**Site visit inspection report on compliance with HTA minimum standards**

**Manor Hospital**

**HTA licensing number 12102**

**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**

**25 March 2014**

## Summary of inspection findings

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

Although the HTA found that Manor Hospital (the establishment) had met the majority of the HTA standards, two minor shortfalls were found in relation to governance and quality systems and disposal. The shortfalls relate to the establishment's approach to internal audit and the need for its disposal policy to include clear guidance on the disposal of tissue retained during consented, hospital post mortem examinations.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

## The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in 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

This report refers to the activities carried out by Manor Hospital, part of the Walsall Healthcare NHS Trust, which has been licensed by the HTA since August 2007. It describes the second routine site visit inspection of the establishment, which took place on 25 March 2014.

Manor Hospital performs approximately 250 post mortem (PM) examinations each year, the majority of which are carried out under the authority of H.M. Coroner for The Black Country. The establishment also carries out a small number of consented hospital PM examinations. In the 12 months leading up to the inspection, only five of these took place. Perinatal and paediatric PM examinations are not performed at the establishment and are transferred to other licensed premises.

The principal body store has space for 69 bodies, including six spaces for bariatric bodies and three spaces for bodies in long term, frozen storage. The mortuary has space for a further eight bodies in a separate dedicated cold room, and overflow storage for an additional 36 bodies in an adjacent building on site. All fridges and freezers in these areas are temperature controlled and alarmed. The PM examination suite has three examination tables with associated dissection areas.

The mortuary is currently staffed by two Anatomical Pathology Technologists (APTs), one permanent and one locum. At the time of the inspection, the establishment was in the process of recruiting another permanent APT.

Tissue samples taken during PM examination are sent to the Pathology Laboratory within the hospital, where they are processed and stored prior to disposal or retention in accordance with the family's wishes.

The inspection included interviews with key members of staff working under the licence, including: the Designated Individual, who is a Consultant Histopathologist; the permanent APT; and the Head Biomedical Scientist. An interview was also conducted with a Coroner's Officer working for H.M. Coroner for The Black Country. A review of documentation relevant to the establishment's activities and a visual inspection of the premises were conducted as part of the inspection. In addition, an audit of bodies stored in the mortuary's fridges was undertaken. Three bodies were chosen from the mortuary register and details of the deceased were cross checked with the information contained on the mortuary white board and the identification tags on the bodies. Although no significant anomalies were found, a minor inconsistency relating to the identification of bodies with the same or similar sounding names was noted (see Advice item 1 below).

A tissue traceability audit was also carried out. Four cases were chosen at random where it was indicated that tissue had been taken as part of the post mortem examination. Paper records of the tissue taken during the examination were cross-checked with the details stored on the establishment's electronic database as were the number of blocks held in storage, where appropriate. Coroner's forms detailing the families' wishes for disposal or retention of the tissue after the post mortem examination and hospital consent forms were also reviewed as part of this exercise. No anomalies were found.

In the weeks leading up to the inspection, the DI reported to the HTA that the Trust was investigating the retention of 86 fetal remains, which had come to light following an audit conducted by the establishment in response to a Freedom of Information request. Although some guidance is included in this report in relation to fetal remains (see Advice item 13 below), a formal review of the steps taken by the organisation to investigate the incident, and the corrective and preventative actions taken subsequently, is being conducted by the HTA separately in line with its procedure for the management of HTA Reportable Incidents.

**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 |
|---|---|---|
| GQ2 There is a documented system of quality management and audit. | Although the establishment has recently implemented a schedule of audits that includes, for example, bimonthly audits of tissue holdings, only a limited number of audits has been performed since the last inspection and these do not adequately encompass the range of activities being carried out under the authority of its HTA licence.<br><br>Documentation relating to recent internal audits lacked sufficient information to facilitate a meaningful review by interested parties such as the Designated Individual. For example, details of the documents reviewed, the non-conformances observed, and any corrective and preventative actions taken were not described fully. | **Minor** |

### Disposal

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| D1 There is a clear and sensitive policy for disposing of human organs and tissue. | The establishment's policy on the disposal of human tissue did not include clear guidance on the procedures to be followed in relation to the disposal of tissue taken during consented, hospital post mortem examinations (see Advice item 12 below). | **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 update the standard operating procedure (SOP) entitled 'Mortuary reception and the handling and removal of bodies' to include specific guidance on the process used for highlighting same or similar names in the register and on the white board (see also Advice item 6 below). Details of the minimum identifiers used in the identification of the deceased during the reception and release procedures should also be documented. |

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|---|---|---|
| 2. | GQ1 | The document entitled 'Cause of Death Form – Retention and Disposal of Tissue' includes space for recording the size of any tissue samples taken during the post mortem examination. However, this field is rarely completed by the pathologists conducting the post mortem examination. The DI is advised to review the need to capture this information and to either update the form or address current working practices accordingly. |
| 3. | GQ2 | The DI is advised to ensure that only the latest version of the consent form is accessible to staff involved in the taking of consent. Older versions of the form, whether hard copy or electronic, should be removed from circulation to ensure that staff are only using up to date documentation. |
| 4. | GQ3 | The DI is advised to update the training given to porters working within the mortuary to include guidance on HTA Reportable Incidents (HTARIs). This will help ensure that the DI and the HTA are made aware of any serious incidents that occur in the mortuary out of hours. |
| 5. | GQ4 | The DI is advised to introduce a procedure for correcting errors in the mortuary register and other important written records. Such an approach, which could include striking through errors with a single line and initialling and dating corrections, would facilitate audit. The use of correction fluid within written records should be avoided. |
| 6. | GQ6 | The establishment has systems in place to identify deceased persons with the same or similar sounding names in both the mortuary register and on the mortuary white board. However, the DI is advised to consider additional ways of reducing the risk of errors in identification, such as the placing of coloured stickers onto wrist tags or the attachment of notices to shrouds. |
| 7. | GQ8 | The DI is advised to review the format of the establishment's risk assessments to ensure there is a clear distinction between existing control measures and additional control measures that need to be implemented to further mitigate identified risks. |
| 8. | PFE2 | The DI is advised to keep records of the routine cleaning and decontamination that is performed within the mortuary. Although the establishment has SOPs in place that outline the cleaning regime to be followed, the carrying out of cleaning in a manner consistent with the specified protocols is not documented and therefore cannot be audited. In addition to fulfilling the primary purpose of helping to ensure that the premises remain fit for purpose, the recording of cleaning and the periodic review of the records may help the establishment identify more general operational issues, such as staffing levels, that need further consideration. |
| 9. | PFE3 | The DI is advised to formally document the capacity threshold at which bodies are moved into the establishment's contingency storage facilities. This will help ensure that new members of staff are familiar with local practices. It will also help ensure that, as far as possible, space is available within the main body store for bodies brought into the mortuary out of hours. |
| 10. | PFE3 | The DI is advised to record the temperature of fridges and freezers following daily checks as this will help ensure that they continue to operate at appropriate temperatures. Periodic review of the records may also facilitate early identification of any issues developing within the storage facilities that require preventative action such as non-routine servicing. |

| | | |
|---|---|---|
| | | The DI is also advised to document any deviations in fridge/freezer temperatures that result in the establishment's alarm system being triggered. Although it may not be appropriate to record such incidents on the Trust's formal incident management system, a local log of such events that is reviewed on a regular basis may help mitigate the risk of a major equipment failure or HTA reportable incident occurring. |
| 11. | PFE3 | The DI is advised to review, and subsequently formalise, the circumstances in which bodies are moved from refrigerated storage into frozen storage and the on-going review of these cases. Consideration should be given to the specific procedures for adults, babies and foetuses. |
| 12. | D1 | The DI is advised to refer to the HTA codes of practice on post mortem examination (code 3) and disposal of human tissue (code 5) when reviewing the establishment's policy on the disposal of human tissue. |
| 13. | N/A | The DI is advised to install temperature monitoring and alarm systems in the freezers used to store fetal remains in keeping with the systems used elsewhere in the mortuary. Staff in the mortuary should also record the temperature of these freezers on a regular basis to help ensure that they are operating appropriately.<br><br>The DI is also advised to implement a formal schedule of audits of fetal remains held in the mortuary to supplement the existing weekly checks that are already conducted. This will help ensure that appropriate corrective action is taken within a defined timeframe to address any issues that may have arisen, such as a delay in the disposal of fetal remains. The DI should give consideration to whether there is value in reinforcing the link between the audits conducted by staff in the mortuary and the Trust's incident management system, again with a view to ensuring that there are robust systems in place to address any issues that are identified through such checks.<br><br>Finally, the DI is advised to review the information that is provided to staff in the mortuary prior to the release of fetal remains for cremation or burial to ensure that the family's wishes are followed. This could include sending staff in the mortuary copies of the signed consent documentation, in addition to the summary sheets that are provided currently. |

## Concluding comments

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

The establishment has a number of comprehensive training packages, including e-learning modules, for those involved in seeking consent for hospital post mortem examinations. This activity is carried out infrequently by the establishment, but the robust systems seen during the inspection help ensure that families are given the information they need to give informed consent for this procedure to be carried out. In other areas, the establishment also makes effective use of competency-based assessments to ensure that staff are appropriately trained to carry out their daily tasks.

Establishment staff appear to work very effectively with representatives of the Coroner's office, helping to ensure that appropriate steps are taken when the Coroner's authority ends.

The establishment has put in place a number of comprehensive risk assessments. Although some guidance has been offered in relation to the format of these, it was clear to the

inspection team that a great deal of thought has gone into identifying and mitigating the principal risks associated with the carrying out of licensable activities.

Two areas of practice were identified during the course of the inspection that require improvement, both resulting in minor shortfalls. These relate to the establishment's current approach to internal audit and the information contained in its disposal policy.

The HTA has given advice to the Designated Individual with respect to the content of several of the establishment's SOPs, forms and risk assessments. Guidance has also been given regarding the need to document the cleaning that is conducted within the mortuary, as well as any fridge/freezer alarm events. The HTA has also provided some advice in relation to the storage of fetal remains prior to cremation or burial.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

**Report sent to DI for factual accuracy: 22 April 2014**

**Report returned from DI: 6 June 2014**

**Final report issued: 12 June 2014**

**Inspection CAPA Plan Closure Statement:**

**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: 21 October 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.<br>• 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).<br>• 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.<br>• Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event.<br>• 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).<br>• 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.<br>• 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.<br>• Refresher training is available (e.g. annually).<br>• Attendance at consent training is documented.<br>• 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.