuary, bereavement service and laboratory.

An audit of traceability was carried out:

- Two bodies were located in the body store and the relevant mortuary register entries, paper documentation and records within the various databases reviewed for presence of consent or authorisations, records of tissue retained at post mortem examination

and consistent traceability.

- A reference number was selected from the electronic records and the corresponding paper documentation reviewed for the presence of consent or authorisations and tissue records. The corresponding blocks and slides were located in store.

- One frozen tissue sample, consisting of three vials, was located in the -80c freezer used for frozen tissue storage and the corresponding records traced.

- With the exception of one discrepancy in the number of blocks stored, corrected by the missing block being recovered, there were no other anomalies identified.

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

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C2	The DI is advised to review the information to parents on the retention of tissue samples following a coroners PM examination and the related consent form to ensure they are clear that retention may only take place with consent for use for scheduled purposes. The HTA notes that, read in context and supported by verbal information provided by staff, the current forms do provide for this but feels that, when read in isolation, the current wording may potentially lead to some confusion on the part of those consenting. The HTA notes that review of the forms is currently ongoing.
2.	C3, GQ3	The DI is advised to incorporate a review of the training package used in training referring centre staff into one of the bi-monthly staff HTA meetings and to record this as evidence of refreshing of consent training of establishment staff.
3.	GQ1	The DI is advised to consider making the receipt of bodies standard operating procedures (SOP) available within the mortuary for access by portering staff. While the HTA noted that portering staff undertake a recorded training programme, the availability of the relevant SOP will allow less experienced porters to access these as required and will support safe practice within the body store.
4.	GQ1, GQ7	The DI is advised to consider drafting and circulating a local procedure for the reporting of HTA reportable incidents (HTARI). The HTA noted that the current Trust incident reporting policy and procedure

		only references the HTA for the purpose of reporting serious adverse events and reactions in the patient treatment sector, but makes no reference to HTARIs. It also notes that a request has been made to amend the Trust document and that this involves a lengthy review process. However, having a local policy will enable the DI to be in control of this procedure and ensure ease of any future update.
5.	GQ8	The DI is advised to review the current suite of regulatory risk assessments to ensure they cover all categories of HTA reportable incidents. By doing so, the DI may be able to identify mitigating actions which may help to reduce the risk of an HTARI occurring.
6.	PFE3	The DI is advised to risk assess and review, as part of contingency arrangements, the practice whereby trays within the body store may be used to store more than one neonatal body simultaneously. The HTA notes that the establishment has limited storage space and that this practice occurs only rarely. However, use of shared storage space introduces an element of risk of confusion and by risk assessing this procedure, and considering it in the light of the overall contingency arrangements, the DI may be able to identify methods to minimise the need for this practice or to mitigate risks arising from it.

The HTA saw various examples of good practice during the inspection. Staff focus on the needs of individual families when dealing with consent rather than following rigid procedures. To that end, there is great flexibility in the consent process, allowing for families to have all the necessary time to consider information, ask questions and make a considered decision. As part of this process, staff members undertake home visits to discuss and complete consent documentation.

The establishment uses an electronic document management system to manage the review of policy and procedural documentation, schedule and record audits and risk assessments, record staff training and manage incident reporting. All staff have access, at various levels, to this system and, when reviewed documentation is issued, the system records staff acknowledgment.

Non conformities found as part of audits automatically trigger the creation of corrective and preventative actions. In addition, the establishment has reviewed the methods used to manage disposal of tissues retrieved during PM examination following an HTARI, resulting in a new database being created, with more robust recording and audit procedures built in. This is currently in the final stages of development testing.

The HTA has given advice to the Designated Individual with respect to the recording of consent training, some elements of documentation and contingency arrangements for storage.

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

Report sent to DI for factual accuracy: 17 December 2013

Report returned from DI: 19 December 2013

Final report issued: 6 January 2014

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 or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- 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.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

  (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

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.