Site visit inspection report on compliance with HTA minimum 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**

13-14 February 2017

Summary of inspection findings

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

Although the HTA found that Darent Valley Hospital (the establishment) had met the majority of the HTA standards, two major shortfalls (against the consent and governance and quality standards) and one minor shortfall (against the premises, facilities and equipment standards) were found. The major shortfalls relate to the lack of formal consent training and sign off for perinatal PM consent training and the lack of formalised training for mortuary staff. The minor shortfall relates to the absence of a formalised contingency plan for when the mortuary reaches capacity.

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 DI, Licence Holder, premises and practices are suitable.

The statutory duties of the DI are set down in Section 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

This report refers to the activities carried out at Darent Valley Hospital (the establishment). This was the fourth site visit inspection of the establishment, the previous one having been a non-routine inspection that took place in 2015 to review corrective actions resulting from an earlier inspection and to provide advice following an HTA reportable incident.

This inspection included a visual inspection of the body store, post mortem (PM) suite, viewing area and area where histology samples are collected prior to transfer for analysis. Interviews with members of staff and a review of governance and quality documentation were also undertaken. A number of audits were also undertaken.

The Designated Individual (DI) responsible for supervising activities taking place under the HTA licence is the Clinical Lead for the Pathology Directorate in the hospital. The Corporate Licence Holder (CLH) is Dartford and Gravesham NHS Foundation Trust and the CLH contact is the Chief Executive of the Trust.

At the time of inspection, the mortuary was under the management of the General Pathology Manager and staffed by a trainee Anatomical Pathology Technologist (APT) and two locum APTs. Approximately 500 PM examinations are conducted each year by a visiting Pathologist, the majority on behalf of the HM Coroner for West Kent and occasionally for the areas of Central and South-East Kent. In busy periods, an additional visiting Pathologist is available. The establishment conducts forensic and high risk PM examinations up to category 3. Hospital consented PM examinations are not conducted.

Perinatal and paediatric cases for PM examination are transferred to another HTA-licensed establishment and, after the PM examination is finished, the body is returned to the establishment for released for burial or cremation. Where there is no coronial involvement, consultants involved in the patient's care seek consent for these cases. The consent form is self-explanatory with step-by-step instructions for the consent seeker; however, despite this being identified as a shortfall in the previous inspection, there is currently no formal training for staff in seeking consent for peadiatric/perinatal cases (see shortfall against standard C3).

Histology samples taken from PM examination are cassetted in the mortuary and then transferred to another HTA licensed establishment for analysis. Toxicology samples are collected every week and sent to Kent Scientific Services for analysis. The Coroner's Office conveys the disposal wishes of the family directly to the Pathologist, who then communicates these wishes to the hospital. The hospital carries out the family's wishes once they have received notification that coronial authority has ended. Paperwork relating to the wishes of the family is kept by the hospital and the Pathologist who carried out the PM examination.

The body store has refrigerated space for 76 bodies and an additional 42 spaces in temporary storage units, which includes three bariatric and three super bariatric spaces. There are three freezer spaces. The fridge and freezer door seals and handles have recently been replaced.

There is a newly-installed dedicated fridge for products of conception, perinatal and paediatric bodies. (There is no fridge on maternity for paediatric bodies and bodies are transferred directly to the mortuary by porters.) A verbal agreement exists with a local funeral home but there is no formal written contingency agreement in the event that the mortuary reaches capacity (see shortfall against standard PFE3).

Access to the mortuary is by swipe card and key. The entrance to the mortuary is in a secure location. The facility is wired and ready for CCTV; however, this is yet to be connected (see advice item 4).

Fridges and freezer temperatures (permanent and temporary units) are continuously monitored using a remote monitoring system and an alarm will trigger when the range goes below or above the set limits, with the exception of the peadiatric fridge; its temperatures are currently being monitored by the APTs until it is connected to the same system. In the case of an emergency out of hours, the porters are contacted to attend the mortuary.

During working hours, porters admit hospital cases and funeral directors admit community deaths into the mortuary. When bodies are admitted, the porter or fuineral director completes a sign-in sheet with the deceased's identification details and then places the body into the fridge. An APT will check the identification tags and transfer the identification details into the mortuary register. They then, attach a new wrist tag with the name of the deceased and a unique mortuary identification number which corresponds to a number in the mortuary register book. Every morning, APTs also do a check of same/ similar names in the mortuary. Where this is identified, a red sticker marked 'same/similar name' is placed on the whiteboard next to the name of the body and the register book is highlighted.

Out of hours, bodies are admitted in the same way and APTs do a check of the body and the identification details the following working day.

The establishment has a contract with an external company for portering. The same company also organises the maintenance and repair of mortuary equipment. Porters are trained in mortuary procedures by a senior porter and undertake competency assessments before being allowed to admit bodies unsupervised.

Bodies are always released during working hours and funeral directors must present paperwork before release. As a minimum, three identifiers are checked by the APT and the funeral director against the paperwork. The funeral director signs and dates the mortuary register book once a body is released. For coroner's cases, the APT highlights the name in the register book in yellow to show that the body is ready for release. This mitigates the risk of release before the Coroner's authority has ended.

The PM suite has two separate rooms. The main room has two down-draft tables and a cut-up dissection bench. The second PM room, which is used for high risk PM examinations, has one down-draft table and a cut-up dissection bench.

The pathologist completes the external examination of the body and identification checks before evisceration takes place. PM examinations are conducted one at a time and a tag with the deceased name is attached to the outside of the bucket of organs to mitigate the risk of returning the organs to the wrong body.

At the time of the inspection, the establishment was getting ready for refurbishment of both PM rooms in accordance with the 'hospital lifecycle' policy, whereby equipment is replaced and upgraded. The mortuary has been liaising with the Coroner to make alternative arrangements for PM examinations during this time.

Viewings for adult bodies are arranged directly between the family and mortuary staff. There are no viewings conducted out of hours. Before a body is prepared for viewing, at least two APTs check the identification details of the body.

During the inspection, the HTA conducted an audit trail on three bodies stored in the refrigerators. Body location and identification details on body tags were cross-referenced against the information in the register book, fridge doors and whiteboard. Same/similar name processes were also checked. No discrepancies were found.

An audit trail was also conducted on three coronial cases where histology samples and a heart were taken during the PM examination and sent off site for analysis. Relevant paper records and consent forms were checked. No discrepancies were found.

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

Two major shortfalls and one minor shortfall were found in relation consent, governance and quality, and premises, facilities and equipment standards. See below.

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 formal documented consent training for clinicians who seek consent for perinatal PM examinations	**Major**

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills	At the time of the inspection there was only one permanent staff member, who is a trainee APT. There is no permanent member of staff at the establishment who can train and sign off new staff in mortuary procedures. There is no formalised training or competency assessment for the trainee APT.	**Major**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	The establishment has a verbal agreement with a local funeral home to provide contingency storage for bodies. However, there is no formal agreement in the event that the mortuary reaches capacity.	**Minor**

Advice

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

No	Standard	Advice
1.	GQ3	The DI is advised to implement a formalised training programme for new staff in the mortuary, including competency checks, and identify a person responsible for mentoring the trainee APT.
2.	PFE3	There is no documented procedure in place outlining when bodies should be moved into long-term freezer storage. The HTA recommends that bodies should be moved into freezer storage at 30 days or sooner, depending on the condition of the body. The DI is advised to align procedures with the HTA's guidance set out on page 7 (paragraph 24) of its report on storage capacity and contingency arrangements in mortuaries: https://www.hta.gov.uk/sites/default/files/Capacity%20and%20Contingency%20Report%20Nov%2015.pdf In the event that a body cannot be moved into long-term freezer storage within the 30 days, the DI is advised to log the reason, make a note of the condition of the body and keep the situation under review in case alternative arrangements have to be made. The DI is also advised to monitor the management of long stay bodies and escalate the matter through the appropriate channels in the Trust when necessary.
3.	PFE3	The establishment has three freezer spaces and they were all occupied at the time of inspection. It is recommended that the DI risk assess current freezer storage capacity and ensure that there are systems in place to mitigate the risk of running out of freezer space.
4.	PFE3	The DI is advised to connect the CCTV outside the mortuary as soon as possible to increase the security of the mortuary.
5.	NA	The DI is advised to appoint a Person Designated (PD) on the licence who can oversee activities and report incidents to the HTA in absence of the DI. The PD should be a permanent senior member of staff who has some involvement in mortuary activities.

Concluding comments

There were some areas of good practice observed during the inspection. Since the previous inspection, there has been an improvement in the oversight and governance of mortuary procedures such as receipt and release of bodies. The trainee APT and locum staff appear to communicate and work well together as a team. There is also a comprehensive training programme for porters, which requires them to shadow an experienced member of portering staff for two weeks, when admitting bodies into the mortuary and complete a written competency questionnaire before sign off. There are thorough audits conducted of activities under the licence.

The HTA has given advice to the DI on a range of issues relating to consent, governance and quality systems and premises, facilities and equipment.

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 time frames 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: 08 March 2017

Report returned from DI: 23 March 2017

Final report issued: 27 March 2017

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 22 March 2018

Appendix 1: HTA standards

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

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

Governance and quality system standards

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

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

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

GQ2 There is a documented system of quality management and audit

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

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

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

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

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

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

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

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- 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.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person’s

family.

- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

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.