Site visit inspection report on compliance with HTA minimum standards

Chesterfield Royal Hospital

HTA licensing number 12029

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**

11 January 2017

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.

Chesterfield Royal Hospital (the establishment) was found to have met all HTA standards. 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. 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 report refers to activities carried out at Chesterfield Royal Hospital (the establishment), which has been licensed since 2006 and was last inspected in 2011. The establishment is licensed to carry out post-mortem (PM) examinations, remove relevant material from the body of a deceased person and store bodies or relevant material for use for scheduled purposes under the Human Tissue Act 2004 (HT Act).

The Designated Individual is the Divisional Director of the Clinical Specialist Services Division. The Corporate Licence Holder is Chesterfield Royal Hospital NHS Foundation Trust, and the Corporate Licence Holder contact (CLHC) is the Executive Medical Director. There are three Persons Designated (PD) identified to support the DI in the conduct of licensed activities (see Advice, item 4). The mortuary has four full time staff, including a Mortuary Manager, a Deputy Manager and a Senior APT.

The establishment carries out approximately 800 post-mortem examinations per year on behalf of the Coroner for Derby and Derbyshire Coroner's area covering the High Peak, Chesterfield and North Derbyshire. Hospital post-mortem examinations are not routinely performed and such an examination has not taken place within the previous three years. Perinatal and paediatric cases are transferred to a nearby HTA-licensed establishment for PM examination.

The mortuary is secured with swipe card access and a door entry system linked to screens in the body store and office, which allows staff to see who is at the entrances before granting entry. The list people authorised to access to the mortuary is reviewed on a six-monthly basis to help assure the DI that only staff with valid authorisation gain entry. CCTV covers the entrances used by porters, funeral directors and mortuary staff as well as the body store. The CCTV system also is linked to a recording device so that, if needed, mortuary staff can review footage taken by the system. Occasionally staff may work alone out of hours. In such instances, staff carry a personal alarm which is linked to security.

There are 121 spaces in the mortuary, including four bariatric fridge spaces, four bariatric freezer spaces and a dedicated bank for paediatric cases. Fridges are alarmed with upper and lower temperature limits set by mortuary staff. The fridges are linked to a remote call-out system, which alerts security and the hospital's blood bank reception to any deviations from the expected temperature range. If necessary, a member of on-call mortuary staff will attend the mortuary to investigate such temperature deviations. The temperatures are monitored manually on a daily basis, which also helps to identify potential equipment failures before they occur by enabling temperature trends to be monitored. Alarms, including the call-out system are tested regularly; however this is not formally documented in an SOP (see Advice, item 3).

Bodies are received to the mortuary from the hospital and community. Hospital porters bring the bodies of patients who have died in the hospital; Coroners' contracted funeral directors bring in bodies of those who have died in the community. Porters are trained and competency assessed by the Mortuary Manager. Upon receipt of the deceased, identification details are verified by mortuary staff.

When a body is released to a funeral director a completed Coroner's release form or a completed green disposal certificate must be provided. A body will not be released without one of these forms. The identity of the deceased is checked by an APT and the collecting funeral director.

The viewing suite is accessed by families through a corridor in the hospital. Viewings are arranged by appointment through either the mortuary or bereavement staff, who meet them and escort them to the mortuary. A visual signal is used to alert mortuary staff and porters that viewings are in progress to remind them to keep noise to a minimum. Out-of-hours viewings are occasionally facilitated by porters, who have received training from the mortuary manager.

The PM suite has five fixed height-adjustable post mortem tables. There is one dedicated dissection area for organs. To help prevent the mix up of organs, they are brought to the dissection area from one body at a time and returned to the body before the next block of organs is examined.

On the occasion that tissue samples or organs are retained for further examination, a laminated tag is placed on the deceased to highlight to staff if tissue is to be returned to the body.

The inspection comprised: a visual inspection of the mortuary; interviews with the Mortuary Manager, a Coroner's Officer, a Consultant Pathologist, staff from the Emergency Department and Maternity wards, and the Designated Individual; and a review of governance documentation.

As part of the inspection, an audit of the bodies within the body store was undertaken. Three bodies were selected at random and the relevant identification details compared to those recorded in the mortuary register; no anomalies were found. In addition, three tissue traceability audits were carried out, where documentation and laboratory records associated with Coronial cases were reviewed, and the physical location of the blocks and slides checked, to ensure the families' wishes had been acted upon. No anomalies 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
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills	Perinatal and paediatric PM examinations are performed at a nearby HTA-licensed establishment. Consent for these is sought at Chesterfield Royal Hospital by clinicians trained in seeking consent; however, specific training on seeking consent for PM examination is not provided.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	There are mortuary standard operating procedures (SOPs) describing the various mortuary processes; however, as processes have evolved, these documented procedures have not been updated. Examples where this has occurred include, but are not limited to, the SOP describing the PM procedure, which does not detail the points of identification checked by the pathologist prior to commencing the PM examination. Additionally, this SOP does not state that the ID is checked by both the pathologist and the anatomical pathology technologist. The DI is advised to review the establishment's SOPs and update them as required so that they describe current practices.
2.	GQ7	The SOP describing the HTA reportable incident (HTARI) reporting procedure has not been updated to include the latest HTARI category defined by the HTA. The DI is advised to update this SOP so that all HTARI categories are included.
3.	PFE5	The remote call-out system for the fridges and freezers is regularly tested; however, there is no formal SOP. The DI is advised to create a new SOP for alarm testing so that he has on-going assurance that the alarms and response procedure are working as expected.

4.	N/A	The DI is advised to appoint a Person Designated in the emergency department and the maternity department to act as points of contact in relation to licensed activity taking place in these areas. This will help the DI to be alerted of any issues that may arise and enable him to disseminate any licensing updates or information to staff in these areas. The DI is also advised to invite these PDs to some of the establishment's governance meetings so that information regarding licensable activity can be shared.
5.	N/A	The form used by the Coroner to record the deceased's family's wishes in relation to tissue retained following a PM examination indicates that material may be held as part of the deceased's 'medical record'. The DI is advised to discuss this with the Coroner with a view to modifying the form so that the potential use of the tissue samples is included, for example 'for the future benefit of the family in light of new medical or scientific information'. In addition, the form does not indicate the relationship to the deceased of the person who has completed the form. The addition of this would help the DI ensure that consent for retention of tissue has been given by the appropriate person.

Concluding comments

During the inspection, a number of areas of good practice were observed. The mortuary is extremely busy, and staff work well and efficiently together. Porters are trained by mortuary staff and a bespoke SOP has been developed to aid their training, which includes pictures and instructions for porters to follow. Two consent forms have been developed to record the wishes of people with regards to the disposal of pregnancy remains. One in relation to miscarriage, and one in relation to social terminations. These forms have been tailored by taking into account the various sensitivities involved and have been informed by the HTA's pregnancy remains guidance. Every morning mortuary staff have a 'huddle' meeting where they discuss staff duties for the day, any issues which arose the previous day, and incidents/complaints/near misses/errors/compliments, any issues from the staff on-call and any other issues that staff need to be aware of.

There are a number of areas of practice that require improvement, including one minor shortfall.

The HTA has given advice to the Designated Individual on a range of matters to improve practices further.

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.

Report sent to DI for factual accuracy: 6 February 2017

Report returned from DI: 15 February 2017

Final report issued: 23 February 2017

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: 16 November 2017

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.

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.