Site visit inspection report on compliance with HTA minimum standards

Basingstoke and North Hampshire Hospital
HTA licensing number 12362

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 June 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.

Basingstoke and North Hampshire Hospital (the establishment) was found to have met all HTA standards.

Particular examples of good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements
The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The establishment consists of a body store and post mortem suite, with laboratory facilities located in another area of the hospital. The body store has 61 fridge spaces, including six which can also be operated as freezer storage if required, and 15 for bariatric cases. At the laboratory, tissue taken during post mortem examinations is processed into blocks and slides, reviewed by pathologists and stored until being archived, disposed of or returned, in accordance with the consent given.

The establishment undertakes adult post mortem examinations, either on behalf of the Coroner or with the consent of the deceased's family where there is clinical interest in a case. Around 400 coronial adult post mortem examinations are performed by the establishment annually. Paediatric post mortem examinations are not undertaken, and these cases are transferred to another licensed establishment. Some high risk cases are performed by the establishment following risk assessment, including HIV, hepatitis B, hepatitis C and tuberculosis.

The establishment reported that it has not undertaken a consented, hospital post mortem examination in the last two years. However, when these do take place, consent is sought by the clinician who was involved in the treatment of the deceased prior to death. Clinicians are supported by anatomical pathology technologists (APTs) from the establishment who have undertaken training in the seeking of consent. The APTs are also able to answer any

questions that the family may have regarding the post mortem examination procedure in addition to helping ensure that all aspects of the consent form are covered in the conversation and recorded appropriately.

Prior to the inspection, the Designated Individual (DI) confirmed that removal of various tissue samples may take place in other areas of the hospital; these include blood, swabs and lavages from deceased children that have either arrived dead or die in the establishment's accident and emergency (A&E) department. During the inspection, the A&E department was visited and staff named on the HTA licence as Persons Designated, and responsible for the oversight of the removal of these samples, were spoken with. Samples are taken in a dedicated room, which is private and is suitable for the procedure. Staff have guidance documents to follow, which detail the types of sample to be taken, and only paediatric consultants are able to undertake the procedure. The coroner is also made aware of the requirement to take the samples prior to any removal taking place.

In the establishment's maternity department, the remains of stillborn infants or miscarriages may be stored temporarily prior to being moved to the mortuary so that, where appropriate, families have the opportunity to view the infants on the ward. Remains are stored in a fridge that is kept in a small room, away from the main ward. Currently the storage fridge is not temperature monitored and advice has been offered to the DI (see advice item 10 below).

This was the second site-visit inspection of the establishment and was a routine inspection to assess whether it continues 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 at the establishment's hub premises was undertaken. Three bodies were chosen at random and the identification details recorded on body tags were checked against details on the mortuary fridge doors and in both the electronic and paper mortuary registers. No anomalies were found during this audit.

A tissue traceability audit was also undertaken during the inspection. Three post mortem examinations were chosen at random. Details of tissue taken during the post mortem examination were cross checked against the mortuary records and laboratory's electronic records. Additionally and where applicable, the physical blocks and slides were reviewed and counted. In two of the three cases tissue taken during the examination had been disposed of. The laboratory's electronic records reflected the disposal and recorded the disposal of both the blocks and associated slides separately. The coronial family wishes forms were also reviewed, which recorded that the deceased's' families had opted for disposal. In the third case, the family had opted for retention. The blocks and slides were sought and their numbers cross checked against the laboratory's electronic records. No anomalies were identified in any of the three cases reviewed.

During the inspection, a review of fetal remains awaiting sensitive disposal in the laboratory highlighted some cases where fetal tissue had not been disposed of within the expected timeframe. This tissue was clearly segregated from routine diagnostic tissue and was identified as being held pending sensitive disposal. Advice has been given to the DI about systems to monitor the sensitive disposal of such tissue might be improved, to ensure that it is sensitively disposed of within an appropriate time frame.

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.	C1	The Coroner's family's wishes form offers the family of the deceased three options regarding the fate of any tissue taken during the post mortem examination: return of tissue to the family or their funeral director; sensitive disposal by the establishment; or retention for use in research and medical training. The DI is advised to consider, in conjunction with the Coroner, whether a fourth option - to retain tissue so that it may be available for review in future for the benefit of the family – should be added.
2.	GQ1	Currently, on release of the deceased to the family's funeral director, the body's identity is checked simultaneously by the mortuary staff and funeral director collecting the body. The DI may wish to consider whether the carrying out of an additional, separate ID check would strengthen the release process. For example, this may include the APT reading out the identity details on the body's ID bracelet to the funeral director collecting the body, who then checks these details against the release paperwork.
3.	GQ1	The DI is advised to review and amend if necessary the mortuary's post mortem examination standard operating procedure (SOP), which currently states that two APTs will check the body's identity prior to starting the examination. The review is required due to this check often being performed by a single APT and the pathologist.
4.	GQ1	Before commencing a post mortem examination, an APT and the pathologist independently check the identity details on the body's wrist tag against the Coroner's post mortem request form (or hospital consent form if applicable). The DI is advised to consider recording these checks on the post mortem record form by requiring the APT and pathologist to sign the form confirming that each of them has performed their check.
5.	GQ1	During the document review, three examples of SOPs that had passed their review date were found. The DI is advised to review all of the establishment's procedural documents to ensure that they remain current and within date.
6.	GQ2	The DI is advised to continue with plans to conduct audits of the establishment's written and electronic records to help ensure that when entering data onto electronic systems it is done accurately.

7.	GQ3	During the inspection, an example was found where a staff competency training record sheet (intended to record competency assessments of staff being observed performing various mortuary tasks) had been used to record that a more experienced member of staff from another hospital within the Trust had read and understood the establishment's SOPs. Use of the incorrect form may lead to confusion when reviewing staff training as it may lead to an assumption that someone has been observed to be competent when, in reality, they have simply signed to say that they understand a procedure. The DI is advised to develop and implement a separate system to capture when staff have read and understood procedural documents rather than use a form which was designed to record staff competency following an observational performance assessment process.
8.	GQ8	The establishment has a good range of risk assessments in place. However, these could be built on and improved by widening their scope. The DI is advised to review the establishment's range of SOPs to ensure that all activities relating to licensed activities have been risk assessed. Examples of additional risk assessments include, but are not limited to, body storage capacity, failure of body storage fridges, timely disposal of fetal remains in accordance with the parents' wishes and the storage of the remains of still born infants or miscarriages which are occasionally stored temporarily in a fridge within the maternity department.
9.	PFE3	The main body storage fridges and freezers within the mortuary are linked to an alarm system which alerts staff to an equipment failure or temperature deviation both during the working day and out of hours. The establishment currently performs a manual challenge to the alarm, alerting the switchboard of the test and ensuring that when the alarm is manually triggered, it sounds at switchboard. This is considered good practice. The DI is advised to further test the alarm by periodically performing a manual challenge of the alarm system where switchboard have not been notified of the test to verify that switchboard call the relevant member of staff. This will help to assure the DI that switchboard staff who initially receive the alarm notification follow the expected procedure.
10.	PFE3	In the Maternity department the remains of still born infants or miscarriages are occasionally stored temporarily in a fridge that is kept in a small room away from the main ward. This storage is so the parents of the infant can see and be with the infant while on the ward and prior to the remains being transferred to the mortuary for storage. The storage fridge's temperature is not routinely monitored and there are no temperature alarms in place should the fridge develop a fault and deviate from the expected temperature. The DI is advised to implement a system by which the fridge temperature is regularly monitored to help mitigate the risk of an equipment failure going unnoticed for an extended period. The DI may wish to consider the suggestion of the ward staff that a manual check of the fridge temperature is undertaken and recorded twice daily.
11.	N/A	A review of fetal remains awaiting sensitive disposal in the laboratory highlighted some cases where fetal tissue had not been disposed of within the expected timeframe. The DI is advised to develop and implement a system whereby these remains are subject to regular audit to ensure that the parent's wishes have been obtained and that these wishes have been acted upon. This will help to mitigate the risk of remains not being dealt with as expected and within a suitable timeframe.

Concluding comments

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

The establishment aims to provide good care of the deceased and to this end, when bodies are brought to the mortuary out of hours, an on-call APT will always attend to receive the body, perform and record its identity and put the body into storage.

In addition to providing an on-call out of hours service, the establishment has developed two important training packages which are delivered to other staff at the hospital. Firstly, new nurses receive training in the activities relating to last offices for the deceased, mortuary practices and what is involved in the performing of a post mortem examination. Secondly, hospital portering staff, who may be transporting bodies between the wards and the mortuary, receive specific documented training on the handling of bodies, procedures for choosing the correct storage location and placing bodies into storage, and the use of mortuary equipment such as body trolleys.

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

Report sent to DI for factual accuracy: 18 July 2014

Report returned from DI: 29 July 2014

Final report issued: 21 August 2014

Appendix 1: HTA standards

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

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

Governance and quality system standards

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

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

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

GQ2 There is a documented system of quality management and audit

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

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

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

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

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

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

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.