Site visit inspection report on compliance with HTA minimum standards

Basildon Hospital

HTA licensing number 12051

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**

5 March 2014

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 Basildon Hospital (the establishment) had met the majority of the HTA standards, minor shortfalls were found in relation to the patient information leaflet for adult hospital PM examinations, and the procedures for reporting HTA Reportable Incidents (HTARIs). The minor shortfall relating to patient information was addressed by the establishment to the HTA's satisfaction before the final report was issued.

The inspectors also took the opportunity to assess the suitability of the person who is to be nominated as the new Designated Individual.

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 (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

Approximately 800 adult post mortem (PM) examinations are carried out each year in the mortuary at Basildon Hospital (the establishment). This total includes high risk (up to Category 3) and forensic cases. Perinatal and paediatric cases are transferred to another HTA-licensed establishment for PM examination, although consent for these is sought by establishment staff using the Stillbirth and Neonatal Deaths (SANDs) consent form and information leaflet for parents. Most adult PM examinations are performed under the authority of HM Coroner for Essex. There are very few adult hospital (consented) PM cases and the establishment has adapted the HTA's model consent form for adult hospital PM examinations.

The establishment has been licensed by the HTA since March 2007. One previous routine site visit inspection took place in March 2011. This report describes the second routine site visit inspection of the establishment in March 2014. The inspectors interviewed staff involved with licensable activities, reviewed documentation, and carried out a visual inspection of the mortuary and pathology laboratory. Procedures for consenting for perinatal PM examinations, and traceability systems for fetal specimens and products of conception, were also reviewed. An audit of identifiers and storage locations of two adult bodies in the mortuary found no anomalies. Records of a further three adult cases which were subject to a PM examination (one consented and two coronial), where tissues were taken for histopathological analysis, were audited from admission of the body to the mortuary through to compliance with the family's wishes for the retained tissue. No anomalies were found.

The establishment intends to replace the current DI with a person holding a more senior position within the Trust, to enable better oversight of activities taking place under the licence in different areas of the hospital. The inspectors discussed with the proposed DI how she intends to oversee activities taking place under the licence and gave advice on this. The inspectors also reviewed evidence to confirm how a minor shortfall against licensing standard D2 identified at the previous inspection had been addressed.

Inspection findings

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

Compliance with HTA standards

Consent

Standard	Inspection findings	Level of shortfall
C2 Information about the consent process is provided and in a variety of formats.	The establishment uses the obsolete Department of Health information leaflet 'A simple guide to the post mortem examination procedure'. This leaflet pre-dates the Human Tissue Act 2004 (the Act), and states that PM tissue blocks and slides will be retained as part of the deceased person's medical record. The HTA considers PM tissue blocks and slides stored as part of the medical record to be stored for potential use for a scheduled purpose. Therefore, consent is required in accordance with Section 3 of the Act and the HTA's Code of practice 1 on Consent. *The establishment submitted an updated patient leaflet which has recently been introduced. It incorporates all of the information from the HTA's 'Post mortem examination – your choices about organs and tissue' leaflet, to address this shortfall, prior to the issue of the final report. The HTA has assessed this information as satisfactory to address the shortfall.* *(Refer to advice item 2)*	**Minor**

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.	The Trust 'Policy for the Management of Incidents and Serious Incidents' (CO/PO/000142) sets out the requirement to report HTA Reportable Incidents (HTARIs), and states which staff can do so. This document does not, however, list the HTARI reporting categories, and has an out of date link to the HTA website. *(Refer to advice item 8)*	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to explore with HM Coroner whether the tissue disposal form used by Coroner's Officers could record the relationship of the 'properly interested person' to the deceased. This will reassure the DI that appropriate consent has been given for retention of PM tissue for a scheduled purpose.
2.	C2	The DI is advised that a model information leaflet for families of the deceased about adult PM examinations is available on the HTA website: http://hta.gov.uk/_db/_documents/Post-mortem_examination_-_your_choices_about_organs_and_tissue_FINAL_v3_0_201201255642.pdf
3.	C3	The Association of Anatomical Pathology Technology (AAPT) runs a training day on consent each year. The DI is advised to encourage staff who may seek consent for an adult hospital PM examination to attend such events to gain refresher training on the Act's consent provisions.
4.	GQ1	The DI is advised to amend the following standard operating procedures (SOPs): • The 'Procedure for carrying out autopsy examinations by APTs' (CELLP-CP44) refers to performing paediatric PM examinations. These are not carried out at this establishment. • The 'Procedure for the disposal of retained organs, blocks, slides and wet tissue reserves' (CELLP-LP102) has recently been revised and now states, incorrectly, that the HTA no longer requires slides to be disposed of. This appears to be a misunderstanding of the HTA's position, described in the February 2013 e-newsletter, that establishments are not required to record the disposal details of every slide.
5.	GQ2	The DI is advised to incorporate audits of mortuary procedures and systems into the audit calendar. For example, audits of bodies in fridges against the mortuary register, and audit of compliance with body release procedures might be considered.

6.	GQ3, GQ7	The establishment has introduced competence-based training for porters, and there are clear written instructions for porters that are available in the mortuary. To supplement this good practice, the DI is advised to instruct porters on what an HTARI is, and what to do should a HTARI (or a near miss) occur.
7.	GQ6	Yellow adhesive labels are placed in the mortuary register and on the body shroud to highlight any deceased persons who have the same or similar sounding, names. The DI is advised to consider extending this good practice by applying such labels to a second wrist tag on the body, so this visual cue remains when a body is unshrouded.
8.	GQ7	The DI is advised that a guidance document on HTARIs is available at: http://hta.gov.uk/_db/_documents/Guidance_for_reporting_HTARIs.pdf
9.	GQ8	The DI is advised that the HTARI reporting categories may be used as a basis for expanding the suite of documented mortuary risk assessments.
10.	PFE1	Temporary racking has been installed in the mortuary as a contingency, should high numbers of bodies require storage at busy times of the year. However, the racking may be used on a regular, prolonged, basis as delays in collection of bodies by funeral directors can sometimes occur. While the racking is adequately maintained and monitored, it is not a suitable long term substitute for dedicated mortuary fridges. The DI is advised to consider putting a business case to the Trust for additional, permanent, mortuary body fridges.
11.	PFE4	The DI is advised to consider erecting fencing around the rear entrance to the mortuary to prevent sight of bodies being delivered to, or released from, the mortuary.
12.	-	The Trust intends to replace the current DI with a person holding a senior position within the Trust, so they can better oversee activities taking place under the licence in different areas of the hospital. This person is well placed to effect necessary changes and improvements, and was very open and receptive to advice given at the inspection. However, their remoteness in the organisational structure from staff working under the licence could, potentially, impact on their ability to fulfil their responsibility under Section 18 of the Act to ensure the suitability of persons and practices under the licence, and that the conditions of the licence are complied with. To mitigate any such impact, the HTA advises the establishment to ensure: • there is a suitable handover period from the current DI to the proposed DI, to enable the latter to understand the role and responsibilities of the DI; • suitable Persons Designated (PDs) are nominated in all areas of the Trust where activities take place under the HTA licence; • the proposed DI has regular communication with all PDs to keep abreast of activities taking place under the licence and, in particular, can be notified promptly in the event of a HTARI or other incident;

Concluding comments

Despite the minor shortfall, some areas of strength were identified. SOPs for mortuary procedures are clear and well written. There is competence-based training for porters on procedures such as admission of bodies and managing requests for viewings, and competence-based training for funeral directors is soon to be rolled out. The ‘huddle board’ in

the mortuary has up-to-date information on activities taking place there. Tissue traceability systems are robust. Premises are well-maintained and, overall, to a good standard. The establishment responded proactively to advice given at this inspection, and has submitted revised documents as evidence in some cases, further demonstrating its commitment to continuous improvement.

There are a number of areas of practice that require improvement, including one minor shortfall. The HTA has given advice to the DI with respect to several standards. Advice has also been given on ensuring the proposed DI retains adequate oversight of licensable activities.

The HTA requires that the Designated Individual 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.

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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 31 March 2014

Report returned from DI: 02 April 2014

Final report issued: 04 April 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: 1 July 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.