Site visit inspection report on compliance with HTA minimum standards

Mid Essex Hospitals NHS Trust

HTA licensing number 12441

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**

27 November 2013

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. Although the HTA found that Mid Essex Hospitals NHS Trust (the establishment) had met the majority of the HTA standards, a minor shortfall was found in relation to the system for reporting incidents or near misses to the HTA.

This inspection provided an opportunity to verify that the establishment has implemented corrective and preventative actions identified during the previous HTA inspection. Examples of strengths and good practice are included in the concluding comments section of the report. Advice and guidance is provided in areas where the HTA identified opportunities for improving existing systems and procedures.

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

The inspection covered licensable activities taking place at Broomfield Hospital, Department of Histopathology, which includes the services provided by the Mortuary. Approximately 675 post mortem (PM) examinations are undertaken at the establishment each year. The vast majority are under the authority of HM Senior Coroner for Essex. PM examinations are conducted by one of six in-house consultant histopathologists or one of two independent pathologists nominated by the Coroner. The establishment also undertakes occasional adult consented PM examinations. Paediatric PM examinations are referred to another HTA-licensed mortuary. The establishment follows guidance issued by the Royal College of Pathologists when assessing high risk PM examinations.

The Department of Histopthology is fully accredited under the UK Clinical Pathology Accreditation (CPA) scheme. The last CPA inspection took place during August 2013.

This was the establishment's second routine HTA site-visit inspection. The timetable for this inspection was developed with due consideration of the establishment's licensing history, the outcome of the previous inspection and pre-inspection discussion with the Designated Individual (DI). The HTA conducted a review of the premises, discussed licensable activities with members of staff involved in licensable activities and reviewed relevant standard

operating procedures (SOPs), documents, registers and databases. Interviews were conducted with the DI, the histopathology laboratory lead scientist, an anatomical pathology technologist and two members of the Trust's Governance and Quality team, whose role includes oversight of the Department of Histopathology.

The HTA also conducted traceability audits of stored bodies, tissues, samples and related records. A horizontal audit was carried out to verify details held within the mortuary register and database against related body storage and identification labels. There were no anomalies. A vertical audit was carried out of three cases where tissue had been removed at PM examination for processing and examination within the histopathology department. Two of these cases were PM examinations carried out under the authority of the Coroner. The other was a hospital consented PM examination. The audit exercise for this case included a review of the establishment's procedures for obtaining consent in accordance with HTA consent standards and codes of practice. All tissue was fuly traceable with no anomalies.

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
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	Since last inspection, the HTA Reportable Incidents (HTARI) system has been implemented across the post mortem sector. Whilst the establishment has a standard operating procedure relating to HTARIs and dealt with these incidents through its internal incident reporting system, three incidents were identified during the inspection that should have been reported to the HTA, either as reportable incidents or near misses. The DI should report these retrospectively to the HTA. From 1 April 2013, notifications must be made using the HTARI form on the HTA web portal. Guidance for reporting HTARIs through the HTA web portal is provided via the link to the HTA website below: http://www.hta.gov.uk/_db/_documents/Guidance_for_reporting_HTARIs.pdf Advice is also offered against this standard (please refer to advice item number 5).	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	The DI is advised to develop and implement a system for documenting that a new or revised standard operating procedure (SOP) has been read and understood by those members of staff to which it applies.

		This could be an acknowledgement either, for example, by email or by a signed or initialled record within an individual's training file.
2.	GQ1	The DI is advised to remind members of staff not to use liquid correction fluid to make amendments within the mortuary register, as it obscures the original record.
3.	GQ2 & D1	The DI is advised to extend the audit of disposal of clinical waste to assure himself that the security arrangments applied to clinical waste bins whilst held by the histopathology department extend to the hospital waste compound.
4.	GQ3	Whilst the Head Porter routinely includes an introduction to the mortuary as part of the induction programme for new members of portering staff, the DI is advised to include a briefing from a senior member of the mortuary team as a mandatory part of the new porter induction programme.
5.	GQ7	The DI is advised to use the HTA Reportable Incidents (HTARIs) system more proactively in order to monitor and manage risk. This should include, but may not be limited to: • Including HTARIs in the programme of training for porters; for example, the need to document and report accidental damage to a body; • conducting audits linked to the ten HTARI categories; • conducting risk assessments linked to the ten HTARI categories; • capturing HTARIs within the rolling agenda items for routine governance meetings.
6.	PFE3	The DI is advised to link the local alarm system for both the fridge units and the freezer units within the mortuary to either the hospital central communications switchboard or the duty mobile phone, in order to provide better cover for breakdown or malfunction out of standard working hours. This will ensure that any alarms are proactively dealt with by a member of the histopathology department and reduce the reliance on notification by members of staff from other departments.
7.	PFE3	The DI is advised to check the threshold temperature at which the mortuary fridge units and freezer units are set to alarm to ensure that the set points are appropriate. The DI relies on the service and maintenance contractor to test the alarms during planned preventative maintenance visits but has not verified set points.

Concluding comments

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

The DI demonstrates a good understanding of regulatory requirements. The inspection identified a number of areas of licensable activity where the DI has influenced and promoted good practice. There is evidence of good teamwork across members of staff involved in licensable activities and a strong commitment to quality and the identification of opportunities for continuous improvement. This is supported by a sound system of governance and oversight.

The inspection provided an opportunity to verify corrective actions that were taken as a result of the previous HTA inspection. The establishment's approach has been comprehensive and has included actions taken in response to items of HTA advice. Storage capacity within the mortuary has been increased with the addition of ten body storage locations. In addition, the establishment has improved existing systems and ways of working. For example, the mortuary has developed its use of information management systems to provide an electronic database containing details of the deceased and all post mortem examinations. This not only provides a secure back up to existing registers but also provides a means for rapid interrogation of data when any questions regarding post mortem cases arise or during audit.

Since last HTA inspection the mortuary has introduced the use of coloured magnetic discs to flag:

- same or similar name;
- an implant device;
- danger of infection and
- embargo on release of a body from the mortuary.

The establishment has found these fridge or board magnets to be an effective method of reinforcing existing procedures that are focussed on risk mitigation.

There is one area of practice that requires improvement and is reported above as a minor shortfall against HTA standard GQ7. This is in relation to the system for reporting incidents or near misses to the HTA through the HTA Reportable Incidents system. The HTA requires that the DI addresses the shortfall 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.

Advice has been provided to the DI where the HTA identified opportunities for improvement to existing systems and procedures.

Report sent to DI for factual accuracy: **27 January 2014**

Report returned from DI: **10 February 2014**

Final report issued: **10 February 2014**

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: 20 October 2015

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

GQ4 There is a systematic and planned approach to the management of records

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.

- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

(Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
    - fridges / Freezers
    - hydraulic trolleys
    - post mortem tables
    - hoists
    - saws (manual and/or oscillating)
    - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.