Site visit inspection report on compliance with HTA minimum standards

Dorset County Hospital

HTA licensing number 12449

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**

30 July 2015

Summary of inspection findings

The HTA found the premises and the practices to be suitable in accordance with the requirements of the legislation.

Although the HTA found that Dorset County Hospital (the establishment) had met the majority of the HTA standards, three minor shortfalls were found in relation to standards on governance and quality systems (GQS) and one major shortfall was identified as a result of findings in relation to one of HTA's premises, facilities and equipment (PFE) standards.

The DI will retire from the establishment before the end of the 2015 and a replacement will need to be identified to take over this statutory responsibility. Mortuary practices require attention and it is important that the DI, both current and future, has support from the senior team in undertaking this role.

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 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

Dorset County Hospital no longer receives the bodies of people who have died in the community, and post-mortem (PM) examinations on behalf of HM Coroner do not take place either; these are conducted at another hospital licensed by the HTA (licensing number 12405). The last adult hospital (consented) PM examination was conducted over eighteen months ago, so this is an activity that takes place infrequently. The establishment does not employ Anatomical Pathology Technologists (APTs) but has bank contracts with APTs employed by the other licensed establishment referred to in this paragraph.

The mortuary primarily stores the bodies of patients who have died in hospital, pending collection by funeral directors. Occasionally, it may store a body brought in by ambulance for a short while, before it is transferred to the other hospital for a PM examination under the authority of the Coroner. The DI, a pathologist, conducts the occasional hospital PM examination at the establishment as well as those for the Coroner conducted at the other hospital.

Four perinatal and paediatric hospital post mortem examinations have taken place at the establishment in the last twelve months. These are conducted by a specialist paediatric pathologist, who undertakes identity checks with support from the mortuary assistant before eviscerating the body. Tissue samples retained during PM examination are placed directly into labelled cassettes and taken to the histology laboratory for analysis.

Porters and nursing staff bring bodies from within the hospital and place them into refrigerator spaces in the body storage area. They complete a form to hand over to mortuary staff detailing the identity of the deceased, property and which location has been used to store the body. Mortuary staff check identification details and patient property before recording all relevant details in the mortuary register and onto a database spreadsheet. Each body received into the mortuary is given a unique, sequential number.

For body release, the identity of the funeral director who has authority to take the body is checked by the mortuary staff. At handover to the funeral director, a mortuary staff member checks identity and property details with them before the register is completed and signed by both to confirm release.

The mortuary staff work closely with the bereavement office, who manage family viewings of the deceased.

Dorset County Hospital (the establishment) has been licensed by the HTA since July 2007. This was the third routine on-site inspection. The first was in October 2009, followed by a non-routine on-site inspection in November 2010. A second routine on-site inspection was conducted in January 2012.

This latest inspection included: i) review of documentation; ii) meetings with those conducting licensed activities; iii) visual inspection of the premises; and iv) traceability audits of bodies in storage and tissue samples taken for histology during the last paediatric post mortem (PM) examination. The HTA licence extends to the Maternity Unit and Casualty Department at the hospital, for the purpose of removing relevant material from deceased children in cases of sudden unexpected death in infancy (SUDI). The Casualty Department was not included in the visual inspection of the premises.

Traceability audits included: (i) inspection of wrist and ankle bands and the ‘ward form’; details were cross checked against the mortuary register, the mortuary board and the electronic database; (ii) samples collected at PM examination were traced to consented

storage in the histology laboratory; (iii) a reverse audit of products of conception (POC) could not be completed satisfactorily as the histology laboratory does not keep an inventory of POCs released to the mortuary (see shortfall against GQ6).

Whilst undertaking the audit of POCs, the HTA observed that the temperature of the maternity fridge is not monitored and there is no alarm system to alert maternity staff if the temperature goes out of range (please refer to PFE3).

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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	The DI does not have oversight of mortuary activities and does not meet with staff working under the licence. Many SOPs lack detail about the processes to be followed and therefore may not reflect current practices. For example: (i) the management of samples taken in cases of SUDI; (ii) the transfer of babies and products of conception from the Maternity Department, via the Histology laboratory, to the mortuary. Service level agreements with the courier company responsible for the transport of the deceased to a second HTA-licensed establishment were not available for review during the inspection. Cumulatively, these findings represent a minor shortfall against this standard.	**Minor**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	The HTA was not able to trace POCs from the Maternity Department through the Histology laboratory to storage in the mortuary because of the lack of records of traceability.	**Minor**
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	There is no system in place for ensuring that HTA reportable incidents are reported to HTA.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	The storage area for bariatric patients is inadequate and no contingency arrangement for such storage is in place. There is no oversight of mortuary fridge maintenance by the estates department. The mortuary alarm is not tested regularly to ensure it works as it should when temperatures go out of range. The fridge in Maternity for storing babies and POC is not temperature monitored or alarmed. Fridges and freezers in the mortuary and the Maternity Department are not subject to routine maintenance. Cumulatively, these findings represent a major shortfall against this standard.	**Major**

Advice

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

No.	Standard	Advice
1.	N/A	In advance of the current DI retiring, the establishment needs to identify a suitable person to take over the role of DI. There should not be a period during which there is no DI and it is preferable for there to be a handover from the current to the new DI. The DI should be in a position to provide sufficient support to any member of staff involved with licensed activities. To assist them in their role, they are advised to identify a number of Persons Designated (PDs) responsible for specific areas where licensed activities take place, for example, in the mortuary, in the Casualty Department, in the Maternity Department and/or in the Histology laboratory.
2.	GQ1	Although the details of funeral directors visiting the mortuary are recorded in the mortuary register, there is no system in place which records the details of people visiting the mortuary; for example, the families of the deceased, tissue retrieval teams, nurses or maintenance staff. Maintaining a log of visitors to the mortuary is a security measure which may help mitigate the risk of unauthorised access.
3.	GQ3	The mortuary assistants have not had training on HTA statutory and regulatory requirements. The DI is advised to consider encouraging staff to interact with more experienced colleagues at HTA-licensed establishments conducting post mortem activities which may be beneficial to their continuing professional development.

Concluding comments

Despite the shortfalls, some examples of good practice were seen during the inspection:

- Mortuary assistants have been proactive in ensuring that known risks are mitigated and that preventative actions are taken.
- The Maternity Department has a well-considered consent training plan.

There are a number of areas of practice that require improvement, including one major shortfall and three minor shortfalls. The HTA has also given advice to the Designated Individual on a range of matters, which include the logging of visitors to the mortuary and professional support for mortuary staff.

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: 26 August 2015

Report returned from DI: 27 August 2015

Final report issued: 27 August 2015

Completion of corrective and preventative actions (CAPA) plan

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

Date: 20 October 2015

Appendix 1: HTA standards

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

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

Governance and quality system standards

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

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

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

GQ2 There is a documented system of quality management and audit

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

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

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

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

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

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

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

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

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