Site visit inspection report on compliance with HTA minimum standards

The Whittington Hospital

HTA licensing number 12099

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**

29 April 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. The Whittington Hospital (the establishment) was found to have met all of the applicable HTA standards.

This inspection provided an opportunity to follow up advice that was offered during the previous HTA inspection. A number of examples of strengths and good practice are included in the concluding comments section of the report. Advice is provided in areas where the HTA identified opportunities for improving existing systems and procedures.

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 inspection covered licensable activities taking place at The Whittington Hospital (the establishment), which includes the services provided by the Mortuary, Pathology Department, Maternity Unit, Estates and Portering. The Whittington Hospital is part of the Whittington Hospital NHS Trust.

The Department of Pathology is fully accredited under the UK Clinical Pathology Accreditation (CPA) scheme.

This was the establishment's second routine HTA site-visit inspection. The timetable for the inspection was developed with due consideration of the establishment's licensing history, the outcome of the previous inspection and pre-inspection discussion with the Designated Individual (DI) and the Service Manager, Mortuary Services. The HTA conducted a review of the premises; held interviews with members of staff involved in licensable activities and reviewed relevant standard operating procedures (SOPs), documents, registers and databases. Interviews were conducted with: the DI; the Services Manager, Mortuary Services; the Pathology Quality Manager; and a Consultant Histopathologist. Discussions were also held with a member of the Estates team and a member of the team working within Maternity. These latter discussions focused on the process for obtaining consent for hospital, consented, post mortem (PM) examinations; the process for dealing with early (intrauterine fetal and neonatal) deaths and the process for respectful disposal of fetal remains and

products of conception. The inspection team also visited the paediatric emergency department to discuss the process and procedures for dealing with sudden infant deaths. No samples are taken from deceased infants within the department. Unexpected infant deaths result in coronial (PM) examinations that are carried out at another HTA licensed establishment.

The mortuary functions both as the hospital mortuary, as well as the public mortuary for the London Borough of Islington. Approximately 330 PM examinations are carried out each year. These are, primarily, carried out on behalf of HM Coroner for Inner North London, whose jurisdiction covers several Boroughs, including Islington and Camden. The PM examinations include both routine and forensic case investigations. The establishment, on occasion, also carries out PM examinations on behalf of HM Coroner for the Northern Districts of Greater London. In addition, the establishment carries out approximately fifteen adult hospital, consented, PM examinations per year. The Mortuary is responsible for bereavement support and services and members of the Mortuary team are involved in the consent seeking process for all adult hospital PM examinations.

The scope of inspection included several traceability audits of stored bodies, tissues, samples and related records. These included checking:

- The identification and storage locations of two bodies in the Mortuary by verifying that the details in the Mortuary register matched details listed in the body store and the identification tags on the bodies;
- Two cases where a whole organ had been taken for specialist analysis at another HTA licensed establishment by tracing information from the Mortuary records and registers to confirmation of receipt and confirmation of the wishes of the family regarding retention for research or disposal;
- One case where tissue had been removed for processing and analysis within histopathology by tracing information entered onto the post mortem record and the Department of Pathology database and verifying that this information matched the associated records, blocks and slides resulting from the process of embedding the small samples of retained tissue into wax blocks and mounting onto microscope slides for histopathological examination.

All tissue was fully traceable with no anomalies.

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.	C2	The inspection provided an opportunity to review the detail of the establishment's process for seeking consent for hospital consented PM examination. The DI is advised that members of staff seeking consent for fetal or perinatal PM examinations should document any discussions with the family where information regarding the PM examination is offered but is subsequently declined. By doing so, there can be no doubt that appropriate information was offered to the family. For example, in cases of intrauterine and neonatal death, the establishment offers literature provided by the stillbirth and neonatal deaths (SANDS) charity. However, whilst this literature is offered to the family it may not always be accepted. The DI is advised to revisit aspects of the consent training to remind those involved in the process that the first section on the consent form should be used to document that relevant information was offered to the family with addition of a note to record occasions when the information was not accepted.
2.	GQ1	The DI is advised to update the same or similar name procedure in the Mortuary to include the addition of a visible warning, such as a laminated notice, next to a deceased individual with the same or similar name to another deceased in the mortuary. This will provide an additional safeguard against the occurrence of an HTA reportable incident in connection with viewing and / or release of the correct body.
3.	GQ1, GQ2 & GQ8	The inspection provided an opportunity to review procedures for handling deaths of babies on the maternity ward. The DI is advised to address the following observations: • Retain records of audit of the storage unit to provide evidence of these periodic audits; • Conduct a formal risk assessment of the premises within the Maternity unit where initial storage of babies, placental tissue and samples for analysis takes place to ensure that security arrangements and control of access are robust.
4.	GQ1	The inspection provided an opportunity to review a number of Mortuary standard operating procedures (SOPs). The DI is advised to address the following: • The SOP relating to HTA reportable incidents needs to be updated to reference the current DI and Persons Designated (PD). • An SOP is required to describe the use of freezers in the Mortuary. • An SOP is required to describe the use of specialist reagent: 'RNA later' during PM examinations. • The SOP on record keeping requires updating to describe the exceptional circumstances when it is acceptable to use a pencil to capture initial information in the register whilst awaiting confirmation of details from the coroner's office. • A number of Mortuary SOPs have been written and authorised by the same member of staff, and are therefore not subject to independent review prior to issue. Review of draft SOPs by a person working in the relevant area, other than the author, provides an additional level of assurance that the document reflects working practice and that any

		errors or inaccuracies are identified prior to issue.
5.	GQ1	There is good use of signature log sheets to confirm that members of staff in the mortuary have read, understood and will adhere to standard operating procedures applicable to their role and responsibilities. The DI is advised to consider adopting this approach in other areas of the hospital carrying out licensable activities.
6.	GQ3	The DI is advised to formalise the training of portering staff who access the mortuary out of hours to admit bodies of the deceased. The formal programme of training should aim to identify all those members of portering staff who may undertake duties in connection with HTA licensable activities and should include, but may not necessarily be limited to: • background to the HTA; • portering staff involvement in licensable activities; • Mortuary SOPs applicable to their role and responsibilities; • completing records / paperwork; • definitions of HTA reportable incidents and reporting requirements.
7.	PFE2	The DI is advised to revise the practice of ticking completed actions on cleaning records to include the responsible individual's initials / signature in order to capture the identity of the person undertaking the task.
8.	Licensing	In light of the recent changes to the Executive team, the DI should inform the HTA of the new Corporate Licence Holder contact for the Trust as soon as practicably possible.

Concluding comments

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

The DI has made good use of the role of Person Designated (PD) across the different areas of licensable activity within the establishment. The DI and PDs demonstrate a good understanding of regulatory requirements. The inspection identified a number of areas of licensable activity where the DI and the PDs have influenced and promoted good practice. There is evidence of good communication and teamwork amongst members of staff who are involved in licensable activities. The Department of Pathology benefits from a dedicated Pathology Quality Manager. The Mortuary benefits from an experienced team that has worked together for the past 10 years. The services provided by the Mortuary extend to bereavement support, which includes full involvement in the process for seeking consent for adult hospital PM examinations. The Mortuary team demonstrates a strong commitment to maintaining the dignity of the deceased and the security and care of the deceased whilst in their care. There is also evidence of a strong commitment to considering the sensitivities and needs of the families of the deceased.

The Maternity Unit has sound procedures and practices in place for instances of intrauterine fetal or neonatal death with a strong emphasis on the health and wellbeing of the mother, respecting the wishes of the mother / parents and showing great sensitivity towards the deceased child and the process for sensitive disposal of remains following pregnancy loss.

Advice has been provided to the DI where the HTA identified opportunities for improvement to

existing systems and procedures.

Report sent to DI for factual accuracy: 25 June 2014

Report returned from DI: 9 July 2014

Final report issued: 18 July 2014

Appendix 1: HTA standards

The HTA standards applicable to this establishment are shown below. 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.