Site visit inspection report on compliance with HTA minimum standards

Sunderland Royal Hospital

HTA licensing number 12281

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 November 2016

Summary of inspection findings

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

Although the HTA found that Sunderland Royal Hospital (the establishment) had met the majority of the HTA standards, one minor shortfall was found against the governance and quality system standards. The shortfall relates to standard operating procedures (SOPs).

Particular examples of 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 (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 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 mortuary at Sunderland Royal Hospital performs approximately 500 adult post mortem (PM) examinations each year on behalf of the Coroner for The City of Sunderland. Hospital consented PM examinations are undertaken occasionally, with only one taking place in the two years prior to the inspection. Home office PM examinations are also undertaken and a small amount of material is held under the Police And Criminal Evidence Act 1984 (PACE). Perinatal and paediatric cases are transferred to another HTA-licensed establishment for PM examination.

The establishment's Cellular Pathology department recently merged with pathology departments at the Queen Elizabeth Hospital Gateshead and South Tyneside District Hospital. Together, the three departments form the South of Tyne Pathology Centre, which is based at Gateshead. The mortuaries of all three hospitals are part of different Trusts, each of which retains responsibility for the premises, and they are licensed separately by the HTA. However, the pathology services for all three hospitals are managed by the Pathology Centre.

The body store consists of 100 spaces, which includes ten freezer spaces and five spaces for bariatric bodies. Of the ten freezer spaces, five can also accommodate bariatric bodies. Ten of the fridges are separated into two banks away from the rest of the body store area; five of these spaces are dedicated for the storage of infectious or badly decomposed cases; the

other five are kept for forensic cases. The forensic bank is locked and mortuary policy states that it can only be unlocked in the presence of a Coroner's Officer. It is double sided and opens directly into a dedicated forensic PM suite.

All fridges are alarmed with upper and lower trigger points; the alarms and follow-up call out system are challenged on a regular basis. Temperature trends are monitored to help pre-empt any potential issues with the fridges.

The mortuary is secured by a swipe card system and CCTV. There is a buzzer entry system for funeral directors. Out of hours, hospital security staff meet the Coroner-appointed funeral directors who are bringing bodies from the community. Release out of hours is rare and is undertaken by the Trust's Duty Manager, if required. Mortuary staff train a number of porters in mortuary procedures, including release and viewing. Trained porters cascade the training to other porters.

As referred to above, the mortuary has two separate PM suites, one for forensic PM examinations, containing one PM table, and the main suite for routine coronial or hospital PM examinations. The main suite has four PM tables with linear downdraft to the sinks at the dissection areas. There are three dissection areas so a 'one at a time' system is in place to avoid any mix up of organs.

Histology samples taken at PM examinations are sent to the Pathology Centre for examination. The Pathology Centre is responsible for disposal or retention of these, in line with families' wishes. The tissue is taken by the APT directly to the pathology department reception, from where it is transported by hospital courier in a hospital transport box to the South of Tyne Pathology Centre.

Viewings of the deceased are arranged via the ward staff or by ringing the mortuary directly. Occasional out-of-hours viewings are undertaken by portering staff. Safety has been taken into account, and there is an emergency call button that alerts mortuary staff and the security office if porters feel vulnerable. Personal alarms are available for staff to wear, which alerts security, if triggered. The doors from the viewing room to the rest of the mortuary are lockable.

The chaplaincy service at the hospital works closely with all departments including maternity and paediatric, and takes responsibility for ensuring that the wishes of the family are met in terms of arrangements for PM examinations and funerals.

The establishment has been licensed since 2007 and this was its third routine site-visit inspection. The HTA conducted a visual inspection of the premises, reviewed documentation and carried out interviews with the Designated Individual, the Corporate Licence Holder and establishment staff.

As part of the inspection an audit of the body store was undertaken, where three bodies were selected at random: two from the hospital and one from the community. Details from the identification tags and the physical location of the bodies were cross checked against the establishment's paper mortuary register and the location information on the chalk board. One minor anomaly in the spelling of a forename on the chalk board was found.

The holdings at the establishment that are under PACE were also reviewed as part of the inspection. Under s39 of the Human Tissue Act 2004 (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, the 2012 report of the Association of Chief

Police Officers' (ACPO) audit of tissue held under police authority contained a recommendation that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process. Therefore, procedures for Home Office PM examinations and the management of tissues and organs taken for criminal justice purposes were reviewed by HTA at this site visit inspection. Any findings in relation to Home Office PM examinations and/or 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
GQ1, GQ4	Following the merger of the pathology services of three separate hospitals, individual mortuary documents and SOPs have been merged into a single document to cover activities taking place under the management of the South of Tyne Pathology Centre at the three mortuaries. As a result, some documents can be difficult to follow. For example, CP-MOR-SOP-001.UN refers to the following as related documents on the front page *QEH* [MORMANFO014 - Information for Portering Staff] *STDH* [MORT4 – Hospital Porters Mortuary Duties] *SRH* [CP-MOR-SOP-018.SR Mortuary Procedures for Portering/ Security Staff] But later refers to them without the hospital prefix so unless the porters refer back to the front page they may not be sure which document relates to their site. The SOP template is laboratory-focused, which may have added to the difficulty in restructuring documents. In addition, abbreviations for the different sites are used repeatedly in SOPs but are not consistent, and often not defined. Staff work across all three sites and some SOPs have the 'Site Location' as SR while others have UN (without clarification for what UN stands for). Additionally other locations are abbreviated without a full description.	**Minor**

Advice

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

No.	Standard	Advice
1.	C3	The establishment has recently undertaken an audit to identify which members of staff are qualified to seek consent for paediatric PM examinations. The DI is advised to make this audit part of the regular audit schedule to ensure information is up to date and that any midwives involved in seeking consent have the relevant training or have a trained consultant with them.
2.	GQ1, GQ4	A number of issues were identified on SOPs, a list of which has been sent separately to the DI; the DI is advised to revise these to ensure clarity.
3.	GQ3	Porters are trained by cascade training; the DI is advised to risk assess the porters not being trained by mortuary staff and to ensure that steps have been taken to ensure all porters bringing bodies to the mortuary have been appropriately trained.
4.	GQ6	The establishment has a number of organs in storage on behalf of families, where there may be a potential court case. A log book is used to record organs taken during PM examination and the wishes of the family. The DI is advised to consider adding details about storage location to this log and to ensure this log is updated whenever the organs are moved.
5.	GQ8	Risk assessments are in place and consider risks to the deceased; however, they attempt to address a number of risks in one document which may not give an accurate reflection of some risks being greater than others. The DI is advised to review mortuary risk assessments to ensure individual consideration has been given to the HTA reportable incident categories.
6.	PFE3	Following PM examination, some bodies are covered loosely up to the neck. It is considered good practice to shroud bodies fully whilst in storage and the DI is advised to ensure that full shrouding becomes routine and that this is reflected in mortuary procedures.

Concluding comments

A number of areas of good practice were observed during the inspection. The service offered by the Chaplaincy is well managed and is valuable to parents as there is an on-call system which makes the service readily available when needed. As it can take some time to arrange hospital funerals, mortuary staff monitor how long bodies have been in the mortuary and contact bereavement services if bodies have been stored for longer than two weeks. This means that any issues or cases where there is no next of kin can be identified early and staff are aware if it is likely that a body will need to be moved to a freezer.

There are a number of areas of practice that require improvement, including the minor shortfall. The HTA has given advice to the Designated Individual with regards to consent, governance and quality systems and premises, facilities and equipment.

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: 20 December 2016

Report returned from DI: 05 January 2017

Final report issued: 13 January 2017

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: 16 March 2018

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: o post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases o record keeping o receipt and release of bodies, which reflect out of hours arrangements o lone working in the mortuary o transfer of bodies and tissue (including blocks and slides) to other establishments or off site o ensuring that tissue is handled in line with documented wishes of the relatives o 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.