Site visit inspection report on compliance with HTA minimum standards

Tunbridge Wells Hospital at Pembury

HTA licensing number 12616

Licensed under the Human Tissue Act 2004 for the

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

20 - 21 January 2015

Summary of inspection findings

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

The HTA found that Tunbridge Wells Hospital at Pembury (the establishment) had met the majority of the HTA standards. Minor shortfalls were found in relation to standard operating procedures and documented risk assessments for licensable activities.

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 (DI) are set out 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

Tunbridge Wells Hospital is part of Maidstone and Tunbridge Wells NHS Trust, which previously held an HTA post mortem (PM) sector licence (licensing number 12211, granted in August 2007). This was revoked at the Trust's request in September 2011, as licensable activities there had ceased. From that time until early 2014, all cases for PM examination were transferred to other HTA-licensed premises within seven days of the person's death, thereby providing an exemption from the licensing requirements of the Human Tissue Act 2004. In April 2014, Tunbridge Wells Hospital at Pembury was granted an HTA licence, as PM examination activity was to commence again. This HTA licences cover Tunbridge Well Hospital at Pembury (the hub) and Maidstone Hospital (the satellite).

The mortuary at Tunbridge Wells Hospital at Pembury admits bodies from the hospital and the community. Up to 35 adult PM examinations each month have been carried out since its licence was granted and, to date, all were performed under the authority of HM Coroner for North West Kent, including one forensic case. No adult hospital (consented) PM cases have taken place to date. Perinatal and paediatric cases, and high risk cases, are transferred to other HTA-licensed establishments, although consent is sought by staff at Tunbridge Wells Hospital.

Maidstone Hospital is licensed as a satellite of Tunbridge Wells Hospital at Pembury. The mortuary at this site receives bodies from this hospital only, and cases are transferred for PM examination at other HTA-licensed establishments. Paraffin wax embedded blocks and microscope slides of PM tissue, for which there is consent for retention for use for scheduled purposes, are transferred to this site and stored in the hospital's Cellular Pathology department.

The establishment has adapted for its local use the perinatal and paediatric PM consent documentation produced by the Stillbirth and Neonatal Death Charity (Sands) and HTA's model consent form for adult hospital cases. Consent for perinatal PM examinations is sought by midwives and consultants in the Obstetrics and Gynaecology department (refer to advice item 1). Only those clinicians who complete the Trust's online consent training are permitted to seek consent for adult hospital PM examination.

The mortuary at Tunbridge Wells Hospital at Pembury has 68 fridge spaces for adult bodies, including eight spaces for bariatric patients. A designated bank of fridges (eight spaces) can operate in freezer mode should bodies require longer-term storage. There is a separate refrigerator for perinatal cases. Maidstone Hospital mortuary has 48 fridge spaces for adult bodies, including eight bariatric spaces, with a separate refrigerator for perinatal cases (refer to advice item 9). Maintenance of premises and equipment is overseen by a private contractor which operates Trust-wide.

The establishment uses a series of 'pathway' documents to record details of body admission, release to a funeral director and the PM examination process (refer to advice items 2 and 4). Bodies at each site are assigned a mortuary admission number (refer to advice item 5). The PM suite at Tunbridge Hospital has two downdraft tables. Wet tissues taken at PM examination for histopathological analysis are placed into cassettes in the mortuary and are transferred to the Cellular Pathology department at Maidstone Hospital. Fluids for toxicological analysis and organs for specialist examination are sent to other HTA-licensed premises. PM samples are tracked internally by the mortuary admission number.

The Cellular Pathology department at Maidstone Hospital has full United Kingdom Accreditation Service (UKAS) accreditation. A proprietary quality management software system is used.

This report describes the first, routine, site visit inspection of the establishment in January 2015. The inspectors interviewed staff involved with licensable activities, reviewed documentation and carried out visual inspections at the hub and satellite sites. An audit of identifiers and storage locations for three adult bodies (two at the hub, one at the satellite) revealed one anomaly; the spelling of the deceased's surname on the wrist tag applied to their body at the place of death did not match exactly that on associated paperwork. Mortuary staff were aware of the anomaly, and had already corrected some records to reflect this. The inspectors observed the establishment's staff make further amendments to local records about details of the person. A further three adult cases subject to a coronial PM examination where tissues were taken for histopathological analysis were audited from records of PM examination to compliance with families' instructions for retained tissues. In two cases, full traceability was readily verified. For the third case, one wax block could not immediately be located in the storage area, but was quickly found following a search of the laboratory.

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.	Standard operating procedures (SOPs) that were in place when the establishment was licensed previously have been updated to reflect current practices. However, further work is required to ensure there is an appropriate level of detail and embodiment of current practices. Examples include: • the SOP for admission and release of bodies does not describe current mortuary procedures, including acceptance of bodies from the community, or the re-licensing of this establishment; • the SOPs for coronial and hospital PM examinations set out which identification points a pathologist must use to confirm a deceased person's identity prior to evisceration, but do not specify which identification points an anatomical pathology technologist must use when removing a deceased person from fridges prior to that, or describe any actions to take if a discrepancy in identification details is identified. These SOPs also do not refer to use of the 'Post mortem pathway checklist'; • the SOP for high risk cases states that HM Coroner can authorise taking of blood samples from a deceased person, outwith of any PM examination, to determine possible infection. As the HTA was informed that such sampling does not occur, this statement should be removed from the SOP. This is not an exhaustive list of the amendments required to SOPs, and to fully address this shortfall, the establishment should review all SOPs relating to the conduct of licensed activities. *(Refer to advice item 2)*	**Minor**

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Some documented risk assessments, such as security of the hub and satellite premises, consider a wide range of potential risks to practice and premises and set out clearly the risk mitigating measures in place. However, several other documented risk assessments are limited in their scope to health and safety considerations. Also some key risks, such as traceability of deceased persons and of tissues and organs, do not appear to have been formally assessed. *(Refer to advice item 7)*	**Minor**

Advice

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

No.	Standard	Advice
1.	C3	The DI is advised to implement his proposals for refresher consent training for staff who seek consent for perinatal and paediatric PM examinations.
2.	GQ1	Regarding SOPs, the DI is advised that: • an SOP for tissue retrieval for human application or research should include, for example: who confirms the identity of the retrieval team, reviews consent documentation and ensures the correct body is removed from storage; how retrieval is recorded in the mortuary, and; what actions to take if the correct procedure is not adhered to; • any differences in process or record keeping between routine coronial and forensic PM examinations should be described in relevant SOPs. In particular, how tissues or organs taken for coronial purposes, and those seized under police powers, are to be recorded on the 'Post mortem pathway checklist' should be explained; • all SOPs should be reviewed to ensure that hyperlinks re-direct the reader to the correct documents.
3.	GQ4	The DI is advised to ensure that staff adopt a consistent approach to correcting errors in traceability records such as mortuary registers. For example, errors may be struck through with a single line, and the initials of the person making the correction, and the date it was made, written beside it.
4.	GQ4	The DI is advised to add new boxes to the top of the 'Post mortem pathway checklist' to record whether a PM examination is a coronial or consented case and whether it is full or limited in extent. Recording such information will reassure the DI that such checks have been carried out and any risk of a PM examination being conducted without appropriate consent or authorisation are appropriately mitigated.

5.	GQ6	Regarding traceability systems, the DI is advised that: • existing systems for highlighting deceased persons 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, could be strengthened by, for example, placing a laminated card bearing such information on the shrouding of the deceased, or application of an additional wrist tag with this information; • prefixing the mortuary admission number with a letter to denote at which site a deceased person was admitted would help mitigate any potential risk to traceability if a body is moved between the hub and satellite sites; • the potential risk of organs being inadvertently returned to the wrong body following PM examination could be reduced by, for example, colour coding PM tables and organ bowls.
6.	GQ7	The DI is advised to place signage in the mortuary to raise awareness amongst all staff working there of the importance of reporting any incident, or near miss, through internal systems and, where applicable, to the HTA.
7.	GQ8	The DI is advised to use the HTARI categories as a starting point for identifying key risks to assess. Documented risk assessments should set out the existing control measures, further steps which may be taken to mitigate risks and, where such steps are identified, deadlines for completion.
8.	PFE1	The DI is advised to periodically review contingency plans in the event of pressures on body storage capacity or interruption of PM examination activity, and to contact the HTA of any issues which could impact on service delivery. The HTA has published guidance on this: https://beta.hta.gov.uk/policies/contingency-arrangements-mortuaries-during-busy-periods
9.	PFE3	The DI is advised to consider: • whether the upper temperature limit for the alarm setting when a fridge is switched to freezer mode (+15 ^{o}C) can be adjusted downwards; • superintendence of the stand-alone refrigerated unit for perinatal cases at the satellite site which is not currently in use, the DI should ensure that if it is to be used in the future, its temperature monitoring and alarm arrangements are robust.

Concluding comments

Despite the minor shortfalls, areas of strength were identified. Staff work well together as a team, and their efforts have been recognised by the Trust through a recent award. Consent documentation is clear. Key elements of a robust governance and quality management framework are in place, and staff are committed to continual quality improvement. Premises are appropriately monitored and maintained. Mortuary staff have a good working relationship with the company overseeing maintenance of the mortuary premises and equipment.

A number of areas of practice require improvement, including two minor shortfalls. The HTA has given advice to the DI with respect to consent, quality management and traceability systems, and body storage.

The HTA requires that the DI 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: 14 February 2015

Report returned from DI: 06 March 2015

Final report issued: 06 March 2015

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: 2 July 2015

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 thatneed 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).

PFE2 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.

PFE4 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.