Site visit inspection report on performance against HTA quality standards
Kingston Hospital
HTA licensing number 12023

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**

07 – 08 September 2011

Executive Summary

A site visit inspection of Kingston Hospital (the establishment) was carried out by the HTA on 07 – 08 September 2011.

The establishment was found to meet a number of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment; and disposal. However, a major shortfall was found in relation to the disposal standards and a critical shortfall was found in relation to the state of disrepair of the mortuary body storage facilities. In addition, some minor shortfalls were found across all areas.

Notwithstanding the shortfalls identified on inspection, overall the HTA found the Licence Holder, the premises and the practices to be suitable in accordance with the requirements of the legislation. The Desiginated Individual (D) has only recently taken on this role; he is committed to making the improvements necessary to meet the standards and has made some progress in doing so. The person identified to be DI must be in a position to fulfil the statutory duties of the role, as set down in Paragraph 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
- that the conditions of the licence are complied with.

The HTA considers the current DI suitable to act in this capacity.

All 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 mortuary at Kingston Hospital (the establishment) undertakes approximately 300 adult post mortem examinations per year. Most of these are undertaken under the authority of the London–West Coroner, with approximately six per year being consented hospital post mortems. Although the establishment takes consent for paediatric post mortems, these are carried out at another hospital in the area. The establishment does not undertake known high-risk post mortems.

The majority of coronial post mortems are undertaken by a visiting Home Office Pathologist, and for these cases any tissue samples removed for analysis are sent off site. The establishment has its own histopathologists who undertake consented hospital post mortems and coronial post mortems if the Home Office pathologist is unavailable. Tissue removed from bodies of the deceased by in-house pathologists is processed and examined within the establishment.

All areas of the establishment were visually inspected, including the body storage area and post mortem suite in the mortuary, and the areas for storage of relevant material within the histopathology laboratory.

Audits of traceability were conducted for bodies in storage, and tissues taken during post mortem were traced through to analysis and storage. Details of anomalies found are given against standard GQ6.

The establishment had been inspected by the HTA approximately six months previously. The HTA then found a high number of shortfalls across the standards covered, as well as discrepancies between the establishment's self-assessment and the inspection team's findings. This inspection was scheduled to assess if sufficient improvements against shortfalls had been made, and therefore the focus was on the findings of the previous inspection and a small number of standards that had not been assessed.

The establishment has worked hard in the six months between the two inspections to rectify the shortfalls that had been identified and progress has been made, details of which are contained in the concluding comments of this report. However, some consent and governance and quality standards remain unmet and the fridges and freezers used to store bodies remain unsuitable. This had been identified as a major shortfall in the previous inspection and is a serious cause of concern for the HTA, which now considers it to be critical.

To address this critical shortfall, the HTA convened a Regulatory Action Panel (RAP) to consider what regulatory action should be taken. The outcome of the RAP was the issue of Directions to ensure that planned works to provide suitable storage facilities for bodies are completed by 25 November 2011, with the submission of contingency storage plans to the HTA within seven days of the Directions being issued. The HTA will review the suitability of the storage facilities upon completion of the works in a focussed non-routine inspection. If the facilities remain unsuitable, the HTA will consider what further regulatory action would be appropriate.

Meeting the HTA's licensing standards

The HTA developed its licensing standards with input from its stakeholders, in order to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA expects licensed establishments to meet these standards.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a licensing standard is not met, the level of the

shortfall will be classified as ‘Critical’, ‘Major’ or ‘Minor’ (see Appendix 3: Classification of the level of shortfall).

Unless otherwise advised, the establishment is required to inform the HTA within 14 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the improvements are addressed. A template for this purpose is provided as a separate Word document.

HTA standards not met

Consent

Standard	Inspection findings	Level of shortfall
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.	The establishment has no suitable written procedure in place for seeking consent for post mortem examination of still births or neonatal deaths. This was a shortfall found at the first inspection and insufficient progress has been made to rectify it. The consent form for post mortem examinations of a baby or child is the old-style NHS consent form provided by the licensed establishment conducting paediatric post mortem examinations. This establishment is awaiting the final version of the consent form that is being developed by the Stillbirth and Neonatal Death Charity (Sands) in conjunction with the HTA, and intends to change to this form as soon as it becomes available.	**Minor**
C2 Information about the consent process is provided and in a variety of formats.	Patient information on paediatric post mortems incorrectly states that retention of tissue samples in the form of blocks and slides following the post mortem is routine, and does not state that retention for use for a scheduled purpose may only take place with appropriate consent.	**Minor**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	The Mortuary Register records a unique identifier for the deceased when they are brought to the mortuary from hospital wards, but no identifier, for example the date of birth, is used in other cases. Since the earlier inspection, the establishment has introduced a system for recording tissues taken during post mortem examinations in the Post Mortem Examination Register, which is documented in standard operating procedure MOR08. Staff are instructed to transfer details from this register to the Specimen Record Sheet, which requires duplication of information and introduces a risk of incorrect information being recorded. There have been errors in transcription, and the HTA found examples of an incorrect list of tissues being recorded, and an incorrect post-mortem code being used. (Note that SOP MOR08 erroniously instructs staff to record tissues taken in the 'Mortuary Register' rather than the 'Post Mortem Examination Register'.)	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE1 The premises are fit for purpose.	The fridges used for storing bodies of the deceased are not fit for purpose. The wooden frames used to support the body trays and doors are rotten and warped. The interiors of the doors are dented. Condensation from the fridges has led to rust and deterioration of the fabric of the fridges and damage to the flooring of the post mortem suite. The runners that support the body trays are not aligned, causing trays to slope, presenting a risk to the bodies they hold. The door seals are partially detached and are tainted with mildew. One of the doors cannot be used safely because it detaches from its hinges when opened, risking the safety of the staff member. The condenser cooling facilities rattle loudly within the ducting, causing an unpleasant working environment.	**Critical**

	The mortuary premises are in a state of disrepair. Wall coverings are damaged, exposing crumbling plasterwork. Floor coverings are worn and in places lifting from the surface beneath, causing a trip hazard. Suspended-ceiling tiles are improperly fitted, exposing the plenum space. Despite good intentions to make significant improvements to the premises, this major shortfall has been left unresolved since the previous inspection. This has raised the classification of the shortfall against this standard from Major to Critical, because the issues identified above combine to pose a serious risk to the dignity of the deceased and the safety of staff working in that area.	
PFE2 Environmental controls are in place to avoid potential contamination.	Clean and dirty areas of the mortuary are separated by a step-over change area. However, there is a double-doorway that traverses the two areas, which gives trolley access to body storage fridges within the dirty area. These fire doors are propped open by the mortuary staff for constant use and circumvent the change procedure. The establishment uses contracted cleaning services to clean the floors of the mortuary twice weekly. This cleaning is not being recorded, though a weekly check of the cleanliness of the floors is recorded. The cleaning of the interior surfaces of the fridges used to store bodies and tissue samples is not conducted to a schedule. Instead, the Standard Operating Procedure (SOP) instructs personnel to clean the fridges during quieter periods on a 'rolling continuous plan', which risks them remaining uncleaned for longer than anticipated. When cleaning is undertaken, the records made are rudimentary, with no indication of who has completed the cleaning, or the procedures that have been followed.	**Minor**

Disposal

Standard	Inspection findings	Level of shortfall
D1 There is a clear and sensitive policy for disposing of human organs and tissue.	Tissue retention has been routine following the end of the coroner's jurisdiction. The establishment has not ascertained the wishes of the Properly Interested Persons with respect to tissue retention or disposal. The HTA was not able to establish that these tissues were being retained with consent. Similarly, retention of tissues has occurred following hospital post mortems, despite records showing that the person who gave consent for the examination requested disposal of tissues after the diagnosis of death had been determined. Written procedures for the disposal of tissues, including blocks and slides, does not instruct personnel to dispose of post-mortem tissue separately from other clinical waste, and to record the disposal.	**Major**
D2 The reason for disposal and the methods used are carefully documented.	Disposal of tissues may be documented in the establishment's electronic database. However, this is no provision to record the reasons for disposal or the methods used.	**Minor**

Advice

Below are matters which the HTA advises the DI to consider.

No.	Standard	Advice
1.	C2	The HTA advises the DI to ensure that information provided by those seeking consent for adult post mortems explicitly states that tissue blocks and slides can only be stored with consent, rather than them being kept routinely as part of the medical record.
2.	GQ1	The HTA advises the DI to ensure a record is kept of all conversations between mortuary staff and the pathologist where the deceased's medical history and external presentation are discussed and permission is given by the pathologist for mortuary staff to eviscerate the body prior to external examination, thereby ensuring that accountability remains with the Pathologist.
3.	GQ2	The establishment has set up an audit schedule of licensable activities. The HTA advises the DI to ensure that horizontal audits are scheduled of records relating to the removal of tissue during post mortem, and its transfer to the histopathology laboratory.

4.	GQ4	The HTA advises the DI to retrain members of staff in the record keeping procedures ratified in the establishment's Control of Process and Quality Records (Kingston 14) SOP, to halt inappropriate use of pencil, scribbling out, overwriting and correction fluid.
5.	PFE3	The HTA advises the DI to provide written instructions for what to do when an audible fridge-alarm is discovered, for example by portering staff out of hours. In addition, the DI is advised to implement a schedule to test the alarms.

Concluding comments

This inspection provided an opportunity for the establishment to demonstrate the progress it has made against shortfalls found during the inspection in February 2011. This has been facilitated by the appointment of a DI who has protected time in which to undertake this role and is in a position to attend to governance issues.

- The consent policy and written procedures for adult hospital post mortems have been established. New information leaflets have been produced and training is scheduled for those seeking consent.

- Governance meetings with the DI and members of staff have resulted in improvements in the overall management of licensable activities. This has led to wide ranging SOP reviews to ensure that they have sufficient detail, and these documents have been properly ratified.

- A system of internal audits has been established covering all licensable activities. In addition, risk assessments of working practices have been extended to cover risks beyond those associated with health and safety, ensuring proper consideration is given to mitigating risks to the dignity of the deceased.

- Training of members of staff has been enhanced, particularly with carefully documented competency assessments of Anatomical Pathology Technologists.

- The establishment has implemented documented procedures for the identification, investigation and notification of serious untoward incidents. These procedures draw on information provided by the HTA on its website.

The focus now needs to be on improving the premises and facilities and addressing as a matter of urgency the continuing and critical shortfalls against the PFE standards.

Report sent to DI for factual accuracy: 23 September 2011

Report returned from DI: No factual accuracy comments were made by the DI.

Final report issued: 16 November 2011

Appendix 1: HTA inspection process

The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, transplantation, and education and training. The legal requirements for establishments which carry out such activities are set out in the Human Tissue Act 2004 and The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

We license establishments in England, Wales and Northern Ireland that carry out these activities, and inspect them to make sure legal requirements are met.

Inspections

We use the term 'inspection' to describe when we:

- visit an establishment to meet with staff, view premises and facilities, and review policies and procedures (a site-visit inspection); or
- assess written information we have requested from an establishment (a desk-based assessment / inspection).

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that:

- other staff working under the licence are suitable;
- suitable practices are used when carrying out the activity; and
- the conditions of the licence are met.

We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

After every site visit inspection, we write a report documenting our findings. Where we find a particular standard is not fully met, we will describe the level of the shortfall as 'Critical', 'Major' or 'Minor'. In most cases, it will be the responsibility of the DI to seek the HTA's agreement on how they will address the identified shortfalls. More information about the classification of shortfalls can be found in Appendix 3.

The majority of our site-visit inspections are announced. If we have concerns about an establishment, we can also undertake an unannounced site visit inspection.

You can find reports for site visit inspections which took place after 1 November 2010 on our website.

Appendix 2: HTA standards

Standards which are not applicable to this establishment have been highlighted.

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 or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

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

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

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

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

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

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

PFE 2 Environmental controls are in place to avoid potential contamination

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

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

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

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

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

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

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

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

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

Disposal Standards

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

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

  (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

Appendix 3: 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.

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.

Follow up actions

A template corrective and preventative action plan is available as a separate Word document. 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.