Site visit inspection report on compliance with HTA minimum standards

King's College Hospital

HTA licensing number 12377

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**

11 July 2012

Summary of inspection findings

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

Although the HTA found that King's College Hospital (the establishment) had met some of the HTA standards, a number of shortfalls were found in relation to consent, governance and quality, and disposal standards. Areas of particular concern, resulting in major shortfalls, include: the lack of a consent procedure and formal training on taking consent; insufficient audit activity; and the lack of a procedure for acting on the wishes of families in relation to tissue samples, leading to the retention of blocks and slides following post mortem examination rather than their disposal. It is also of concern that the establishment's 2010 audit submission in relation to blocks and slides was incorrect.

Despite the shortfalls, some examples of good practice were observed, and these 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 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
- 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

King's College Hospital is an acute care facility in the London Borough of Southwark and is part of King's College Hospital NHS Foundation Trust. Around 240 coronial post mortem (PM) examinations and 20 consented PM examinations are carried out in the mortuary at the establishment every year. There are facilities within the mortuary to conduct forensic and paediatric PM examinations, although these cases are currently being transferred to other HTA licensed establishments. The mortuary is the only area in the hospital where tissue from the deceased is removed.

Clinicians take consent from families for PM examination with the support of bereavement staff (see standards C1 and C3 for further details relating to consent).

Tissue samples removed during PM examination are placed into small cassettes in the mortuary, which are sent to the onsite histopathology laboratory for processing. Small pieces of excess tissue remaining after cassetting are kept in pots in the mortuary before eventual disposal (see standards D1 and D2). Microscope slides and blocks are recorded on the electronic system in histopathology. Currently all blocks and slides are being stored indefinitely (see standard GQ6.)

There is a separate Neuropathology laboratory on site. Brain tissue samples and whole brains are sent to the lab and there are systems in place to ensure that they are dealt with in accordance with the families' wishes when examination of them is complete.

The establishment has been licensed since 2007 and was previously inspected in June 2009, at which time no conditions were put on the licence but a number of items of advice and guidance were given. It was noted that this advice had been acted upon.

This was a routine site visit inspection. The inspection timetable was developed in consideration of the previous inspection findings, the establishment's last self assessment report and audit submission and information provided by the establishment prior to the inspection. During the site visit, interviews with key staff working under the licence were conducted, as well as a review of key documentation and a number of audits (see below). A visual inspection of the mortuary area and the satellite was undertaken. The labelling and storage of three randomly selected bodies were checked. Information on fridge doors was checked against the wristband and death notice on the deceased, as well as against information entered in the mortuary register and on the electronic computer system. No anomalies were found.

A tissue traceability audit was also carried out as part of the inspection. Three entries in the mortuary specimen book, which specified numbers of blocks taken during post mortem, were checked against the electronic system in the histopathology lab. The electronic system recorded the number of slides taken from each block. Blocks and slides were then located. All records matched and all blocks were located; however, all the slides from one case (20 in total) and one slide from another case (out of a total of eight) could not be located in the laboratory (see standard GQ6). The audit also highlighted inconsistencies between mortuary records and data held in the electronic system in relation to tissue trimmings (see standards GQ4 and D2).

An audit of disposal records could not be carried out as currently all PM material (consented and coronial) is being retained (see standard GQ6). There is no system in the histopathology lab for recording and adhering to the wishes of families with regards to the use or disposal of post mortem tissue blocks and slides.

The satellite site, which is an archival storage area for blocks and slides in a trading unit, was also inspected. Some PM tissue (most of which is neuropathology tissue) is held in the satellite along with diagnostic material. The alarm system on the unit links to security on the trust site. Paper records of blocks and slides stored in the unit are kept. The histopathology laboratory also has an agreement in place with another HTA licensed establishment for storage of archival blocks and slides.

Inspection findings

The HTA found the Licence Holder to be suitable in accordance with the requirements of the legislation.

Although the HTA found the Designated Individual to be suitable in accordance with the requirements of the legislation, the shortfalls identified by the HTA call into question his capacity to fulfil the role effectively given his workload and clinical commitments. The HTA has made recommendations about how governance arrangements in respect of HTA licensed activities could be strengthened and will be monitoring the situation, particularly in relation to rectification of the shortfalls identified below.

Compliance with HTA standards

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.	Although the Trust consent strategy and policy refer to the requirements of the Human Tissue Act, the establishment does not have a Standard Operating Procedure (SOP) on obtaining consent for a PM examination that ensures that legal and regulatory requirements are met (see advice against standard C1 below for more information).	**Major**
C2 Information about the consent process is provided and in a variety of formats.	Consent forms reviewed during the inspection indicated that those giving consent had not always received written information about the consent process.	**Minor**
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	There is no formal training programme for staff involved in taking consent for PM examination that ensures that they are aware of the legal and regulatory requirements. Staff taking consent do not receive annual refresher training. There is no documented evidence of any training on consent for PM examination and HTA requirements having taken place.	**Major**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.	Although the establishment showed evidence of conducting vertical audits in the mortuary, there are no audits of the whole process from reception of the body to its release, including tissue removal, storage of tissue in the histopathology and neuropathology labs, and eventual disposal, repatriation, or further use of tissue with consent. Audits which incorporate all areas of licensable activity would help improve traceability (see standard GQ6) In addition, there was no evidence of horizontal audits being conducted or audits of stored material.	**Major**

GQ4 There is a systematic and planned approach to the management of records.	Records of tissue retained and disposed of are misleading and open to interpretation. This is best evidenced by the incorrect audit information submitted to the HTA in 2010, which did not reflect the actual situation with regards to the retention of blocks and slides. The error came about because entries of 'discarded' in the mortuary specimen book, which referred to tissue trimmings, were mistakenly believed to refer to the disposal of blocks and slides (see also standards GQ6 and D2).	**Major**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	Currently all blocks and slides taken during PM examination are kept indefinitely. There is no formal system in place in the mortuary or in the histopathology laboratories to ensure that blocks and slides are disposed of, or kept for future use, in line with the family's wishes. Where it is specified that tissue is to be returned to the family, a note is made in the mortuary register to ensure that this happens; however, this practice is not formalised. (See advice against standard GQ6 below for more information). As highlighted in the audit carried out as part of the inspection, no record is made when slides are taken out of the histopathology laboratory area to be used by pathologists, which means traceability is compromised.	**Major**
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The establishment has a 'HTA Serious Untoward Incident Reporting' SOP but it does not specify that there is a requirement to report incidents to the HTA within five working days. It does not clearly define who is responsible for reporting to the HTA, especially in the DI's absence, and the lines of internal communication. The Serious Untoward Incident (SUI) classification table in the SOP is not consistent with current HTA information. It is not clear that all staff are aware of the SOP.	**Minor**

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment's risk assessments currently cover areas relating to health and safety. Risk assessments do not currently cover procedures relating to licensable activity and do not cover risks associated with non-compliance with HTA standards. Currently, prior to PM examination, the body is checked by one person only increasing the risk of a PM examination being carried out on the wrong body (see advice against standard GQ8 below for more information).	**Minor**

Disposal

Standard	Inspection findings	Level of shortfall
D1 There is a clear and sensitive policy for disposing of human organs and tissue.	The disposal policy covers disposal of tissue from histopathology only, and does not include disposal of the tissue in the mortuary or Neuropathology. It should reflect HTA requirements as set out in the HTA code of practice on disposal.	**Minor**
D2 The reasons for disposal and the methods used are carefully documented.	There is no system in place to ensure that tissue is disposed of in a timely fashion, or that it is disposed of in accordance with the documented wishes of the deceased person's family (see standard GQ6) and the HTA code of practice on disposal.	**Major**

Advice

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

No.	Standard	Advice
1.	NA	The DI is advised to strengthen his oversight of all areas where licensable activity is taking place by increasing communication with persons designated and appointing further persons designated where appropriate.
2.	C1	The DI should develop an SOP for consent which outlines who is responsible for taking consent, what training they should have, how often they should undertake refresher training and what support those taking consent have. It should also outline how consent is taken, which paperwork is used, what the process is if families change their mind, and who is the most appropriate person to give consent under the HT Act.
3.	GQ1	The DI should consider putting a system in place to record and monitor deviations from SOPs which are not sufficiently serious to constitute an 'adverse incident'.

4.	GQ4	Although the neuropathology department has good systems in place to ensure the traceability of tissue it receives from the mortuary, stronger and more systematic lines of communication regarding the fate of neuropathology tissues would mean that mortuary records could be kept up to date.
5.	GQ6	The establishment plans to use a new form to record tissue samples taken and their destination, along with the family's wishes. Information about samples removed will be taken from the tracking form which is completed in the PM room and travels with samples. The new forms will be kept by the mortuary as a more detailed record. In addition, the establishment plans to create an electronic system accessible by both the mortuary and the laboratory to track the fate of tissues. These new procedures should be implemented as soon as possible and may help address the shortfalls identified above. In liaison with the Coroner, all PM tissue (coronial and consented) that post dates the Human Tissue Act should be audited with a view to disposing of any samples that have been kept without the knowledge and consent of families. The DI should refer to the HTA codes of practice on post mortem examination and disposal for further guidance.
6.	GQ8	There is an SOP for PM examination which sets out that Anatomical Pathology Technicians may eviscerate before the pathologist arrives, but that this should only be on the instruction of the pathologist, who is responsible for the conduct of the PM. In order to mitigate the risks this may pose, the practice should be formally risk assessed and the SOP should be revised to incorporate a list of situations where it would not be appropriate to eviscerate in the absence of a pathologist. In addition, a checklist/ sign off would help to assure that appropriate ID checks are made in a consistent manner prior to evisceration.

Concluding comments

The mortuary is well maintained and kept in good condition and there is a good level of compliance with premises, facilities and equipment standards. The commitment of the mortuary staff to providing a good level of service to the bereaved was noted.

There are a number of areas of practice that require improvement, including six major shortfalls and four minor shortfalls. The HTA has also given advice to the Designated Individual on how improvements may be made.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 03 August 2012

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 28 August 2012

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 30 November 2012

Appendix 1: HTA standards

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

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

Governance and quality system standards

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

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

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

GQ2 There is a documented system of quality management and audit

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

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

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

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

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

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

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

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs 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 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.