Site visit inspection report on compliance with HTA minimum standards

Belfast Health and Social Care Trust

HTA licensing number 12229

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**

15 – 17 January 2014

Summary of inspection findings

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

Belfast Health and Social Care Trust (the establishment) was found to have met all HTA standards.

The establishment's last inspection was in 2009 and there was evidence of improvement in standards since then. The Designated Individual is newly in post and demonstrated a commitment to further improving systems.

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 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

For the purposes of HTA licensing, the establishment operates under a hub and satellite arrangement. Licensed premises on the hub site encompass a mortuary and laboratory in the pathology department and a neuropathology archive. The establishment has two satellites. One, Belfast City Hospital, where storage of relevant material took place, is now inactive and shortly to close; all material has been moved to the second satellite. The second satellite is a storage warehouse owned by the Oasis Group, a private company, where post-mortem (PM) blocks and slides are stored under secure, controlled conditions. The hub has an agreement in place with the satellite to ensure that material is transferred and stored in line with HTA standards.

The establishment undertakes approximately 105 adult PM examinations a year, the majority of which are for HM Coroner for Northern Ireland. About 25 a year are hospital consented. One or two PM examinations a year are high-risk cases. The establishment undertakes approximately 270 paediatric PM examinations a year. Of these around 30 to 50 are cases of sudden unexpected death in infancy investigated by the Coroner. The majority are with the consent of the parents and are as a result of obstetric-related deaths.

In Northern Ireland all post mortem processes are structured to ensure that burial or cremation of the deceased takes place within 48 hours if possible and no longer than 72 hours. When a body arrives in the mortuary, the deceased is assigned a mortuary number. If a PM examination is required, this same number is used for PM examination and retained tissue. The pathologist undertakes the identification checks immediately before the PM examination. Details are recorded using a Body Transfer Form. In the case of community deaths, this is confirmed directly with the police officer and in the case of hospital consented PM examinations, with the consultant from the referring unit. After identification, the body is moved into the PM suite and the PM examination is completed. The body is generally taken by funeral directors immediately after PM examination. Tissue samples are taken at every PM examination. Blocks and specimen pots are prepared with the assigned PM numbers and counted by the pathologist and assisting anatomical pathology technologist (APT) or mortuary assistant, before sending material to the pathology laboratory for analysis. Everything is recorded on the PM Specimen Tracking Form. Specimen pots are labelled with stickers and signed by the pathologist and APT or mortuary assistant. At the laboratory, specimens are recounted and the counts are recorded on the PM Specimen Tracking Form.

The establishment employs a full-time archivist to manage samples, including managing collections held at the satellite. Material is stored and disposed of in line with guidance from the Royal College of Pathologists; and in line with the wishes of the next of kin.

The establishment has taken action in response to shortfalls found on the last inspection, including shortfalls and advice around premises, facilities and equipment. In particular, the establishment has recently upgraded its premises to install bariatric fridges and a new high-risk PM examination suite. This has not yet been used due to some problems with the current layout, although these should be resolved shortly. The establishment is planning a final instalment of works to adjust the layout of the mortuary, to further improve the quality of its facilities.

This was the establishment's second, routine inspection. The inspection encompassed a visual inspection of the premises, interviews with staff and document review. The visual inspection included an observation of the confirmation of identification that takes place between the designated individual and the police officer before each coronial PM examination.

There were very few deceased stored in the body storage area at the time of the inspection, due to the high turnaround times at the establishment. The following traceability audits were completed:

- one body was traced from the details on the Body Transfer Form sheet to details on the fridge and on the body tags;
- two whole organs in specimen pots were traced to the consent forms;
- three boxes sent to the satellite site were traced from the database to the location on the shelf; and
- one box sent to the satellite was traced from its position on the shelf to the database.

No anomalies 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.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

The HTA advises the Designated Individual (DI) to consider the following to further improve practices:

No.	Standard	Advice
1.	GQ1	There is a high turnaround of bodies through the mortuary and PM examinations must be completed quickly in order to ensure bodies can be buried or cremated within 48 hours. The advantages of this system include better traceability of bodies and tissue through careful identification checks and limited body storage times. This accelerated process may, however, introduce a greater risk that the subject of a PM examination may be an unexpected high-risk case. The establishment manages this risk in a number of ways, including treating all cases as high-risk, but the DI is advised to update the high-risk standard operating procedure (SOP) to document the steps that would be taken in the event of discovering an unexpected high-risk case.
2.	GQ7	The establishment has a good system currently in place for reporting and managing events. A review of previous incidents, showed one incident which the establishment considered reporting. There was evidence of some internal follow-up, but no evidence to show actions were completed. While the HTA does not think the incident is reportable, the DI is advised to consider reviewing past incidents to ensure all actions are closed and there are no incidents that should be reported to the HTA.
3.	PFE1	The premises have been recently refurbished, however there have been some problems identified with the layout. As a result, the high-risk PM suite cannot be used until these are rectified. To prevent such issues reoccurring in the future, the DI is advised to ensure that all staff involved in working in the mortuary are consulted on the next stage of works. This will assist in ensuring that the mortuary is designed to take into account staff's working practices.
4.	PFE1	There is double-ended access to the paediatric PM examination area. The set-up means that it can be easily used as a thoroughfare. Precautions should be taken when paediatric PM examinations take place, for example, locking the outer door and / or placing additional signage on the doors. Porters may on occasion collect or deliver material from this area, so the DI is also advised to train portering staff on any new procedures.
5.	PFE3	The satellite site maintains a secure, controlled storage area. Boxes containing PM blocks are kept in a separate area, but boxes are spread amongst other collections, which include paperwork. Spreading boxes out, rather than keeping them in only one place, may reduce the risk of damage to the whole collection. However, the DI is advised to improve demarcation of human material, through clearer indications of the boxes' contents. This information should be shared with staff working at the satellite, to ensure they are aware of what they are handling and to contribute to raising awareness of maintaining the dignity of the deceased.

Concluding comments

There were a number of strengths and areas of good practice observed during the inspection. There is a hard-working team in place and there was evidence that all staff work together efficiently. The high turnaround system maintained by the mortuary is also supported well by coroners, police, general practitioners and other medical staff. There is good communication in place between the satellite and the hub.

The Bereavement Service has developed a good range of regional resources and provides training on consent for PM examination. Staff from the mortuary and other areas in the hospital confirmed they knew where these resources were, they were easy to access and they felt well-supported in seeking consent for hospital PM examinations. The paediatric pathology consultants visit other trusts to teach staff at referring sites about the PM examination process. As a result, consent forms received are completed properly, and these are audited.

There is a good governance structure in place to support discussion of issues such as the Local Control Group meetings and the Trust Licensing Meetings. The inspection team spoke with Consultants working outside the mortuary, in other specialties such as emergency medicine and intensive care. The Designated Individual regularly attends case review meetings outside the mortuary, so that staff working in other areas can receive feedback at about pathology reports. This is appreciated by staff in other departments, and generally improves communication and collaboration across all areas.

The HTA has given advice to the Designated Individual with respect to documenting the process for managing unexpected high-risk cases, reviewing previous incidents, management of any further upgrade or changes to the premises and clearer marking of human material held at the satellite.

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

Report sent to DI for factual accuracy: 7 February 2014

Report returned from DI: 28 February 2014

Final report issued: 3 March 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 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 preventive 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 preventive 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 preventive actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventive 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 preventive 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.