Site visit inspection report on compliance with HTA minimum standards

Royal Cornwall Hospital

HTA licensing number 12208

Licensed under the Human Tissue Act 2004 for the

- **making of a post mortem examination;**
- **removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation; and**
- **storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose**

27 & 28 January 2016

Summary of inspection findings

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

Royal Cornwall Hospital (the establishment) was found to have met the majority of applicable HTA standards. One major shortfall was found in relation to ventilation in the post mortem (PM) room. The HTA has given advice to the DI with respect to consent training, evisceration in the absence of a pathologist and traceability of tissue samples taken in the A&E department.

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

The HTA's regulatory requirements

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

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The establishment has been licensed by the HTA since November 2007 for the making of a post mortem (PM) examination, removal of relevant material from the deceased and storage of the deceased and relevant material for use for scheduled purposes.

Royal Cornwall Hospital (the establishment) is based in Treliske, near Truro in Cornwall. The mortuary undertakes approximately 1,500 post mortems per year, most of which are carried out under the jurisdiction of the Cornwall Coroner. Approximately two consented hospital post mortems are conducted annually. The establishment does not undertake paediatric PM examinations; however, tissue may be taken from deceased children, normally a skin biopsy for cytogenetic analysis, in two areas of the hospital related to paediatric care. The establishment does not conduct PM examinations where there is a known high risk of infection.

The mortuary is staffed by 4 permanent members of staff, one of which is the Mortuary Manager. There is storage for 78 bodies on site, including four freezer spaces. In addition, there are 24 body storage spaces available off-site at an unlicensed body store, four of which are freezer spaces. A contingency plan is in place, providing 60 additional spaces. Of these, 36 are permanently deployed in a dedicated, secure area within the hospital, while 24 are available in reserve.

Within the post mortem suite, there are four PM tables with dedicated tissue preparation areas, one of which is downdraught. Following post mortem examination, tissue taken from bodies may be stored for a scheduled purpose in the histology laboratory or in a dedicated storage facility on the hospital premises.

Bodies admitted to the mortuary during office hours are dealt with by mortuary staff, who check identification details and log details of the deceased in the mortuary's records. Out of hours, bodies may be delivered to the mortuary by the Coroner's removal team or the local ambulance service, both of which have swipe card access the mortuary. People admitting bodies out of hours use specific forms to record details of the deceased placed into storage for the information of mortuary staff when they attend the next working day.

All bodies brought to the mortuary have an ankle and wrist band containing details of the deceased's name, age and place and date of death. A further wrist band is applied by mortuary staff after admission to the mortuary, which includes the unique mortuary number.

This was the third routine inspection of the establishment, the previous inspection having been carried out in 2011. The inspection comprised a visual inspection of the premises, including the mortuary, maternity department, histopathology laboratory and A&E department, a document review and interviews with key staff, including mortuary staff, maternity ward staff and histopathology laboratory staff.

A traceability audit was conducted for three bodies in storage and their identity and location compared with entries in the case management system. No discrepancies were found. Blocks from two PM cases were located in storage and traced back through the laboratory register and management system to ensure consistency of recording and appropriate consent. No discrepancies were found. Details of blocks retained from three further PM cases were located on the CMS from the relevant request form and traced back to storage. No discrepancies were found.

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
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored	Air handling and ventilation in the PM suite and body store areas are poor, and failed the last re-validation visit. This poses a risk to the health and safety of staff working in the mortuary and makes for an unpleasant working environment for staff who, on occasion, undertake PM examination of decomposed bodies.	**Major**

Advice

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

No.	Standard	Advice
1.	C3	The DI is advised to consider extending consent training to midwifes in the maternity department, and ensure that members of staff who seek consent have observed a PM examination (either in person or on video) and can confidently address any questions that may arise during the consent process.
2.	GQ1	The procedure governing PM examination at Royal Cornwall Hospital allows evisceration to take place before the pathologist has made a full examination of the body. This practice is contrary to latest guidance from the Royal College of Pathologists. The establishment has carried out a risk assessment to mitigate the risks of this, however, there is no clear policy setting out the circumstances in which evisceration should not proceed prior to the arrival of the pathologist and their examination of the body, and who is accountable in the event that an error is made. The DI is advised to implement a system where the pathologists will provide written confirmation that evisceration can take place, and to update the relevant SOP to reflect current practice and include specific situations when evisceration cannot take place in the absence of a pathologist.
3.	GQ6	The DI is advised to appoint a new Person Designated to oversee activities undertaken in the A&E department and consider the implementation of a system to improve traceability of tissue samples taken from deceased children in A&E. In addition, the DI is advised to attend, or be represented by the PD, at the quarterly meetings held by paediatric and A&E members of staff where paediatric death cases are discussed.
4.	PFE3	When addressing the major shortfall identified above, the DI should be mindful of guidance contained in HSE's document: 'Safe working and the prevention of infection in the mortuary and post-mortem room' from which the following extracts have been taken: 'There should be an adequate fresh airflow throughout the mortuary and post-mortem room. The design requirements of the mortuary and post-mortem room specify the importance of odour control. Airflow from ventilation systems is best directed away from observers, preferably by drawing air into the mortuary at a high level and discharging it at a low level.' 'Before a post-mortem examination begins, anatomical pathology technicians should ensure . . . air supply and extract systems are working properly'. In addition, COSHH specifies that there should be a thorough examination of ventilation and air flow every 14 months, and sets out what constitutes a thorough examination. The DI should seek advice from the Trust's health and safety advisor to ensure compliance with COSHH guidance.

Concluding comments

This report describes the third HTA site visit inspection of the Royal Cornwall Hospital. During the inspection, several areas of strength were observed.
Staff in the mortuary and other departments where licensed activities take place have developed good training packages, with robust competence assessment procedures in place. The team is dedicated to ensuring that the dignity of the deceased is maintained and staff members work together to ensure that body release for burial or cremation is expedited as quickly as possible.

Document control is well managed and any major changes of SOPs are tested by the SOP being followed by a member of staff unfamiliar with the process, to ensure that they are clear and accurately reflect current practice.

There is a good management system linking information between the mortuary and pathology departments, which, in combination with a system of colour coding blocks and slides ensures that traceability is maintained at all times and tissue is managed appropriately according to the consent given. This practice is further strengthened by the frequent horizontal and vertical audits.

The HTA has given advice to the DI with respect to consent training, evisceration in the absence of a pathologist and traceability of tissue samples taken in the A&E department.

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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 22 February 2016

Report returned from DI: 4 March 2016

Final report issued: 8 March 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: 12 June 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.

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.

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 outlines 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.