Site visit inspection report on compliance with HTA minimum standards

University Hospital of North Tees

HTA licensing number 12446

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**

20-21 January 2016

Summary of inspection findings

A routine site visit inspection of University Hospital of North Tees and its associated satellite, University Hospital of Hartlepool, (together: 'the establishment'), was carried out by the HTA on 20 and 21 January 2016.

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.

University Hospital of north Tees (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

This inspection covered the licensable activities taking place at the University Hospital of North Tees (UHNT; the 'hub') and the University Hospital of Hartlepool (UHH; the 'satellite'). Both hospitals are part of North Tees and Hartlepool NHS Foundation Trust.

UHNT carries out adult post mortem (PM) examinations either under coronial authority or with the consent of the deceased's family following a hospital death. Paediatric cases are transferred to another HTA-licensed establishment for PM examinations to be carried out. Consent for paediatric PM examinations is taken by trained staff at UHNT using consent documentation provided by the establishment that conducts the PM examinations. Home Office contracted pathologists carry out forensic PM examinations at both UNHT and UHH.

There are fifty-five fridge spaces and four freezer spaces at UHNT. Four of the fridge spaces are assigned to neonatal and paediatric cases but may be used as contingency storage space for deceased adults. Twelve of the fridge spaces are in the form of a semi-permanent Nutwell fridge, which is maintained at the correct temperature by a dedicated chiller unit. Only mortuary staff are allowed to place the deceased in the Nutwell body store. As part of its resilience plan, UHNT has an additional 26 fridge storage spaces in two cold rooms located close to the body store. There is a separate fridge for the storage of products of conception. The temperatures for all these storage units are monitored daily with a temperature

monitoring system. Temperature exception alerts sound locally as well as with the switchboard.

The UHH generally treats day cases and has one ward, with any A&E or maternity cases taken to UHNT. The mortuary at UHH therefore mainly receives bodies of the deceased from the community. It has 20 fridge spaces of which four are assigned to neonatal and paediatric cases.

There are no mortuary staff permanently based at UHH, and trained hospital porters are responsible for the admission of community and hospital deaths**.** Anatomical Pathology Technologists (APTs) based at UHNT regularly visit the mortuary at UHH to take temperature readings of the refrigerated body store, complete receipting records and carry out general checks. Any viewings and release of bodies only takes place in the presence of an APT. CCTVs linked to UHNT have recently been installed. These provide 24 hour coverage of each fridge, the mortuary whiteboard and the temperature monitoring unit. This allows staff at UHNT to record the temperatures of the fridges at UHH, and review the admission board to cross check against the names of new admissions placed in the body store. Although UHH maintains provision for conducting PM examinations only forensic PMs are conducted there. In the event that a deceased patient requires a PM examination, their body is transferred to UHNT by contracted funeral directors. A record of the transfer is entered into the mortuary log and also onto an electronic database which is shared between the hub and satellite.

UHNT and UHH use the same procedure for identifying deceased with same or similar names. A red magnetic label is placed on the fridge door next to the name of the deceased. A note is also made on the electronic records. In addition other magnetic labels are used to inform staff of high-risk bodies or patients with pacemakers.

In 2015, approximately 546 adult coronial post-mortem (PM) examinations were carried out at UHNT under the authority of HM Coroners for Teesside and Hartlepool. In the same year, Two adult hospital (consented) PM examinations were conducted. UHNT also carries out some high risk PM examinations and these are scheduled to take place when all others have been completed. Blocks and slides are immediately taken to the Pathology department. On occasion, the pathologist may decide that the PM examination has to be carried out by a specialist. In such cases, the body is transferred by contracted funeral director to another licensed establishment. All transfers are supervised by an APT and occur during working hours.

Six forensic PM examinations were carried out by Home Office contracted pathologists at UHNT and two at UHH in 2015. Samples are taken to forensic centres by the visiting forensic pathologist immediately following a forensic PM examination. The mortuary keeps an electronic record of material retained. Under s39 of the Human Tissue Act 2004, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, activities relating to the retention of samples by the police were reviewed by HTA at its site visit inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

This was the third routine HTA site visit inspection. The A&E department was visited as the licensed activity of removing tissues from infants in cases of sudden and unexpected death in infancy (SUDI) takes place. A visit to the Maternity unit was also made as consent for PM is sought following still births and pregnancy loss. Staff working in these two areas were

interviewed during the visual inspection to ascertain the nature of the activity taking place and provide advice.

A number of traceability checks were conducted. The identification tags of two bodies stored in the mortuary at UHNT, one body being stored at UHH and one body transferred to UHNT from UHH were checked and all associated paper and electronic records were reviewed. In the Histology laboratory, tissue blocks from two cases were reviewed. In all cases no discrepancies were observed however some transcription errors were noted. Refer to advice and guidance (2).

During the inspection, a telephone discussion was held with a member of the Coroner's office. The purpose of the interview was to discuss how the establishment's systems and processes work in practice. It was noted that the establishment has a close working relationship with the Coroner's Office, which helps expedite the prompt release of bodies to families.

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.	GQ1	The DI is advised to use a visual marker to highlight cases where tissue has to be repatriated with the body before release of the deceased.
2.	GQ2	Staff at the establishment carry out a number of detailed audits; nevertheless, some errors were noted during the inspection: • in one of the records examined, the PM examination number recorded in the mortuary register did not match the electronic record. • in the pathology laboratory, the disposal date for blocks and slides was not consistently recorded. • in some documents, errors were overwritten or scribbled out. The DI is advised to remind staff of the need to maintain accurate records; any errors should be crossed out once and initialled.
3	GQ2	Some of the SOPs make reference to SUIs in relation to the incidents that must be reported to the HTA. The term SUI has been replaced by 'HTARI' (HTA reportable incident). The DI is advised to make amendments to the relevant SOPs when the documents are next reviewed.
4	GQ4	The establishment has agreements with the Manchester and Bristol eye banks. These organisations are now part of NHSBT. The DI is advised to review the agreements and ensure that these are updated to reflect the changes.

5	GQ6	When porters transfer the bodies of infants from the body store to maternity, for viewing by parents, a white board in the body store is completed with the date and time of collection and return. The DI is advised, in keeping with the practice for deceased adults, that the initials of the porter responsible for transferring or returning the body is also recorded on the white board.
6	GQ6	The DI is advised to maintain a permanent record of the transfer of babies to and from the mortuary.
7	PFE3	Placenta and clinical remains are stored in the body store freezer prior to disposal. The DI is advised to review this arrangement to ensure this does not compromise the establishment's ability to store bodies appropriately when long term storage is required.

Concluding comments

The mortuary is a clean, well-kept facility.The mortuary and bereavement staff work closely together as part of a combined service and are clearly dedicated to their roles. The DI attends the daily mortuary meeting as well the formal weekly meeting where minutes are recorded. There are clear guidelines detailing the responsibilities and actions required by staff following a hospital death. The establishment has a clear plan of action to monitor capacity in the body store and effective contingency arrangements. When conducting audits of records the initials of the APT who carried out the audit of records and cross check against details on the deceased are recorded against the name of the deceased on the body store. There is visible signage to indicate deceased with same or similar names, high risk individuals and those wearing pacemakers. The A&E department has developed a clear flow chart setting out the procedure to following in SUDI cases and has a dedicated box of equipment to assist staff. The pathology department makes use of clear visual markers to indicate the number of blocks and slides created after a PM examination.

The HTA has assessed the establishment as suitable to be licensed for the activities specified. There are no shortfalls against the HTA standards, but the HTA has offered advice on a range of issues to help the DI facilitate further improvements.

Report sent to DI for factual accuracy: 16 February 2016

Report returned from DI: 19 February 2016

Final report issued: 8 March 2016

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 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.