Site visit inspection report on performance against HTA quality standards
Darent Valley Hospital
HTA licensing number 12226

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**

25 August 2011

Executive Summary

A site visit inspection of Darent Valley Hospital (the establishment) was carried out by the HTA on 25 August 2011.

The establishment was found to meet most of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment; and disposal. However, several shortfalls were found. In particular, two minor shortfalls were identified in relation to obtaining consent for hospital post-mortem (PM) examinations. There were two minor shortfalls and one major shortfall found in relation to governance and quality systems, the latter relating to the establishment's coding and recording system for the traceability of bodies, body parts and tissues. A further two minor shortfalls were found in relation to the premises, facilities and equipment standards. Examples of strengths or good practice were also found and these are outlined in the concluding comments section of the report.

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

The Designated Individual (DI), also the Pathology Directorate Clinical Director, is removed from the daily operational oversight of licensable activities due to his seniority within the hospital. His imminent retirement calls for the selection of a more suitable individual to take on this role, that is, an individual who has closer involvement in the management of licensed activities. The Corporate Licence Holder Contact, also the Chief Executive Officer of Darent Valley Hospital, has been advised of the procedure to follow to replace the DI.

All 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

This report refers to the activities carried out in relation to the post-mortem services provided by Darent Valley Hospital, Dartford, which is under the governance of Dartford and Gravesham NHS Trust.

The hospital was built under a Private Finance Initiative (PFI) and opened in 2000. Approximately 550 adult PM examinations are carried out there each year under the authority of a HM Coroner for Kent County. No adult hospital-consented PM examinations have taken place since 2007. Coronial PM examinations are carried out by independent Home Office pathologists appointed by the Coroner. The pathologists transport any wet tissue removed during PM examination to another licensed establishment for processing and examination. Tissue is not returned to the establishment for disposal at this establishment. This means that only blocks and slides taken for the purpose of a hospital-consented PM examination are stored in the hospital's own histopathology department. At the time of the inspection, there was no tissue from the deceased stored on site. Paediatric cases are transferred to other licensed establishments.

The mortuary has previously been limited for space, particularly over the winter. In light of this, temporary fridges were installed approximately 18 months ago. The DI informed the inspection team that additional fridges needed to be rented last year to cope with deaths over the winter months. This remains the contingency arrangement until any future plans for the mortuary service have been agreed and finalised.

The establishment has been licensed by the HTA since November 2007. The first HTA site visit inspection took place in August 2007. All conditions imposed on the establishment's licence were subsequently actioned by the Designated Individual and closed by the HTA. This report describes its' second routine site visit inspection in August 2011.

Inspectors met with staff involved in licensable activities, inspected the mortuary and the histopathology laboratory, and reviewed documentation. A vertical audit of tissue removed at PM examination for histopathological analysis was carried out for two deceased persons. Another audit was carried out of two bodies stored in the mortuary. Identification tags were checked and all associated paper records were reviewed.

Meeting the HTA's regulatory requirements

The current DI is due to retire in March 2012 and therefore a new DI needs to be identified. The person identified must be in a position to fulfil the statutory duties of the role, as 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
- that the conditions of the licence are complied with.

The HTA will assess the suitability of the proposed DI on receipt of an application to change the DI from the Trust.

Meeting the HTA's licensing standards

The HTA developed its licensing standards with input from its stakeholders, in order to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA expects licensed establishments to meet these standards.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a licensing standard is not met, the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor' (see Appendix 3: Classification of the level of shortfall).

Unless otherwise advised, the establishment is required to inform the HTA within 14 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the improvements are addressed. A template for this purpose is provided as a separate Word document.

HTA standards not met

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.	There is no documented policy which governs consent for PM examination and the retention of tissue. There is no documented procedure 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 PM examination). Although the hospital has not conducted a hospital consented PM examination since 2007, it retains the ability to carry out such activity.	**Minor**
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	The Lead Consultant Histopathologist was able to describe the procedure for taking consent. However, not all consultant histopathologists expected to be involved in this procedure have received formal training in the implications and essential requirements of taking consent for post-mortem examination.	**Minor**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ4 There is a systematic and planned approach to the management of records.	Documented procedures for records management exist within the pathology directorate but these did not extend to the mortuary service.	**Minor**

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	Current identification systems and associated records rely on the name and age of the deceased (which are not unique identifiers) to provide traceability of bodies, body parts, tissues and cells. An identification number exists but it does not strengthen traceability, for example: • an identifier based on a sequential number is recorded in the mortuary register on receipt of a body, and reverts back to the number 1 at the beginning of each year. This allows the establishment to keep track of the number of bodies that come through the mortuary but does not provide a unique identifier. • the identifier is not utilised when recording identifying information on wrist/ankle bands, pathologist's records, pot labels or any other record pertaining to the deceased. • if the body of an unknown person is brought into the mortuary, staff rely on the location it was found as the main identifier for their purposes, with information from Coroner's records used as a backup where there are multiple bodies. • to reduce the misidentification of a body with the same or similar name as another body stored in the mortuary, the mortuary register is marked with a star. However, when inspectors reviewed the register, they noted that on one occasion this system had not been implemented. These findings represent a system that has significant risks of misidentification which have not been suitably mitigated.	**Major**
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	Written polices and procedures do not include the requirement to report Serious Untoward Incidents to the HTA. Staff are not trained in how to use the incident reporting system.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE2 Environmental controls are in place to avoid potential contamination.	Demarcation within the mortuary of 'clean', 'transition' and 'dirty' areas, and the procedures to be followed in each case, are not clear.	**Minor**
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	The temporary fridges for the storage of 18 bodies are monitored for their temperature during normal working hours only. There is no alarm system for monitoring out-of-hours including weekends and so variations outside of normal temperature ranges are not made known to staff. Although these fridges are for the purpose of managing overflow, the quality and integrity of bodies would be seriously compromised in the event of an equipment failure.	**Minor**
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.	The PFI partner is responsible for the maintenance of equipment and premises. An exhaustive list of maintenance activity was not available to the DI, making it difficult for him to assure himself that the premises and equipment are well maintained and subject to a programme of planned preventative maintenance.	**Minor**

Advice

Below are matters which the HTA advises the DI to consider.

No.	Standard	Advice
1.	GQ1	There are documented policies and procedures covering all aspects of mortuary activity and the post mortem process. However, Standard Operating Procedures (SOPs) could be improved by: • providing accurate links to other SOPs • providing actions to be taken when a 'pitfall' is identified.
2.	GQ2	Policies and procedures are subject to document control, which could be extended to forms and key documents used in the daily operation of the mortuary.
3.	GQ3	Staff retention levels are high within the establishment. Some staff have been in post for over 20 years. To keep abreast of current issues and best practice in the field of post mortem and human tissue regulation, it is recommended they subscribe to HTA newsletters and complete e-learning modules provided on the HTA website.
4.	GQ4	In drafting a SOP and implementing a system for records management, the following should be considered: • the records which must be maintained • how they are backed up • where records are kept • how long each type of record is retained • who has access to each type of record.
5.	GQ6	Current systems for repatriating tissue with the body of the deceased after the pathologist's analysis and examination and prior to the release from the mortuary to the undertaker could be enhanced by placing a visible reminder on the deceased.
6.	GQ7	Prior to revision of the documented incident reporting procedures to include reporting of Serious Untoward Incidents to the HTA, it is recommended that the information contained on the HTA website is reviewed: (http://www.hta.gov.uk/licensingandinspections/reportingtothehta/seriousuntowardincidentreporting.cfm)
7.	GQ8	All SOPs have been assessed for health and safety risks to staff. SOPs identify other significant practice-related risks and these are described under the header: 'pitfalls'. The DI may wish to consider more formally assessing these risks and identifying the actions taken to mitigate them.

Concluding comments

While a number of shortfalls were noted at this inspection, several areas of strength and good practice were also apparent, including a strong team working ethos amongst staff and a close working relationship with the Coroner's Office. Staff were provided with regular training as well as other opportunities for professional development. There is also a robust quality management system with a good range of SOPs. A dedicated quality manager for the pathology department has worked with mortuary staff to review existing documents and risk assessments for licensable activities.

Report sent to DI for factual accuracy: 16 September 2011

Report returned from DI: 30 September 2011

Final report issued: 31 October 2011

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: 21 September 2012

Appendix 1: HTA inspection process

The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, transplantation, and education and training. The legal requirements for establishments which carry out such activities are set out in the Human Tissue Act 2004 and The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

We license establishments in England, Wales and Northern Ireland that carry out these activities, and inspect them to make sure legal requirements are met.

Inspections

We use the term 'inspection' to describe when we:

- visit an establishment to meet with staff, view premises and facilities, and review policies and procedures (a site-visit inspection); or
- assess written information we have requested from an establishment (a desk-based assessment / inspection).

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that:

- other staff working under the licence are suitable;
- suitable practices are used when carrying out the activity; and
- the conditions of the licence are met.

We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

After every site visit inspection, we write a report documenting our findings. Where we find a particular standard is not fully met, we will describe the level of the shortfall as 'Critical', 'Major' or 'Minor'. In most cases, it will be the responsibility of the DI to seek the HTA's agreement on how they will address the identified shortfalls. More information about the classification of shortfalls can be found in Appendix 3.

The majority of our site-visit inspections are announced. If we have concerns about an establishment, we can also undertake an unannounced site visit inspection.

You can find reports for site visit inspections which took place after 1 November 2010 on our website.

Appendix 2: HTA standards

Standards which are not applicable to this establishment have been highlighted.

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 3: 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.

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.

Follow up actions

A template corrective and preventative action plan is available as a separate Word document. 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.