Site visit inspection report on compliance with HTA licensing standards

St Peter's Hospital

HTA licensing number – 12542

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 & 31 January 2019

Summary of inspection findings

The HTA found the Designated Individual (DI), the Licence Holder (LH) and the Corporate Licence Holder Contact (CLHc) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that St Peter's Hospital had met the majority of the HTA's standards, six major and sixteen minor shortfalls were found against the Consent, Governance and Quality, Traceability and Premises, Facilities and Equipment standards. These related to policies and Standard Operating Procedures (SOPs); training for seeking of consent for PM examination; audits; records management; the use of three identifiers; premises and equipment and temperature monitoring.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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.

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

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. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, 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 provided.

HTA inspection reports are published on the HTA's website.

Background to the establishment

This report refers to activities carried out by the mortuary at St Peter's Hospital, Chertsey. The Designated Individual (DI) is a Consultant Pathologist, based predominantly at the establishment. The Corporate Licence Holder (CLH) is Ashford & St Peter's Hospitals NHS Foundation Trust and the Corporate Licence Holder contact (CLHc) is the Director of Operations for Planned Care.

The establishment has been licensed by the HTA since April 2009 for: 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 scheduled purposes. There have been some changes to the DI, Persons Designated (PDs) and CLHc on the licence since the last inspection, with a change of DI in January 2018.

St Peter's Hospital is part of the Ashford and St Peter's Hospitals NHS Foundation Trust which is one of the three Trusts that collectively formed the Surrey Pathology Services (SPS). In 2016, SPS underwent a further merger to form the Berkshire Surrey Pathology Services (BSPS).

The mortuary at St Peter's Hospital receives bodies from the hospital and the community, conducting both adult hospital (consented) and coronial post-mortem (PM) examinations. During times of high demand, the hospital also conducts PM examinations for any of their partner hospitals, depending on pathologist availability. Approximately 2,100 bodies are admitted to the mortuary annually and approximately 700 PM examinations are performed, which are mostly under the authority of HM Coroner for Surrey. Home Office PM examinations are not conducted at the establishment; these are transferred to another licensed establishment. Consent for perinatal and paediatric PM examinations is sought by a suitably trained Bereavement Midwife, but are performed at another HTA-licensed establishment. Hospital staff seek consent for adult hospital PM examinations (see shortfall under C2 (b)), however, these are not carried out frequently.

Following a hospital death, porters transfer bodies from the hospital wards to the mortuary during and outside of normal working hours using a concealment trolley. They complete a mortuary admission form and place the body into an unoccupied space in the refrigerated body store. All porters are either trained by the mortuary staff, or the portering supervisor who has been trained by the mortuary staff. Community bodies are transferred to the mortuary by Coroner approved funeral directors. This normally occurs within normal working hours, with the exception of one authorised funeral director who transfers and admits all bodies out-of-hours (see shortfall against GQ3 (g)). The funeral directors are granted access to the mortuary by security staff, complete the necessary documentation and place the body in the refrigerated body store. Every week day morning, the mortuary staff perform checks for any new admissions. During these checks, the information from the admission forms is transcribed into the mortuary register and used to check the identification of the bodies.

However, the Coroner has requested that bodies admitted from the community are not checked until the Coroner has given their authority to do so (see shortfall against GQ1 (c)).

Access to the mortuary during normal working hours is controlled by the mortuary staff using an intercom system. The mortuary is monitored 24/7 with CCTV and there is secure access arrangements. Outside of normal working hours, mortuary access is controlled by security.

Both the release and viewing of bodies is conducted during normal working hours. In special circumstances, these can occur outside of these hours, with the attendance of the on-call Anatomical Pathology Technologist (APT) and security. Viewings are carried out in the designated viewing rooms by appointment only (see shortfall against T1 (c)), facilitated and arranged by the Bereavement Office in working hours.

The mortuary has a single PM suite which contains three height-adjustable downdraft PM tables. At the time of the inspection, the establishment had activated their contingency plan A temporary body storage unit was erected in the PM suite, which restricted access to one PM table so that it cannot be used. During PM examination, any tissue that is removed is placed into tissue cassettes and recorded on the relevant forms, before being sent to a HTA licensed Histopathology Department within the BSPS network. Traceability for all tissue is maintained through paper records (see shortfall GQ4 (a)) and electronic communications between the establishment, the Coroner and hospital that processes the PM tissue specimens.

The establishment has refrigerated storage capacity for 75 bodies, some of the fridges are double-ended for direct access into the PM suite; 30 spaces can accommodate bariatric bodies and six spaces are allocated for perinatal and paediatric cases. In addition, there are ten bariatric freezer storage spaces (see shortfall against PFE2 (c)). All the fridges and freezers are alarmed but not consistently monitored to identify trends (see shortfall against PFE2 (f)). In addition, the establishment has a refrigerated ‘bier’ room which can accommodate two super bariatric bodies at the same time, if required.

At the time of the inspection, the establishment were operating at almost full capacity and had activated their six-phase contingency plan. They were utilising all three refrigerated temporary storage units, two of which were located in a designated area on the lower floor of the mortuary. The temporary body storage units provide an additional 36 spaces. However, due to the limitations with the body hoist equipment, nine of these spaces are not suitable for bariatric bodies (see shortfall PFE3 (a)). One phase of the contingency plan includes transferring bodies that are awaiting release to funeral directors to another body store within the Trust.

The establishment has a Maternity Department, where there is a fridge for the short-term storage of pregnancy remains, fetuses and stillbirths, prior to transfer to the mortuary (see shortfall against PFE2 (e) and (f)).

Description of inspection activities undertaken

This was the fourth HTA routine site visit inspection of the establishment in January 2019. A visual inspection was carried out of the mortuary body store, PM suite, viewing rooms, the contingency body storage area and the Maternity Department. Interviews were conducted with key members of staff at the establishment. Although the inspection team were scheduled to interview a Coroner's Officer, this was not possible during the course of the inspection or at a later date, following the inspection.

Traceability audits were completed for eight bodies from the main body store and the contingency body store area, including two perinatal bodies, two adult community and three adult hospital bodies and one adult body in frozen storage. Body identifiers, storage locations, mortuary register details and associated documentation was checked for consistency and completeness in all cases. No anomalies were identified.

Inspection findings

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

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
b) There is a documented standard operating procedure (SOP) detailing the consent process.	Whilst there is a SOP detailing the process for seeking consent for PM examination, this does not include all the staff responsible for this task. The SOP states that the clinicians and Bereavement Officer seek consent for PM examination. In addition, the DI stated the pathologists were also responsible for this task. However, the Bereavement Officer and a pathologist were interviewed during the inspection and stated that they were not involved in the process. The DI is required to be clear about who is responsible for seeking consent for PM examination and ensure that this is properly documented and that the appropriate procedure is documented and followed by those staff to help prevent inconsistencies and ensure consent is sought in line with the HT Act 2004. In addition, the HTA's previous codes of practice are listed in the "Guidance For Doctors On Post-Mortem Examinations" document and there are several references to the "next of kin". This presents a risk that someone other than the person ranked highest in the hierarchy of qualifying relationships could give consent. The SOP for consented adult PM examinations (MORT-ASPH-SOP-10) has not been reviewed within the specified review date.	**Minor**

d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.	Issues were identified with the PM examination information sheets: Adult PM examinations: • the information given to relatives is unclear and misleading; a particular example of this is on page 3, which outlines what happens to tissue following PM examination and states that blocks and slides will be kept permanently as part of the medical record. However, consent is required for this; furthermore, the information given does not list all possible options for tissue that relatives can choose following PM examination. Paedeatric/perinatal PM examinations: • When consent is given for tissue to be used for scheduled purposes, the length of time for which tissue will be retained is not discussed or specified; furthermore, the information sheet states that blocks and slides will be kept permanently as part of the medical record, however, this would be dependent on appropriate consent having being given.	**Minor**
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.	There are two different consent forms being used for paedeatric/perinatal PM examinations, one is listed in the "Guidance For Doctors On Post-Mortem Examinations" and a different one was presented during the inspection. The consent form presented during the inspection was stated to be the current version. Having two different forms in use at the same time and not updating the guidance document to refer to the correct, current consent form, creates a risk that the incorrect consent form may be used and that an inconsistent approach is taken to seeking consent. (See *Advice*, item 1)	**Minor**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training.	There are no training records for those staff identified as being responsible for seeking consent for PM examination in the SOPs or verbally by the DI. The DI should ensure that training requirements for seeking consent for PM examination is included in the PM consent SOP.	**Minor**
d) Competency is assessed and maintained.	There is no evidence that competency is assessed or maintained for either adult consented PM examination or paedeatric/perinatal PM examinations.	**Minor**

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	Four SOPs have not been developed and implemented: • for external staff, visitors and funeral directors that attend the mortuary; • a mortuary procedure for repatriation of tissue to bodies before they are released; • for archiving and retention of all documents, including raw data; • completion of the mortuary register. In addition, all SOPs should be reviewed before their next review date and be reflective of current procedures, particularly where there has been a change of process. For example, the SOPs for transfer of bodies to contingency storage at another hospital and the change of location for paediatric/perinatal PM examinations have not been reviewed by the required date.	**Minor**
c) Procedures on body storage prevent practices that disregard the dignity of the deceased.	When the establishment receive a Coroner's case, the staff have been requested by the Coroner not to check the body until the Coroner has given authorisation. There can be a significant delay, in some cases, up to a week, before the authorisation is received. Not being able to check bodies as soon as possible after admission means the condition of the bodies cannot be assessed to help identify any possible damage or decomposition and check they are labelled appropriately with the minimum number of identifiers. In addition, the description of the transfer practices for bodies from the Neonatal Intensive Care Unit could create a risk of not ensuring the dignity or safety of these bodies and could lead to complaints.	**Major**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits.	The current audit schedule will be completed at the end of February 2019. The establishment do not have a schedule of audits planned beyond this date. The number and frequency of audits is also insufficient in relation to licensable activities. Although the HTA compliance audit is thorough and encompasses all licensable activities, this is only completed every third year. The frequency of this audit does not provide the DI with sufficient assurance of the processes in place or help identify any issues or areas or improvement. (See *Advice*, item 3)	**Minor**

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.	The establishment allows one firm of funeral directors to admit community bodies out-of-hours unaccompanied. The funeral director staff are not trained in the relevant establishment's processes or in the use the equipment. This poses a potential health and safety risk and a risk to the bodies they are admitting.	**Minor**

GQ4 There is a systematic and planned approach to the management of records		
a) 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.	The establishment use a paper mortuary register to record the necessary information and have not considered how this can be backed up, for example, by scanning or using an electronic record. In addition, the establishment do not back up their records for tissue taken during PM examination and there is no system for the retention of raw data records (for example, for temperature monitoring). (See *Advice*, item 5)	**Minor**
b) There are documented SOPs for record management which include how errors in written records should be corrected.	There is no documented procedure for the amendment of paper records, for example, when changes need to be made to the mortuary register.	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.	The following procedures/equipment have not been risk assessed to identify actions that may be required to mitigate any potential risks: • not being able to check Coroner's cases upon admission potentially increases the risks of not identifying issues such as damage and dignity to the deceased, health and safety of staff and could increase the risk of incorrect identification; • transporting bodies in and around the hospital site - for example, the transfer of neonatal, bariatric and super bariatric bodies to the mortuary; • the use of body hoists that are not always fit for purpose; • admitting bodies out of hours without the presence of an APT; • although a low volume, decanting formalin in the Maternity Department and an area in the PM Suite without suitable ventilation. (See *Advice*, item 6)	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records).	The system that the mortuary uses to track each body is the mortuary register. In its current form, there is a limit to the information that can be recorded; only the full name and address of the bodies are documented. In addition, important information is not being recorded or highlighted in the register, for example, when tissue has been retained following PM examination or when bodies have been transferred off-site for contingency storage. Paediatric/perinatal cases transferred for PM examination and bodies transferred for contingency storage are signed out of the mortuary register. If these bodies are returned, they are re-entered into the mortuary register and given another mortuary register number. However, these entries in the mortuary register are not cross-referenced to help maintain the traceability of these bodies. In addition, it was identified during inspection that a door tag for a body that had been released three weeks previously was still on the bodystore door, indicating that the system for checking bodies in storage is not robust. (See *Advice*, item 7)	**Major**
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier.	Community bodies are being admitted to the mortuary labelled with only two identifiers, meaning they are not identified with the required three identifiers prior to PM examination or when they are released. In addition, three identifiers should be checked for all bodies that relatives are coming to view, cross checking those identifiers on the body before the viewing takes place.	**Major**
d) There is system for flagging up same or similar names of the deceased.	Although there is a process outlined in the SOPs, this is not being followed by staff. The inspection team noted bodies with same/similar names were not flagged in the mortuary register or on the bodystore doors. (See *Advice*, item 9)	**Minor**

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.	Although the establishment have a documented system for communicating with the Coroner, which includes telephone and email follow-up, they do not receive relatives' instructions for tissue in a timely manner. The establishment currently has tissue retained from PM examinations in 2017 awaiting families' decisions. This presents a risk that the establishment may be storing tissue for which they no longer have authority or appropriate consent to retain. (See *Advice,* item 11)	**Major**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained.	There were some issues with the cleanliness and maintenance of the establishment, such as: • the floors within the PM suite showed areas near the PM tables where the top surface has eroded exposing the undersurface of the floor and multiple areas where the floor has separated from the adjoining walls. This could allow ingress of water, causing further damage and prevent adequate cleaning and disinfection; • there was a collection of waste and organic material in the PM suite drain.	**Major**
b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors.	As the establishment does not have pass through fridges for all fridge banks into the PM Suite, the establishment are required to use a body trolley to transfer some bodies from the body store to the PM suite. There is no demarcation between clean and dirty areas between the body store and the PM suite, the trolley is not being decontaminated between the dirty to clean areas.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.	The freezers were occupied at full capacity (Due to the delays in the Coroner communicating when bodies are clear for release) and there were some bodies in refrigerated storage that needed to be transferred to long-term storage. There is also no back up or contingency freezer storage arrangements.	**Minor**

e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.	The following issues were identified. Maternity Department: • the fridge alarm is challenged monthly during cleaning and decontamination. However, this is not documented or detailed in a SOP; • when there has been a temperature excursion and an alarm has been raised, the alarm activation is not recorded, or the corrective action taken. Mortuary: • the alarm has been manually challenged. However, this is not documented as completed and this process is not detailed in a SOP.	**Minor**
f) Temperatures of fridges and freezers are monitored on a regular basis.	There were issues identified in both the Maternity Department and the mortuary. There is evidence of some monitoring of the fridge temperatures, however, this is not done consistently every day and temperatures are not being reviewed for trends.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use.	Areas of rust were observed on body hoists and trolleys. Maintenance records from November 2018 confirmed that it had been identified that the trolleys and hoists needed to be reconditioned. The rust creates a porous surface, meaning the trolleys and hoists cannot be adequately cleaned or decontaminated. In addition, not all of the four body hoists are fit for purpose. There are limitations when using these as some cannot reach the top fridge spaces when fully raised, or bottom fridge spaces when fully lowered. This poses a health and safety risk to staff and a risk to bodies when removing and replacing them from the bodystore.	**Major** **(Cumulative)**
b) Equipment is appropriate for the management of bariatric bodies.	The establishment staff highlighted the following limitations in the equipment for bariatric bodies: • due to the small width of some refrigerated storage spaces when capacity is limited, staff need to use the top fridge spaces for bariatric bodies; • only one of the four body hoists is able to accommodate bariatric bodies. This is one of the hoists that does not reach the top or bottom fridge spaces properly; and • they do not have trollies that can be used when storing bariatric bodies in the bier room, if required. These issues further increases the risk to staff and bodies as outlined in PFE3(a).	

Advice

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

No.	Standard	Advice
1.	C1 (g)	The DI is advised to use the paedeatric/perinatal consent forms and PM examination information sheet produced by the stillbirth and neonatal death charity, Sands.
2.	GQ1 (f)	The DI is advised to ensure that all deviations from documented procedures are recorded and regular audits are implemented to capture deviations in the process against the SOP.
3.	GQ2 (a)	In addition to the full HTA compliance audit every three years, the DI may wish to consider having smaller, more regular audits, for example, of each separate HTA standard. The DI is also advised to regularly include a variety of horizontal and vertical audits of mortuary activities in the audit schedule, for example, admission and release of bodies, which will also help provide assurance that staff are following documented procedures and assess competency. The audit for bodies in storage ("Time spent in storage") should also be regularly completed to mitigate the risk that bodies remain in refrigerated storage for longer than the recommended 30 day period.
4.	GQ3 (f)	The DI is advised to add training in relation to the HT Act in the induction checklist for new staff.
5.	GQ4 (a)	The DI is advised to implement a more secure method for recording information that can be securely maintained and backed up in order to preserve a suitable audit trail. The DI is advised to ensure that all raw data records are kept for a reasonable length of time to ensure that they can be sufficiently reviewed when needed.
6.	GQ6 (a)	Although there is a SOP for lone working, the DI is advised to review the risk assessment for this activity to assess whether the use of panic alarms should be considered. The current process includes the use of a mobile phone, however, the phone signal can be poor. The DI is also advised to risk assess using a paper-only mortuary register as this information is not stored elsewhere. The DI is advised to ensure that all risk assessments are within their review dates.
7.	T1 (a)	The DI may wish to consider including a section in the mortuary register to include the transfer and return of bodies to the mortuary. Transfer information can then be recorded in one entry and would be easy to refer to. In addition, the DI is advised to consider recording property in the mortuary register that bodies are admitted to the mortuary with, in case of any queries. The property can then be cross checked upon release to ensure no items have been lost since admission. The DI is also advised to ensure that the tags on the bodystore doors are legible and that information is correctly recorded.

8.	T1 (b)	The DI is advised to implement a whiteboard to assist with the management of bodies and storage capacity. The board can also act as a visual aid to highlight bodies with same/similar names, body storage locations and when bodies need to be moved into frozen storage. The DI is also advised to implement a more robust system for capturing all information relating to bodies and tissue retained at PM examination, including transfer to other establishments and movement of bodies into long-term storage.
9.	T1 (d)	The DI may wish to consider the use of coloured labels or magnets on the body store doors to flag same/similar names and other pertinent information, for example, 'danger of infection'.
10.	T1 (f)	The DI is advised to implement a visual aid to identify those bodies in long-term storage in the mortuary register. This will help staff to locate the entries and information for these bodies which may be further back in the register
11.	T2 (b)	The DI is advised to explore how to improve communication with the Coroner to help speed up the release of bodies and mitigate the risk of storing tissue without authority or appropriate consent. For further information please see Code B: Post-mortem examination, Annex B.
12.	PFE1 (c)	The DI is advised to ensure that cleaning records are consistently signed to indicate when cleaning tasks have been completed.
13.	N/A	Although high-risk PM examinations have not been carried out recently, there is a possibility that they may be conducted. The DI is advised to ensure that these cases are adequately labelled to highlight the risk they may present.

Concluding comments

The HTA observed a number of areas of strength and good practice during the inspection.

All of the staff that were involved with the inspection were very dedicated and committed. This was evident through their high-levels of care and sensitive approach to the work they undertake.

The mortuary also have a good working relationship with key members of staff throughout the hospital and work closely with other hospitals within the Trust, meaning there is effective communication and management throughout.

All mortuary staff attend regular meetings relating to HTA matters and communicate effectively to raise issues and action them during these meetings.

There are a number of areas of practice that require improvement, including six major shortfalls and sixteen minor shortfalls.

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, 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: 28 February 2019

Report returned from DI: 08 March 2019

Final report issued: 15 March 2019

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: 04 October 2019

Appendix 1: HTA licensing standards

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

Consent

C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice

a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice.

b) There is a documented standard operating procedure (SOP) detailing the consent process.

Guidance

This should include who is able to seek consent, what training they should receive, and what information should be provided to those giving consent for post-mortem examination. It should make reference to the use of scanning as an alternative or adjunct to post-mortem examination.

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.

Guidance

Information on consent should be available in different languages and formats, or there is access to interpreters/translators. Family members should be given the opportunity to ask questions.

d) Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (for example, repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use), and what steps will be taken if no decision is made by the relatives.

e) Where consent is sought for tissue to be retained for future use, information is provided about the potential uses to ensure that informed consent is obtained.

f) The deceased's family are given an opportunity to change their minds and it is made clear who should be contacted in this event and the timeframe in which they are able to change their minds.

g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.

Guidance

This may be based on the HTA's model consent form for adult post-mortem examinations available on the HTA website, or in relation to infants, the resources pack developed by the

Stillbirth and neonatal death charity, Sands. The consent forms should record the consent given for the post-mortem examination and for the retention and future use of tissue samples.

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent

a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice.

Guidance

Refresher training should be available (for example annually).

b) Records demonstrate up-to-date staff training.

c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual.

d) Competency is assessed and maintained.

Governance and quality systems

GQ1 All aspects of the establishment's work are governed by documented policies and procedures

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath. These include:

i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk;

ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage;

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

vi. receipt and release of bodies, which reflect out of hours arrangements;

vii. lone working in the mortuary;

viii. viewing of bodies, including those in long-term storage, by family members and others such as the police;

ix. transfer of bodies internally, for example, for MRI scanning;

x. transfer of bodies and tissue (including blocks and slides) off site or to other establishments;

xi. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached;

xii. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family;

xiii. access to the mortuary by non-mortuary staff, contractors and visitors;

xiv. contingency storage arrangements.

Guidance

SOPs should reflect guidance contained in the HSE's document: Managing the risks of infection in the mortuary, post mortem room, funeral premises and exhumation.

Individual SOPs for each activity are not required. Some SOPs will cover more than one activity.

b) Procedures on evisceration ensure that this is not undertaken by an APT unless the body has first been examined by the pathologist who has instructed the APT to proceed.

c) Procedures on body storage prevent practices that disregard the dignity of the deceased.

Guidance

For example, placing more than one body on a tray, placing bodies unshrouded on trays, or storing bodies in unrefrigerated storage should not take place.

The family's permission should be obtained for any 'cosmetic' adjustments or other invasive procedures prior to release of bodies, for example, sewing the deceased's mouth to close it or the removal of a pacemaker. It is also good practice to discuss with the family any condition that may cause them distress, for example when viewing or preparing the body for burial, such as oedema, skin slippage of signs of decomposition.

If identification of the body is to take place before a post-mortem examination, if available, a Police Family Liaison or Coroner's Officer should have a discussion with the family about the injures and let them know that reconstruction may be required.

However, the Pathologist should see the body without any changes being made, so if there is a need to reconstruct or clean a body before the post-mortem examination, it should be with the agreement of both the Pathologist and the Coroner. In Home Office cases, a viewing cannot normally take place until after the post-mortem examination.

d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.

e) There is a system for recording that staff have read and understood the latest versions of these documents.

f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.

g) All areas where activities are carried out under an HTA license are incorporated within the establishment's governance framework.

Guidance

These areas include maternity wards where storage of fetuses and still born babies takes place, areas where material is stored for research, the Accident and Emergency Department where removal of samples may take place in cases of sudden unexpected death in infancy. There should be an identified Person Designated in areas of the establishment remote from the main premises.

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

As a minimum, the schedule should include a range of vertical and horizontal audits

checking compliance with documented procedures, the completion of records and traceability.

b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these.

Guidance

Staff should be made aware of the outcomes of audits and where improvements have been identified.

c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention.

Guidance

Audits of stored tissue should include samples held under the authority of the police, where applicable.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks

a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.

Guidance

This includes portering staff, who have responsibility for bringing bodies to the mortuary out of hours and who may not be aware of the potential risks to the deceased during transfer into refrigerated storage, and unqualified mortuary 'assistant' staff.

APTs should be trained in reconstruction techniques to ensure that the appearance of the deceased is as natural as possible. APTs should be encouraged to work towards the achievement of the RSPH Level 3 Diploma in Anatomical Pathology Technology.

b) There are clear reporting lines and accountability.

c) Staff are assessed as competent for the tasks they perform.

Guidance

Assessment of competence should include the standard of APTs' reconstruction work.

d) Staff have annual appraisals and personal development plans.

e) Staff are given opportunities to attend training courses, either internally or externally.

Guidance: attendance by staff at training events should be recorded.

f) There is a documented induction and training programme for new mortuary staff.

g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.

Guidance

The qualifications of locum staff should be checked prior to them commencing work in the mortuary and their competency to undertake each task should be assessed.

Contractors, visiting and temporary staff and funeral service staff bringing bodies out of hours should be required to read relevant standard operating procedures and sign to confirm their understanding.

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

a) 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.

Guidance

Records include mortuary registers, PM examination records, tissue retention forms and records of transfer and return of organs/tissue sent elsewhere for examination.

b) There are documented SOPs for record management which include how errors in written records should be corrected.

c) Systems ensure data protection, confidentiality and public disclosure (whistle-blowing).

GQ5 There are systems to ensure that all untoward incidents are investigated promptly

a) Staff know how to identify and report incidents, including those that must be reported to the HTA.

Guidance

HTA-reportable incidents must be reported within five days of the date of the incident or date of discovery.

Incidents that relate to a failure of hospital staff to carry out end of life care adequately should be reported internally and the incidence of these monitored.

b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.

c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.

d) Information about incidents is shared with all staff to avoid repeat errors.

e) The establishment adopts a policy of candour when dealing with serious incidents.

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored

a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.

Guidance

Risks to the dignity and integrity of bodies and stored tissue should be covered. The HTA's reportable incident categories provide a good basis for risk assessments. Risk assessments should be reviewed at regular intervals, for example every 1-3 years or when circumstances change. Staff should be involved in the risk assessment process.

b) 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.

Guidance

Relevant staff should have knowledge of risks and the control measures that have been taken to mitigate them.

c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.

Traceability

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail

a) Bodies are tagged/labelled upon arrival at the mortuary.

Guidance

The condition and labelling of bodies received in body bags should always be checked and their identity confirmed. They should be labelled on the wrist and/or toe. Body bags should not be labelled in place of the body.

b) There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records).

Guidance

Body receipt and release details should be logged in the mortuary register, including the date and name of the person who received/released the body and, in the case of release, to whom it was released. This includes bodies sent to another establishment for PM examination or bodies which are sent off site for short-term storage which are subsequently returned before release to funeral service staff.

c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier.

Guidance

Identification details should not be written on bodies. Where bodies are moved off site for contingency storage the DI should ensure that suitable systems are in place to identify same or similar names.

d) There is system for flagging up same or similar names of the deceased.

e) Identity checks take place each time a body is moved whether inside the mortuary or from the mortuary to other premises.

Guidance

Mortuary white boards containing the names of the deceased give potential for error if wiped clean (such as when visitors attend for reasons of confidentiality), and should not be relied upon as the sole source of information about the locations of bodies.

Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place present a risk to traceability. Full identification checks should be made when they are placed back into normal storage.

f) There are procedures for releasing a body that has been in long term storage and is therefore not in the current register.

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings). The traceability system ensures that the following details are recorded:

i. material sent for analysis on or off-site, including confirmation of arrival

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

Consent information which covers retention/disposal of tissues should be made available to the other site, as appropriate.

h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements.

Guidance

Formal written agreements with funeral services are recommended. Coroners usually have their own agreements for transportation of bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.

a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete.

b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary.

c) Disposal is in line with the wishes of the deceased's family.

Guidance

Organs and tissue returned to the body prior to its release should be contained in clear viscera bags, which prevent leakage, are biodegradable and pose no issues for crematoria in relation to emissions and pollution. Clinical waste bags or household bin bags should not be used for this purpose.

Tissue blocks and glass slides should not be placed inside the body for the purpose of reuniting tissues with the deceased. Blocks and slides should be placed in a suitable container and transported with the body should the family wish to delay the funeral until the slides are returned.

d) The method and date of disposal are recorded.

Premises, facilities and equipment

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue

a) The premises are clean and well maintained.

Guidance

Floors, walls and work surfaces should be of non-porous construction and free of cracks and chips. The premises should be subject to a programme of planned preventative maintenance, which ensures that the premises, facilities and equipment remain fit for purpose.

b) There is demarcation of clear, dirty and transitional areas of the mortuary, which is observed by staff and visitors.

c) There are documented cleaning and decontamination procedures and a schedule of cleaning.

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).

Guidance

Relatives who visit for a viewing should not be able to access the body store area. Security systems and lone working arrangements should take into account viewings which take place out of hours.

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.

PFE2 There are appropriate facilities for the storage of bodies and human tissue

a) Storage arrangements ensure the dignity of the deceased.

Guidance

Refrigeration of bodies should be at a temperature of approximately 4 degrees Celsius. The optimal operating temperature for freezer storage is around -20 Celsius, +/- 4 degrees.

b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.

Guidance

Capacity should be regularly reviewed, particularly if contingency arrangements are used for an extended period.

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.

Guidance

There should be sufficient frozen storage for the long-term storage of bodies; the HTA advises

that bodies should be moved into frozen storage after 30-days in refrigerated storage if there is no indication they are soon to be released or further examined, or before, depending on the condition of the body. Where there is insufficient freezer storage to meet needs, there should be arrangements with other establishments, or other contingency steps, to ensure that bodies can be stored appropriately.

Bodies in long-term storage should be checked regularly; this should include confirmation of their identity and the reason for their continued storage.

Where new fridges are installed, these should measure 24"-26" in width and consideration should be given to the proportion that should be larger to accommodate bariatric bodies.

d) Fridge and freezer units are in good working condition and well maintained.

e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.

f) Temperatures of fridges and freezers are monitored on a regular basis.

Guidance

Temperature monitoring should enable the establishment to identify trends and may mitigate the risk of a possible fridge failure.

g) Bodies are shrouded or in body bags whilst in storage.

h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.

Guidance

Where contingency arrangements involve the transfer of bodies to other premises, these should be assessed to ensure that they are suitable and that traceability systems are of the required standard. Stacking bodies on the same fridge tray is not considered suitable practice.

Establishments should have documented agreements with any funeral services that they may use for contingency storage. Consideration should be given to whether the funeral service provides contingency storage for other mortuaries. SOPs should address issues such as risk assessments and same/similar name systems.

The hire of temporary storage units should not be the sole contingency arrangement for an establishment. Establishments should put in place other formally agreed arrangements for contingency storage. Where the hire of temporary storage facilities

forms part of establishments' contingency arrangements, consideration should be given well in advance and steps taken to ensure availability of funds, and of units for hire.

Establishments should consider entering in to Mutual Aid Agreements

with neighboring organisations in order that they can provide and obtain support during periods

of capacity shortages.

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored

a) Items of equipment in the mortuary are in a good condition and appropriate for use:

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

   Guidance

   Equipment should be made of material that is easy to clean, impervious, non-rusting, non-decaying and non-staining.

b) Equipment is appropriate for the management of bariatric bodies.

c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually.

   Guidance

   COSHH requires a thorough examination of the ventilation system at 14-month intervals, and sets out what the examination should cover.

d) Staff have access to necessary PPE.

   Guidance

   Where face masks should be worn, they should be face fitted.

e) Where chemicals are used for preservation of tissue samples, there is adequate ventilation.

f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept.

   Guidance

   This includes fridges in Maternity where fetuses or still born babies are stored prior to examination. Maintenance records may be held by the mortuary or centrally by the Trust, such as the Estates Department. They should be available for review during inspection by the HTA.

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.