Site visit inspection report on compliance with HTA minimum standards

Torbay Hospital

HTA licensing number 12181

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**

22 October 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 Torbay Hospital (the establishment) had met the majority of the HTA standards, one major and one minor shortfall were found in relation to governance and quality standards. Several documented procedures for mortuary activities are insufficiently detailed, and there is no formal process for auditing of mortuary procedures. The Designated Individual is advised to strengthen communication links with, and between, staff working under the licence. This will enable him to satisfactorily fulfil his statutory duty to ensure suitable practices are used in the course of carrying out licensable activities.

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 (DI) are set out 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

Torbay Hospital ('the establishment') performs approximately 600 adult post mortem (PM) examinations each year, including high risk (up to Category 3) and forensic cases. Most adult PM examinations are performed under the authority of HM Coroner for Torbay and South Devon. Only one or two adult hospital (consented) PM examinations are performed annually, consent for which is sought by the Bereavement Officer or her deputy. Perinatal and paediatric cases for PM examination are transferred to another HTA-licensed establishment, with consent being sought by one of the consultant paediatricians (for a neonatal death) or by an obstetrician (for a stillbirth). The establishment has adapted HTA's model consent form for adult hospital PM examination, and the Stillbirth and Neonatal Death (SANDS) charity's consent form for perinatal and paediatric PM examinations (refer to advice items 1, 2).

Bodies of the deceased are assigned a unique identification (ID) number upon admission to the mortuary, which is also used to ensure traceability of samples of relevant material taken at PM examination. Tissues retained at PM examination for histopathological analysis are processed into wax blocks and slides by the establishment. Toxicology samples and organs requiring specialist examination, such as brains or hearts, are transferred to other HTA-licensed establishments. HM Coroner's Office is contacted every month for confirmation on whether coronial interest in outstanding cases has ended.

The mortuary has storage capacity for 33 adult bodies (30 fridge spaces and three freezer spaces) with a separate, stand-alone, fridge for neonatal bodies. Bariatric fridges will be installed in late 2013; currently, bariatric bodies are transferred to a funeral director for storage. The hospital's Delivery Suite has a fridge for the temporary storage of neonatal bodies prior to their transfer to the mortuary. There is a robust system to record movement of a neonatal body between these areas.

The establishment has been licensed by the HTA since June 2007. A routine site visit inspection of the establishment took place in February 2010. This report describes the second, routine, site visit inspection of the establishment in October 2013. The HTA inspected the mortuary, pathology laboratory and Delivery Suite, interviewed staff involved with licensable activities and reviewed documentation. An audit of identifiers and storage locations of two bodies revealed a minor discrepancy for one, between the date of birth written on the wrist tag and on the body bag; the patient's electronic record confirmed the correct date of birth to be that on the wrist tag. Records for a further four bodies which had been subject to a PM examination (three coronial cases and one consented), where tissue was retained for histopathological analysis, were audited. Two minor anomalies were found during this vertical audit:

- on the hospital PM examination consent form, the options for retention of PM tissue for a scheduled purpose, and also for disposal of retained tissue, were ticked;
- for one PM examination under coronial authority in October 2012, records were unclear as to whether the Coroner's Office had given instruction on when coronial authority had ended. For this case, there were no relatives of the deceased to give instruction on the use or disposal of retained tissues. Four large tissue blocks from this case remained in the Pathology Department (refer to advice item 7).

Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation (refer to advice item 9).

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	Documented standard operating procedures (SOPs) do not contain sufficient detail on mortuary practices and procedures. Three examples are given below; this is not an exhaustive list, and all SOPs will need to be reviewed to ensure they accurately describe mortuary practice: - SOP MO17 'Evisceration' does not specify what checks APTs undertake on the identity, external appearance and documentation relating to the deceased prior to the arrival of a pathologist in the mortuary, and under what circumstances they may or may not proceed to eviscerate a body without a pathologist being present; - SOP MO02 'Body storage' does not specify the temperature limits for the freezer and the neonatal fridge, nor does it state that bariatric patients are transferred to a named funeral director for storage, or explain the actions to take if a fridge or freezer alarm is ringing during normal working hours or outside these hours, when portering staff may access the mortuary; - SOP MO05 'Use of the mortuary register' does not specify which points of identification are used when a deceased person is to be released to a funeral director, or state what action to take if a funeral director does not have the correct documentation when they come to collect a body. *(Refer to advice items 3, 4)*	**Major**
GQ2 There is a documented system of quality management and audit.	There is no schedule of audits for mortuary procedures such as release of a body to a funeral director or of the checks on the deceased undertaken by APTs prior to evisceration.	**Minor**

Advice

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

No	Standard	Advice
1.	C1	The DI is advised that Appendix M of the Trust 'Consent to examination and Treatment' policy, which sets out procedures for seeking consent for a hospital PM examination, should: • state the title of the consent form used for perinatal and paediatric PM examinations (alternatively, the form could be appended to the policy, as with the adult consent form); • reference the HTA's Code of practice 1 on Consent and Code of practice 3 on Post mortem examination; • explain the key role of the Bereavement Officer in seeking consent for an adult PM examination, and that she is also able to support a clinician seeking consent for a perinatal or paediatric PM examination.
2.	C2	The DI is advised that an information leaflet for relatives on adult hospital PM examinations is available on the HTA's website, and that the SANDS Charity has developed model guidance documents for consent takers and for parents, (also available on the HTA website): • http://www.hta.gov.uk/_db/_documents/Post-mortem_examination_-_your_choices_about_organs_and_tissue_FINAL_v3_0_201201255642.pdf • http://www.hta.gov.uk/_db/_documents/6._Sands_Compiling_local_information_for_consent_takers_Jan_2013.doc • http://uk-sands.org/sites/default/files/SANDS-DECIDING-ABOUT-A-PM.pdf
3.	GQ1	The DI is advised that a body for PM examination can be stored for up to one week at unlicensed premises, such as a funeral director, incidental to transportation to licensed premises.
4.	GQ1, GQ4	It was noted that three different methods are used to amend errors in the mortuary register; also it was unclear who had made amendments and when they did so. This inconsistent approach could increase the risk of misidentification of a deceased person. The DI is advised to document an agreed procedure for correcting errors in the mortuary register, which includes recording the identity of the person making an amendment and the date they did so.
5.	GQ3	Portering staff admit bodies of the deceased to the mortuary and perform some viewings. Written instructions on how to perform viewings are on display in the mortuary, and new porters are accompanied by an experienced colleague when entering the mortuary. However, porters are not formally trained in all of the mortuary procedures they may be required to carry out. The DI is advised that the Head Porter should receive training in mortuary procedures, and cascade this to new portering staff, as and when required. A record of completion of such training should be kept.
6.	GQ6	Deceased persons who have the same, or similar sounding, names are highlighted in the mortuary register with a fluorescent marker pen. The DI is advised that the risk of misidentification can be reduced further by, for example, placing a coloured sticker onto their wrist tags, or by attaching a notice to their shrouds.

7.	GQ6, D2	The DI is advised to review communication procedures with HM Coroner's office to ensure that clear instruction on the end of coronial authority is received promptly in all cases.
8.	GQ7	Following advice given during the inspection, the establishment updated its SOP for reporting incidents to the HTA, so that it now correctly describes HTA requirements and local escalation protocols. The DI is advised to ensure that all staff working under the licence, including portering staff, are made aware of this updated SOP and of the incident reporting categories. The HTA is currently producing a guidance document on serious incidents in the PM sector. The DI is advised that this document should be circulated to staff working under the licence.
9.	PFE5	The DI is advised to ensure the alarm on the Delivery Suite fridge undergoes testing during the annual maintenance of this fridge.
10.	-	The DI holds a senior position within the Trust, which necessarily limits his contact time with staff involved with licensable activities. The DI and Licence Holder are advised to consider whether another person more closely involved with licensable activities may be more suitable to act in the capacity of DI. The DI is also advised on the following points: • to nominate one or more Persons Designated (PDs) in the Delivery Suite, and to initiate regular meetings, or some other routine form of communication with them, so that he retains oversight of storage of neonatal bodies there and the seeking of consent for perinatal and paediatric PM examinations; • to ensure that all staff involved with licensable activities have regular minuted meetings. While updates and new SOPs are circulated by the Laboratory Manager to mortuary staff by e-mail, face-to-face meetings provide an opportunity to disseminate information about new documents and procedures, and to review corrective and preventive actions taken to address audit findings. This is of particular relevance in the coming months, as the shortfalls identified at this inspection are being addressed.

Concluding comments

Despite the shortfalls identified, some strengths were noted. The Laboratory Manager provides valuable support to the DI in overseeing quality management systems. There is a good working relationship with the Coroner's Office, and Anatomical Pathology Technologists (APTs) and pathologists are well-versed in local procedures. The risk of organs being returned to the wrong body after PM examination is mitigated as in each case organs are dissected on a dissection board adjacent to the body. Systems for transferring a neonatal body from the Delivery Suite to the mortuary are robust; a midwife must sign out the body, and an APT must sign for its receipt, in the 'Mortuary Transfer Book'.

Some areas of practice require improvement, including one major shortfall and one minor shortfall. The HTA has given advice to the DI regarding consent procedures and information for hospital PM examinations, strengthening documented mortuary procedures, and oversight of licensable activities.

The HTA requires that the DI 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.

Report sent to DI for factual accuracy: 18 November 2013

Report returned from DI: 19 November 2013

Final report issued: 22 November 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: 6 January 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 thatneed 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.