Site visit inspection report on compliance with HTA minimum standards

Royal Bolton Hospital

HTA licensing number 12035

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 April 2014

Summary of inspection findings

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.

Royal Bolton Hospital (the establishment) was found to have met all HTA standards.

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

This report refers to the activities that take place within the mortuary at the Royal Bolton Hospital (the establishment), which conducts around 500 post-mortem (PM) examinations each year. The majority of these are routine coronial cases on behalf of HM Coroner for Greater Manchester West, including high risk cases. Paediatric cases are transferred to another HTA-licensed establishment. In 2013, the establishment conducted two hospital PM examinations. Consent for hospital and paediatric PM examinations is obtained by a core team of trained staff from the Mortuary. The DI, who is a consultant histopathologist, conducts a training course for those responsible for seeking consent from the next of kin. Annual refresher training is also given.

Consent for perinatal PM examination is also sought by the team with the input of the consultant involved in the care of the mother. The establishment uses its own consent form in both cases. Patient information leaflets are available for families and the perinatal process is supported by the SANDS information leaflet.

The mortuary is staffed by three qualified Anatomical Pathology Technologists (APT) and one part time Assistant Technical Officer. There is storage capacity for 56 adult bodies, including four bariatric bodies, and three designated spaces for babies and foetal remains. Four fridge spaces can be used as freezer storage if required. There is also an external storage facility, which is used for long term storage of the deceased as well as being part of the Trust contingency plan. Fridge temperatures are monitored and recorded daily and fridges are alarmed. A local audible alarm sounds if the fridge temperatures rise above their set maximum level. The PM Suite comprises four down-draught tables and a galleried viewing area. Identification of the deceased is always checked by the pathologist and the APT prior to evisceration, and the "Post Mortem body risk assessment form" is completed for all PM examinations.

Entry to the mortuary is via a keypad access system and limited to certain personnel during and out of working hours. For families attending the mortuary for viewings, there is a separate entrance.

During working hours, receipt and release of the deceased are overseen by the mortuary staff. Out of hours, hospital porters transfer bodies from hospital wards to the mortuary. Community deaths and other activities such as out of hours release of a body are overseen by the on-call APT.

The mortuary register is completed for all hospital and community deaths. On arrival to the mortuary, bodies are assigned a unique identification number. A "risk assessment for patients brought in dead to the Royal Bolton Mortuary" form is completed for community deaths to ascertain the risk of infection and the level of personal protective equipment necessary. An index card system is then used to record all patient information and is signed by the funeral director on the release of the deceased. All information is recorded on the establishment's electronic tracking system.

Any samples that are taken for histology during the PM examination are given a unique histology number and transferred to the onsite laboratory for processing. Tissue is stored with the consent from the family, short term in the Pathology Department and long term in a secure external facility within the Trust. There is a robust system in place for the sensitive disposal of tissue samples in line with the wishes of the family.

This was the second routine inspection of the establishment. Included in the one day inspection was a visual inspection of all facilities, a document review and interviews with key members of staff. During the visual inspection the HTA was able to observe the procedure for releasing a body to the funeral director.

Traceability audits were completed as part of the inspection as detailed below:

- Three bodies were selected from the white board and found to be in the specified location in the mortuary using the identification tag on the deceased. The information was also verified with the mortuary register and database.

- Details of two cases where PM tissue had been removed for histology were selected from mortuary records. Tissue blocks from these cases were traced through the histopathology laboratory database and block storage area, and the relatives' wishes for the retention of this tissue were verified.

- A further two traceability audits of blocks in storage within the laboratory were also verified by reversing the above process.

No anomalies were found during any of the audits.

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

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C2	The “Guide to an adult hospital Post Mortem examination” patient information leaflet used when seeking consent for adult post mortem examinations does not clearly state that tissue blocks and slides will only be retained if the family give their consent. The DI is advised to consider adopting the HTA document for offering families informed choices. http://www.hta.gov.uk/_db/_documents/Post-mortem_examination_-_your_choices_about_organs_and_tissue_FINAL_v3_0_201201255642.pdf
2.	GQ1	The HTA reviewed standard operating procedures and advises the DI to update some of the procedures to reflect current working practice. For example, relevant procedures should be updated to include the minimum number of identifiers for the identification of the deceased and the use of both wrist and ankle bands as part of the checks used on receipt and release of bodies. The procedures should state which identifiers are checked when identifying the deceased, what they are checked against and the actions to take should these identifiers not be present or correct.
3.	GQ6	When an unknown deceased is brought into the mortuary from the community there may be no clear identifiers for their immediate identification. The DI may wish to consider documenting the police identification tag number in the mortuary register as a form of traceability to reduce the risk of an HTA reportable incident such as release, viewing or PM of the wrong body.
4.	GQ6	Tissue taken during PM examination is accompanied by a histology request form when transferred to the laboratory. The number of samples taken is not recorded on the database until they have been processed. The DI is advised to consider recording each piece of tissue taken in the “tissue samples record book” and on the histology request form. This will strengthen the traceability of tissue from the PM room to the laboratory.
5.	GQ7	There is a good standard operating procedure for the reporting of incidents to the HTA. The HTA has recently updated the classifications of incidents reportable to the HTA, and the DI is advised to update the SOP accordingly.
6.	PFE5	At present there is an informal agreement between the Trust and a funeral director for the transfer of paediatric cases to another HTA licenced establishment for post mortem examination. The DI should fomalise this agreement in writing and set out the expectations of the establishment and the service provider. These expectations should include, but not be limited to the requirement for the provider to report untoward incidents to the establishment, and setting out the use of the establishments paperwork in relation to traceability.
7.	PFE5	Temperatures of the fridges are recorded daily. On occasion, the fridges undergo a routine defrost cycle and this is recorded on the temperature monitoring record as “Def”. The DI is advised to delay the recording of the temperature until a definitive temperature can be obtained, to ensure that the cycle is routine and that the temperature has returned to within normal limits. If it does not, a potential fridge failure may be identified.
8.	PFE5	The fridge alarm system only alarms locally. Out of hours the mortuary relies on other members of Trust staff hearing the alarm and reporting it to switchboard in order that the on-call APT is contacted. To reduce the risk of an equipment failure going unnoticed, the DI is advised to consider a system whereby designated staff visit the mortuary at scheduled intervals outside of normal

		working hours, to check and record the fridge temperatures. Furthermore, the DI is advised to consider expanding the information available for the procedure for a sounding alarm in the mortuary using visual aids. The mortuary staff do challenge the alarm system on a regular basis and the DI may wish to formalise and record these checks.
9.	-	The DI is advised to identify a Person Designated (PD) in the Accident & Emergency Department to help ensure compliance with HTA requirements in that area.
10.	-	Leading up to the HTA inspection, formal meetings were held to discuss HTA issues. The DI is advised to continue these meetings with staff involved in licensable activities and to include HTA updates via the HTA newsletter and HTARI reporting information on agendas.

Concluding comments

During the inspection, examples of good practice were observed. Royal Bolton Hospital mortuary is a clean, well-kept facility with a small dedicated team of staff. The viewing room for relatives to view loved ones has a designated area with specific facilities for parents wishing to spend time with their baby or child. This shows a high level of respect and sensitivity by staff towards the bereaved.

Since the last HTA inspection, the consent process has evolved and the DI has responded positively to the areas requiring improvement. The consent process is now tightly controlled by the DI with robust practices in place for seeking consent for both adult and paediatric PM examinations. The DI has also developed a good training programme which is carried out annually.

During periods of high volume there is sometimes a need to move the location of the deceased within the mortuary. To ensure traceability and to mitigate the risk of a reportable incident occurring, for example the release of a wrong body, the establishment uses a “relocation check list”. This allows staff to ensure all areas where records are kept are updated accordingly.

Overall there is evidence of robust systems in place and excellent communication between staff and the DI.

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

Report sent to DI for factual accuracy: [date]

Report returned from DI: [date]

Final report issued: [date]

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 program 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.

Comment [j1]: Delete as not applicable!

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.