Site visit inspection report on compliance with HTA minimum standards

Northampton General Hospital

HTA licensing number 12253

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**

21 April 2015

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 Northampton General Hospital had met the majority of the HTA standards, a minor shortfall was found in relation to the number of identifiers being checked when a body is either received into or released from the mortuary.

Particular examples of strengths and good practice are included in the concluding comments section of the report.The establishment was provided with advice and guidance about areas that could be improved further.

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 describes the second site visit inspection of Northampton General Hospital (the establishment), which is licensed to carry out post mortem (PM) examinations and the removal and storage of PM tissue for use for scheduled purposes under the Human Tissue Act 2004.

The establishment undertakes approximately 600 PM examinations a year under the jurisdiction of the HM Coroner for Northamptonshire. Hospital consented PM examinations are rare and Pathologists are responsible for seeking consent for these. All consented paediatric and neonatal/fetal PM examinations are transferred to another licensed establishment. Potential high risk cases such as CJD are also transferred to another licensed establishment, which has suitable facilities.

Shortly before the inspection, the DI, a Pathogist, took over the role of Designated Individual. The Pathology Quality Manager has oversight of aspects of mortuary practice, includuing audit and quality management, whilst the Mortuary Manager manages the day to day operation of the mortuary and supervises a trainee APT, Senior APT and Mortuary Assistant.

The mortuary has 131 fridge spaces with five freezer spaces and five bariatric spaces. There is also an overflow area in the mortuary with appropriate temperature controls to ensure that bodies can be stored on trays when needed. The paediatric fridge is located in the post-mortem suite. The mortuary fridges are monitored using a system which allows staff members to review temperature readings on their computers.The system notifies mortuary staff via switchboard in the event of temperature fluctuations both during and out of hours.

The inspection involved a visual inspection of the mortuary, including the body store and post mortem suite. Interviews took place with a Bereavement Officer, Senior APT, Mortuary

Manager, Pathology Quality Manager, Designated Individual (DI) and a Clinical Head for Histopathology. A Coroner's Officer was interviewed over the telephone prior to the inspection. As there were areas outside of the mortuary where removal of tissue from the deceased takes place, the inspection team also visited accident and emergency (A&E) and a maternity ward.

In A&E, the inspection team met with a Lead Consultant in sudden unexplained infant death cases. They demonstrated an understanding of the requirements of the Human Tissue Act 2004 in relation to removal of tissue from the deceased and explained the establishment's governance systems; the HTA was satisfied with the arrangements in place covering this activity. The establishment was advised during the inspection to consider adding the Consultant Lead as a person designated (PD) under the licence, who can provide oversight of licensable activites in this area (advice and guidance item, 8).

A discussion also took place with a Lead Nurse in the maternity labour ward, which houses a fridge that is used to store products of conception, fetuses and still births for a 24 hour period prior to transfer to the mortuary. The fridge temperature is monitored every day by ward staff. The establishment had been advised on the previous site visit inspection to consider connecting the fridge alarm to the switchboard, so that any fridge failures are attended to promptly. The advice remains (advice and guidance item, 6). This area too would benefit from the Lead Nurse acting as PD for the purpose of HTA licensing (advice and guidance item, 8).

Traceability audits of three bodies were carried out. Two of these bodies had tissue removed during post-mortem examination under coronial authority. Records were checked, including details in the mortuary register and identification details on the wrist bands, and an audit of retained tissue blocks and slides in histopathology was carried out. A minor discrepancy was noted for one of the bodies that had been moved from the over flow area to the main body store. The location of the deceased was correct on the whiteboard, but had not been corrected in the mortuary register as they are now required to do under a recent change of mortuary procedure (advice and guidance item, 4). There were no other discrepancies.

A second traceability audit was carried out in the histopathology laboratory. The electronic records were checked for two cases where tissue had been retained under coroner's authority. In one of the cases, diposal had taken place and this was evidenced by the use of a disposal slip in the block storage drawer. No anomalies were found.

Inspection findings

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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ6	Mortuary staff are not following documented procedures that state the points of identification that need to be checked during receipt, post mortem examination and release procedures. Mortuary staff only check more than one identifier in cases of same/similar name. This poses a potential risk of misidentification of the deceased. The HTA advises that three identifiers are used, including one that is unique to the deceased.	Minor

Advice

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

No.	Standard	Advice
1.	C1	The establishment has demonstrated a conscientious approach to seeking consent for hospital post-mortem examinations, including providing consent training for clinicians and a comprehensive consent policy and procedure. However, the DI is advised to review the flow chart that has been produced by the PALS/Bereavement Office, as it states that consent should be sought from the 'next of kin'. This should be amended so that it accurately reflects the HTA's requirement that consent must be obtained from the appropriate person in the hierarchy of qualifying relationships.
2.	D1	Once coroner's authority has ended, where the family's wishes are for tissue to be retained for use for a scheduled purpose, the tissue blocks and slides are stored and possibly archived off site for a period of 30 years. The establishment may continue to store this tissue for unspecified research, however, if there is no specific research or other use, the establishment may lawfully dispose of tissue blocks and slides.
3.	GQ4	During the review of the mortuary register, it was noted that several corrections had been made using correction fluid. As good practice, mortuary staff should stop using correction fluid and instead, place a line through any error, so it is still visible and place their initials next to the correction. This will ensure robust traceability of all records.
4.	GQ6	There are three pieces of advice under GQ6: 1. The establishment's 'Cause of Death' form should be amended so that it records more clearly when a whole organ is retained and where tissue samples are retained. Mortuary staff are currently making notes on the form in its current format; changing the format to accommodate the additional information will make it easier to use and reduce the risk of error. 2. Toxicology samples may also be removed from the deceased alongside histology, with the authority of the Coroner. Occasionally, these samples are stored in the mortuary until the results of the histology are known and a decision is made as to the necessity of toxicology. The samples are recorded temporarily on a white board in the mortuary office. Where histological examination of tissue determines the cause of death and the toxicology samples are no longer required, the Pathologist informs mortuary staff who dispose of the samples. The current procedure for toxicology samples is not consistently followed by all pathologists. The DI is advised to ensure that all staff adhere to standard operating procedures. It is good practice for all samples removed for toxicological analysis to be recorded on the mortuary tissue register, even where the samples may not be used. The date and time of disposal of such samples should be documented.

		3. At the time of the inspection, mortuary staff had begun recording the fridge locations of all bodies in storage in the mortuary register. Upon review of the register, a discrepancy was noted. A body had been stored in the overflow area and subsequently moved to the main body store. The location had been updated on the mortuary whiteboard to maintain traceability, however, the location had not been written into the mortuary register. As this is a relatively new procedure, the DI should update relevant SOPs to ensure that all staff document any changes to locations in a specific column of the mortuary register. Furthermore, to maintain traceability, previous locations should not be crossed out.
5.	PFE1	There are two pieces of advice under PFE1: 1. The DI is advised to place a sign in book in the mortuary, so that all those attending the mortuary (funeral directors, organ retrieval teams etc), particularly out of hours, sign in and out. 2. The DI may wish to consider placing a curtain over the door that connects the viewing room to the mortuary body store.
6.	PFE3	There are two pieces of advice under PFE3. 1. The body store fridges, including the paediatric fridge in the post-mortem suite, are connected via a temperature monitoring system recently procured by the Trust. Mortuary staff log in to the system daily to check the temperatures, which are reviewed for trending analysis. However, during the visual inspection, the system was not functioning and was not producing a read out of the temperature. The DI is advised to consider manual recording of the fridge temperatures on a daily basis so that the fridge temperatures can still be monitored where the system malfunctions. 2. The DI is advised to carry out a formal documented risk assessment of the maternity fridge located in the labour ward and consider the possibility of connecting the fridge to switchboard or to the mortuary fridge monitoring system to mitigate the risk of a fridge failure going unnoticed during very busy periods in the labour ward.
7.	PFE5	The mortuary has undergone refurbishment within the last few years and the fridges are all around two years old and in good condition. Going forward, the DI is advised to ensure that the fridges are subject to regular maintenance and servicing to ensure that they are functioning optimally.
8.	N/A	As the licensable activites extend outside of the mortuary into other areas, for example, A&E and maternity labour ward, the DI is advised to add persons designated (PD) to each respective area to provide oversight of the licensable activities taking place.

Concluding comments

The establishment demonstrated a strong commitment to ensuring compliance with the HTA standards and is keen to ensure that is is continuously improving. A number of areas of good practice were observed during the inspection. For example, the Pathology Quality Manager and the Data, Audit and Compliance Manager are responsible for co-ordinating vertical, horizontal and examination audits across the mortuary and pathology. The audits are carried out in an independent manner, where pathology staff will audit the mortuary and mortuary staff will audit pathology. The mortuary assistant is responsible for ensuring that the tissue tracking spreadsheet is kept up to date as well as the mortuary register. Porters undergo a competency assessment, where they are observed carrying out a mortuary procedure and asked questions about their understanding of that particular procedure. A positive reflection of the establishment's approach to ongoing staff development, was demonstrated through the trainee APT's responsibility for providing training to the porters. An example of a competency assessment was reviewed during the inspection and was completed to a high standard.

There are some areas of practice that require improvement, including one minor shortfall in relation to GQ6. The HTA has given advice to the Designated Individual on a range of issues to make further improvements.

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 shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 14 May 2015

Report returned from DI: 15 May 2015

Final report issued: 19 May 2015

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: 15 June 2015

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 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.