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**

6 November 2012

Summary of inspection findings

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

Although the HTA found that the Wexham Park Hospital (the establishment) had met the majority of the HTA standards, three minor shortfalls were found in relation to Governance and Quality. The shortfalls relate to a subset of the establishment's standard operating procedures (SOPs) which do not accurately reflect current working practices and to the requirement for risk assessments to be carried out in relation to all licensable activities. The DI is also required to complete HTA training as this is a standard condition of the licence.

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 Paragraph 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 by the Wexham Park Hospital, which has been licensed by the HTA since 2007. It describes the second routine site visit inspection of the establishment, which took place on 6 November 2012.

Wexham Park Hospital, Slough, was established in 1965 and is now part of the Heatherwood and Wexham Park Hospitals NHS Foundation Trust. The hospital performs approximately 450 post mortem (PM) examinations each year, the majority of which are carried out under the authority of H.M. Coroner for Berkshire. This includes a small number of forensic cases. The establishment also carries out a small number of consented, hospital PM examinations. In the twelve months leading up to the inspection, only two such PM examinations were performed. Although the establishment no longer has dedicated facilities for high risk PM examinations, these are also undertaken within the mortuary. Specific procedures are in place for these, which are scheduled to take place following completion of other PM examinations. Perinatal and paediatric PM examinations are not performed at the establishment and are transferred to other licensed premises.

The mortuary has refrigerated storage space for 75 bodies. A further five spaces are available for bodies in long term storage. Overflow storage for an additional twelve bodies is available on site and the hospital has access to 25 more spaces at the body store at the

Heatherwood Hospital in Ascot if this is needed. The PM examination suite has three examination tables and two dissection areas. The mortuary is currently staffed by three Anatomical Pathology Technologists (APTs), one of whom is the Chief APT. The majority of tissue samples taken during PM examination are sent to the Cellular Pathology Laboratory within the hospital where they are processed and stored. Samples taken for toxicological analysis, and certain tissue samples requiring specialist analysis, are sent to other licensed establishments under formal agreement.

The inspection included interviews with key members of staff working under the licence, including the Divisional Clinical Chair for Diagnostics, who is also the Designated Individual, the Chief APT, a Consultant Histopathologist, and the Pathology Quality, Health and Safety Manager. An interview was also conducted with a Coroner's Officer working for H.M. Coroner for Berkshire. A review of documentation relevant to the establishment's activities and a visual inspection of the premises were conducted as part of the inspection. In addition, an audit of bodies stored in the mortuary's fridges was undertaken. Two bodies were chosen at random from the mortuary register and details of the deceased were cross checked with the mortuary 'day sheet' and the identification tags on the bodies. No anomalies were found; identification details matched and the bodies were being stored in the assigned fridge spaces.

A tissue traceability audit was also carried out. Two cases were chosen at random from the mortuary register where it was indicated that tissue had been taken as part of the PM examination. Paper records of the tissue taken during the PM examination were cross-checked with the Cellular Pathology Laboratory's electronic database and with the number of blocks held in storage. Although a minor transcription error was noted in the mortuary register relating to the date of one of the PM examinations, this was readily resolved using associated records. In both cases, the number of blocks held in storage matched the electronic and paper records. Slides relating to these cases were not in the establishment's slide archive. However, staff indicated that the slides were still with the pathologist for review. As both cases were very recent, the HTA was satisfied that the whereabouts of the slides was known. The forms used by the Coroner to record the family's wishes for tissue retention or disposal/repatriation/return following the PM examination were also reviewed for each case. No anomalies were found.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	The establishment has in place a wide range of standard operating procedures (SOPs) covering the majority of the activities conducted under its licence. However, a number of these do not accurately reflect current practice within the mortuary such as the recording of information in the mortuary 'day sheet', the practice of recording the pre-evisceration discussions with the pathologist in the 'Identification / RA PM' book, and the use of personal protective equipment during PM examination.	**Minor**
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Although the establishment has conducted a number of risk assessments in relation to the work conducted under this licence, those relating to the work conducted in the Cellular Pathology Department focus primarily on the health and safety of staff involved in the work and do not address the risks to the samples themselves (e.g. through storage, distribution or disposal), whilst those conducted by the mortuary do not currently cover the full range of licensable activities undertaken (e.g. body storage and release). Risk assessments were not always assigned a unique reference number, in line with the establishment's approach to document control in other areas. Contrary to guidance on the risk assessment forms, the establishment had also not clearly defined acceptable risk levels or the risk levels that would necessitate implementation of additional control measures.	**Minor**

Standard	Inspection findings	Level of shortfall
N/A	At the time of the inspection, the DI had not completed HTA training (online or otherwise); it is a standard condition of the licence issued to the establishment that such training is to be completed to the HTA's satisfaction within a period of twelve months from the date of issue of the licence.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	Although communication between the Coroner's office and the establishment was found to be good, the DI is advised to officially nominate a member of staff to handle communication between the pathology department/mortuary and the Coroner's office with a view to ensuring that when relevant material is stored beyond the Coroner's authority for a scheduled purpose, consent to do so has been given by the appropriate person in the hierarchy of qualifying relationships.
2.	C3	The DI is advised to amend the wording of the SOP that deals with the taking of consent for hospital PM examinations (MMPC 59) to bring it in line with the HTA's Code of Practice on consent and the establishment's own consent policy which states that consent should be sought from the person ranked highest in the hierarchy of qualifying relationships if the wishes of the person in life are not known. References to 'next of kin' should be removed for clarity.
3.	GQ1	The DI is advised to review the information recorded in the 'Identification / RA PM book' to ensure that it accurately captures what activities, relevant to evisceration, have been authorised by the pathologist prior to his/her arrival in the mortuary. Signature logs within this record should also be checked on a regular basis to ensure they remain up to date.
4.	GQ4	The DI is advised that all staff should adhere to a consistent, accepted procedure for correcting errors in written records. Such an approach, which could include striking through errors with a single line and initialling and dating corrections, would facilitate audit. SOPs relating to the management of records should be updated accordingly.
5.	GQ8	The DI is advised to put in place an SOP for the completion, use and review of risk assessments to facilitate this process.
6.	PFE3	The establishment has put in place a number of contingency arrangements to deal with issues such as equipment failure or a lack of storage space within the mortuary. However, the DI is advised to document clear trigger points to ensure that all staff working under the licence are aware of when appropriate action needs to be taken.

Concluding comments

The HTA saw numerous examples of good practice during the course of the inspection.

The establishment has implemented a robust system of internal audits. This includes a clear schedule of audits which sets out to assess compliance against all relevant HTA standards. Audit findings are clearly documented and any non-conformances are assigned to a member of staff to be resolved. Actions arising from audits are reviewed on a regular basis to ensure timely completion.

Communication between members of staff working under the licence was found to be good. Staff meet regularly face-to-face and are supported in their roles by effective training and regular, well-documented meetings. Establishment staff also appear to work very effectively with representatives of the Coroner's office, thus helping to ensure that appropriate steps are taken when the Coroner's authority ends.

The establishment has also put in place effective incident management systems, including those relating to the handling of Serious Untoward Incidents (SUIs). All staff were aware of the HTA's reporting requirements and were actively looking for ways of improving working practices to avoid incidents happening in the first place. This was most clearly reflected in steps taken by the establishment recently to reduce the number of bodies being sent to the mortuary with incomplete identification.

Three areas of practice were identified during the course of the inspection that require improvement, resulting in minor shortfalls. These relate to the establishment's SOPs, a number of which do not accurately reflect current practices within the mortuary, and to the requirement for the establishment to conduct risk assessments in relation to all licensable activities, such as storage and release of bodies. The DI is also required to complete HTA training as set out in Annex B of the establishment's licence.

The HTA has given advice to the Designated Individual with respect to the content of several of the establishment's SOPs, specifically those relating to the consent process and contingency planning, and also the establishment's approach to the amendment of written records. Advice and guidance has also been given regarding the information that should be recorded in the 'Identification / RA PM' book. The HTA has also suggested that the establishment draw up an SOP relating to risk assessments to support staff members who are involved in writing and using such documents.

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: 29 November 2012

Report returned from DI: 11 December 2012

Final report issued: 13 December 2012

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: 26 March 2013

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 or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- 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.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

  (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

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.