Site visit inspection report on compliance with HTA minimum standards

Wexham Park Hospital

HTA licensing number 12323

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**

26 November 2015

Summary of inspection findings

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

Although the HTA found that Wexham Park Hospital (the establishment) had met the majority of the HTA standards, one minor shortfall was found against the Consent standards in relation to lack of appropriate consent training and one minor shortfall was found against the Governance and Quality Systems (GQS) standards in relation to standard operating procedures. Advice has been given on matters across the range of 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

Wexham Park Hospital (the establishment) has been licensed by the HTA since September 2009. The establishment is licensed for the making of a post mortem (PM) examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

The establishment conducts approximately 450 adult PM examinations each year, the vast majority of which are under the authority of HM Coroner, Berkshire. Paediatric cases are transferred to other HTA-licensed establishments for PM examination. The establishment also carries out high-risk category 3 PM examinations.

Consent for adult hospital PM examinations is sought by clinicians, using the Trust's consent form and information leaflet. These take place very occasionally, with only two so far this year.

Consent for perinatal/paediatric PM examinations is sought by clinical staff, who have received training in the requirements of the Human Tissue Act 2004 (the HT Act). The consent form and information leaflet are based on those provided by the HTA-licensed establishment to which these cases are referred. Sampling of tissues from deceased children

in SUDI cases is performed in A&E department by a core team of staff, under pre-emptive coronial authorisation.

Wexham Park Hospital has joined the Surrey Pathology Services network and is now one of four hospitals within the Frimley Park NHS Foundation Trust since September 2014. At the time of the inspection, work was ongoing towards standardising mortuary procedures across the Trust.

Entrance to the mortuary is by swipe-card access. The body store contains 89 refrigerated spaces; five of these can accommodate bariatric bodies. In addition, there are nine fridge spaces in a Nutwell storage unit which is used routinely for body storage and eight permanent freezer spaces located in a separate secure area of the mortuary. There are 25 storage spaces in Heatherwood hospital, which acts as a contingency storage. There is no designated paediatric storage in the body store; instead they are stored within the adult fridges.

All refrigerators are connected to an automated temperature monitoring and call out alarm system. In the event of fridge failure, the automated system sets off a local alarm and alerts the hospital switch board. Fridge temperatures are recorded by mortuary staff every day for monitoring purposes.

The PM suite has three designated workstations, each with height-adjustable stands that hold the mortuary trays on which PM examinations are performed. There is one downdraft dissection bench. Tissue samples are placed in cassettes in the mortuary and transferred to the hospitals' histopathology department for examination. Whole organs are stored in a temperature-monitored fridge within a secured room near the PM suite prior to transfer to other establishments for specialist analysis. Samples for toxicological analysis are sent to other HTA-licensed establishments. With appropriate consent, PM tissue blocks and slides are stored for use for scheduled purposes. Records of PM samples are held on a series of paper forms and an electronic database.

The mortuary admits bodies from the hospital and the community. Body identification tags are placed on the wrists and ankles of the deceased when they are placed into storage. The establishment uses the mortuary register, a series of forms and the mortuary database to record the details of body admission, PM examination, transfer to another establishment for PM examination and release of bodies to funeral directors. Perinatal cases are labelled with the mother's name, hospital number or address, and a unique mortuary number.

The last HTA site visit inspection of Wexham Park hospital was in November 2012. This report describes the third, routine site visit inspection of the establishment. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted a visual inspection of the mortuary, PM suite, histopathology and A&E department, where licensed activities take place.

Audit trails were conducted on three bodies (two adult and one paediatric) in the refrigerators. Body location and identification details on the bodies were cross referenced with information from paper and computer records in the mortuary. No anomalies were found. In addition, audits of traceability records were conducted for tissue blocks taken from three PM cases, one of which included consent for tissue retention. No discrepancies were identified. Consent forms for one perinatal and one adult hospital PM examinations were also reviewed. No anomalies were identified.

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

Consent

Standard	Inspection findings	Level of shortfall
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	Clinical staff seek consent for hospital and paediatric PM examinations. There is no formal consent training in place to ensure that they have sufficient knowledge and understanding of the consent requirements of the HT Act to ensure that appropriate consent is obtained.	**Minor**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	Standard operating procedures (SOPs) do not cover all mortuary procedures. Some SOPs relating to mortuary activities detail out of date processes and many do not contain sufficient details of procedures. Particular examples include: • there is no SOP describing the arrangements for the set up and use of the temporary refrigerator unit; • the SOP governing the movement of bodies in the body store does not specify the timeframe in which bodies should be moved from refrigerated to freezer storage; • staff are not complying with establishments SOP on the storage of infants, which should be stored in a dedicated fridge location. The contract with funeral directors for moving bodies from the mortuary to other HTA licensed establishments for PM examination, and contingency storage at Heatherwood hospital expired in Jan 2015.	**Minor**

Advice

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

No.	Standard	Advice
1.	N/A	Further to the discussions held during the inspection, the DI is advised to identify Persons Designated (PD) to support him in overseeing licensed activities in the mortuary and the reporting of HTA Reportable Incidents (HTARIs) within five working days; they should then be registered on the portal to report HTARIs and the HTA informed of their names of the PDs.
2.	C1	The DI is advised to review the establishment's documented consent policy and procedure to provide clarity on who may give consent for a hospital PM examination, thereby ensuring that consent is given by the appropriate person in the hierarchy of qualifying relationships as set out in the HT Act.
3.	C1	The DI is advised to remind staff seeking consent for hospital PM examinations that they should date as well as sign the consent seeker section of the consent form. This may help to ensure that consent forms are completed in a consistent manner.
4.	C1	The hospital has developed policy on disposal of pregnancy remains based on the HTA guidelines. However, full range of options as suggested in the guidelines are not available to the women undergoing pregnancy loss or termination. For this, special consideration should be given whether the current hospital policy sufficiently covers all the disposal options provided to the women as advised in the HTA's guidance on the disposal of pregnancy remains.
5.	C3	The establishment is in the process of developing a training programme for staff seeking consent for hospital PM examinations. The DI is advised to ensure that all new staff with this responsibility complete the training and are assessed as competent prior to seeking consent for PM examination. The DI should also ensure that there is refresher consent training is provided at regular intervals.
6.	GQ1	The establishments' quality manual should be reviewed and standardised for the Frimley NHS Foundation Trust Hospital.
7.	GQ1	An annual governance meeting for the HTA licence is held. The DI is advised to have regular meetings with staff carrying out licensable activities at the establishment.
8.	GQ1	The DI is advised to update the establishment's SOP for carrying out PMs to include the current working practice of evisceration and the checkpoints when APTs will stop and ask the pathologist before continuing with the PM examination. The DI may also wish to risk assess the process.
9.	GQ6	The DI is advised to consider strengthening the existing systems for highlighting bodies of deceased with same or similar sounding names, or cases where tissues or organs need to be repatriated with the body prior to release to the funeral director. For example, coloured stickers on the body identification tag, the mortuary register and coloured magnets on storage fridges could be used.

10.	GQ8	The DI is advised that the HTARI reporting categories may be used as a starting point for identifying key risks. Further advice on mitigating the risks associated with undertaking licensed activities can be found in the HTA's 'Sharing learning: lessons learned from HTARIs in the PM sector': www.hta.gov.uk/sites/default/files/HTARI_Review_2012-13.pdf.
11.	PFE3	The fridge in maternity which is used to store products of conception (POCs) and babies born at less than 24 weeks is connected to a min max recorder. The fridge is set at 3-5 degrees Celsius; however, the recorder alarm range is set between -4.4 to 23 degrees Celsius. In the event of fridge failure this arrangement will fail to alarm locally and could lead to decomposition of samples stored. The DI is advised to ensure the temperature range is set in the working range of the fridge.
12.	PFE3	There is no dedicated paediatric storage, and the bodies of infants are stored alongside those of adults. This practice should be risk assessed.
13.	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 switchboard as expected and that alarm notifications are responded to appropriately. These checks and any resulting actions should be documented.
14.	PFE5	The DI is advised to visit the contingency body store at the Heatherwood hospital to ensure similar governance and quality systems are in place and the premises are fit for contingency storage.

Concluding comments

This report outlines the third HTA site visit inspection of Wexham Park Hospital. Despite the three shortfalls identified, areas of good practice were observed.

The DI and senior APT have a good working relationship with HM Coroner's Office, and there is regular contact between the Coroner, his officers and mortuary staff. The DI is working with the maternity department to develop new paediatric consent documentation in line with the SANDS and HTA consent guidelines.

The establishment has robust approach to carry out audits of mortuary procedures and practices, which are carried out regularly, and there is a system to assess the competency of mortuary staff to carry out day to day activities. The establishment's SOP for the disposal of tissue samples outlines the staff member responsible for carrying out each step, which acts as a reminder to all staff of their individual responsibilities in relation to disposal.

There are a number of areas of practice that require improvement, including three minor shortfalls. In addition, the HTA has given advice to DI on a range of issues, including consent procedures and training, governance documents and mortuary facilities.

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: 18 December 2015

Report returned from DI: 08 February 2016

Final report issued: 16 February 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: 09 December 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.

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: 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 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.