**Site visit inspection report on compliance with HTA minimum standards**

**Ashford and St Peter's Hospitals NHS Foundation Trust**

**HTA licensing number 12542**

**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**

**23 October 2012**

## Summary of inspection findings

Ashford and St Peter's Hospital NHS Foundation Trust (the establishment) was subject to a themed inspection focusing on consent, quality management and prevention of major equipment failures.

Although the HTA found that the establishment had met the majority of the HTA standards in these areas, some shortfalls were found. Two major shortfalls were identified in relation to consent, particularly to the retention of tissue blocks and slides, and the identification procedures followed when the deceased are received in the mortuary.

The DI and the Licence Holder were assessed and found to be suitable in accordance with the requirements of the legislation at the establishment's previous inspection in July 2009. The DI continues to remain suitable, demonstrated by the overall high level of compliance the establishment has achieved against HTA standards. However, since the DI is not directly involved in post-mortem related activities, a member of staff with day-to-day operational oversight of the licensable activity may be better placed to fulfil this role.

Following the last inspection, the establishment has continued to comply with the majority of HTA standards; in addition, areas for improvement previously identified have been addressed. 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.

A themed inspection may be carried out at establishments which have been found previously to represent a lower risk of regulatory non-compliance. Themed inspections focus on standards against which the HTA has identified common shortfalls across the post mortem sector and areas of risk identified from analysis of serious untoward incidents reported to the HTA. The themes selected for 2012/13 business year are outlined in the table below.

| **Themes** | **HTA Standards** |
|---|---|
| **Appropriate consent is in place for post-mortem examinations not under the Coroner's jurisdiction and in the event that tissue is to be retained for future use. Where there is no consent for retention, tissue is disposed of.** | |
| 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. | C1 |
| Information about the consent process is provided and in a variety of formats. | C2 |
| Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent. | C3 |

| | |
|---|---|
| **Governance and quality systems promote robust traceability systems, reducing the risk of serious untoward incidents.** | |
| All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process. | GQ1 |
| There is a documented system of quality management and audit. | GQ2 |
| A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail. | GQ6 |
| There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly. | GQ7 |
| Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately. | GQ8 |
| **Fridges and freezers safeguard the integrity of the deceased.** | |
| There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records. | PFE3 |

In addition to the standards listed above, the HTA will follow-up on any other issues that have arisen since the establishment's last inspection.

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**

Ashford and St Peter's Hospital NHS Foundation Trust carries out approximately 600 routine coronial post-mortem examinations every year. Adult consented hospital PM examinations are undertaken very rarely and none have been completed in the last 12 months. Forensic and paediatric cases are transferred to another licensed post-mortem facility, though staff at the establishment are responsible for taking consent for paediatric hospital PM examinations. The establishment is also licensed for the activity of removal.

This was the second routine inspection of the establishment, the first one having been undertaken in 2009. The areas of non-compliance and advice given following the previous inspection had been duly acted upon. This establishment had been selected for a themed inspection; however, following submission of a serious untoward incident to the HTA relating to minor damage to a body that is believed to have occurred prior to receipt in the mortuary, the HTA decided it would be appropriate to review the admission process in detail as part of

this inspection. A shortfall was found in the identification checks carried out as part of this process and details are provided under GQ6 below.

The inspection comprised interviews with members of staff, a review of relevant documentation and visual inspections of the following departments at St Peter's Hospital: neonatal intensive care unit, mortuary, body store and histology laboratory tissue storage area. The body store has capacity for 75 adult fridge spaces, ten deep freeze spaces and six dedicated paediatric trays. An audit was carried out in the body store, during which the details on the wrist bands of three of the deceased were compared with the notice of death form attached to the shroud and corresponding details in the mortuary register and the admission paperwork, which is completed by the porters or funeral directors. No anomalies were found. In addition, two cases in which tissue had been retained at PM examination were selected. The blocks and slides from these cases were audited against the mortuary records of the wishes of the next of kin for retention, repatriation or disposal of tissue samples. The number of blocks and slides located tallied with the records held and the consent for retention.

## Inspection findings

The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation. The DI is not directly involved in the mortuary, and oversight of licensable activity is managed through established governance systems and appropriate persons designated. Advice has been provided by the HTA on the role of the DI.

## 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.<br>&<br>C2 Information about the consent process is provided and in a variety of formats. | Consent to non-coronial paediatric PM examinations is recorded on the 2003 NHS Paediatric consent form, which includes a statement about blocks and slides being kept indefinitely as part of the medical record. This does not comply with the requirement for consent to be obtained for the storage of tissue for a scheduled purpose, as set out in the Human Tissue Act.<br>The practice of retaining blocks and slides without specific consent is also reflected in the outdated NHS guide to PM examination involving a baby or child; the information leaflet for parents provided by the establishment to which paediatric cases are transferred for PM examination; and the Trust Simple Guide to the Post Mortem examination Procedure, which is normally used when obtaining consent for adult PM examinations. | **Major** |

**Governance and Quality**

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail. | Bodies brought to the mortuary from the ward are wrapped in a clean sheet with the notice of death attached to it; bodies brought in from the community are sealed in body bags and accompanied by paperwork completed by the funeral director with details of the deceased's identity. When receiving bodies into the mortuary the mortuary staff do not check the identity of the deceased by their wrist tag, as written in the admission procedure SOP. This check is only performed on the accompanying paperwork.<br><br>An incident has occurred recently, where the wrong hospital label was attached to the notice of death form and went undiscovered until enquiries were made to the mortuary about a deceased person for whom they held no records. Opening the shroud or body bag to carry out an identity check on the wrist band enables reconciliation of gender and age with the details provided and also review of the condition of the deceased to ensure they are handled and stored appropriately.<br><br>The absence of such checks could lead to a reoccurrence of the error in identification and avoidable deterioration of the deceased. | **Major** |

## Advice

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

| No. | Standard | Advice |
|---|---|---|
| 1. | C1, C2 & C3. | The Sudden and Neonatal Death Charity (SANDS) will be publishing a model consent form, guidance for consent takers and information for bereaved parents in January 2013. The DI is advised to review the establishment's paediatric consent procedures in light of these, and make adjustments as appropriate. |
| 2. | C2 | The policy on consent refers to an information video which is available for relatives to view. The DI is advised to ensure that the content of the video is |

| | | |
|---|---|---|
| | | reviewed at the same time as the policy to ensure the information it provides remains accurate. |
| 3. | GQ1 | The establishment has a good range of SOPs, which cover all licensable activity; however the DI is advised to include additional detail to some SOPs to ensure clarity and consistent practices, such as defining the personal protective equipment that must be used for high risk cases and detailing that the mortuary number is to be added to the label of histology pots. |
| 4. | GQ1 | Two deceased have been stored within the freezer in the body store for over a year whilst attempts are made to find and contact family members so that funeral arrangements can made. The DI is advised to work with the Trust and the local authority to implement a policy for dealing with cases where it is not possible to contact the family and to set a maximum storage period. |
| 5. | GQ6 | The DI is advised to ensure the mortuary reference is recorded as a unique number by the addition of the year or sequential letters, so that when the numbering begins again at the start of each year, cases with the same number but from different years can easily be recognised. |
| 6. | GQ6 | A reminder is entered in the mortuary register to make staff aware that there is more than one individual with the same or similar name. The DI is advised to ensure staff also place a reminder on the shroud or wristband of the deceased, so that the prompt remains even when the body has been moved into the PM examination room. |
| 7. | PFE3 | The body store fridges are monitored and alarmed. Staff print out the temperatures from the associated data logger, which provides a detailed output for a single day. The DI is advised to review the temperature variations seen over the course of a week or month to look for trends in fridges working above or below the intended temperature, which may indicate a fault. |
| 8. | PFE3 | Toxicology samples are stored in a fridge pending courier collection for offsite analysis. The fridge temperature is monitored manually by staff on a daily basis but the fridge is not alarmed. The DI is advised to consider moving toxicology samples to a dedicated part of the alarmed body store, should samples not have been collected, particularly before a bank holiday weekend. |
| 9. | - | The HTA advises Ashford and St Peter's Hospitals NHS Foundation Trust to consider whether a member of staff with more direct involvement in mortuary activities would be more suited to undertake the role of Designated Individual. |

## Concluding comments

A number of strengths and areas of good practice were noted during the inspection and examples are given below.

The establishment ensures that only trained staff obtain consent to a PM examination by bereavement staff checking the training status of staff before they are provided with the consent form for completion. Bereavement staff also try to be present when consent is being obtained to support the relatives and help ensure they fully understand the information provided in order for valid consent to be given.

When samples that have been removed at PM examination are requested to be repatriated with the deceased, wet tissues are returned to the body. As this is not appropriate for blocks

and slides, the establishment staff place the body and the tissue blocks and slides within a body bag to ensure that the body and all samples are released together.

There are a number of areas of practice that require improvement, including two major shortfalls. The HTA has given advice to the Designated Individual on a range of issues, including ensuring that up to date consent information is used, staff have clear SOPs and policies to refer to and that trends in fridge temperatures are reviewed over a suitable time period.

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:** 20/11/12

**Report returned from DI:** 21/11/12

**Final report issued:** 30/11/12

**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 January 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.<br>• 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).<br>• 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.<br>• Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event.<br>• 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).<br>• 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.<br>• 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.<br>• Refresher training is available (e.g. annually).<br>• Attendance at consent training is documented.<br>• 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.