Site visit inspection report on compliance with HTA minimum standards

North Tyneside General Hospital

HTA licensing number 12261

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**

4-6 March 2014

Summary of inspection findings

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

North Tyneside General Hospital (the establishment) was found to have met all HTA standards.

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 licensed establishment consists of a body store, post mortem suite and laboratory facilities at North Tyneside General Hospital, the hub premises. The laboratory facility processes tissue taken during post mortem examinations into blocks and slides. These are then reviewed by pathologists and stored until being archived, disposed of or returned to the family, in accordance with the consent given. There is also a separate satellite site located at Hexham General Hospital consisting of a body store and post mortem suite. Fewer post mortem examinations are undertaken at the satellite site, with any tissue taken being transferred to the hub premises for processing and review by the pathologists.

Prior to the inspection, the DI confirmed that removal of various tissue samples takes place in other areas of the hospital, including blood, swabs and lavages from deceased children that have either arrived dead or die in the Hub premises' accident and emergency (A&E) department. This activity, which is licensable, does not take place at any of the other hospital sites within the Trust. During the inspection, the A&E department was visited and staff responsible for taking these samples were spoken with. The establishment has a child death clinical pathway procedure in place governing the taking of these samples, with instructions on the type of samples to take, liaising with the Coroner, speaking with parents and giving information to parents. Checklists contained within the pathway document help to ensure that all of the required steps take place. At the time of the inspection, the DI had not appointed a

Person Designated (PD) in the A&E department to act as a point of contact in relation to the licensable activity. Advice has been given below in this regard.

At the time of planning the inspection, it was understood that removal of samples from deceased children may take place at another of the Trust's hospitals, Wansbeck Hospital. A visit there confirmed that this is not the case. The Wansbeck Hospital has a newly refurbished body store. However, no tissue is stored there and bodies awaiting post mortem examination are only stored there for a few days (and never longer than a week) before being transferred to the hub premises for post mortem examination. An HTA licence is therefore not required.

The establishment undertakes around 850 adult post mortem examinations each year, either on behalf of one of two Coroners or, on rare occasions, with the consent of the deceased's family where there is clinical interest in a case. Paediatric cases are sent to another licensed establishment.

In the case of hospital consented post mortem examinations, consent is sought by the clinician who was involved in the treatment of the deceased prior to death. These clinicians are supported by anatomical pathology technologists (APT) who have been training by the DI in the consent process and who are also able to answer any questions that the family may have regarding the post mortem examination procedure.

The body storage fridges at the hub premises are not connected to a remote alarm system that would alert staff to an equipment failure out of working hours. However, establishment staff informed the HTA that porters visit the body store at least once per day delivering deceased to the mortuary and would detect and act upon any local fridge alarm that may be sounding if a fridge was out of its normal temperature range. The body store contains notices which remind the portering staff to call the on-call APT if a fridge alarm is sounding. During working hours, mortuary staff monitor and records the temperatures of the fridges and freezer in the body store and use this data for trend analysis, which may help prevent a breakdown.. Additionally, a new remote alarm system is due to be installed, which will alert establishment staff to an equipment failure during out of hours periods via the hospital switch board. The body store at the satellite site is connected to a remote alarm system. The post mortem suites at both the hub and satellite site premises are well maintained and suitable for use.

This was the second site-visit inspection of the establishment and was a routine inspection to assess whether it is continuing to meet the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's last self-assessed compliance information, as well as pre-inspection discussions with the DI and review of the previous inspection findings. During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment and Coroner's office staff were undertaken.

An audit of bodies stored in the establishment's fridges was undertaken during the inspection. Three bodies were chosen at random and identification details recorded on body tags were checked against details on the mortuary fridge doors, mortuary location white board, the notice of death on the body and the electronic mortuary body records. Additionally, the same cross checks were undertaken on details from two randomly chosen bodies being stored at the satellite site. No anomalies were found during this audit.

Tissue traceability audits were also undertaken during the inspection. Details were taken of three coronial cases where tissue was taken during post mortem examinations performed at the hub premises. Details of the tissues retained at post mortem examination were cross checked between the mortuary's electronic records and the histopathology laboratory's electronic records. Additionally, the physical blocks and slides were located and again the numbers checked against the histopathology laboratory's records.

In all three cases, signed coronial forms confirming family wishes were reviewed. In all three cases, the deceased's family had opted for retention of the tissue taken during the post

mortem examination. In one of the three cases, a whole brain was taken and had been sent to another licensed establishment for specialised review. Records of the transfer and disposal of the organ in accordance with the family's wishes were reviewed.

Two post mortem examination cases from the satellite site where tissue had been retained during the examination were also chosen at random. Again, the blocks and slides were sought in addition to undertaking a review of the laboratory's electronic records and the coronial family wishes forms.

In the audits that were undertaken during the inspection on bodies and tissue, 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.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C3	APT staff who provide support to clinicians seeking consent for post mortem examinations have received appropriate training in the establishment's consent procedures. The DI is advised to undertake refresher training with the APTs during which past cases and any new guidance issued by the HTA can be reviewed. As consented PM examinations take place infrequently, this will help keep APTs up to date and competent..
2.	GQ1	Prior to commencing a post mortem examination, a final check on the identity of the deceased is undertaken by the pathologist and APT. This includes a review of any hospital notes, coronial documentation and the identity tags on the body. This final check by the pathologist and APT is not reflected in the establishment's standard operating procedure (SOP) relating to the post mortem examination procedure. The DI is advised to amend the post mortem procedure SOP so that a description of the checks undertaken by the pathologist and APT is reflected within the document.
3.	GQ2	The establishment plans to undertake more frequent procedural audits whereby staff observe other members of staff undertaking a particular procedure to verify that the SOP is being followed, remains appropriate and reflects the documented procedure. The establishment plans to use staff from the laboratory to undertake some of these audits of mortuary staff and mortuary staff to observe some laboratory procedures relating to licensable activity. The DI is advised to continue with plans to undertake more of this type of procedural audit, as they will assist the DI in reviewing the establishment's procedures and help to assure him that they remain appropriate.

4.	GQ2	The DI is advised to appoint a PD in the hub premises' accident and emergency department to act as a point of contact in relation to the licensed activity taking place there. 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.
5.	GQ2	Regular governance meetings of senior laboratory and pathologist staff take place. However, mortuary staff do not attend. Although the DI is in daily contact with the mortuary staff and the working relationship is such that an informal exchange of issues takes place, the establishment would benefit from including mortuary staff in governance meetings. The DI is advised to introduce regular governance meetings to which the staff working under the licence are invited to facilitate a process by which any issues and suggestions for improvements to procedures can be shared. In addition, the DI is advised to invite the newly appointed PD in the accident and emergency department to these meetings
6.	PFE3	The establishment is anticipating that the fridges at the hub premises will soon be connected to a remote alarm system which will alert staff to equipment failures outside of normal working hours. The DI is advised, once the new system is installed, to schedule a program of regular checks on the new alarm system to help assure him that the system is functioning as expected. These checks will also enable the DI to verify that security staff respond to the remote alarm system as expected and alert the mortuary staff of the alarm being triggered.
7.	PFE4	The establishment occasionally sends tissue to other licensed establishments for specialist review. The DI is advised to consider if, when sending tissue elsewhere, obtaining a signature from the driver collecting and transporting the tissue to acknowledge the collection would strengthen the establishment's tissue traceability records.

Concluding comments

Good practices were observed during the inspection, some examples of which are included below.

The establishment has good risk assessments in place. The range and scope of these assessments demonstrated that that the establishment has considered the risks associated with the licensed activity. In addition, the establishment's risk assessments consider the risks of HTA reportable incidents occurring, such as release of the wrong body or accidental damage. The risk assessments are particularly thorough and will help to minimise the risk of such adverse events occurring.

To ensure that bodies being stored for long periods in the establishment's freezers remain in suitable condition, the establishment undertakes and records weekly checks of the bodies being stored in the freezer.

The establishment has developed a good range of procedural documents and has endeavoured to standardise practice and procedures as much as possible between the hub and satellite site, which helps staff to deliver a consistent service. Additionally, it was noted that there were good working relationships between staff working at both sets of

establishment premises and additionally, with the coroner and coroner's officers. These good working relationships mean that communication remains effective despite the dispersed nature of the two establishment sites.

The HTA has given advice to the Designated Individual with respect to some consent, governance and quality and premises facilities and equipment standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 1 April 2014

Report returned from DI: 17 April 2014

Final report issued: 18 May 2014

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below; those not assessed during the inspection are shown in grey text. Individual standards which are not applicable to this establishment have been excluded.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

GQ4 There is a systematic and planned approach to the management of records

- There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
- There are documented SOPs for record management.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's

family.

- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.