Site visit inspection report on compliance with HTA minimum standards

Princess Alexandra Hospital

HTA licensing number 12458

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**

5 December 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 Princess Alexandra Hospital (the establishment) had met the majority of the HTA standards, shortfalls were found, particularly in relation to the consent standards.

The form used to record consent for paediatric/perinatal PM examination is based on an obsolete Department of Health form, which does not meet HTA requirements. In particular, although it gives families of the deceased a range of options with regards to any whole organs that have been removed and retained for further analysis, the form states that blocks and slides will be kept as part of the deceased's medical record.

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

The HTA's regulatory requirements

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

The statutory duties of the Designated Individual are set down in 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

Princess Alexandra Hospital has a mortuary carrying out approximately 660 post mortem (PM) examinations per year. Around 610 of these take place under the authority of the Coroner, with the remaining 50 being consented, hospital PM examinations. Of these, the majority are perinatal and paediatric PM examinations, with the remainder being adult consented PM examinations. The establishment also undertakes forensic and some known high risk PM examinations, such as Hep B, Hep C, HIV, TB. Known high risk cases involving higher grade pathogens such as CJD are transferred to another licensed establishment.

This was the second routine site-visit inspection of the establishment to assess whether it is continuing to meet the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's last self-assessed compliance information and audit of stored material, as well as pre-inspection discussions with the DI and review of the previous inspection findings. During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken.

Prior to the inspection, the DI identified an area outside the mortuary where the licensable activity of removing tissue from the body of the deceased may take place: the maternity department where samples may be taken from still born babies. The establishment's licence covers the Princess Alexandra Hospital's site meaning that although remote to the mortuary, the area where this removal may take place is appropriately licensed.

Therefore, as part of the inspection the maternity department was visited and a brief discussion held with a senior sister and ward manager. The maternity department staff demonstrated an understanding of the requirements of the Human Tissue Act 2004 and the establishment's governance systems, and the HTA was satisfied with the arrangements in place covering this activity.

Although staff demonstrated an awareness of the requirements of the Human Tissue Act 2004 and the establishment's governance systems, they are not formally recognised on the licence as Persons Designated and advice has been given with regards to this below. A shortfall was also identified which relates to the paediatric/perinatal consent for PM examination form that is being used to record families consent. The form that is being used is based on an old Department of Health form which does not fully detail the scheduled purposes that retained tissue may be used for. In addition, although giving families of the bereaved a range of options with regards to any whole organs that have been removed and retained for further analysis, the form states that blocks and slides will be kept as part of the deceased's medical record. The form should make it clear that blocks and slides will only be retained if appropriate and valid consent is given for their retention and the possible uses for which the tissue may be used.

An audit of bodies stored in the establishment's fridges was undertaken during the inspection. Three bodies were chosen at random and identification details recorded on body tags (those attached on the ward or in the community as well as the tags containing the unique mortuary reference number) were checked against details in the mortuary register and on the mortuary fridge doors. No anomalies were found during this audit.

A tissue traceability audit was also undertaken as part of the inspection. Four coronial cases where tissue had been taken during the PM examination were selected at random. Details of the tissues retained were cross checked between the mortuary's paper and electronic records and the histopathology laboratory's electronic records. Additionally, the physical blocks and slides were sought, and the numbers checked against the establishment's electronic records. Coronial family's wishes forms were checked as part of the audit. In one of the four cases, the records indicated that one block and one slide should be in the establishment's tissue archive. The block could be found, but the slide was missing. Although this minor discrepancy was identified, the establishment does have systems of audit that should detect further discrepancies. As all blocks and slides from the other three cases were found and tallied with the electronic records, the HTA was satisfied that there is not a systemic issue; however, the establishment is advised to continue with its audits of retained tissue to help identify any other discrepancies.

In another case, the establishment had not yet received the family's wishes form from the Coroner. The establishment has a database which tracks PM examinations and whether the family's wishes form and the notification of the end of Coronial authority has been received. The DI has identified a Person Designated to maintain this database and records of family's wishes and coronial authority. Advice has been given to the establishment below suggesting that regular audits of this database should be undertaken to assure the DI that appropriate documentation is received for all cases. No other anomalies were found during the tissue traceability audit.

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 form that is being used to record consent for paediatric/perinatal PM examination is based on an obsolete Department of Health form, which does not reflect the range of potential uses for which consent must be obtained. In addition, although giving families of the deceased a range of options with regards to any whole organs that have been removed and retained for further analysis, the form states that blocks and slides will be kept as part of the deceased's medical record. The form should make it clear that blocks and slides will only be retained if appropriate and valid consent is given for their retention and future use.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	Two weeks prior to the inspection, a body storage fridge alarm system was fitted, which became operational the day before the inspection. Therefore, the establishment has not yet produced SOPs covering how high and low limits are set, how temperature monitoring takes place and how frequently the alarm, and especially the auto dialler that contacts switchboard in the event of a breakdown, are tested. The DI is advised to include a schedule for testing and a system to record that the fridge alarm has been tested when producing SOPs related to the fridge alarm system.
2.	GQ1	Some of the establishment's SOPs refer to undertaking identity checks on the deceased. The SOPs however do not detail which details are used to confirm identity. The DI is advised to amend the SOPs to detail which forms of identifying information should be used when confirming the identity of the deceased, for example, name, date of birth, address, unique mortuary number.
3.	GQ2	The establishment has a database which tracks PM examinations and whether the family's wishes form and the notification of the end of Coronial authority have

		been received. The DI is advised to develop a schedule of audits of this database with the aim of finding any cases where family's wishes or end of Coronial authority notifications have not yet been received. These can then be followed up with the Coroner and appropriate action taken which will help the DI assure herself that any retained tissue is being dealt with in accordance with the relatives' wishes.
4.	GQ7	The establishment has copies of the HTA guidance for reporting Serious Untoward Incidents (SUIs) to the HTA which details what constitutes an SUI and how it should be reported to the HTA. In the establishment's quality manual, there are details of who should report an SUI and who should do this in the absence of the DI. The DI is advised to consider producing a single SUI SOP which can be more easily shared with staff working under the licence so that they are aware of what constitutes an SUI and how to report one to the HTA.
5.	GQ8	The establishment does have some risk assessments which specifically assess the risks to the bodies and tissues stored at the establishment. The DI is advised to build upon the existing suite of risk assessments using the SUI categories as a framework to do this. Assessing the establishment's risk of each of the SUI categories occurring and indentifying actions to mitigate the risks of them occurring will strengthen the establishment's risk governance system.

Concluding comments

Despite the minor shortfall, areas of good practice were observed throughout the inspection.

The establishment's bereavement staff have undertaken an extensive training program covering the seeking of consent for PM examination. Clinicians who undergo consent training have given positive feedback on the training and there is a rolling program of training events to ensure as many clinicians as possible are able to access it. In addition, bereavement staff work through a checklist with the person giving consent at the end of the meeting, checking that they are the most appropriate person to give consent and that they have fully understood what they have consented to.

In the mortuary, staff have acted on findings from a recent CPA audit and have purchased a new fridge alarm system. Mortuary staff also explained plans to roll out a new unique identifying number system to local funeral directors. This will add a level of traceability and security when releasing bodies, as the funeral director will have to quote this unique reference number when collecting bodies.

The mortuary runs part of the nurse induction programme, briefing them on mortuary practice, body identification and the requirements of the Human Tissue Act 2004.

There is one area of practice that requires improvement which constitutes a minor shortfall (C1, above) and the HTA has given advice on a range of issues for the DI to consider.

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: 21 December 2012

Report returned from DI: 15 January 2013

Final report issued: 31 January 2013

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: 27 February 2013

Appendix 1: HTA standards

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

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

Governance and quality system standards

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

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

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

GQ2 There is a documented system of quality management and audit

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

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

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

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

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

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

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.

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

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