Site visit inspection report on compliance with HTA minimum standards

Central Manchester University Hospitals NHS Foundation Trust

HTA licensing number 12554

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**

13 – 14 November 2012

Summary of inspection findings

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

Central Manchester University Hospitals NHS Foundation Trust (the establishment) was found to have met all HTA standards.

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

The HTA's regulatory requirements

The HTA must assure itself that the 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

The establishment consists of premises at the Central Manchester University Hospitals NHS Foundation Trust, Oxford Road site. Under the licence there are two distinct mortuary services, an adult service located in the Manchester Royal Infirmary building and a paediatric service located in the St Mary's Hospital building. Both of these buildings are located in the Central Manchester University Hospitals NHS Foundation Trust campus. The establishment undertakes adult and paediatric post-mortem (PM) examinations on behalf of multiple Coroners, in addition to consented, hospital PM examinations. Additionally, the paediatric service undertakes forensic PM examinations.

The adult service performs around 1,000 PM examinations per year, including few (around one) consented, hospital PM examinations. The paediatric service performs around 400 PM examinations: 115 coronial (including around 15 forensic cases), the remainder being consented, hospital PM examinations. The establishment is a referral centre for paediatric PM examinations which also receives bodies from other hospitals; these are consented for locally by the referring establishment. Known high risk cases are undertaken at both mortuaries.

Currently, products of conception (POC) of less than 14 weeks are sent to the adult mortuary with older POCs being sent to the paediatric mortuary. The DI explained plans for all POCs to be sent and managed by the paediatric service in the near future.

As both services operate from separate buildings, each has its own dedicated body storage facility, PM suite and histopathology laboratory. Where possible some procedures have been harmonised between the two services. However, due to the different nature of the services, some procedures and practices remain distinct between the two.

This was the second site-visit inspection of the establishment and was a routine inspection to assess whether it is continuing to meet the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's last self assessed compliance information and audit of stored material, as well as pre-inspection discussions with the DI and review of the previous inspection findings. During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment staff and a Coroner's Officer were undertaken.

Prior to the inspection, the DI identified areas outside the mortuary where the licensable activity of removing tissue from the body of the deceased takes place. These areas include the paediatric intensive care unit (PICU) and the neonatal intensive care unit (NICU). As part of the inspection of the paediatric PM service, both the PICU and NICU departments were visited and brief discussions held with the persons designated (PD) in those areas. The PDs demonstrated an understanding of the requirements of the Human Tissue Act 2004 and the establishment's governance systems during the visit. Both departments hold copies of standard operating procedures, family information leaflets and consent forms. These are used by the clinical staff, should tissue need to be taken from the deceased, in order to inform the families about the process and record consent. Both PDs attend meetings held by the DI as part of the establishment's governance systems.

An audit of bodies stored in the establishment's fridges was undertaken at both the adult and paediatric services. At both services three bodies were chosen at random and identification details recorded on body tags were checked against details in the mortuary registers, on the mortuary fridge doors and location white boards. No anomalies were found during this audit.

Tissue traceability audits were also undertaken at both the adult and paediatric mortuaries. At the adult mortuary, details were taken of three coronial PM cases where tissue was taken during the examination. Details of the tissues retained at PM examination were cross checked between the mortuary records and the histopathology electronic records. Additionally, the physical blocks and slides were located and again the numbers checked against the establishment's electronic records. In one case a minor discrepancy was found where an extra slide had been cut but not recorded in the electronic system. This slide was from a frozen section which the establishment explained would have been for rapid analysis and might explain why the normal procedure of logging the slide was not followed. In another case, 16 slides were located. However the records indicated that 17 had been cut. The establishment indicated that this slide was still with the pathologist for review. In all three cases, all blocks were found and the numbers correlated with the laboratory's records. Additionally, signed coronial family wishes forms were found for each case indicating that the families of the bereaved had consented to retention of tissue for use for scheduled purposes.

A similar traceability exercise was undertaken in the paediatric mortuary. Four cases were chosen for the audit, one of which was a hospital, consented PM examination. Again, blocks and slides were sought, the relevant consent or family's wishes forms reviewed and the laboratory's electronic database checked. No anomalies were found other than on the hospital consent form, where the family had ticked an extra box, meaning that their intention with regards to the fate of tissue was ambiguous. The DI has already started to implement a new system where the pathologist will take responsibility for checking that the consent forms are completed properly and clearly, before starting the PM examination. Further advice on this has been given below. Apart from this, no other anomalies were found during the audit.

Despite finding minor discrepancies in the numbers of slides when undertaking the adult traceability audit, the HTA was satisfied that the establishment has suitable audit procedures in relation to the tissue archive. These procedures should detect discrepancies and help the DI to determine if errors are one-off events or systematic procedural failings. During the audit it was felt that, based on information provided by the establishment, the discrepancies were sporadic rather than systemic.

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.	C1, GQ1	During the traceability audit of the paediatric mortuary, a consent form was found which had been ambiguously completed by the family of the bereaved. Although staff had ascertained the appropriate intention of the family, a system of checking consent forms, especially forms completed by other establishments, should be implemented. The DI has already identified this need and has started to implement a new system where the pathologist takes responsibility for checking that the consent forms are completed properly and clearly before commencing the PM examination. The DI also indicated that she will be starting further training of establishment staff who refer paediatric cases to the establishment for PM examination. The DI is advised to continue with both of these ventures to help assure herself that consent forms are completed appropriately.
2.	GQ1	During the document review in the paediatric mortuary, the HTA noted that some SOPs cross reference each other. However, the establishment had recently (within the previous four weeks) migrated its documentation to Q-pulse. In doing so SOPs have been renamed, and the cross referencing is now out of date. Additionally, some old SOPs that are no longer in use have been migrated to Q-pulse but have not been archived. The DI is advised to review the SOPs to ensure that they correctly cross reference each other and that out of date SOPs are archived. In addition, in some cases there are several SOPs that cover the same mortuary practice. Although the process is correctly represented, it is not always clear which SOP to go to in order to find specific information. The DI may wish to review the SOPs in place to determine if they could be rationalised in order to make it clearer which SOPs are needed for certain procedures.
3.	GQ4	During the visual inspection of the adult mortuary, the use of correction fluid to amend some records was seen. The DI is advised to ensure staff no longer use correction fluid and correct errors with a single strike through so that the original information can be read in case it is needed in the future for audit purposes.

4.	GQ8	The establishment has recently developed its risk assessments to improve their utility. Risk assessments now reference the HTA SUI categories, make an assessment of the establishment's risk of each of these occurring, and state what measures the establishment has to mitigate any of these events occurring, also referencing which SOPs help to mitigate the risk. Although these risk assessments are satisfactory, the establishment indicated that they have plans to migrate the paper assessments into Q-pulse allowing them to be linked to different procedures so that staff have easier access. The DI is advised to continue with these plans.
5.	PFE1	During the visual inspection of the adult PM suite, some minor deterioration of the floor was observed. The DI indicated that the mortuary was scheduled to have some life cycle improvements made to the fabric of the premises which would include the floor. These improvements are scheduled to begin in early 2013. The DI is advised to monitor the condition of the PM suite floor so that any further deterioration may be detected and remedied as appropriate. This will help to assure that the PM suite remains serviceable until the life cycle refurbishment.
6.	PFE3	The DI is advised to review the maximum and minimum temperature settings on the paediatric fridge alarm to assure herself that the alarm will sound at an appropriate temperature should the fridge cooling units fail.

Concluding comments

Areas of good practice were observed throughout the inspection, some of which are included below.

The establishment described good procedures around consented PM examinations. These include a final telephone call to the family of the bereaved to confirm consent prior to the examination commencing. This phone call occurs as the 'cooling off' period expires and acts as a final safeguard for the establishment as they can assure themselves that the families still wish to go ahead with the PM examination.

The establishment's audit programme includes the work being undertaken in the mortuary. However, it recognises the benefits of undertaking more audits and has trained some staff specifically in audit processes to assist. This will both increase the frequency and range of audits, while at the same time give staff valuable insight into existing processes.

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

Report sent to DI for factual accuracy: 10 December 2012

Report returned from DI: 19 December 2012

Final report issued: 7 January 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.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.

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.