Site visit inspection report on compliance with HTA minimum standards

Birmingham Women's Hospital

HTA licensing number 12565

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**

7 May 2015

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 Women's Hospital had met the majority of the HTA standards, a minor shortfall was found against standard PFE3 in relation to the absence of an audible alarm connected to the maternity ward fridge where POCs, fetuses and placentas are stored, and the lack of documented fridge temperature monitoring of the maternity ward and delivery suite fridges.

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

The establishment was provided with advice and guidance about areas that could be improved further.

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 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 describes the second site visit inspection of Birmingham Women's Hospital (the establishment), which is licensed to carry out post mortem (PM) examinations and the removal and storage of PM tissue for use for scheduled purposes under the Human Tissue Act 2004. The establishment provides a regional peri-natal PM examination service to 15 other hospitals. There is no adult body store and no adult PM examinations are carried out at this site. If there is a ward death the deceased is referred to the Queen Elizabeth Hospital, Birmingham, which is nearby.

The establishment undertakes between 600-700 hospital PM examinations a year, including referrals from other hospitals. The bereavement team is involved in seeking informed consent from parents as well as providing them with guidance and support throughout the process, and the establishment has adopted the SANDs consent form and information sheet. There are approximately 100 PM examinations carried out under coronial authority in addition to the hospital cases. Category 4 and certain category 3 cases are transferred to another hospital. Appropriate personal and protective equipment is available for infectious cases.

The inspection included a visual inspection of the mortuary, post-mortem suite and delivery suite , each having dedicated private bereavement suites for use by patients suffering from pregnancy loss. The inspection also included interviews with a Bereavement and Spiritual Care Service Manager, Trainee APT, Quality Manager, Consultant Perinatal Pathologist,

Deputy Mortuary Manager and the DI. Key documents were reviewed and a traceability audit was undertaken to ensure that peri-natal cases (bodies) and tissue are in the correct location and appropriately labelled. The DI, the Pathology Services Manager, has oversight of licensable activities and there are persons designated (PDs) in specific areas. The Deputy Mortuary Manager has oversight of activities taking place in the mortuary and line management responsibility for the Anatomical Pathology Technologists (APTs).

Peri-natal cases are stored in a cold room which has a shelving system offering up to 100 spaces. This is located in the mortuary. The cold room has an audible alarm connected to switchboard to notify mortuary staff of temperature flucatuations during and out of hours.The alarm is tested on a weekly basis by the Trust's estates department.The temperature records are reviewed, on a monthly basis, by the Cellular Pathology Manager for trend analysis. At the time of the inspection, the establishment had recently procured a web-based fridge temperature monitoring system, with a view to using this to review fridge temperatures as opposed to using manual temperature monitoring.There are three contingency fridges located in a store room in the mortuary; however, these are not connected and ready for use (advice and guidance item, 3). The establishment has a service level agreement (SLA) in place with a local funeral director for contingency purposes.

Products of conception (POCs) and fetuses are stored in the gynaecology ward fridge, whilst placentas from live births and fetal deaths are stored in the delivery suite fridge. No POCs or fetuses are stored in the delivery suite fridge. Specimens are stored in either fridge for a few hours and are collected regulary throughout working hours by porters, six days a week. The estates department ensure that both fridges are serviced twice each year. Neither he gynaecology ward nor the delivery suite fridge isconnected to an audible alarm. Furthermore, there is no documented temperature monitoring of either fridge (minor shortfall against PFE3). The establishment was advised during the inspection to consider adding a person designated (PD) under the licence who can provide oversight for licensable activites in the gynaecology directorate (advice and guidance item, 4).

A traceability audit was carried out of three peri-natal cases; two of these cases were hospital consented PM examinations and one was under coronial authority. In two of the hospital cases, tissue had been removed during PM examination; in the first case, skin removed from the baby and placenta had been sent to the genetics department in the hospital for genetic screening. In the second case, tissue blocks and slides were stored for a scheduled purpose under the HT Act 2004. The consent forms, mortuary records and electronic database were reviewed for all three cases. No discrepancies were found.

Inspection findings

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

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3	Placentas from fetal deathsare stored in fridge in the delivery suite. POCs & foetuses are stored in the fridge within the gynaecology ward. Currently, neither fridge is subject to temperature monitoring; in addition, neither fridge is connected to an audible alarm. There is a risk that any fridge failures may go unnoticed and may impact on POCs and tissue being stored that may be subject to a PM examination. See advice and guidance item 3.	Minor

Advice

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

No.	Standard	Advice
1.	C1	The 'Coronial Consent Procedure' document states that any tissue retained is kept as part of the deceased's medical record. The DI is advised to amend the wording, so that it refers to tissue retention for a scheduled purpose under the HT Act 2004, for which consent is required. The form used to record the parent's wishes with regards to disposal of tissue meets the HTA requirements.
2.	GQ7	It was noted during the inspection that an incident had occurred involving major equipment failure, which had an impact on the mortuary cold store and should have been reported to the HTA. The establishment dealt with the incident appropriately and remedial actions were taken. The DI must ensure that all incidents are reported as HTARIs through the HTA web portal. In addition the DI is advised to review the HTARI SOP to ensure that it states the HTA reporting timeframe, which is five working days from the point of discovery.
3.	PFE3	In relation to standard PFE3, there are three areas of advice for the DI to consider: 1. The contingency fridges in the mortuary are not connected and ready for use in the event of equipment failure. The DI is advised to carry out a formal risk assessment of the current arrangement and consider how this may impact on the mortuary should an incident occur which means that the fridges are not able to be used. In particular, consideration should be given to how long it may take for the fridges to reach an appropriate temperature for the storage of peri-natal cases. 2. During the visual inspection, the mortuary cold storeupper limit

		temperature was unclear and the temperature figures provided by two members of staff were conflicting. The DI is advised to review the alarm set points of the fridges to ensure they are set correctly. The DI is also advised that this information is clearly documented in appropriate SOPs so that mortuary staff are aware of the upper and lower limits. 3. The DI may wish to consider extending the web based temperature monitoring system in place in the mortuary, to the gynaecology ward and delivery suite fridges to strengthen the governance in these areas.
4.	N/A	The DI is advised to formally add PDs in the delivery suite and gynaecology ward where products of conception, placentas, fetuses and still births may be stored for a short period of time before transfer to the mortuary. The HTA should be notified of this in writing.

Concluding comments

The establishment provides a high level of service to its own patients as well as to those of the hospitals in the region which refer cases to it. The mortuary and bereavement staff work cohesively together and have an excellent working relationship with bereavement staff.

A number of areas of good practice were observed during the inspection. For example, the establishment has developed a robust consent procedure, in which the bereavement midwives play a key role. They demonstrated an informed and conscientious approach to seeking consent for hospital cases and have been involved in providing consent training internally as well as more recently to bereavement staff located at other sites. The Peri-natal Pathologist(s) and Bereavement and Spiritual Care Service Manager provide training to junior doctors as well as new doctors as part of their medical training. Careful consideration has been given to patient information sheets, which are available in languages that suit the demographics of the region and, more recently, in braille.

The mortuary staff are involved in carrying out weekly vertical audits that focus on the location of each case; all cases are reviewed to ensure they are in the correct location and that full traceability is maintained in terms of records and physical location. The audit results are reviewed by the Cellular Pathology Manager to follow up any discrepancies.

The establishment has procured magnetic badges to be placed on the mortuary white board to flag particular cases: ‘same/similar name’, ‘danger of infection’, ‘do not release’ and ‘organs to be returned’. The perinatal database is used to capture all the information for each case dealt with by the mortuary. The records are an electronic version of the paper records that are completed for each case. The database is able to demonstrate full traceability of each case from the time it is received into the mortuary to the time it is released. It was noted during the inspection, that the establishment plans to upgrade to another database in future which will improve systems.

There are some areas of practice that require improvement, including one minor shortfall in relation to PFE3. The HTA has been given advice to DI on a range of issues to strengthen practice further.

Report sent to DI for factual accuracy: 1 June 2015

Report returned from DI: 8 June 2015

Final report issued: 11 June 2015

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 9 November 2015

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.