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

**Croydon Health Services NHS Trust**
**HTA licensing number 12305**

**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**

**28 February 2012**

## Summary of inspection findings

The establishment was found to have met nearly all HTA standards. Two minor shortfalls in relation to standards on consent (C2) and governance and quality systems (GQ8) were identified. The HTA considers that these two areas could be improved by maintaining an active list of staff formally trained to take consent and by establishing a set of risk assessments with a clear focus on mortuary-specific practices and procedures.

The HTA found the Designated Individual (DI), the Licence Holder (LH), the practices and all aspects of the premises to be suitable in accordance with the requirements of the legislation.

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**

The mortuary at Croydon Health Services NHS Trust (the establishment) carries out a small number of hospital consented post-mortem (PM) examinations, six (or fewer) in each of the last three years. The mortuary also provides storage for deceased patients from the hospital and bodies from the community. However, it does not carry out PM examinations on behalf of the Coroner. Post-mortem examinations for paediatric and high risk cases are sent to other HTA licensed establishments. The mortuary has two full time members of staff, both qualified Anatomical Pathology Technicians (APTs). The senior APT is also the mortuary manager.

The DI is the Pathology Services Manager. The LH is Croydon Health Services NHS Trust with the Medical Director acting as the named contact.

The establishment was first inspected in November 2008. There were no conditions imposed on the establishment's licence at that time. This inspection, undertaken on 28th February 2012, was a routine inspection, which also provided an opportunity for the HTA to review on site goveranance arrangements in respect of licensed activities following a change in Designated Individual in 2010.

The site visit included a visual inspection of the premises (body store and post mortem room) and formal interviews with the Desigated Individual, Consultant Histopathologist, Mortuary Manager, Specialist Midwife and the Corporate Licence Holder Contact.

A number of traceability checks were conducted. An audit was carried out on two bodies stored in the mortuary. Identification tags were checked and all associated paper and electronic records were reviewed. Three hospital consented PM cases where histology had

been taken were selected for audit. All paper and electronic records were reviewed and the number of blocks and slides stored in the Pathology Laboratory was checked. A further audit trail was undertaken in relation to a body that was sent to another HTA licensed establishment for PM examination and subsequently returned. Finally, a consent form and documentation relating to brain and spinal tissue removed and transported to another HTA licensed establishment for the purpose of research were also checked.

A document review of the establishment's policies and operational procedures was also undertaken. This included review of consent forms and information, risk assessments, audit reports for 2011/12, incident reports, meeting minutes, maintenance records and the quality manual (histopathology department).

**Inspection findings**

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

Consent procedures are documented and staff who take consent - clinicians, APTs and midwives - are generally knowledgeable about the procedure to be followed when taking consent. However, there is no system to ensure that consent is always taken by formally trained staff.

The premises are clean and well maintained with appropriate marking of transitional zones. Fridge temperatures are monitored and alarmed. The premises, facilities and equipment are generally fit for purpose.

The operational practices undertaken are generally suitable. Staff are trained and able to update their skills. The quality management system is effective. However, some policy and operating procedures do not specifically refer to the HTA (please see example documents in the advice section). Risk assessments do not currently address mortuary practices and processes but focus on general health and safety issues. In relation to disposal standards, currently disposal of human tissue from the deceased does not take place as all material is repatriated with the body prior to funeral/cremation arrangements. However, the existing disposal policy (M005) does not make this clear and therefore does not distinguish between the nature of any potential material to be disposed of (i.e. whether the material is from the living or deceased), reasons for disposal, or specifically how tissue from the deceased would be disposed of.

With regard to the audits of traceablility undertaken, there were no discrepancies found on the selected examples either within mortuary or histology records.

Working practices are generally 'paper-lite' with patient records mainly managed electronically, including details relating to the initial receipt of bodies at the mortuary through to return of bodies to funeral directors.

## Compliance with HTA standards

## HTA standards not met:

### Consent

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent. | There is no established consent training programme for staff. Additionally, a list of individuals including clinicians, midwives and APTs who have been trained to take consent is not currently maintained. Staff should be formally trained to take consent for perinatal and adult PM examinations as required by HTA's code of practice 1 – Consent. | **Minor** |

### Governance and Quality

| Standard | Inspection findings | Level of shortfall |
|---|---|---|
| GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately. | Existing risk assessments deal with health & safety issues. Risk assessements of risks directly related to bodies and tissues have not been undertaken. | **Minor** |

## Advice

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

| No. | Standard | Advice |
|---|---|---|
| 1. | C2 | The current 'Guide to PM examination procedure (2003)' pre-dates the Human Tissue Act and should be updated. Please refer to the HTA website for an example up-to-date version. |
| 2. | C3 | The DI may wish to consider the potential benefits of mortuary staff undertaking the HTA e-learning package. |
| 3. | GQ1 | Existing SOPs and policies should specifically reference and accurately reflect HTA requirements set out in the relevant Codes of Practice, e.g. M005 (Disposal of Materials), M017 (Removal of Organs/Tissues for Donor Purposes), M019 (Body Donation for Medical Research) and M025 (Retention and Preparation of Organs and Tissue) need to be updated accordingly. |
| 4. | GQ7 | The SUI reporting categories set out in M037 (Adverse Incident Reporting) should be updated to reflect the current HTA criteria for SUI classification. The |

| | | |
|---|---|---|
| | | DI should be assured that relevant staff have read and understood the SUI reporting requirements, e.g. a signed record of staff training related to this SOP may be beneficial. |
| 5. | GQ8 | Risk assessments based on defined SUI categories should be prioritised. |
| 6. | PFE3 | The DI should establish a policy which clearly sets out the maximum time for which bodies may be stored in refrigerated units. Contingency arrangements should be in place if this period of time is exceeded. The mortuary does not have a freezer and so arrangements may have to be made to transfer bodies to another establishment which has suitable long-term storage facilities. |
| 7. | D2 | Currently there is no disposal of human tissue from the deceased. However, it is advised that the existing disposal policy (M005) be updated to include detail as to the nature of the material potentially being disposed of, how and why disposal should take place (if and when appropriate). |

## Concluding comments

The establishment has an experienced team which is fully engaged and committed to maintaining a fully functional post-mortem facility, despite the limited number of PM examinations conducted each year. The DI communicates regularly and effectively with personnel mortuary staff. The establishment of formal bi-monthly mortuary meetings within corporate and governance Trust structures, with clear reporting lines, provides a mechanism for engagement with key staff at an operational and strategic level. A number of examples of strength and good practice were seen. The establishment has a simple but very effective recording system for current body storage; multiple (recorded) checks for release of bodies from the mortuary; and a systematic audit schedule for mortuary activities, including an audit against HTA standards.

A new policy is currently being drafted for consent taking and this should be cognisant of the comments above (particularly under C2 and C3). Additionally, consent procedures for paediatric post-mortem examination should be updated in line with recommendations by SANDS (stillbirth and neonatal death charity), anticipated in Summer 2012.

There are some areas of practice that require improvement and the HTA has given advice to the Designated Individual with respect to these.

The HTA requires that the Designated Individual addresses the two identified 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 shortfalls identified during the inspection.

**Report sent to DI for factual accuracy: 19 March 2012**

**Report returned from DI: No factual accuracy comments received from DI**

**Final report issued: 30 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: 31 August 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.<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.