Site visit inspection report on compliance with HTA minimum standards

Taunton & Somerset NHS Trust

HTA licensing number 12083

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**

22 July 2015

Summary of inspection findings

A site visit inspection of the mortuary of Taunton & Somerset NHS Trust, based at Musgrove Park Hospital (the establishment), was carried out by the HTA on 22 July 2015.

Although the HTA found that the establishment had met the HTA standards under consent, governance and quality and disposal, a minor shortfall was identified under premises, facilities and equipment standards in relation to the condition of the post mortem suite walls.

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

Taunton & Somerset NHS Trust has been licensed by the HTA since 2007. The establishment conducts approximately 400 coronial post-mortem (PM) examinations each year, as well as occasional hospital consented PM examinations, for which consent is sought by trained and experienced mortuary or hospital staff. High risk, perinatal/paediatric and forensic cases are transferred to another HTA-licensed establishment for PM examination.

The fridges and current mortuary equipment limit the size of body that can be accommodated in the mortuary to below 140kgs. Any larger bariatric cases are therefore sent to other HTA-licensed establishments for PM examination.

The mortuary is in a separate building at the rear of the hospital, which mortuary staff access via secure keypad. Funeral directors and porters use an entrance at the side, which has covered vehicular access. Porters have a key and funeral directors must be buzzed in by staff.

The mortuary receives bodies from the hospital and from the community. Bodies arriving from the hospital have a hospital identification tag, which includes all the key identifiers of the deceased. If there are any issues with the tag, the mortuary ensures that someone from the ward comes to the mortuary to confirm the identity of the deceased and apply the correct information. Bodies from the community sometimes have limited information and where this is the case, the mortuary follows this up with the coroner to ensure that they have sufficient identifiers.

The mortuary has 50 fridges spaces, eight of which can accommodate bariatric bodies; there is currently no freezer capacity. There is dedicated space for infants and babies. There is additional emergency storage capacity of 12 spaces in other secured premises in the hospital grounds; this unit has its own dedicated cooler. The main mortuary fridges are alarmed at an upper temperature, which is regularly checked by staff, but due to their age cannot be alarmed for a lower temperature. The fridges and trays are old and are scheduled to be replaced this year which will increase capacity and allow for upper and lower temperature alarms.

Unusually, the premises still have porcelain post-mortem tables, which, while fit for purpose, present a number of challenges for staff, particularly as the tables are not height adjustable. Some staff have to use a standing platform whilst conducting a PM examination, which presents an additional risk. In addition, sinks attached to the end of the PM tables appear unstable when weight is applied. The establishment is planning to replace one of the three PM tables with a stainless steel height-adjustable table; however, two porcelain tables will remain.

Organ dissection is carried out on separate portable dissection tables which are placed at the bottom end of the PM tables; this helps to avoid possible mix up of organs. Any tissue required by the pathologist is put into cassettes in the PM suite, ensuring that only the amount of tissue specifically required by the pathologist is retained.

The HTA has some concerns about the premises. There is deterioration of the plaster work on the walls of the PM suite, which, despite repeated repair, continues to disintegrate. This raises concerns, as the exposed plaster is porous and can compromise decontamination of the suite. There are signs of rust around the radiator pipes and some cracks on the floor of the body store area. In addition, the hot water supply fails intermittently; when this happens, proper cleaning of the PM suite, which is carried out by mortuary staff, cannot take place. Mortuary staff also reported issues with water drainage, which may indicate that there is a build-up of detritus in the drainage system.

This was the second routine site inspection, the first having taken place in February 2011. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted a visual inspection of the Mortuary and PM suite. In addition, an audit was carried out against three bodies in the body store and the mortuary register, and the traceability of three tissue samples taken during PM exam against storage or disposal in line with the wishes of the next of kin was undertaken, no anomalies were found in either audit.

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

Standard	Inspection findings	Level of shortfall
PFE1 Premises are fit for purpose	A number of issues with the fabric of the PM suite and body store were identified: • The state of disrepair of the PM suite walls is a risk to staff as porous materials are exposed. • The intermittent lack of hot water, even if only once or twice a month, is a contamination risk as staff are not able to undertake proper cleaning. • Poor drainage in the PM room may indicate that the system is becoming blocked. • There are cracked and broken tiles in the floor of the body store.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The Coroner's Officer current process to record the family wishes with regard to tissue taken during a PM examination is to discuss options with the family over the phone and to complete and sign the consent form on their behalf. This form is then faxed to the mortuary for their information. We advise the DI to consider how he assures himself that appropriate consent is in place for retained tissue.
2.	C3	All those involved in seeking consent for hospital PMs have been trained, and ongoing peer support and training is planned; however, due to difficulties with clashing calendars, this has not happened recently. The DI is advised to ensure that refresher training takes place, for example, annually.
3.	GQ2	The establishment completes a number of regular horizontal and vertical audits across its activities; however, these do not include an audit of the information transcribed onto the tissue database. The DI is advised to include this in the audit calendar to check that the consent option selected on the spreadsheet matches that given by the next of kin. As PDFs of the consent forms are embedded in the database, this should be a relatively simple process.

4.	GQ6	Standard Operating Procedures for the receipt and release of bodies and for PM examinations all require that the identity of the deceased is confirmed before proceeding with the activity; however, they do not clarify exactly what identifiers should be used. Although established practice is to use three identifiers, including one that is unique, when releasing a body or identifying it prior to PM examination, this process should be set out in the SOP.
5.	PFE1	The DI is advised to risk assess the impact of not having height-adjustable PM tables for staff and assess the risks presented by the temporary measures implemented to counter this.
6.	PFE2	The DI is advised to obtain an HSE assessment of the damaged walls and implement any recommendations that result from this.

Concluding comments

This report outlines the second HTA site visit inspection of the mortuary at Taunton & Somerset NHS Trust. In addition to the areas of advice and guidance given a number of areas of good practice were observed.

The tissue tracking spreadsheet has a PDF image of the consent from the next of kin on what they would like to happen to tissue that was retained. It also highlights when tissue is due for disposal, regardless of whether this is at the request of the family of because the tissue has come to the end of the 30-year retention period set out in the Trust's disposal policy. Colour coding is used so, at a glance, staff can clearly see what tissue needs to be repatriated prior to the release of the body. Colour coding is also effectively used on the whiteboard, where the names of the deceased admitted out of hours are written in green to highlight to staff they need to be processed.

All babies from maternity come through the mortuary, even if being sent off site for PM examination; details of both parents are recorded, as well as the name of the child. This mitigates the risk of releasing the wrong baby.

Risk assessments are comprehensive and cover risks to the deceased.

It was clear that the mortuary team works well together and place emphasis on providing a quality service. There is also evidence to suggest effective interdepartmental communication, with policy developed in consultation with all parties that may have a vested interest to ensure that any issues can be addressed for each department. Additionally, the establishment has a good working relationship with the Coroner, which means that bodies are usually released within three to four days, to the benefit of the family.

There are a number of issues in relation to premises, facilities and equipment that require improvement. The HTA has also given advice to the Designated Individual on a number of areas for improvement.

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. 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: 19 August 2015

Report returned from DI: 28 August 2015

Final report issued: 1 September 2015

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: 25 January 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.