Site visit inspection report on compliance with HTA minimum standards

East Surrey Hospital

HTA licensing number 12117

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**

22 February 2012

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.

Although the HTA found that East Surrey Hospital (the establishment) had met the majority of the HTA standards, shortfalls were found in relation to consent and governance and quality systems. The establishment has fallen behind with the implementation of some planned audits and review of some SOPs; however on the whole the SOPs are of a good standard and reflect the activities carried out. Plans are in place to train staff in obtaining consent for paediatric post-mortem (PM) examinations to the same high standard as for adult cases; however this has yet to be carried out. Further detail needs to be recorded for tissue samples collected at PM examination in order to ensure full traceability from removal through to retention or disposal.

Since the last inspection the establishment has continued to comply with HTA standards and areas for improvement previously identified have been acted upon. Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

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

The statutory duties of the Designated Individual are set down in 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

East Surrey hospital carries out approximately 800 adult post-mortem (PM) examinations each year, the majority of which are coronial cases with approximately ten forensic cases undertaken for the West Sussex Coroner and only a small number of consented hospital PM examinations. The establishment refers paediatric cases to two other licensed establishments in the region. The maternity and emergency departments are also licensed for removal of tissue from the deceased, which is occasionally necessary in the event of a sudden unexpected death of an infant or child up to the age of 18 years. Whilst this has occasionally occurred within the emergency department it has not yet taken place within the maternity department.

This was the second routine inspection of the establishment, the first one having been undertaken in 2009. It was noted that the condition placed on the licence and advice given following the 2009 inspection had been duly acted upon.

The inspection comprised interviews with members of staff, a review of relevant documentation and visual inspections of the following: emergency and maternity departments, mortuary, body store and histology laboratory tissue storage area. An audit was carried out on the body store during which the details on the wrist bands of two of the deceased

were compared with corresponding details in the mortuary register. No anomalies were found. Four cases in which tissue had been retained at PM examination were selected, one of which was a hospital consented PM examination. The blocks and slides from these cases were audited against the mortuary records of the wishes of the bereaved for retention, repatriation or disposal of tissue samples and all samples audited were being retained with appropriate consent. It was not possible to verify the number of blocks and slides that should have been present in the histology laboratory, as the record of tissue samples collected at PM examination is held in the mortuary and only tissue type not quantity is recorded. This has been recorded as a shortfall against GQ6. The histology database detailed the number of blocks and slides processed. Comparing the database with the blocks and slides stored identified one block was missing from the storage tray and a number of the slides had been removed and were being held by a pathologist. Records of organs transferred offsite for analysis and returned for repatriation were also reviewed and were complete.

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

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 procedure for obtaining consent for adult hospital consented PM examinations is documented; however there is no such procedure for taking consent for paediatric cases, which follow a different process (not least because they are transferred to another hospital) and for which consent is taken by different staff. Parents should be given specialist information about what the pathologist is seeking to find out and what this could mean for parents and future children. In the absence of a specific documented procedure it is unclear what information is provided and there could be inconsistency between different members of staff.	**Minor**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	Some SOPs were noted to have passed their review date, and whilst some had a table of signatures indicating that individuals had read and acknowledged that version of the document, this was not standardised for all SOPs. The trust SOP for serious untoward incident (SUI) reporting does not include the requirement to notify the HTA of relevant SUIs within five working days and it does not incorporate incidents involving paediatric cases. There is a policy and protocol detailing the process for dealing with the death of an infant or child within the emergency department. This includes a flowchart detailing steps to be taken and a checklist for samples that are required. However, these documents have not been ratified and hence are not appropriately authorised, approved or controlled. Staff are aware of the procedure for dealing with unexpected high risk cases during a PM examination, however this is not documented.	**Minor**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	The type of tissue samples collected at PM examination is written on the coroner's form; this information is held within the mortuary but is not shared with histology staff and does not include the number of samples for each tissue type. Several samples, of same or different tissue type, are placed within each formalin pot and only the number of pots is recorded on the histology request form that accompanies the samples. If a sample were misplaced, laboratory staff would not be aware of the discrepancy. In addition, when mortuary staff dispose of tissue samples in line with the wishes of the bereaved, they do not have a record of samples taken to check against and ensure all samples are disposed of. This could lead to unintended retention.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	SANDS, the Stillbirth and Neonatal Death Charity, is producing some guidance on PM examination of babies later this year, which includes a model consent form. This may be useful to the DI in developing consent procedures for paediatric PM examinations.
2.	C3	Staff taking consent for paediatric PM examinations have not received specific consent training. The DI is advised to ensure that the consent training by the licensed establishment where paediatric cases are transferred for PM examination goes ahead as planned.
3.	GQ1	The DI is advised to consider involving all staff (APTs, Pathologists and others), who work within the mortuary in mortuary meetings. This will enhance discussions of any issues and make everyone aware of any changes in practices.
4.	GQ2	Audit reports are completed in a variety of formats. The DI is advised to ensure that the audit report template and the way it is completed is standardised, so that, for example, the use of 'yes' and 'no' to indicate compliance and the 1-5 scoring system used is clear.
5.	GQ2	The DI is advised to ensure that all actions from audits are implemented and closed off and that these steps are documented. Some actions were noted still to be open and it was unclear if the actions had been completed.
6.	GQ6	To help make the identification procedure more robust, the DI is advised to consider using the mortuary 'M number' as an additional identifier on deceased with the same or similar names.
7.	GQ6	In the case of a paediatric death, nursing staff have implemented a checklist to ensure that the details of any tissue or fluid samples collected are recorded. However, more information is needed to provide a complete audit trail. The DI is advised to ensure that further details are recorded including who took consent, the nature of the sample taken and when/by whom/to where it was transferred. The DI is further advised to include these additional details within the relevant SOP.
8.	GQ7	Incidents are reported and investigated to identify root causes which are documented. However the DI is advised to ensure that the lessons learnt and any subsequent changes in procedures which mitigate the risk of the incident reoccurring are also formally documented and shared with members of staff to maximise the learning and improvements made as a result of the incident.
9.	PFE2	The DI is advised to replace the mortuary floor squeegee and drain plunger, which both have wooden handles, with alternatives that do not contain porous materials to ensure that they can be effectively cleaned and decontaminated.

Concluding comments

During the inspection a number of areas of good practice were identified. APT staff have received consent training from the Association of Anatomical Pathology Technologists and

work with clinicians to ensure valid consent to adult hospital PM examinations is obtained.

To safeguard against commencing a PM examination prematurely, a red wrist tag is placed on the deceased after the pathologist has identified the deceased and authorised the APT to eviscerate following the external examination.

Issues with identification of the deceased had been identified by mortuary staff when deceased were brought in from the community by ambulance. Mortuary and ambulance staff held a meeting to discuss the issue, and as a result all staff are now aware of the procedure of wrist tagging that must be carried out in order to ensure the deceased is identifiable. A simple flowchart has also been devised to remind staff of the correct procedure.

The establishment has carried out a number of risk assessments around misidentification of the deceased, particularly during receipt and release of bodies in the mortuary. As a result, good procedures to mitigate the risks have been identified.

The mortuary has recently been renovated in consultation with the mortuary staff. New mortuary flooring has been installed and improvements have been made to changing areas facilitating better movement between clean and dirty areas. Additional fridges have been added to the body store so that half of the 100 fridges as well as 8 freezers are suitable for storage of bariatric cases.

The system and procedures for dealing with the death of an infant or child within the emergency department have been well considered. The use of a 'bereavement box' is a good practice. The bereavement box is prepared, sealed and stored in the emergency department pending a requirement for use. It contains the necessary sample containers together with a checklist of the required samples, associated forms and a flowchart summarising steps to be taken.

Several areas of practice requiring improvement have been identified, including 3 minor shortfalls. The HTA has given advice to the Designated Individual with respect to strengthening traceability and record keeping, finalising audit and incident reports and staff attendance at training and meetings.

The HTA requires the Designated Individual to address the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report. Appendix 2 of this report contains recommended timeframes within which to complete actions. Following receipt of the completed CAPA plan, the HTA will 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: 20 March 2012

Report returned from DI: 3 April 2012

Final report issued: 11 April 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: 22 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.