Site visit inspection report on compliance with HTA minimum standards

Derriford Hospital

HTA licensing number 12034

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**

16 July 2013

Summary of inspection findings

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

Although the HTA found that Derriford Hospital had met the majority of the HTA standards, a minor shortfall was found in relation to confirming the identity and condition of bodies after they are received by the mortuary.

The establishment has made a number of improvements since the last inspection, taking into account the advice and guidance provided at the time.

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

Derriford Hospital is a specialist tertiary referral centre and acts as a major trauma centre which serves Devon and Cornwall. This was the establishment's third routine site visit inspection of the post-mortem licence. The establishment carried out 975 coroner's post-mortem examinations last year. The number of coroner's post-mortem examinations have declined over the years since the last site visit inspection. Coroner's post-mortems examinations are carried out under the authority of two coroners; H.M. Coroner for Cornwall and H.M Coroner for South Devon. The establishment carried out five hospital (consented) post-mortem examination last year. High risk cases are carried out by the establishment. Paediatric post-mortem examinations are referred to another HTA-licensed establishment.

The mortuary is secure, with swipe card access provision for relevant staff and designated funeral directors collecting bodies. There is CCTV both within the mortuary and outside. The annex of the mortuary contains contingency fridge storage for up to 36 bodies. These fridges were not operational during the inspection and would be used only if the main storage area were full. There is a 'decant' area, which is a separate storage room that can be accessed from outside of the mortuary and which is securely locked. This area contains two units which offer temporary storage for up to 24 bodies. This is also only used as an over-flow area during times when the mortuary expects to receive more bodies. The main mortuary body store can hold up to 96 bodies, including storage for bariatric bodies as well as freezers for long term storage. The mortuary also holds a baby fridge which stores foetuses of less than 24 weeks gestational age as well as more than 24 weeks gestational age.

All fridge and freezer temperatures are monitored daily by mortuary staff and any fluctuations in temperature investigated by the Head of the Mortuary. The storage areas are alarmed and connected to the hospital's switchboard that sends out a recorded message to the on-call technician both during working hours and out of hours. The establishment also engage in testing of the alarms to ensure that they work. On the last site visit inspection advice had been provided in relation to potential fridge/freezer failure as the majority of these were over 30 years old and were not subject to regular maintenance or servicing. During the visual inspection of the mortuary it was noted that all fridges and freezers had been replaced within the last year.

The inspection included a visual inspection of the mortuary, post-mortem suite and Histopathology laboratory. The inspection also comprised of interviews with the DI, PDs and a Coroner's Officer as well as a traceability audit of bodies in storage and tissue taken during post-mortem. The establishment's removal licence extends to the accident and emergency (A&E) department, the High Dependency Unit (HDU), several wards and theatres to cover the activity of removal of tissue from deceased children for determining the causes of death in cases of sudden deaths of infants and children.

During the visual inspection of the licensed premises, the inspection team selected a paediatric ward where samples may be taken in cases of sudden unexplained infant death. The DI and Nurse in charge on the ward demonstrated an understanding of the requirements of the Human Tissue Act 2004 and the establishment's governance systems, and the HTA was satisfied with the arrangements in place covering this activity. During the visual inspection of the mortuary, the inspection team were able to observe the body release procedures as two Funeral Directors had come to collect five bodies. The release of the bodies was conducted in accordance with the establishment's documented procedures.

The traceability audits were carried out on two bodies in storage. The mortuary register and the post-mortem register were used to trace the first body where a coroner's post-mortem examination had been conducted and where tissue was removed for histology purposes. A second body was identified from storage and traced back to the mortuary register. All bodies were correctly labelled with a wrist band and were in the correct storage locations. A histology traceability audit of the tissue removed from the first body was carried out. The pathology system demonstrated that 9 blocks had been processed and were in storage. All 9 blocks were stored and the supporting paperwork demonstrated full traceability. An audit trail was also carried out of a coroner's case where organs were to be repatriated with a body on the day of the inspection. The paperwork was reviewed to ensure it was complete, however the pathology system had yet to be updated by the Organ Retention team. No discrepancies were noted.

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
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail	Bodies are shrouded when they are received into the mortuary. The mortuary staff do not check the identification or condition of the bodies that are received into the mortuary during working hours or out of hours, until such time, when a post mortem examination is required or when the body is released. Failure to check the bodies after receipt means that staff cannot be sure of the identification or condition of the body whilst it is in storage and are unable to determine whether any possible damage or decomposition occurred prior to receipt or during storage in the mortuary. **See Advice and Guidance item 1.**	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	1. The DI should undertake a risk assessment on the current receipt procedures of bodies into the mortuary and assess the risks associated with not checking the ID or state of the body until such time of release or post-mortem examination. **This should be undertaken to assist in addressing the minor shortfall in relation to GQ6.** 2. The DI should also consider updating relevant SOPs to demonstrate the establishment's same/similar name procedure and ensure that SOPs reflect the mimum number of identifiers that should be checked during the receipt, release and post-mortem procedure. This should ensure consistency amongst mortuary staff when identifying bodies as well as reducing any risks associated with misidentification if there are bodies with a same or similar name.
3.	GQ3	The establishment has documented training logs for all members of staff. The DI is advised to ensure that the competency logs are made relevant to each staff member. Currently where competencies are not applicable to a member of staff, the log does not state 'not applicable', but instead there is a blank entry.
4.	GQ4	The DI is advised to ensure that all records relevant to mortuary register, post mortem registers are maintained appropriately to avoid loss of pages. At the time of the inspection, it was noted that some pages were loose and therefore could be misplaced or lost, leading to loss of records.

Concluding comments

The establishment staff have a good working relationship which is underpinned through regular meetings between the mortuary staff, DI and PDs. The Coroner's Officers are based on site which supports effective communication with the DI and establishment staff.

An Organ Retention team are responsible for ensuring that all organs and tissue that are removed from the deceased during post-mortem examination are tracked through a database and disposed of, retained for a scheduled purpose or repatriated with the deceased in line with the family's wishes. The Organ Retention team take an active role in contacting the family once a Coroner's Authority has ended. Notably, they enquire - in writing - about the wishes for any tissue retained following post-mortem examination.

Other areas of good practice relate to having clear audit schedules and the establishment's involvement in regular independent audits. Furthermore, any reported incidents affecting the mortuary or Histopathology laboratory are fully investigated by the DI and the 'Incident Lead'. Once the incident is formally closed, the Incident Lead is tasked with developing areas that require improvement to reduce the risk of future incidents occuring.

There are a few areas of practice that require improvement, including one minor shortfall in relation to GQ6 The HTA has given advice to the Designated Individual with respect to GQ1, GQ3 and GQ4.

The HTA requires that the Designated Individual addresses the shortfall 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: 26 July 2013

Report returned from DI: 29 July 2013

Final report issued: 29 July 2013

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: 18 October 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 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.