Site visit inspection report on compliance with HTA minimum standards

St Mary's Hospital

HTA licensing number 12357

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**

24 July 2014

Summary of inspection findings

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

The HTA found that St Mary's Hospital, Isle of Wight (the establishment), had met all the HTA standards. The HTA has given advice relating to the standards in the advice section of this report. Good practice identified during the inspection is given in the concluding section of this 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

St Mary's Hospital, Isle of Wight, is licensed to carry out PM examinations and the removal and storage of post mortem (PM) tissue for use for scheduled purposes under the HT Act. The corporate licence holder is the Isle of Wight NHS Trust and the corporate licence holder contact is the Medical Director. The hospital serves a population of around 140,000, which can increase to over 200,000 during the summer holiday period.

The establishment undertakes around 400 PM examinations each year. They include adult PM inspections, which are undertaken on behalf of the Coroner for Isle of Wight, and forensic PM examinations. Adult consented PM examinations are conducted infrequently, the last one having taken place two years ago. The establishment does not undertake perinatal or paediatric PM examinations; these cases are sent to other HTA-licensed establishments.

The mortuary is staffed by two senior Anatomical Pathology Technologists (APTs) and one trainee APT. On occasion, depending on staffing needs, visiting pathologists and locum APTs attend the mortuary. Trained mortuary and nursing staff retrieve eyes for human application on behalf of other HTA-licensed establishments.

The mortuary has capacity for 75 bodies, including six bariatric spaces; there is an additional refrigerated room with 16 spaces, which can also be used to hold a bed if a bariatric patient who is not able to fit onto a fridge tray, is admitted to the mortuary. There are four freezer spaces and an isolation fridge. There is a separate fridge for storing still births and non-viable fetuses.

In 2013, the mortuary received funding and upgraded many of the fridges. The mortuary uses a proprietary temperature monitoring service for fridges and freezers which is linked to local alarms and to the central switchboard. The alarms for the fridges are activated in the event of deviation of normal operating temperature ($3^{o}C$ - $8^{o}C$) for more than 30 minutes. High risk PM examinations are undertaken in an area within the PM room which can be isolated using a sliding partition. Staff are trained to handle high risk cases and are provided with appropriate protective equipment.

There is secure access to the mortuary and CCTV cameras monitor all entrances. CCTV images are kept for 28 days. A laminated card, 'Model rules for visitors', which states how visitors are to conduct themselves whilst in the mortuary, is displayed near the entrance.

Porters bring bodies from hospital wards; they also provide out of hours access to Funeral Directors who bring bodies from the community. Porters and Funeral Directors complete a 'brought in dead' form when delivering bodies out of hours. APTs check bodies each morning and assign a mortuary number to each one received during the night. The establishment uses three points of identification for all checks: NHS/hospital identity number, name and date of birth or address. A whiteboard is used to record the names of the deceased and storage location. Same or similar names are highlighted in the mortuary register.

On call APTs release bodies if they are to be released out of hours. APTs provide annual training to porters. Viewings are usually undertaken only during working hours.

The coroner's officer faxes authorisation for a PM examination to the mortuary. The pathologist and the APT independently check the identity of the deceased before external examination and evisceration take place. The pathologist is responsible for ensuring that all tissues and organs removed are noted on the 'Tissues retained following a coroner's Post-Mortem examination' form. The APTs record tissues and organs removed from the deceased in the 'mortuary specimen register'. Once tissues are taken to the histopathology laboratory, details of the tissues, including blocks and slides, are entered in a database which is used to track them. The Coroner's officer provides the Minstry of Justice's 'A guide to coroners and inquest' booklet to families, which contains information on PM examinations and explains why tissue may be removed during a PM examination. The coroner's officer obtains the wishes of the next of kin and informs the laboratory. The laboratory usually disposes of tissue within three months, once they are informed that the coroner's authority has ended.

Senior APTs, senior midwives and named consultants have received training in seeking consent for PM examinations. In cases of pregnancy loss, parents are asked for their wishes with regard to the disposal of pregnancy remains. The remains are kept for six weeks in the event that the parents change their minds. When the remains are to be disposed of, they are removed from each tissue pot and packed together in a pouch which is sealed, ready to be collected by the Funeral Director (see advice item 3 below). The establishment conducts a 'born too soon' service three times a year, when pregnancy remains are buried.

St Mary's Hospital has a designated member of staff who ensures that tissues and organs which are removed during a PM examination are tracked and disposed of, or retained, in accordance with the wishes of the next of kin. There are procedures in place to ensure that all blocks and slides are accounted for; tissues, organs or slides which are sent away, including slides issued to pathologists, are recorded in an 'away file' database.

There is a dedicated bereavement suite near the labour ward for mothers who have had terminations or lost their babies. Viewings of babies take place in the suite and the babies are brought up to the ward and kept in a cold cot. Following a recent CQC inspection, deceased babies and young children are brought into the A&E department instead of the paediatric wards. This is because the paediatric ward is not staffed at all times of the day.

A site visit inspection of St Mary's Hospital was undertaken on 24 July 2014. This was the second inspection of the establishment and included interviews with the Clinical Lead for Histopathology (also the DI), a Coroner's Officer, Quality Management Administrator, Lead APT and Trainee APT.

A document review was carried out. The documents reviewed included standard operating procedures (SOPs) relating to PM examinations, receipt and release of bodies, seeking consent, and receipt and release of fetal tissue; as well as policies, the mortuary register, meeting minutes, paper and computer records of tissues removed during PM examinations, disposal records, records of incident reports and investigations, audit records and training records.

An audit trail was undertaken of two bodies stored in the mortuary. Details in the mortuary register and on the whiteboard were cross-checked and the storage location and identity tags in each case were also checked; no discrepancies were noted. In addition, computer database records and paper records relating to a coroner's PM examination and a consented adult PM examination, were traced from the mortuary register to written and computer records of stored blocks or disposal records, as appropriate. The number of blocks relating to each case was checked against the records. The consent form completed for one adult consented PM examination was also reviewed. There were no discrepancies.

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

All applicable HTA were assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to include references to the Trust's 'Consent Policy for removal, storage and use of human organs and tissue for scheduled purposes' in the mortuary SOP for Consent (MOR-LP-consent).
2.	GQ1	The mortuary recently implemented a system whereby visiting professionals, including pathologists, APTs and staff who retrieve tissues for transplantation, sign a declaration ('Self Declaration for visiting Practitioners') which states that they will abide by HTA regulations, HTA codes of Practice, appropriate Health and Safety requirements and follow instructions issued by appropriately authorised hospital staff. The DI is advised to consider introducing a check list for staff to use which covers key information which has to be conveyed when briefing visiting professionals, who may attend at short notice, about mortuary practices. The DI is advised to review and update SOPs to use the term 'HTARI' in place of SUI, to reflect the change to the terminology made by the HTA.
3.	PFE2	The DI is advised to consider implementing an annual schedule for monitoring airflow and air change rates in the PM room. The airflow monitoring should take into consideration the reconfiguration of the PM room when high risk PM examinations are undertaken.
4.	D1	The DI is advised to ensure that tissues from each pregnancy loss are placed in individual packages before they are grouped together and placed in a pouch for

		collection by the contracted Funeral Director.

Concluding comments

There is good communication between the DI, pathologists, Cell Path Head of Department, Quality Management Administrator, APTs and the coroner's officers. Key members of staff in each area of activity, including the mortuary, histopathology laboratory, maternity and paediatrics, have been appointed as persons designated under the HTA licence. Regular management meetings take place which cover the mortuary and histopathology.

There were several examples of good practice. The Quality Management Administrator has excellent links with the Coroner's office and ensures that the wishes of the next of kin are obtained; the administrator is responsible for managing the disposal or retention of tissues and slides in accordance with the wishes of the next of kin. The Coroner's office is informed before disposal takes place to provide a second chance for the Coroners office to review the status of the case before all tissues relating to the case are disposed of by the hospital. There are a wide range of SOPs, including an SOP which covers the responsibilities of staff including persons designated, when the DI is absent, and steps to take in the event of long term absence of the DI.

There is a comprehensive training programme for porters and annual refresher training; the training programme is documented in an SOP and includes a checklist to ensure that all relevant topics are covered. APTs are kept upto date and recently attended training in seeking consent, which was delivered by the AAPT in conjunction with the HTA. All external professionals who provide services to the mortuary have to sign a self declaration which states that they will abide by HTA regulations, HTA codes of Practice, appropriate Health and Safety requirements and follow instructions issued by staff at St Mary's hospital.

There are robust systems in place to track bodies and tissues. The transfer of babies who are transferred to the bereavement suite in maternity for viewing are tracked using a 'baby tracking' form. Tissues are tracked using several spread sheets including a 'mortuary away file' which records the transfer and return of tissues and organs. The establishment uses 'mortuary error forms' to record incidents which are followed up, and appropriate corrective actions are put in place. The audit calendar includes audits of processes, including PM examination, reconstruction of bodies, receipt and release of bodies, viewings, and sample management. As the mortuary is inspected by the CPA and the HTA, each audit is designed to cover Clinical Pathology Accreditation (CPA) standards and HTA standards.

The HTA has given advice to the Designated Individual with respect to SOPs, visiting professionals, monitoring air change rates in the PM room and disposal of pregnancy remains. The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 19 August 2014

Report returned from DI: 2 September 2014

Final report issued: 5 September 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.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.

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.