Site visit inspection report on compliance with HTA minimum standards

Warwick Hospital

HTA licensing number 12080

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**

07 June 2016

Summary of inspection findings

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

Although the HTA found that Warwick Hospital (the establishment) had met the majority of the HTA standards, two minor shortfalls and one major shortfall were found in relation to governance and quality systems and premises, facilities and equipment 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

This report refers to the activities carried out at Warwick Hospital (the establishment) but managed by an external pathology network, which is separate from the South Warwickshire NHS foundation Trust (the Licence Holder), of which the establishment is a part. The mortuary premises and facilities are owned and managed by Warwick Hospital. The staff working there are employed by the Coventry and Warwickshire Pathology Services Network.

The Designated Individual (DI) is employed by the Trust and is a Consultant Histopatholgist and the Associate Medical Director for support services in the hospital.

The establishment carries out approximately 450 post mortem (PM) examinations each year, on behalf of HM Coroner for Leamington and Warwickshire. Very few adult hospital (consented) PM examinations take place. During working hours, consent for adult PM examinations is sought by a trained member of staff with a Bereavement Officer present. There may be occasions, usually out of hours, when a clinician seeks consent unaccompanied (see advice item 1). Perinatal and pediatric cases are sent to the Birmingham Women's Hospital. Paeditric Consultants at Warwick Hospital seek consent for these using consent forms based on the Stillbirth and Neonatal Death Charity (SAND) forms. Forensic and high-risk cases are transferred to other HTA-licensed establishments for PM examinations to be carried out.

Staffing at the mortuary is the responsibility of the Coventry and Warwickshire Pathology Services Network. At the time of the inspection, a full-time locum Anatomical Pathology Technologist (APT) was working in the mortuary. Occasionally, a Biomedical Scientist assists with administrative duties. However, lone working takes place during periods of high demand, increasing the risk of an HTA reportable incident occurring (see major shortfall against standard GQ8 and advice item 2). Mortuary procedures reflect working arrangements, and the low level of staffing means that funeral directors and porters are required to complete

some activities unobserved by an APT, for example the admission of bodies into the mortuary.

The mortuary has 50 fridge spaces and three spaces for bariatric bodies. There is a separate fridge for storage of infants and babies. There is no freezer storage on site (see minor shortfall against PFE3). The establishment has a temporary mortuary unit and a documented contingency arrangement with other hospitals within the external pathology network.
All fridges temperatures in the mortuary are documented on a daily basis. There is a local alarm system, which alerts security in case of fridge failure and APTs are on-call in case of an emergency.

When bodies are admitted to the mortuary, porters or funeral directors write the identification details in the 'incoming register' book. This is then checked by the APT and the details transferred to the mortuary register. Details of paediatric bodies are recorded in a separate mortuary register. Upon release of bodies, funeral directors must present the relevant paperwork or the release will not take place. At least three identifiers are checked when releasing the body of a patient who has died in the hospital. These include the full name, address and hospital number. For bodies brought in from the community, the full name, date of birth, and place the body was found are checked on release by the APT and the funeral director.

Access to the mortuary is by key and there is CCTV inside the body store.

The PM suite has three height-adjustable tables. There are two dissection benches that are used for examination of organs by the pathologists. Organs taken during the PM examination are dissected by the Pathologist one at a time to help reduce the risk of mix up of organs. Advice was given by the HTA to further mitigate this risk (see advice item 3). Tissue retained at PM examination is cassetted in the mortuary, sent to the Histology department in the hospital for analysis and then stored in histology or returned to the mortuary for disposal according to the consent provided.

This was the third routine site visit inspection of the establishment since it was licensed in 2007 (the last inspection having taken place in 2011). The inspection included a visual inspection of the body store, PM suite, viewing area, Histology and Maternity where POCs and fetuses are stored prior to transfer to the mortuary. Interviews with members of staff and a review of documentation were undertaken.

A release of two adult bodies from the body store to funeral directors was observed during the inspection. The procedure was compared with the documented standard operating procedures. No anomalies were found.

Audit trails were conducted on two adult bodies stored in the refrigerators. Processes for storage of Products of Conception (POCs) and fetuses were also checked. The adult bodies shared the same surname. Body location and identification details were cross referenced against the information on the, identification tags, and paper records. Systems for same/similar names were also checked against standard operating procedures. No discrepancies were found.

An audit trail was also conducted on one coronial and two hospital consented (adult) PM cases where histology samples had been retained during the PM examination. Paper records, computer records, consent forms and location of the samples in Histology were checked. 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

	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process	The current arrangement with the Pathology network does not allow for a system of shared governance of mortuary activities. For example, there are no regularly scheduled meetings between the DI and mortuary staff to discuss matters relating to the conduct of activities taking place under an HTA licence.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment has not sufficiently addressed the risk posed by having a single locum APT staffing the mortuary and undertaking the bulk of mortuary activities, including those related to PM examination. *See advice item 2*	**Major**

Premises, facilities and equipment

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	There are plans for a refurbishment of the mortuary in 2017, which includes incorporating freezer storage in the body store. At the time of the inspection, the mortuary did not have a documented procedure to indicate the point at which bodies may need to be transferred into long term storage and how this would take place. Although the mortuary has not experienced difficulties in relation to long-term storage of bodies, a contingency arrangement should be put in place should the need arise.	**Minor**

Advice

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

No	Standard	Advice
1.	C1	The DI should keep a record of staff that have attended consent training to ensure that staff have completed the consent training before seeking consent. The DI may also wish to consider adding a checklist to the consent documentation for clinicians that seek consent for PM examinations so they are aware of what to cover. This will help strengthen the process for seeking consent, particularly when consent is sought outside of normal work hours.
2.	GQ3/ GQ8	In relation to the shortfall against GQ8, steps should be taken by the establishment to ensure that risks presented by mortuary activities, which are currently being undertaken by a single locum APT, have been adequately mitigated. If it is not possible to implement a system whereby staff from other hospitals within the pathology network provide cover during periods of high demand and staff leave, the hospital and the network should consider the recruitment of a permanent APT for the mortuary at Warwick Hospital.
3.	GQ6	To further mitigate the risk of mixing up organs during PM examination, the DI may wish to consider using a visual reminder such as marking the PM table and buckets for organs removed during the PM with corresponding colours or letters
4.	PFE3	There is a fridge in maternity for storage of POCs and fetuses before their transfer to the mortuary. The fridge has a dial that indicates when the fridge is in the 'safe zone'. Staff use this as a reference point to inform them that the fridge is within an acceptable temperature range. Staff are not aware of the appropriate temperature range and rely upon this dial working correctly. Furthermore, there is no documented monitoring of the fridge temperatures. Staff should identify the acceptable temperature range and monitor and record temperatures daily to ensure that the fridge maintains the appropriate temperature.
5.		The hospital has developed a policy on the disposal of pregnancy remains. However, the full range of options set out in the HTA's guidance on the disposal of pregnancy remains is not available to women undergoing pregnancy loss or termination and the DI should consider whether it should updated to incorporate incineration as an option.
6.	PFE3	The DI is advised to schedule manual checks of the fridge temperature alarms to ensure that they are operating as expected. This should include checks that the system notifies the hospital security as expected and that alarm notifications are responded to appropriately. These checks and any resulting actions should be documented.
7.	PFE5	There was no documentary evidence that checks of air change in the PM room had been undertaken. The DI is advised to ensure that regular checks are undertaken and recorded.
8.		The mortuary is currently holding samples from PM examinations for use for research, where the family has indicated that this is what they would like done

		with the samples. However, the material may not be used. The DI should consider developing a policy on the retention and disposal of material donated for research and making families aware that the samples may be disposed of if not used.

Concluding comments

Despite shortfalls identified, areas of good practice were observed:

- competency training for mortuary staff is very thorough;
- there is a large range of SOPs covering licensable activities, which are subject to a robust system of document control.

There are areas that require improvement where shortfalls were identified in relation to the arrangements for storage of long-stay bodies, governance meetings between the DI and mortuary staff and risks of having a single locum APT working in the mortuary. In addition, the HTA has given advice to the DI relating to consent, governance and quality systems, premises, facilities and equipment and disposal.

The HTA requires that the DI addresses the shortfall identified 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: 29 June 2016

Report returned from DI: 7 July 2016

Final report issued: 18 July 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: 05 February 2018

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.