Site visit inspection report on compliance with HTA minimum standards

Barnsley Hospital NHS Foundation Trust
HTA licensing number 12346

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**

4 September 2012

Summary of inspection findings

The establishment was found to have met the majority of HTA standards. However, two minor shortfalls in relation to governance and quality systems (GQ1 and GQ7) were identified.

The HTA found the Designated Individual (DI), the Licence Holder (LH), the practices and all aspects of the premises to be suitable in accordance with the requirements of the legislation, subject to the identified shortfalls.

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 Paragraph 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

Barnsley Hospital NHS Foundation Trust is a district general hospital with a wide range of acute and specialised hospital services. The Pathology Directorate has three main departments. Mortuary facilities and post mortem activities are managed within the Department of Cellular Pathology.

The establishment undertakes approximately 600 post mortem (PM) examinations per annum. The last hospital (consented) PM examination was conducted in 2010. The majority of autopsies are conducted at the request of HM Coroner (South Yorkshire). Since 2010, some PM examinations for high risk cases are now accepted by the establishment. Cases with suspected or confirmed Transmissable Spongiform Encephalopathies (TSEs) continue to be sent to another HTA licensed establishment. Those paediatric and perinatal cases considered by the establishment to be of a complex nature are also routinely sent to another licensed establishment.

The mortuary has two full time Anatomical Pathology Technicians, both are qualified. The senior APT is also the Mortuary Manager. The DI is the Clinical Director for Pathology

Services. The LH is Barnsley Hospital NHS Foundation Trust with the Medical Director acting as the named contact.

The establishment was first inspected in February 2009. There was one condition imposed on the establishment's licence at that time. Evidence received by the HTA following the 2009 inspection was assessed and the condition was deemed to have been subsequently met. This inspection, undertaken on 4 September 2012, was a routine inspection, which provided an opportunity for the HTA to review again governance arrangements in respect of licensed activities.

The visit included a visual inspection of the body store, post mortem room and laboratory facilities, and formal interviews with the Desigated Individual, representative on behalf of the Corporate Licence Holder Contact, Consultant Histopathologist (Head of Histopathology), Head BMS (Cellular Pathology), Chief APT/Mortuary Manager, APT and Coroner's Officer for Barnsley.

A number of traceability checks were conducted. The identification tags of two bodies stored in the mortuary were checked and all associated paper and electronic records were reviewed. An audit trail of two further coronial cases where histology had been taken was conducted. All paper and electronic records were reviewed and the number of blocks and slides stored in the Pathology Laboratory was also checked.

A document review of the establishment's policies and operational procedures was also undertaken. This included review of risk assessments, audit reports for 2011/12, incident reports, meeting minutes, maintenance records and the quality manual (Cellular Pathology).

Inspection findings

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

Although hospital (consented) PM examinations are rare, procedures are documented and are compliant with HTA requirements.

With regard to the audits of traceablility undertaken, there were no discrepancies found on the selected examples either within mortuary or histology records.

Records are mainly managed electronically using an integrated pathology system across mortuary and histopathology activities.

Compliance with HTA standards

HTA standards not met:

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	A technical SOP (SOP-CP-Mort-002) is in place, which details general mortuary procedures relevant to the management of PM examinations. However there is no specific reference (or procedural detail) relating to the management of high risk (or suspected high risk) cases.	**Minor**
GQ7 There are systems to ensure that all adverse events, reactions and/or incidents are investigated promptly.	SOP-CP-Mort-D-27, finalised in early September 2012, includes the requirement to report Serious Untoward Incidents (SUIs) to the HTA and a definitive list of reporting categories. This is a newly created procedure. As such, at inspection, the HTA was unable to satisfy itself that staff working under the licence have a sufficient understanding of requirements for timely reporting of SUIs or that mortuary-related incidents are investigated promptly.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	There is a documented SOP detailing the consent process including those able to take consent and details of relevant, mandatory training. Given the relatively small number of hospital autopsies, the DI may wish to consider whether additional authorised consent takers should include staff routinely involved with the process of PM examination, e.g. histo-pathologists or APTs.
2.	GQ1	It is recommended that the mortuary should maintain its own record of entry for portering staff accessing premises out-of-hours. This will aid traceability for hospital deaths where the deceased are moved to the mortuary outside normal working hours.
3.	GQ6	There is an existing procedure for the recording and checking the identification of deceased individuals with identical or similar sounding names. However, in order to further reduce the risk of incorrect identification, the DI is advised to: • Highlight same or similar names in the mortuary register; • Strike through and initial recording errors rather than using correction fluid to

		delete recorded information. Additionally, a number of PM examinations are conducted simultaneously on a daily basis. The DI is advised that an identification system, for example, numbering or colour coding mortuary tables and the bowls used to move organs to / from dissection boards may mitigate the risk of organs being inadvertently repatriated with the wrong body.
4.	GQ7	Staff working under the licence were unaware of HTA SUI requirements in 2011 and consequently did not report two SUIs and one near miss to the HTA at that time. The DI has been advised to now report these incidents retrospectively. Additionally, to further raise awareness of SUI reporting requirements, it is recommended that a checklist of SUI reporting categories is maintained within mortuary premises.
5.	GQ8	While the establishment had completed a number of risk assessments, risk assessments based on HTA SUI categories should be prioritised in order to mitigate risks to the bodies and tissue in the care of the mortuary.
6.	PFE2	In addition to the current cleaning schedule, it is recommended that the DI establishes a regular deep clean schedule with a stated minimum frequency suitable to the activities undertaken at the premises.
7.	PFE5	During anticipated upgrades, the DI is advised to minimise the use of porous surfaces (e.g. remaining wooden work tops) within the mortuary and formally risk assess any existing use of these surfaces.
8.	D2	The establishment records when material has been disposed and reasons for disposal are traceable, however, in the event that disposal of coronial material is required, it is recommended that a clear process is agreed with the Coroner's Office, which sets out how the mortuary formally confirms that retained material has been disposed of (according to the wishes of the family / next-of-kin). The DI may find it useful to review the HTA Code of Practice on Disposal: http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code5disposal.cfm

Concluding comments

The establishment has an experienced team, which is fully engaged and committed to delivering a high quality service. The DI communicates effectively with mortuary staff, primarily through the Head BMS (Cellular Pathology) (PD). Formal mortuary meetings take place within corporate governance Trust structures with clear reporting lines, and provide a mechanism for engagement with key staff at an operational and strategic level.

A number of examples of strength and good practice were seen. For example, the establishment has a suite of mortuary operating procedures and related documents with integrated risk assessments; competency-based staff training with formal end-of-level assessment tests; an effective, high visibility card system for identifying autopsy cases within mortuary facilities and pathologist verification of the deceased prior to PM examination using a three-step identification process.

As highlighted above, there are some areas of practice that require improvement and the HTA has given advice to the Designated Individual with respect to these. It is important that for recently developed SOPs relating to HTA regulatory requirements, the DI puts in place

mechanisms to ensure that staff working under the licence develop a sufficient level of understanding to comply with HTA standards.

The HTA requires that the Designated Individual addresses the two identified 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 shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 2nd Oct 2012

Report returned from DI: No comments regarding factual accuracy

Final report issued: 6th Nov 2012

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: 25 January 2013

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: o post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases o record keeping o receipt and release of bodies, which reflect out of hours arrangements o lone working in the mortuary o transfer of bodies and tissue (including blocks and slides) to other establishments or off site o ensuring that tissue is handled in line with documented wishes of the relatives o 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 or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- 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.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

  (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

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.