Site visit inspection report on compliance with HTA minimum standards

Hull Royal Infirmary

HTA licensing number 12170

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 September 2015

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.

The mortuary at Hull Royal Infirmary (the establishment) was found to have met all applicable HTA standards. The HTA has given advice to the Designated Individual with respect to records management, contingency arrangements, process optimisation and disposal arrangements.

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

The establishment has been licensed by the HTA since May 2007 for the making of a PM examination, removal of relevant material from the deceased and storage of the deceased and relevant material for use for scheduled purposes.

The establishment carries out approximately 1,000 post mortem (PM) examinations a year on behalf of HM Coroner, as well as approximately 30 Home Office PM examinations under coronial authority. In addition, around 5 hospital (consented) PM examinations are carried out each year. There are no paediatric PM examinations undertaken at the establishment.

The establishment houses a main PM room, which contains five PM tables, as well as a separate forensic/high risk PM suite and an additional PM room used for training.

Bodies of the deceased are stored in two areas at the establishment. Hospital and Coroner's cases are stored in the main mortuary facility, where there are 68 fridge spaces available, eight of which are bariatric. High risk/forensic cases are stored in a separate area on the first floor, adjacent to the forensic/high risk PM suite, where 28 spaces are available. Eight freezer spaces are also available in this area for long term storage.

The establishment is staffed by eight members of staff; Six qualified Anatomical Pathology Technologists (APTs), including the Mortuary Manager and Mortuary Supervisor, a trainee and a Mortuary Apprentice.

Bodies are received into the establishment from the community and from wards within Hull Royal Infirmary. Bodies received from the community during normal working hours are logged in the mortuary register by staff in the presence of attending funeral directors or police officers, who confirm the identity of the deceased. If a body from the community is brought to the mortuary outside of normal working hours, the on call technician attends to deal with the logging in procedure in the presence of the police. Standardised admission forms are used.

During normal working hours, bodies from within the hospital are brought to the mortuary by porters using hospital transport. Staff confirm the identity of the deceased person with the porter and log the deceased's details in the mortuary register. Out of hours, trained porters deal with this procedure, placing the body into an available fridge space and completing a patient transfer form, which is left for mortuary staff to process the admission the next working morning. Mortuary staff then complete the mortuary register having checked the identity of the deceased and confirmed any patient property present. Any bodies arriving from the hospital without two identity bands (one each on the wrist and ankle), which are required according to the hospital's operational procedures, are recorded on the Trust's incident reporting system.

Each body received into the mortuary is given a sequential mortuary register number, which is prefixed with a code to indicate where in the cycle of mortuary activity it is at any time. The number remains with the body throughout its stay in the mortuary, and is also used to track tissues samples or organs that are retained for examination.

When a PM examination is necessary, authorisation is received from the Coroner by email. The APTs remove the body from storage, checking identification details which are re-checked by the visiting pathologist and assisting APT prior to commencement of the PM examination.

Where tissues are retained, a Tissue Retention Form (TRF) is completed by the pathologist detailing what tissues or organs have been retained. The TRF form is e-mailed to the Coroner, who takes instructions from relatives of the deceased on what they would like to happen to any tissue that has been retained. A copy of the TRF form is then e-mailed back by the Coroner to inform the mortuary of relatives' wishes and, when the wishes of the relatives have been actioned, the date of this is completed on the form and the form signed off by a member of the mortuary team. All disposal of tissue is co-ordinated by the laboratory staff.

An electronic system is used to capture information related to histological samples retained in cases of hospital and coronial PM examinations carried out on site. However, this database does not include information on paediatric cases, where the PM examination takes place at another establishment, forensic cases or independent PM examinations as the tissues for such cases are taken under the relevant licence for the establishment where the PM examination is undertaken (refer to advice items 1 and 2).

Procedures on release of bodies for burial or cremation specify that a member of staff at the establishment, together with receiving undertakers, must check the identity of the deceased. Two members of staff are required to confirm identification when the deceased is recorded as having same or similar name as another patient or is released from long term storage.

This was the third inspection for the establishment, the previous inspection having been carried out in 2011. The inspection comprised a visual inspection, document review and interviews with key staff.

A traceability audit was conducted for two coronial and two hospital cases in storage. Associated samples taken were also tracked in the electronic system used by the establishment and the histopathology department. No discrepancies were found.

Inspection findings
The HTA found the Designated Individual and the Licence Holder to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

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.	GQ2	The DI is advised to include in the current audit schedule audits of toxicology request forms, to ensure that these are completed properly. The use of an inter-departmental electronic system would highlight any missing information and help optimise the current activities.
2.	GQ4	Records are kept archived in paper format at the establishment and the information is not electronically stored in its entirety. This raises the risk of information loss and uses up valuable storage space. The DI is advised to consider the use of an electronic database for storage and management of records, which would facilitate effective back up of records.
3.	PFE3	Contingency arrangements currently in place involve the use of storage space at a nearby hospital, part of the same Trust, where no PM examinations are carried out. However, the reorganisation of the Trust in early 2015, whereby three elderly care wards were moved to the establishment, has led to a significant increase in the number of bodies being admitted to the mortuary, which was already reaching full capacity during the summer months. As these numbers are expected to increase further during winter, it is highly likely that the establishment will need to use its contingency arrangements for storage. Only patients having undergone PM examinations or hospital patients with completed documentation will be eligible for transfer. Transfer will only be undertaken with the consent of HM Coroner (coronial cases) or relatives' consent. All cases awaiting PM examinations will be admitted directly to the mortuary at the establishment. The establishment is advised to undertake a risk assessment of current contingency arrangements and consider alternative arrangements to either increase capacity onsite or decrease the strain put on the services. The risk assessment should also consider risks to the deceased resulting from the movement of bodies between sites.
4.	-	The DI is advised to encourage current Persons Designated to request HTA portal access, in order to be able to report any HTA reportable incidents when required.

Concluding comments

This report describes the third HTA site visit inspection of the Hull Royal Infirmary. During the inspection, several areas of strength were observed.

The mortuary staff have worked at the establishment for a number of years and are motivated and experienced in their roles. They are well trained and have worked towards developing

robust mortuary procedures. The team is dedicated to ensuring that the dignity of the deceased is maintained and that relatives visiting the mortuary are treated sensitively.

The mortuary staff have developed good working relationships with staff in other establishments and at the Coroner's office, visiting pathologists and local funeral directors.

The DI has a good understanding of the HT Act and works to ensure improvements are implemented as required. The DI is well supported in his role by the Persons Designated, having good oversight of licensable activities at the establishment.

Management of SUDIC cases at the establishment is carried out by a strong multi-disciplinary team, working under detailed procedures in a chain of custody manner. The dedication of the team has recently won them an award, recognising their commitment to quality.

The HTA has given advice to the Designated Individual with respect to record management, contingency arrangements, process optimisation and disposal arrangements.

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

Report sent to DI for factual accuracy: 20 October 2015

Report returned from DI: 30 October 2015

Final report issued: 30 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.

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 outlines 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.