Site visit inspection report on compliance with HTA minimum standards

Pinderfields Hospital

HTA licensing number 12086

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**

7 – 8 May 2014

Summary of inspection findings

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

Although the HTA found that Pinderfields Hospital (the establishment) had met the majority of the HTA standards, one minor shortfall was found in relation to governance and quality systems. The shortfall identifies the current disconnect between documented standard operating procedures (SOPs) and practices taking place at the mortuary.

Since the last HTA inspection, the establishment has put in place a number of measures to address recommendations made in the last inspection report.

Although the DI has previously acted as a Person Designate (PD) on the licence, she has recently started as DI and has started to implement further improvements, such as a new audit schedule, in order to improve processes.

During the inspection, the inspection team identified another site, which should also be licensed. The DI was provided with advice and submitted a satellite licence application immediately. This application has been approved based on the information submitted and the evidence of suitability seen during the inspection.

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

The establishment undertakes approximately 600 post mortem (PM) examinations a year. Of these, the majority are coronial PM examinations under the authority of the Coroner for Bradford and the Coroner for Wakefield and Leeds. A small number, approximately two or three annually, are hospital cases.

The inspection encompassed a visual inspection, document review and interviews and discussions with staff including: the mortuary manager; Head Anatomical Pathology Technologist (APT); trainee APT; Consultant Pathologist; and Biomedical Scientist (BMS).

The licensed premises cover Pinderfields Hospital; however, on the day, the inspection team also followed the pathway of tissue removed at PM examination to a laboratory based at Dewsbury District Hospital.

A number of traceability audits were completed including:

- details of two hospital cases with a same / similar name were checked on the fridge, identification tags, mortuary register and electronic record;
- details of one community case were checked on the fridge, identification tags, mortuary register and electronic record; and
- details of two archived PM block samples stored at the establishment were checked against details on the electronic record.

At Dewsbury District Hospital further traceability audits were completed as follows:

- two sets of PM paper records held at the Dewsbury site were traced to the electronic records;
- two sets of PM blocks stored on the site were traced to the paper and electronic records; and
- one disposed record was traced from the paperwork to the electronic record.

There was one discrepancy found in the number of blocks, but this was due to the way the establishment records large and small blocks in the electronic record. Large and small blocks were not recorded together. In this case the discrepancy was due to a larger block being recorded separately from the small blocks. Advice is provided below.

At Dewsbury District Hospital it became apparent that the establishment should be licensed for activities taking place at that site. This is to cover the storage of blocks and slides in the histopathology laboratory and potential removal of tissue from the deceased, which may take place in the accident and emergency (A&E) department. The DI submitted a satellite application form to correct this oversight and a licence has been granted. Advice is provided below.

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. GQ2 There is a documented system of quality management and audit.	The establishment has a range of SOPs in place to cover licensed activities. The practices observed during the inspection and described by staff were suitable; however, there are many SOPs which do not match the processes described during the visual inspection. Particular examples include: • SOP-MORT-002, *Policy for the receipt of bodies into the mortuary* does not reference the establishment's new mortuary checklist; the process for the same / similar name does not match practice; and there is not enough detail on the process for moving bodies between spaces in the mortuary's fridges; • SOP-MORT-003, *Release of bodies from the mortuary* does not list the identifiers used to check identity of the deceased, or who is responsible for completing identification checks. The SOP also requires a minimum of two funeral directors for body release, when one funeral director was observed picking up a body with the assistance of staff during the inspection. The SOP also does not make it clear whether the mortuary checklist applies to hospital deaths; • SOP-MORT-004, *The PM examination* does not reference the mortuary checklist consistently and identifiers referenced are only suitable for coroner's and not hospital cases. • SOP-MORT-007, *Viewing of the deceased* does not list the identifiers to check or the people responsible for checking these before undertaking a viewing. Additionally, there are some practices which are not fully captured by the existing SOPs, such as a procedure for transferring bodies from a fridge to a freezer or the process governing repatriation of organs to a body before release. The establishment's consent procedure forms part of the training package rather than the establishment's governance documentation. The establishment has an audit schedule in place, however only a limited number of audits have been completed. These do not include process audits.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	At present, mortuary staff and / or pathologists are not consulted before clinicians seek consent for a PM examination. It may be helpful for those involved in the PM examination to be involved in the consent seeking process at the earliest possible stage. The DI is also advised to update the patient information leaflet. A model template is available on the HTA's website at: http://www.hta.gov.uk/_db/_documents/Post-mortem_examination_-_your_choices_about_organs_and_tissue_FINAL_v3_0_201201255642.pdf As the DI is new in post, the DI is advised to work with the coroner on the establishment's processes, and may wish to have a meeting to discuss coronial PM examinations.
2.	GQ1 and GQ2	Mortuary staff currently participate in minuted meetings. The DI is advised to discuss any new SOPs in meetings, which include all people involved in PM examinations, such as mortuary staff, pathologists and bereavement staff.
3.	GQ2	A full review of all SOPs should occur to ensure that they are reflective of practice as described in the minor shortfall above against GQ1 and GQ2. Once the SOPs have been reviewed, process audits would provide evidence that practices match documents.
4.	GQ2	One slight discrepancy was found in the number of blocks found on the electronic system and the number in the physical store. This was explained by the BMS, however the DI is advised to audit the block store against the electronic system, to ensure records are accurate.
5.	GQ2	The establishment has an electronic system and the same identifiers are used at the mortuary and in the laboratory at Dewsbury District Hospital. The DI is advised that staff in the mortuary could input data about histology removed during a PM examination into the electronic system, to improve the ease of auditing for consent / coroner's authorisation at Dewsbury District Hospital.
6.	GQ7	The establishment has a system in place for reporting incidents to the HTA. The DI is advised to update the related SOP to reflect the current system for reporting through the online portal.
7.	GQ8	The establishment has completed some risk assessments. The DI is advised to increase the range of risk assessments to include, for example, the movement of bodies through the mortuary, staffing levels and HTARI reporting categories. The establishment undertakes a separate check by two people at different times, rather than a joint identification check by two people at the same time. The DI may wish to consider risk assessing this process, as separate checks by the APT and the pathologist, may increase the risk that checks are not completed fully, because staff rely on each other to do the check.

8.	N/A	The DI is advised to identify PDs to assist her with her responsibilities, especially to ensure oversight of areas outside the mortuary, such as at the Dewsbury laboratory and in the A&E departments. A PD in each of these areas can act as a contact point in relation to the licensed activity taking place. In this way, the DI will be made aware of any issues that arise and will, in turn, be better able to disseminate any licensing updates or information to staff in these areas. The DI is also advised to invite the PDs to governance meetings so that information regarding licensable activity can be shared.

Concluding comments

Examples of good practice were observed during the inspection. The facilities are well-equipped for the activities and staff undertake regular alarm testing, which is recorded. The staff work well with families and often receive thanks from families for their work.

There are a number of areas of practice that require improvement, including one minor shortfall. The HTA has given advice to the Designated Individual with respect to the consent procedure and documents, audits, updating the incident reporting SOP and risk assessments.

The HTA requires that the Designated Individual addresses the shortfall by submitting a completed corrective and preventive 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 preventive actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 2 June 2014

Report returned from DI: 20 June 2014

Final report issued: 23 June 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: 13 August 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.

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 preventive 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 preventive 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 preventive actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventive 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 preventive 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.