Site visit inspection report on compliance with HTA minimum standards

Worcestershire Royal Hospital

HTA licensing number 12079

Licensed under the Human Tissue Act 2004 for the

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

20 May 2014

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.

The HTA found that Worcestershire Royal Hospital (the establishment) had met the majority of the HTA standards, with two minor shortfalls in relation to governance and quality standards. There was no evidence of documented risk assessment of the establishment's practices and processes in relation to licenced activities, and there is no training in mortuary procedures given to hospital porters.

The Designated Individual (DI) has been in the role since January 2014 and has established good communication links between key members of staff and departments.

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

This report refers to the activities that take place within the mortuary at the Worcestershire Royal Hospital (WRH), which conducts around 550 post-mortem (PM) examinations each year. The majority of these are routine adult coronial cases on behalf of HM Coroner for Worcestershire, including high risk cases. Paediatric cases are transferred to another HTA-licensed establishment. The establishment no longer conducts forensic PM examinations or stores tissue on behalf of the police.

In 2013, the establishment conducted four consented hospital adult PM examinations. Consent for these is obtained by a core team of trained staff from the mortuary. The DI, who is a consultant histopathologist, is responsible for training those seeking consent from the family.

Consent for perinatal PM examination is sought by either the obstetric consultants or other midwifery staff, all who have been trained in seeking consent. The establishment uses the consent form supplied by another HTA-licensed establishment. Patient information leaflets are available for families and are provided by the Trust.

The mortuary is staffed by two qualified Anatomical Pathology Technologists (APTs) and two trainee APTs. The fridge room comprises two storage areas, one for ward deaths and another for community deaths. There is overall capacity for 83 adult bodies, including eight

bariatric bodies; babies and foetal remains are stored in the adult fridges in appropriate containers. Five fridge spaces can be used as freezer storage if required. Temperature and alarm systems are monitored electronically for the ward storage area; however, the community death fridges are temperature monitored and recorded manually. WRH are awaiting a new electronic monitoring system (refer to advice item 10). The PM Suite comprises three down-draught tables and a galleried viewing area. There are also viewing facilities for families with a private entrance via a fenced garden area.

During working hours, receipt and release of the deceased are overseen by the mortuary staff. Out of hours, hospital porters transfer bodies from hospital wards to the mortuary. They also oversee the admittance of community deaths and undertake other activities such as out of hours viewings with a senior nurse present. There is an APT on-call for emergencies.

The mortuary register is completed for all hospital and community deaths. On arrival to the mortuary, bodies are assigned a unique identification number. All information is recorded on the establishment's electronic tracking system. A daily capacity audit is carried out as well as a weekly audit to highlight bodies that have been held in the mortuary for longer than seven days. This identifies the potiental need to move the deceased to the freezer storage facility to help preserve the condition of the body.

The identity of the deceased is always checked by the pathologist and the APT prior to evisceration. Any samples that are taken for histology during the PM examination are given a unique histology number and transferred to the onsite laboratory for processing. Tissue is stored for use for scheduled purposes with the consent of the family, in line with the hierarchy of qualifying relationships, in the Pathology Department and then long term in an external HTA licensed facility. There is a system in place for the sensitive disposal of tissue samples in line with the wishes of the family.

This was the second routine inspection of the establishment. Included in the one day inspection was a visual inspection of all facilities, a document review and interviews with key members of staff.

Traceability audits were completed as part of the inspection:

- Three bodies were selected from the white board and found to be in the specified location in the mortuary using the identification tag on the deceased. The information was also verified with the mortuary register and database.

- Details of a consented hospital adult PM examination where tissue and a whole organ had been removed for histology was selected. Tissue blocks from this case were traced through the histopathology laboratory database, the PM examination register, relevant paperwork; the relative's wishes for the disposal of this tissue were verified. Consent for the retention of the organ for use for a scheduled purpose was also confirmed.

- A traceability audit of a PM examination under the authority of the Coroner was also verified by the above process, including whether tissue had been disposed of in line with the family's wishes. Again, there was consent for a whole organ to be retained for medical education.

- A further case was traced from the block storage area to the paperwork relating to the tissue, the PME register and the histopathology laboratory database. All tissue was awaiting disposal in line with the family's wishes.

No anomalies were found during any of the audits; however advice and guidance has been given to strengthen the disposal procedure.

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	Portering staff are responsible for out of hours access to the mortuary to admit bodies of the deceased from the hospital wards. There is no formal training or system in place to assess the competency of porters or their compliance with mortuary operating procedures. See advice and guidance 5	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment does not undertake formal documented assessments of the risks presented by the licensed activities being carried out; for example, the risk of a major equipment failure or release of the wrong body. The lack of documented risk asessments means that the DI cannot assure himself that all potential risks have been identified and that these are being satisfactorily mitigated. In addition, a risk assessment of the security of the premises has not been undertaken.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1 GQ1	There is a good consent process in place to ensure that families give informed consent for the rentention of tissue for a scheduled purpose or disposal of tissue The DI is advised to review the number of SOPs in relation to the consent process and to develop a single consent procedure, setting out who can sek consent, what documentation to use and the hierarchy of qualifying relationships.
2.	C3	Consent training is delivered by the DI. The DI is advised to review the existing PowerPoint training presentation and use it as refresher training for staff seeking consent. Furthermore, the DI may wish to consider extending the training to core team members who seek consent to ensure that there is always a trained member of staff available in the hospital.

3.	GQ1	The HTA advises the DI to update procedures to ensure that they reflect current working practice which goes beyond what is currently documented. For example: • The use of name cards on community fridges; • The minimum number of identifiers that should be used for the identification of the deceased as part of the checks used on receipt and release of bodies; • The difference in procedure for the identification of deceased from the ward and the community i.e. that ankle bands are applied to bodies from the hospital wards. • The pathologist must always identify the deceased with an APT before evisceration.
4.	GQ2	The mortuary carries out a range of audits on the storage of the deceased including last offices, as well as an annual vertical audit against HTA standards. The DI is advised to schedule these audits into the departmental audit calendar and extend the programme to include, for example: • traceability of retained tissue samples; • storage of blocks and slides; • disposal in line with family's wishes; • hospital PM Consent documentation.
5.	GQ3	The HTA advises that portering staff, who are provided under contract with a third party, should be fully trained to undertake their mortuary duties. Training should include how to place bodies into fridges, what paperwork to complete, how to report an untoward incident and the transportation of the deceased from the ward to the mortuary. Because of the high turnover of portering staff, training should be delivered regularly so new members of staff are familiar with, and work to, mortuary procedures.
6.	GQ6	When the body of an unknown person is brought into the mortuary from the community, the DI may wish to consider documenting the mortuary identification number on the body tag as an additional, unique, point of identification for the deceased
7.	GQ6	Deceased persons who have the same or similar sounding names are highlighted in the mortuary register with a red marker pen. The DI is advised that the risk of errors in identification could be reduced further by, for example, higlighting persons with same or similar names on the fridge door. The DI may wish to also consider placing a coloured sticker onto wrist tags or attaching a notice to shrouds as additional visual reminders.
8.	GQ7	There is a good standard operating procedure for the reporting of an HTA Reportable Incident (HTARI) to the HTA. The DI is advised to update the SOP with the names and contact details of those Persons Designated (PDs) that can report incidents to the HTA via the portal.
9.	PFE5	The mortuary has had a new electronic fridge monitoring system installed, however this at present has limited functionality due to a transmission fault. To reduce the risk of a reportable incident to the HTA the DI has been advised, as an interim measure, to implement a system whereby a designated member of mortuary staff visits the mortuary to manually monitor the fridge temperature outside of normal working hours. The DI has advised that this is now in place

		until the electronic system is fully implemented.
10.	D2 GQ1	There is a system in place to oversee the traceability and disposal of relevant material in line with the family's wishes. The SOP 'Management of tissue from coroner's PMs' does not cover all aspects of the process. The DI is advised to state in the SOP: • the recording of the number of blocks and slides in the department database; • what to do where there are no instructions from the next of kin on the retention or disposal of relevant material; • the reason and route of disposal of tissue;
11.	-	The DI is advised to consider identifying a Person Designated (PD) in other areas within the hospital where activities under the licence are carried out to help ensure compliance with HTA requirements.
12.	-	The DI is advised to consider regular meetings with staff involved in licensable activities, to discuss HTA related issues, HTA updates via the HTA newsletter and HTARI reporting information. Furthermore, the DI may wish to introduce more frequent meetings with the portering services providers to build on communication concerning matters arising from training and HTA reportable incidents.

Concluding comments

During the inspection, examples of good practice were observed. Worcestershire Royal Hospital mortuary is a clean, well-kept facility with a dedicated team of staff. The relatives' viewing room overlooks a designated garden area, which is in the process of becoming a garden of remembrance for families. This shows a high level of respect and sensitivity by staff towards the bereaved.

The consent process is tightly controlled by the DI, with robust practices in place for seeking informed consent from families for both adult and paediatric cases. The patient information leaflet is comprehensive and gives visual guidance in relation to the potential size of tissue taken during a PM examination.

A care after death audit is carried out daily by the mortuary staff. They check the identification, correct positioning and condition of the body as well as personal effects. The information is then analysed to identify trends and shared with the DI and associated ward within the hospital. Again this shows a high level of care towards the dignity and respect of the deceased.

Overall there is evidence of robust systems in place and excellent communication between staff and the DI.

There are a number of areas of practice that require improvement, including two minor shortfalls. The HTA has given advice to the DI with respect to some elements of governance systems, reviewing the content of SOPs to reflect working practice and strengthening the audit schedule to include other licensable activities, as well as risk assessment of the security of the premises.

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: 11 June 2014

Report returned from DI: [date]

Final report issued: 30 July 2014

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: 01 August 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.

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.