Site visit inspection report on compliance with HTA minimum standards

John Radcliffe Hospital

HTA licensing number 12052

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**

26 March 2015

Summary of inspection findings

This inspection was conducted jointly with assessors from the United Kingdom Accreditation Service (UKAS), who gathered evidence in the mortuary against selected licensing standards on behalf of the HTA.

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.

Although the HTA found that the John Radcliffe Hospital (the establishment) had met the majority of the HTA standards, minor shortfalls were found in relation to the scope of audits and procedures for reporting HTA Reportable Incidents (HTARIs); in addition a major shortfall was identified in relation to the storage of deceased babies.

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 (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 John Radcliffe Hospital (the establishment) is part of the Oxford University Hospitals NHS Trust. The establishment has been licensed by the HTA since October 2007 for the making of a post mortem (PM) examination, removal of relevant material from the deceased, and storage of the deceased and relevant material for use for scheduled purposes.

The establishment conducts approximately 1,400 post mortem (PM) examinations each year. This includes approximately 950 adult and 450 perinatal and paediatric PM examinations. The establishment undertakes high risk (up to Category 3) and Home Office cases.

Most adult PM examinations undertaken at the establishment are performed under coronial authority. The establishment conducted 84 adult hospital PM examinations in 2014. Consent for hospital PM cases is sought by staff at the establishment using a consent form and information leaflet developed in conjunction with the Bereavement Services team.

The establishment is a specialist centre for perinatal and paediatric cases. The majority are hospital (consented) PM examinations, of which there were 419 in 2014. Consent for these is either sought by staff at the establishment using the Stillbirth and Neonatal Deaths (Sands) consent form and information leaflet, or, where cases are referred to them, by staff at the

referring centre. The establishment encourages referring centres to use the Sands consent package, and provides feedback to on the completion of the consent forms it receives.

All staff at the establishment who seek consent for PM examinations are required to complete its consent training package.

The mortuary and PM facilities are secured by key code and swipe card access. There is CCTV both within and outside the mortuary. The mortuary has dedicated facilities for conducting adult, perinatal/paediatric and high risk PM examinations.

The establishment has contingency arrangements for the storage of bodies at two nearby hospitals. It also has access to temporary storage facilities, which can be erected at short notice to provide additional storage capacity. Storage temperatures are continually monitored and there is an automated alarm call-out procedure in the event of temperature deviation.

There is a dedicated facility for the storage of deceased babies of greater than 24 weeks gestation at the hospital's Women's Centre, prior to transfer to the mortuary. This facility is secured by key pad access and contains one refrigerated storage unit. Storage temperature is checked and recorded by staff twice per day, and connected to a locally audible temperature alarm. This fridge is not subject to regular servicing and preventative maintenance and the HTA observed from temperature records, and from inspection of the fridge on the day of inspection, that the temperature is frequently outside acceptable levels. This may be because of frequent access to the fridge.

Material taken at PM examination may be transferred to the establishment's Cellular Pathology department for histological analysis, or to other establishments for toxicology or other tests. Neurological tissues are sent to the hospital's Neuropathology department, which also receives material from other establishments. Organs and tissue samples may be kept, with consent, for use for scheduled purposes, including for education and training, and research.

The Cellular Pathology department has separate dedicated storage areas for tissue blocks and slides from perinatal/paediatric and adult cases. The department uses an electronic database to record sample details, including consent for the use of samples after determining diagnosis or the cause of death. At the time of the inspection, the establishment was in the process of transferring archival samples to another HTA-licensed establishment for storage.

The Neuropathology department operates a specialist analysis laboratory. Samples, including whole brains, spinal cords and brain tissue samples, are formalin-fixed and stored at room temperature, or fresh-frozen and stored at -80°C or -20°C. The establishment has a temperature alarm system providing continual temperature monitoring and a call-out procedure in the event of temperature deviation. Samples stored in the Neuropathology department are recorded on an electronic database to ensure sample traceability.

The mortuary, Women's Centre, Cellular Pathology and Neuropathology departments operate under separate departmental standard operating procedures (SOPs). The licensed activities conducted in these departments are overseen by Persons Designated (PDs) for each area, under the overall oversight of the DI.

This report describes the third, routine site visit inspection of the establishment, which was conducted jointly with the United Kingdom Accreditation Service (UKAS). UKAS visited the mortuary and gathered evidence against HTA licensing standards GQ1-6, PFE1-5 and D1 on behalf of the HTA. The HTA conducted a visual inspection of the Women's Centre, Cellular Pathology and Neuropathology departments. Storage locations and identifiers for three bodies, and traceability records for three coronial PM examinations where tissues were taken for histology, were checked and cross matched. Audits were performed of sample traceability in the Cellular Pathology and Neuropathology departments. No anomalies were found.

Home Office PM examinations take place at this establishment. Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, the management of tissues and organs taken for criminal justice purposes were reviewed by the HTA at this site visit inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

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
GQ2 There is a documented system of quality management and audit.	The establishment undertakes audits of tissues retained during PM examination and stored in the Cellular Pathology and Neuropathology departments. The establishment does not, however, undertake regular audits in the mortuary. *(See advice item 4)*	**Minor**
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The Trust 'Incident Reporting and Investigation Policy' sets out the procedures for identifying, reporting and investigating incidents. The policy includes details of reporting incidents to external organisations, including reporting incidents in the human application sector to the HTA. This document does not, however, detail the requirements to report HTA Reportable Incidents (HTARIs) in relation to activities taking place under its PM sector licence. *(See advice item 7)*	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	The fridge used for the storage of deceased babies in the Women's Centre is not subject to regular servicing and preventative maintenance, and was observed on the day of inspection to be outside of the set acceptable temperature range. The fridge is connected to a temperature alarm, which provides a locally audible alarm, but this is often muted because frequent access to the fridge causes rises in temperature, which take some time to return to an acceptable level. This may indicate that the fridge is no longer operating effectively. These storage arrangements present a significant risk to the integrity of the bodies stored, and therefore are considered to represent a major shortfall against this standard.	**Major**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to remove references to the next-of-kin from SOPs. This will ensure that the terminology used in SOPs and consent information is consistent, and reflects the establishment's practice of seeking consent from the appropriate person, as defined in the HT Act.
2.	GQ1	The DI is advised to review SOPs to ensure that they contain sufficient detail. In particular, the DI is advised to include additional details of the procedure to follow to identify the deceased, including the minimum number of unique identifiers, and the minimum paperwork and information that must be checked. The HTA recommends that three identifiers are used, including one that is unique (for example: full name, date of birth, hospital / mortuary number), to confirm the identity of the deceased.
3.	GQ1	The DI is advised to review the SOP for performing PM examinations to detail the checks performed prior to commencing a hospital PM examination to confirm that the timeframe for the family to withdraw their consent has passed.
4.	GQ2	The establishment should review its audit schedule to include the mortuary. This should include, for example, audits of bodies in storage against the mortuary register and audits of compliance against mortuary procedures. The DI is also advised to extend the schedule of audits in the Neuropathology department to include samples stored prior to processing for use in research.

5.	GQ3	The DI is advised to maintain records of the training of porters undertaking activities in the mortuary. This will help to ensure that training records are kept up to date, and that new porters receive training in mortuary activities.
6.	GQ6	The DI is advised to review the system for ensuring that tissues and organs are returned to the body prior to release of the body from the mortuary, where required. For example, the DI may wish to use coloured-coded identification tags for these bodies to provide an additional visual prompt for staff.
7.	GQ7	The DI is advised that the Trust 'Incident Reporting and Investigation Policy' should be reviewed to include the requirement to report HTARIs to the HTA. This should include details of the categories of HTARIs, responsibilities of staff for reporting HTARIs to the HTA, and the timeframe for reports to be submitted to the HTA. Further information on reporting HTARIs can be found on the HTA website: www.hta.gov.uk/policies/post-mortem-hta-reportable-incidents.
8.	GQ8	The establishment has assessed a number of risks associated with undertaking licensed activities. The DI is advised to extend these to include other mortuary risks, for example: misidentification of the deceased and breach of security. The DI is advised that the HTARI reporting categories may be used as a basis for extending the scope of the mortuary risk assessments. Further advice on mitigating the risks associated with undertaking licensed activities can be found in the HTA's 'Sharing learning: lessons learned from HTARIs in the PM sector': www.hta.gov.uk/sites/default/files/HTARI_Review_2012-13.pdf.
9.	PFE3	The establishment is advised to review the storage of a collection of samples in the Neuropathology department in a -20°C freezer, which is not temperature monitored. A risk assessment should be conducted of this storage facility.
10.	D1	The establishment is in the process of reviewing its policy and procedures for the disposal of pregnancy remains. The HTA published updated guidance on the disposal of pregnancy remains shortly before the inspection. The DI is advised to refer to this guidance when reviewing the establishment's policy and procedures. Further information on this guidance can be found on the HTA website: www.hta.gov.uk/faqs/disposal-of-pregnancy-remains-faqs.

Concluding comments

This report outlines the third HTA site visit inspection of the John Radcliffe Hospital. Despite the shortfalls identified, areas of strength were observed. There are robust processes for seeking consent for PM examination, including support from the Bereavement Services team. The Cellular Pathology and Neuropathology departments manage a large number of samples and have good systems to provide sample traceability, including consent for the use of samples for research. The DI has a good understanding of the HT Act and is supported by a dedicated team of PDs in each department working under the HTA licence.

There are a number of areas of practice that require improvement, including one major and two minor shortfalls. In addition, the HTA has given advice to the DI on a range of issues, including consent, governance and quality systems, storage facilities and disposal.

The HTA requires that the DI addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the inspection.

Report sent to DI for factual accuracy: 27 April 2015

Report returned from DI: 8 May 2015

Final report issued: 8 May 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: 17 November 2015

Appendix 1: HTA standards

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

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

Governance and quality system standards

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

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

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

GQ2 There is a documented system of quality management and audit

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

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

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

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

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

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

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

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

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's

family.

- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. **Critical shortfall:**

   A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

   or

   A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

   A critical shortfall may result in one or more of the following:

   (1) A notice of proposal being issued to revoke the licence

   (2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

   (3) A notice of suspension of licensable activities

   (4) Additional conditions being proposed

   (5) Directions being issued requiring specific action to be taken straightaway

2. **Major shortfall:**

   A non-critical shortfall that:

   - poses a risk to human safety and/or dignity, or
   - indicates a failure to carry out satisfactory procedures, or
   - indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
   - has the potential to become a critical shortfall unless addressed

   or

   A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

   In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. **Minor shortfall:**

   A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.