Site visit inspection report on compliance with HTA minimum standards

Birmingham Children's Hospital

HTA licensing number 12132

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**

14 March 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.

Although the HTA found that Birmingham Children's Hospital (the establishment) had met the majority of the HTA standards, two minor shortfalls were found. In relation to the Governance and Quality Systems (GQS) standards, the shortfall relates to the lack of training for portering staff involved in mortuary duties; in relation to the Premises, Facilities and Equipment (PFE) standards, the shortfall relates to fridge temperature monitoring.

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, the Licence Holder, the premises and the practices are suitable.

The statutory duties of the Designated Individual 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 by the mortuary and other areas of Birmingham Children's Hospital (BCH; the establishment). This was the second site-visit inspection of the establishment since it was issued an HTA licence in 2007 (the first was in October 2009). It was a routine inspection to assess whether the establishment is continuing to meet the HTA's standards.

The mortuary consists of a body store and body handling area, post mortem (PM) room and observation gallery, clearly demarcated transition areas, a body viewing suite, changing rooms and an office. The fridge capacity is for ten bodies. There is no freezer storage. Cases requiring long term storage are transferred under coronial authority to other HTA-licensed premises.

The mortuary is currently staffed by two full-time pathologists and one locum. BCH also has one trainee anatomical pathology technologist (APT) who works part-time in the mortuary and part-time in the Histopathology Department. This person is supported by a senior APT from a neighbouring hospital, who has an honorary contract with BCH and who oversees the training of

this individual, and by a senior Biomedical Scientist at BCH who is experienced in mortuary procedures (*see Advice item 6*).

On average, around 25 routine paediatric PM examinations are undertaken in the mortuary each year. These are under the authority of HM Coroners (for the districts of Birmingham and Solihull, Black Country, Staffordshire South and Warwickshire). In addition, approximately five consented paediatric PM examinations are performed each year and one forensic paediatric PM examination. The establishment also has a collection of identifiable existing holdings.

Known high risk (hazard group 3 pathogen) PM examinations are performed.

The Emergency Medicine Department at BCH has procedures for dealing with cases of sudden unexpected deaths in infants (SUDI) under coronial authority. Samples for analysis, including skin biopsies, are removed in this Department. The skin biopsies are stored in a freezer in the Clinical Chemistry Department in case there is a need to culture fibroblasts to investigate an inherited metabolic disorder as a cause of death. Samples are disposed of on an annual cycle, in accordance with the establishment's procedures and in agreement with the coroners concerned (*see Advice item 2*). The Paediatric Intensive Care Unit (PICU) also deals occasionally with consented and coronial SUDI cases and tissue is removed in a similar fashion (*see Advice item 1*).

Tissue samples and whole organs are occasionally sent off-site for examination at other HTA-licensed premises. These include hearts and brains for specialist examination and toxicological samples. These arrangements, and those with the local Funeral Director, are all subject to formal agreements.

The establishment also stores tissue from the living retained for use for research under the licence. Most of this is under ethical approval. In the Histopathology Department, tissue samples are held in freezer storage pending transportation under a Material Transfer Agreement (MTA). This is part of the Children's Cancer and Leukaemia Group Biobanking Study. In the Clinical Chemistry Department, blood, urine and skin biopsies are held in freezer storage pending transportation under MTAs to other centres. These are under clinical trials ethical approval (about 100 studies). In a separate study, about 200 samples of liver tissue and matched blood are held in freezer storage pending transportation (under an MTA) to the Human Biomaterials Resource Centre at the University of Birmingham Research Tissue Bank. In addition, there are a small number of samples held under the licence which have been collected (since 2006) without consent pending anonymisation and use in a REC-approved study (*see Advice item 5*).

The site-visit inspection included a visual inspection of the premises. The mortuary and Histopathology Laboratory were inspected as well as the Emergency Medicine and Clinical Chemistry Departments. Interviews were conducted with: the DI; a Consultant Paediatric Histopathologist; the Paediatric Histopathology Section Head; a senior APT; the Pathology Manager; a Consultant Clinical Biochemist; the Lead Nurse for Participation, Patient Experience and Bereavement; the Laboratory Research and Development Co-ordinator; the Head of Research and Development; and two Coroners' Officers (from separate coroners' offices). A documentation review and audit trails were also carried out. Details of these are provided below.

As part of the site-visit inspection, two audit trails were carried out at the establishment. The first tested arrangements for labelling and storage of bodies in the mortuary fridges. One body was chosen and identification details on the body tag were checked against the mortuary register and on the mortuary fridge door; no anomalies were found. The second was a vertical audit of tissue removed at PM examination for histological analysis. Two coronial cases and one

consented case were selected at random. Details of the tissues retained were cross checked between the mortuary and histopathology records. No anomalies were found. The wishes of the relatives (for one set to be disposed of, one set retained for education/training and one set returned to the Funeral Director for cremation) had been followed.

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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	Porters, accompanied by a member of the nursing staff, transport bodies from wards to the mortuary during and out of working hours. New porters receive local induction training by senior porter colleagues, and records of such training are kept by the head porter. Mortuary staff are not involved in the development or delivery of this training and therefore the DI is not assured of porters' competency in performing mortuary activities.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	The temperatures of all the fridges and freezers in the establishment, including those in the body store, Histopathology and Clinical Chemistry Departments, are monitored externally on a 24 hour basis. However, the testing of the fridge and freezer alarm system is not routine practice at the establishment.	**Minor**

Advice

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

No.	Standard	Advice
1.	N/A	Licensable activities are undertaken in the PICU and Emergency Medicine Department at BCH. The DI is advised to appoint a Person Designated (PD) in each of these areas to oversee licensable activities, to facilitate communication about HTA relevant issues and to ensure the prompt reporting of HTA-reportable incidents (HTARIs).
2.	C1/D2	Communication with the coroners' officers is via the consultant histopathologist. However, in relation to SUDI cases, the flow of communication is less well established. To ensure a consistent approach, the DI is advised to appoint a nominated person to handle all communications between the coroners' officers and the Histopathology and Clinical Chemistry Departments and, where necessary, the family. This person should ensure that decisions are passed to and within these Departments, and that there is no uncertainty about tissue disposal or retention when the coroner's authority has expired. The DI is referred to the HTA communication flowchart for coroners' post-mortem (PM) examination: http://www.hta.gov.uk/_db/_documents/Model_communication_pathway_final.pdf
3.	C1	There are sound consent procedures supported by a training programme and detailed consent form. The DI is advised to create a documented SOP for the consent procedure to reflect the good consenting practices at the establishment.
4.	GQ1	Governance meetings are currently conducted on an informal basis. If these were on a formal footing, with discussions documented, there would be scope for PDs and other staff to discuss issues such as reportable incidents, changes to SOPs, audits, risk assessments, HTA training, communications with coroners and updates from the HTA (e.g. e-newsletter items), and to learn from these.
5.	GQ2	The establishment has a detailed audit schedule. The DI may wish to add to this schedule: horizontal audits to ensure that SOPs accurately reflect the practices being carried out; an audit of retained tissue and families' wishes; a vertical audit of all material held under storage for research (to include details of consent given, ethical approval obtained, expiry date of ethical approval). The results of all audit findings, and actions taken, should be formally recorded.
6.	GQ3	The DI is advised to risk assess the staffing levels within the mortuary to ensure that they are appropriate for the level of activity.

7.	PFE1, PFE2	The DI is advised to ensure that there are regular, recorded maintenance visits of the mortuary premises. These visits should ensure that the PM suite air ventilation meets the minimum requirement of ten air changes per hour and that formalin concentrations are maintained below 2 ppm (see link 1, below).
8.	PFE5	The DI is advised to ensure that there are regular, recorded maintenance checks of all items of critical equipment in the mortuary. This includes fridges, respirators for high risk PM examinations, cranial saws, PM tables and scales.
9.	D2	The method and reason for disposed tissue are the same for all cases. The DI is advised that these could be incorporated into the SOP on disposal of human tissue.

Link 1:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4119258

Concluding comments

During the inspection of Birmingham Children's Hospital, several areas of good practice were noted:

- The consent meeting for hospital consented PM examinations always involves the treating clinician, a bereavement officer and a pathologist. This helps to ensure that any questions that the family may have can be answered and that the person giving consent is fully informed.
- There is a detailed bereavement pack providing information about the family's options for retention or disposal of blocks and slides following the PM examination.
- There is good communication between the bereavement staff and the family, which continues for several weeks after the PM examination.
- There is a formal consent training programme provided by the bereavement staff and given to clinical (and coronial) staff every six months. Training is recorded and refresher training is provided on an annual basis.
- There is good communication between the coroners' officers, the pathologist and the mortuary which ensures that bodies of the deceased are able to be buried or cremated in a timely fashion following the PM examination.
- There is a comprehensive audit schedule and set of risk assessments, which include audits against HTA standards and risk assessments against the various categories of reportable incidents.

- There is a ‘mortuary and activity communications sheet’, which remains with the body and ensures that all activities associated with it are recorded in a sequential fashion.

- Staff demonstrate a very sensitive and sympathetic approach to families, which is reflected in the sensitive and tasteful decoration of the body viewing suite.

- The DI has risk assessed the PICU and Emergency Medicine Department to ensure that those premises are suitable for the removal of tissue from SUDI cases to take place.

There are two areas of practice which require improvement and these constitute minor shortfalls. The HTA has given advice to the Designated Individual in several areas, including consent, governance and quality systems, premises facilities and equipment and disposal, as well as licence management.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan 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.

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.

Report sent to DI for factual accuracy: 11 April 2013

Report returned from DI: 26 April 2013

Final report issued: 7 May 2013

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.

- **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:

  - 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

- **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.

- **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.