Site visit inspection report on compliance with HTA minimum standards

Great Western Hospital

HTA licensing number 12003

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 January 2016

Summary of inspection findings

A site routine visit inspection of the Great Western Hospital in Swindon (the establishment) was carried out by the HTA on 28 January 2016.

Although the HTA found that the establishment had met the majority of the HTA standards, three minor shortfalls were identified in relation to governance documentation (standard GQ1), the coding and records system facilitating traceability of bodies (GQ6) and documented risk assessment (standard GQ6).

The HTA found the Designated Individual, the Licence Holder, the premises and the practices 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, along with advice and guidance on how to improve systems further.

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 (DI) are set down in Section 18 of the Human Tissue Act 2004 (HT Act). 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 licenses 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 Great Western Hospital (the establishment) has been licensed by the HTA since 2006. This was the third inspection for the establishment, the previous ones being in 2007 and 2011.

The establishment conducts over 400 coronial post mortem (PM) examinations each year, including high risk cases. Hospital consented PM examinations are rare and none were carried out in the 12 months prior to the inspection. When they take place, consent is sought by trained hospital staff, supported by mortuary staff, who ensure that families have a clear understanding of what is involved in a PM examination and are given the opportunity to ask questions; additionally mortuary staff contact the family before the PM examination itself to double check that they wish to proceed.

Perinatal and paediatric cases are transferred to other HTA-licensed establishments.

The mortuary is located on the lower ground floor of the main hospital building and has separate entrances for hospital deaths, community deaths and for visitors coming for

viewings. Access to the mortuary is by swipe card and the DI regularly gets information from the system to monitor who has entered the mortuary and confirm that only those who should have access, do. The areas outside the mortuary are also secured by CCTV.

The coroner has a nominated funeral director to bring bodies to the mortuary; their employees are trained by mortuary staff. In order to gain access to the mortuary out of hours, the funeral directors must go to hospital security and sign out a key card; the card must be returned to security when they are finished. Deceased patients from the hospital are brought down from the wards by porters who have been trained in the admission process.

The mortuary has space for 74 bodies; this includes five freezer spaces and 12 temporary spaces provided by a temporary body storage system erected within the PM suite. Twenty two of the fridge spaces can accommodate bariatric bodies, four of them being suitable for larger bariatric bodies. Funding for an additional 12 permanent fridge spaces has been approved, which will replace the temporary unit. There is a separate fridge for infants and babies. The main adult fridges are alarmed and there is a call-out procedure in the event of temperature variation beyond the higher trigger. The paediatric fridge and temporary storage have alarms which sound locally. The temperature monitoring system for the fridges is soon to be replaced (see advice item 3).

The PM suite has four fixed PM tables; however, one of these was not being used at the time of the inspection due to the placing of the temporary body storage system in the PM suite. Pathologists examine organs from the deceased one case at a time in a dedicated area of the PM suite. By only examining organs from one body at a time, the establishment aims to minimise any potential risk of mixing up organs from different cases.

There are three pathologists located at the hospital, who work on a rota system for carrying out PM examinations; they are always involved in identification of the deceased and examine the body before evisceration, although this is sometimes the day before the PM examination takes place. Where this is the case, the establishment's procedure is that the pathologist checks the ID of the deceased against the relevant paperwork and adds a red wristband to the body to indicate that the ID checks have been performed. The anatomical pathology technician (APT) then re-checks the ID on the day of the PM examination prior to evisceration.

The establishment has a viewing room for family viewings and identification purposes; access from here to the rest of the establishment is restricted and a member of mortuary staff is always on the premises during viewings. Viewings are arranged directly with mortuary staff, who collect visitors from an agreed location and escort them to the viewing room. As viewings are sometimes undertaken out of hours and staff may be working alone, there are two separate panic buttons linked to hospital security. The establishment's lone working policy requires staff to inform security when they arrive on site and when they leave.

In addition to managing the mortuary, mortuary staff operate the bereavement service. This means they know the circumstances in which a local authority burial is required and can expedite arrangements with the council to make sure this takes place promptly.

The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted a visual inspection of the mortuary and PM suite.

An audit of bodies stored in the establishment's fridges was undertaken. Three bodies were

chosen at random, two of which had same or similar surnames. Identity details on each body including the mortuary unique identifier number were cross checked against details on the mortuary's body location whiteboard, fridge doors and the mortuary register. One body did not have a mortuary identification number at the time of the audit, but this was because it had been brought into the establishment overnight from the community and the mortuary staff had not yet conducted the routine body receipt checks during which a second wristband is added to the body containing the unique identifier.

Some minor discrepancies were found in other parts of the traceability system (see advice item 2).

Tissue traceability audits were also undertaken. Details of tissue samples removed during three PM examinations were taken, all of which were under coronial authority. In each case, the mortuary unique identifier was used to trace tissues. Records checked include the mortuary records, the laboratory's traceability systems and copies of the 'family wishes' forms. In two of the three cases, the blocks and slides were located and the numbers of each correlated with the laboratory records, which was in line with the families wishes for retention. In the third case, the family had opted for disposal with regards to retained tissue and these blocks and slides had been disposed of as coronial interest in the case had ceased. Records of disposal were seen.

Additionally, during the audit a case was reviewed where a whole organ had been retained during the post mortem examination for specialist analysis. Records were reviewed detailing the transfer of the organ for analysis, the return of the organ following analysis and release of the organ to the family's funeral director. No anomalies 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

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are supported by ratified documents policies and procedures as part of the overall governance process	The establishment has a comprehensive list of SOPs however the inspection team found some inconsistencies where they didn't reflect practice, for example: - SOP MOR-S-013 describes the same name system; in practice, this is applied to same and similar names; - SOP MOR-S-012 states that family members may choose to collect the deceased themselves but makes no further comment as to what the process is if that occurs. It also refers to two funeral director representatives transferring the deceased to their trolley, but in practice this may be one funeral director representative and one member of mortuary staff; - Current SOPs do not describe how to report an HTARI if the DI is away. *(See advice item 1)*	**Minor**

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells ensuring a robust audit trail	On inspection there were some issues identified that could affect accurate location of the deceased. During the audit, a minor discrepancy was found where the card with a name on the fridge door did not match the details on the body, whiteboard or mortuary register. Staff thought this had been due to the some name cards being knocked off the fridge doors and the wrong card being replaced on that particular fridge. The incorrect card was removed during the audit. The establishment also has an additional 12 fridge spaces in a unit outside the mortuary in a secure hospital yard. A review of the bodies in this storage showed a discrepancy between the mortuary body location whiteboard and the number of bodies in the fridges. A review of the body identifiers on one body and the mortuary register showed that this was due to a body having been released but its details not being removed from the whiteboard. Additionally, another body had been removed and then returned to this fridge but upon return, due to its size, was placed on a lower shelf than it had been on previously, again the details on the whiteboard had not been updated. (See advice item 2)	**Minor**
GQ8 Risk assessments of the establishments practice and process are completed regularly and are recorded and monitored appropriately	Risk assessments cover areas of health and safety but do not address risks to the deceased, such as accidental damage, release of or PM on the wrong body or disposal of tissue samples, contrary to the family's wishes.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	The DI is advised to review all SOPs and update them to ensure that they accurately reflect current processes.
2.	GQ6	The establishment carries out a nightly check of the fridges to tally the number of bodies in the fridge against the white board. The DI is advised to enhance this audit to include the specific fridge space.

3.	PFE3	The main bank of fridges has an upper alarm limit and the temperature is monitored. A new temperature monitoring system will shortly be installed and the DI is advised to extend this system to the paediatric fridge and the fridges not in the main body store area. The fridge alarm has an upper temperature trigger set but the DI was uncertain of the exact details or whether there is a lower trigger option available. The DI is advised to check these and, if possible, activate a lower temperature trigger. The fridge alarms are checked regularly; however, the entire call out process is not. The DI is advised to carry out occasional checks of the system and associated procedures.

Concluding comments

This report outlines the third HTA site visit inspection to Great Western Hospital. A number of areas of good practice were observed.

The mortuary team appear to work well together; they are conscientious and are keen to add value to the service and the Trust where possible. They are proactive in their dealings with the coroner's service and have worked closely with the coroner's staff to develop paperwork that works well for them.

There is an additional whiteboard in the mortuary office for hospital deaths, which contains all the information required at a glance, if staff are asked about what stage in the process the deceased is at; for example, there are tick boxes for when each cremation form is completed.

Labelling for the same and similar name system is clear and there is an additional bright sticker placed on the shroud, which is easily visible when the fridge door is opened. Babies from maternity come through the mortuary, even if being sent off site for PM examination; details of the mother's full name and date of birth are required for release. This mitigates the risk of releasing the wrong body.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 23 February 2016

Report returned from DI: 3 March 2016

Final report issued: 3 March 2016

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: 28 July 2016

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.