Site visit inspection report on compliance with HTA minimum standards

Addenbrooke's Hospital

HTA licensing number 12318

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**

20-21 April 2016

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.

Although the HTA found that Addenbrooke's Hospital (the establishment) had met the majority of the HTA standards, two minor shortfalls were found against the governance and quality system standards.

The shortfalls relate to the procedure for releasing bodies to funeral directors and the database system used by the Brain Bank operating under the HTA licence. The HTA has given advice to the Designated Individual on these issues as well as on temperature trending.

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 Section 18 of the Human Tissue Act 2004 (HT Act) 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 is a large teaching hospital with a range of licences from the HTA including Research, Anatomy, Transplant and Post Mortem (PM). This report covers an inspection of their PM licence, which in addition to the mortuary covers tissue from the deceased that is removed or stored in the emergency department, the neonatal intensive care unit, theatres, the bone bank, the brain bank, the molecular genetics laboratory, the human research tissue bank and the clinical school museum.

The mortuary at Addenbrooke's Hospital performs approximately 250 adult PM examinations each year for the Coroner and ten to fifteen hospital consented adult PM examinations, for which consent is sought by a dedicated team within the hospital. A further 250 hospital consented perinatal and paediatric PM examinations take place each year, referred from a number of hospitals in the area after consent has been obtained.

The mortuary forms part of the hospital premises and is secured by CCTV and electronic access control systems. There is also an alarm which rings through to the main hospital security services and which is tested on a monthly basis.

Bodies of the deceased from the hospital are brought to the mortuary by porters. Bodies of those who die in the community are brought in by funeral directors appointed by the Coroner.

Hospital porters and funeral directors receive training from mortuary staff, which is refreshed annually. The hospital security services is contacted when the Coroner's appointed funeral director attends out of hours to gain access to the mortuary. The mortuary on-call technician comes in to meet with the ambulance service out of hours. Mortuary staff are also present when tissue retrieval teams attend.

The body store comprises a number of banks of fridges, including a separate bank for perinatal and paediatric bodies. There 120 spaces for adults, five of which are dedicated freezer spaces and ten of which can accommodate bariatric bodies. There is also a fridge room that can accommodate up to three super bariatric cases. The fridge temperatures are monitored but the information is not regularly reviewed to identify any trends that could indicate a possible potential fault *(see advice item 5).*

All the fridges are alarmed with upper and lower temperature triggers; there is a local alarm in the mortuary and an audible alarm located in the in the estates and facilities department. There is a procedure in place that must be followed when an alarm sounds; however this is not tested *(see advice item 6)*.

The mortuary has a viewing suite which was recently re-furbished. Viewings, which are usually arranged by bereavement services, take place both during and out of hours and may require mortuary staff to work alone. There is an alarm that staff can use to alert the hospital security office if there is a problem and this is regularly tested to ensure it is functioning correctly.

The establishment has three separate post mortem rooms; one for adults, one for high risk cases and one for perinatal/paediatric cases. The adult suite has five tables, four of which are porcelain, and one stainless steel height-adjustable bariatric table. Organs are dissected on a board at each table. As the porcelain tables are not height adjustable, a number of sets of small steps, with non slip feet, have been made to give additional height to the APTs and pathologists if required. Use of these steps have been risk assessed by the establishment.

The negative pressure high risk post mortem suite has a single post mortem table and all the equipment necessary for infectious cases, including vCJD cases. The paediatric suite has three post mortem tables and a downdraft dissection area.

Pathologists review the list of requested post mortem examinations from the Coroner the afternoon prior to the scheduled examination. In some cases, the identity checks and external examination by the pathologists happen at that point and the Anatomical Pathology Technologists (APTs) proceed with evisceration the following morning before the pathologist arrives. When the body is taken out of the fridge prior to the PM examination, the APTs undertake an identity check using xx points of identification. Advice has been given by the HTA on ways to mitigate potential risks involved in this process *(see advice item 1).*

The HTA conducted a number of audits in the mortuary. Three bodies were selected at random and the details on the identification tags on the deceased were compared with the details held on the mortuary database and associated paper records. A second audit was carried out, tracking tissue taken as part of the PM examination through to the pathology laboratory and checking that any disposal or retention was in line with the wishes of the next of kin. No anomalies were found during the audits.

Included in the visual inspection of the premises were areas, outside of the mortuary, where tissue may be removed from bodies of the deceased. These areas included the Emergency Department, Neo-natal Intensive Care Unit and the Main theatres. A good level of compliance

with HTA standards was found and it was notable that the Persons Designated on the licence in each department were aware of the establishment's procedures and governance systems and that the DI has oversight of the activity taking place in these areas.

There is a fridge where stillborn babies may be kept for a short period on the maternity ward; this area was also visited as part of the inspection. The area is secured and the fridge temperature regularly monitored. Advice was given by the HTA on how these monitoring systems might be strengthened *(advice item 6)*. Consent for paediatric PM examinations is sought on the maternity ward by trained staff using the SANDS information booklet and consent form. The maternity unit has a porter assigned to the unit, who has a clear understanding of the sensitive nature of the work involved.

The establishment is a large teaching hospital, with multiple areas where tissue from the deceased is being stored for use for research and training. The HTA conducted an inspection to review activities taking place under the separate HTA research licence a few weeks prior to this inspection.The Bone Bank and Human Research Tissue Bank were visited as part of that inspection and as a result were not re-visited on this inspection, which was to review activities taking place under the establishment's post mortem licence. The Molecular Genetics Laboratory is included within the scope of the PM licence but was not storing any relevant material at the time of the visit and therefore was not included in the inspection.

The Cambridge Brain Bank is also under the governance of the DI supervising activities taking place under the post mortem sector licence and was visited during the inspection. Consent is sought by a specifically trained team who spend time with potential donors, answering any questions they may have. In the event of the death of the person, the family is free to decide not go ahead with the donation. The brain bank uses a courier to collect any brains retrieved at other mortuaries. Upon receipt, brains are divided in half; one half is fixed in formalin and the other half is dissected and frozen in -80°C freezers. The freezers are located in locable rooms; they are temperature alarmed and monitored with an on-call system in place for staff to move samples to a contingency freezer in the event of a freezer breakdown.

An audit of stored tissue in the brain bank was undertaken; details were taken from paper records, compared against information on the system and tracked to the freezer and to other relevant storage areas. The audit identified an issue with the electronic traceability system, which allows for more than one donor to be registered under the same number. Additionally there was an input error identified where there were more blocks and slides in storage than was recorded on the system *(see shortfall 2).*

Material stored at he Clinical School museum is also covered by the establishment's PM sector licence. A robust governance system is in place and the DI has oversight of the activities taking place. Access to specimens at the museum, which is not open to the public, is tightly controlled. All the specimens were acquired or donated prior to 1 September 2006, and as such fall outside the consent provisions of the HT Act. If specimens are removed for teaching purposes, staff must be informed when the class will be over and they collect the specimen themselves so they are never left unattended when outside the museum. A traceability audit was conducted whereby specimens were selected randomly from the paper location records and traced to the relevant shelf in storage. All items were accounted for and found to be within the areas recorded in the database.

The establishment has been licensed since 2007 and this was its third routine site-visit inspection. During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process.	In the mortuary the 'Release of Bodies' SOP lists the identifiers staff should check with funeral directors before release. However, on occasion, funeral directors may only confirm the name of the deceased they have come to collect.	**Minor**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	During the audit of the database used at the brain bank, two separate donors were recorded under the same code. This means that the establishment cannot accurately trace brain tissue used without referring to other coding systems which are soon to be made obsolete. The establishment will need to identify how many cases this applies to and correct the records so that each donor has a unique code to ensure accurate traceability. In addition, anomalies were found between the number of blocks listed on the database and the actual number in storage. The establishment should undertake an audit in this area.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	Whilst the pathologist always does an external examination and identification of the deceased prior to commencement of a PM examination, they are not always present during evisceration. The DI is advised to enhance the SOP for the evisceration procedure to include any circumstances when an APT should cease evisceration and contact the pathologist before proceeding.
2.	GQ1	The DI is advised to ensure that funeral directors always have at least three identifiers for any body before release.
3.	GQ6	The current database used in the hospital (EPIC) has the patient journey ceasing at death. The DI is advised to continue efforts to get the system extended to cover the mortuary.

4.	GQ6	In the Brain Bank whole brains donated for research and education are divided into two, with half being fixed in formalin and the other being frozen. The frozen half is then divided into sections which are provided to researchers. Although the Brain Bank database includes the number of sections, the technical staff do not currently record which section of the brain has been supplied for research use. The DI should consider adding this information to facilitate for effective traceability.
5.	GQ7	Incidents in the mortuary are fully investigated and preventative steps taken. However incident records suggest that, despite these steps, similar incidents happen again. The DI should consider additional steps to take to mitigate repeat occurrences.For example signage in the mortuary to remind porters to ensure the fridge space is large enough to accommodate a body comfortably.
6.	PFE4	Fridge temperatures are recorded daily in both the mortuary and maternity but not currently reviewed for trends; the DI is advised to add this step to the process as it may identify issues before they happen.
7.	PFE4	The mortuary fridge alarms are tested regularly; however, there is no test of the follow-up procedure that takes place after an alarm triggers; the DI should add this to the regular system checks.

Concluding comments

Despite the two minor shortfalls, areas of good practice were observed during the inspection, examples of which are set out below.

The overall governance and structure of such a large site is clearly laid out and the DI has good oversight of the areas covered by HTA licences. Training by mortuary staff for all porters and funeral directors, and annual refresher training, ensures that those accessing the premises out of hours are well trained on systems and processes. Security staff meeting with the funeral director appointed by the Coroner out of hours gives the hospital good oversight of who enters the mortuary.

A member of the mortuary team talks at the ‘End of Life Care’ training for ward staff, which gives them a better understanding of the importance of associated procedures. There is a weekly check of the duration of stay for all bodies in the mortuary and steps are taken to identify any possible delays to their release.

The dedicated team who speak to potential brain donors are well trained, and the consent process involves staff contacting potential donors every five years to confirm they are still happy to go ahead with the donation when they die.

There are a few areas of practice that require improvement, including two minor shortfall. The HTA has given advice to the Designated Individual with traceability systems and premises, facilities and equipment.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection / subject to compliance with the additional conditions applied to the licence.

Report sent to DI for factual accuracy: 18 May 2016

Report returned from DI: 2 June 2016

Final report issued: 8 June 2016

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: 10 October 2016

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: o post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases o record keeping o receipt and release of bodies, which reflect out of hours arrangements o lone working in the mortuary o transfer of bodies and tissue (including blocks and slides) to other establishments or off site o ensuring that tissue is handled in line with documented wishes of the relatives o 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.