Site visit inspection report on compliance with HTA minimum standards

Wythenshawe Hospital

HTA licensing number 12203

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**

27 February 2014

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.

Wythenshawe Hospital (the establishment) was found to have met all HTA standards.

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

The HTA's regulatory requirements

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

The statutory duties of the Designated Individual are set down in 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

The establishment consists of a body store and post mortem suite with laboratory facilities located in another area of the hospital. At the laboratory facility, tissue taken during post mortem examinations is processed into blocks and slides, reviewed by pathologists and stored until being archived, disposed of or returned, in accordance with the consent given.

The establishment undertakes adult post mortem examinations, either on behalf of the Coroner or with the consent of the deceased's family where there is clinical interest in a case. Paediatric cases are sent to another licensed establishment. Around 400 coronial adult post mortem examinations are performed by the establishment annually, with only one or two consented post mortem examinations taking place within the same period.

The mortuary and body store are older than the laboratory facility; however, the post mortem suite was refurbished around ten years ago and additional fridge and freezer units were installed, alongside the older bank of fridges, which remains in the body store. The post mortem suite and associated plant equipment are regularly maintained by the hospital's estates department. Therefore, although some failures of the older fridges have occurred and establishment staff are aware that they are approaching the end of their useful life, the fridges are able to maintain an appropriate temperature for the storage of bodies. The older fridges do contain wooden doors and frames. Being a porous material, the wood may make the fridges difficult to clean.

The establishment has installed a fridge alarm system to the older fridges, which alerts establishment staff via switchboard of any equipment failures both within and outside of normal working hours. The newer fridges are not connected to this remote alarm system and to mitigate the risk of an equipment failure going unnoticed, mortuary staff attend the establishment once per day during weekend and holiday periods to verify that the storage fridges and freezers are functioning correctly.

In the case of hospital consented post mortem examinations, consent is sought by the clinician who was involved in the treatment of the deceased prior to death. Clinicians are supported by pathologists from the establishment who have received training from the DI in the consent process and who are also able to answer any questions that the family may have regarding the post mortem examination procedure.

Prior to the inspection, the DI confirmed that storage of fetal remains and still born infants takes place within the hospital's maternity department. Remains are stored in a fridge that is kept in a small dedicated room away from the main ward, which also has facilities where parents can be with their child if requested. Occasionally, maternity department staff assist in the seeking of consent for paediatric post mortem examination. Staff have attended training at the licensed establishment undertaking the examination as well as to training given by the DI at Wythenshawe hospital. The maternity department's arrangements for dealing with fetal remains and still born infants have been well developed with the dignity of the deceased and their families in mind. The storage facility's temperature is monitored once per day by ward staff with these measurements being recorded in a diary. In addition, staff are currently tendering for the purchase of an alarm system which would alert staff to a fridge failure remotely. The DI has appointed a Person Designated and has assisted in the development of suitable standard operating procedures (SOPs), all of which are document controlled and managed within the establishment's governance systems.

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, 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 and Coroner's staff were undertaken.

An audit of bodies stored in the establishment's fridges was undertaken during the inspection. Two bodies were chosen at random and identification details recorded on body tags were checked against details on the tracking sheets, the mortuary fridge doors and mortuary location white board. No anomalies were found during this audit.

Tissue traceability audits were also undertaken during the inspection. Details were taken of three Coroner's cases where tissue was taken during the post mortem examination. In the histopathology laboratory, tissue is booked into the laboratory's electronic laboratory information management system (LIMS). A separate record of each post mortem case where tissue was taken is held by a senior Biomedical Scientist (BMS), who tracks communications with the Coroner in addition to the family's wishes and the end of coronial authority. Details of the tissues retained were cross checked between the mortuary's post mortem tissue records and the various histopathology records. Additionally, the physical blocks and slides were located and again the numbers checked against the LIMS. In all three cases the post mortem examinations were too recent for the establishment to have received notification of the families' wishes from the Coroner; however, records of the communication sent to the Coroner were reviewed in the BMS database. In all three cases, the number of blocks found matched the LIMS records. In two of the three cases, the number of slides found also matched the LIMS records. Slides were not sought for the third case since no anomalies were identified in the previous two cases.

So that examples of compliance with families' wishes communication could be reviewed, two further coronial cases were selected by randomly choosing post mortem identifiers from the tissue block archive. Again, the number of blocks and slides for both cases were cross checked against the LIMS records. Additionally, the BMS database was checked and the written family's wishes form sought. In one case the family had indicated that they wished the hospital to dispose of the tissue. The laboratory's LIMS correctly recorded the number of blocks and slides that had been disposed of and tracer cards were placed in the block and slide store to indicate that the tissue had been removed for disposal. In the second case, the family had asked for the tissue to be retained for future use. In both cases, signed forms detailing the families' wishes were reviewed.

Finally, details relating to a heart that was being stored at the establishment were reviewed. In this case the heart had been sent to the hospital by another licensed establishment for specialist review. Records relating to the organ were sought and a signed form indicating that the family had consented to retention of the organ was reviewed.

In summary, no anomalies were found in any of the audits that were undertaken.

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.	GQ1	Mortuary staff have already identified an improvement to the body receipt and release forms, which form the establishment's body traceability records. The DI is advised to continue with plans to implement the changes that are being suggested so that the body release form contains a section to highlight when a post mortem examination has taken place and tissue has been taken. In addition, a section should be added to highlight if any tissue taken during the post mortem examination has been requested to be returned to the body prior to release, or released to the funeral directors with the body. As these tracking forms are used during the establishment's release procedure, the new sections will act as an alert to establishment staff releasing bodies to verify that tissue has been repatriated with the body as requested.
2.	GQ6	When sending tissue to other licensed establishments for specialist review, the establishment sends a form containing the tissue details which is faxed back to the establishment once the tissue has arrived at its destination. The DI is advised to amend the standard operating procedure (SOP) which relates to sending tissue elsewhere (HI-S-OR-4) so that it includes details of the fax back notification system in use. Additionally, this SOP should include actions to take should a fax back from not be received in the expected timeframe.
3.	GQ8 PFE1 PFE5	The establishment has risk assessed the continuing use of the older body storage fridges and has identified some risks relating to their use. It has identified measures to mitigate these risks as much as possible. However, the establishment staff consider the fridges to be approaching the end of their useful life. Quotations for the installation of new fridges have already been obtained and the

		establishment is making a business case for the replacement of the fridges. In the meantime, the DI is advised to keep the use of the older fridges under review and to consider whether the risk of their continuing use should be identified on the Trust's risk register. This may be appropriate, since the impact of an equipment failure and the need to transfer bodies would have a significant impact on the work of the mortuary and pose a potential risk to the integrity of the bodies in periods of high capacity.
4.	PFE3	The newer bank of fridges at the establishment is not connected to the remote alarm system. To mitigate the risk of an equipment failure going unnoticed, mortuary staff attend once per day during weekend and holiday periods to verify that the storage fridges and freezers are functioning correctly. The DI is advised to continue with the plans to extend the remote alarm system to these newer fridges. It is envisaged that this will take place at the same time as the replacement of the older fridge units.

Concluding comments

Areas of good practice were observed during the inspection. The arrangements in the Trust's maternity department regarding the care of the deceased are well established and sensitive to the needs of parents. There are good links to the DI and the establishment's governance arrangements. Additionally, steps have been taken to help ensure that the dignity of the deceased is maintained, for example, special facilities for the dressing of babies and areas where parents can be with their baby in a private room if requested.

The mortuary manager keeps details of current tasks, cleaning rotas and items for discussion at the next governance meeting pinned to a notice board in the mortuary office. This helps to ensure that all staff are aware of current issues and tasks and can access relevant information quickly and easily. It also helps foster a positive approach to continuous improvement. Evidence of this continuous improvement of the establishment's systems was seen during the inspection, such as the improvements that had already been identified to the body receipt and release forms mentioned above, about which details were pinned to the notice board for discussion at the next governance meeting.

Finally, a range of governance meetings take place, which include mortuary staff, so all staff working under the licence have a mechanism to be updated on new procedures and other governance issues.

The HTA has given advice to the Designated Individual with respect to seeking consent, governance arrangements, and premises facilities and equipment.

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

Report sent to DI for factual accuracy: 31 March 2014

Report returned from DI: 3 April 2014

Final report issued: 22 April 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.

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 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 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.
- 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 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.