Site visit inspection report on compliance with HTA licensing standards

Countess of Chester Hospital

HTA licensing number 12049

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**

19 & 20 September 2018

Summary of inspection findings

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

Although the HTA found that The Countess of Chester Hospital had met the majority of the HTA's standards, five major and eleven minor shortfalls were identified against the Consent, Governance and Quality systems, Traceability and Premises, Facilities and Equipment standards. The shortfalls relate to post-mortem (PM) examination consent training and seeking procedures; standard operating procedures (SOPs); policies on record management; risks assessments for licensable activities; audits; traceability; maintenance of premises, equipment and body store alarms.

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

Countess of Chester Hospital (COCH) (the establishment) is licensed under the Human Tissue Act 2004 (HT Act) for: carrying out post-mortem (PM) examinations; removal from the body of a deceased person of relevant material (for scheduled purposes) and storage of the body of a deceased person or relevant material which has come from a human body for use for scheduled purposes. The establishment has been licensed by the HTA since May 2007 and this report describes the third routine inspection with the previous inspection occurring in April 2015. The current DI has been in post since February 2014 and this is their second HTA site visit inspection.

Access to the mortuary from the hospital is via a hospital corridor and the mortuary is secured by a proximity card system and CCTV. Access for community deaths and funeral directors is via a concealed porch area with minimal oversight. This entrance to the mortuary has a door spy hole and is covered by CCTV and a motion sensor. The CCTV is linked to both the mortuary office and hospital security.

The portering staff transfer all hospital bodies to the mortuary through the main hospital using a concealment trolley located in the mortuary. Upon arrival at the ward the porters conduct a identification check of the deceased using the information on the wrist and ankle bands and compare this to the information on the notification of death (NOD) form. Deceased patients are transferred from the wards to the mortuary with the NOD form. Out-of-hours and when the mortuary staff are busy in the PM room, the porters are responsible for identifying a fridge location and transferring the body into refrigerated storage. The name of the deceased is written on the wipe board of the relevant fridge location and a door card is completed and put into the holder on the door. The NOD form is left in a dedicated tray. Out-of-hours porters are also responsible for receipt of bodies brought into the mortuary from the community by the Coroner's contracted funeral director. All bodies admitted out-of-hours are recorded in the 'out-of-hours' register. Community bodies enter the mortuary through the rear entrance. A door card is completed by the funeral director and a wrist band is attached to the body with three points of identification. During working hours, the mortuary staff review the out-of-hours register, complete body identity checks of the deceased and enter all details onto the electronic mortuary register. The deceased are then issued with a unique mortuary identification number which is written on the wipe board against the relevant fridge location. Any discrepancies identified during these checks are followed up with the ward or Coroner's Officer. Release of bodies is only conducted by the Anatomical Pathology Technologists (APTs) via the mortuary and is restricted to between certain times, within working hours. On occasion, out-of-hours releases are conducted by the on-call APT (see shortfall against T1(c)).

The establishment runs a post-mortem (PM) examination service. There are five fully qualified pathologists and three full-time APTs, one of which is the Mortuary Manager.

The establishment receives approximately 1800 bodies per year from both the hospital and community, performing around 500 coronial PM examinations per year, including high risk (up to biological hazard group 3). No forensic PM examinations are undertaken and no material is held under the Police And Criminal Evidence Act 1984 (PACE). Adult hospital consented PM examinations are conducted on rare occasions; on average one per year. Consent for these cases is undertaken by clinical staff with a pathologist present and recorded on locally devised consent forms. Perinatal and paediatric cases are transferred to another HTA-licensed establishment for PM examination. However, consent is sought for these PM examinations on site by clinicians and midwives using the SANDs documentation (see shortfall against C2(a)).

The body store consists of 62 refrigerated spaces, three of which are suitable for bariatric cases and five are dedicated for use for babies. There is an additional temporary unit that can be erected in peak periods which gives an additional twelve refrigerated spaces. A freezer unit with four spaces is located in a padlocked caged enclosure adjacent to the rear entrance of the mortuary under the covered porch area. There is also a standalone fetal fridge.

All fridges and freezers are alarmed with upper and lower trigger points which, when triggered sound in the mortuary, blood sciences laboratory and alerts the hospital switchboard staff who contact the on-call APT out-of-hours (see shortfall against PFE2(e)). Temperatures are recorded continuously by the monitoring system and are reviewed via computer based software for trends in an attempt to identify any potential issues with the equipment.

The mortuary has one PM suite with two height adjustable, custom-made, downdraught PM tables, one of which is suitable for bariatric cases and two dissection areas. The pathologist completes each PM examination prior to commencing the next to help mitigate the risk of mixing up organs and tissue samples. Any high risk cases are conducted at the end of a PM session. The Coroner's Officer email and/or fax authorisation for a PM examination to the pathologist and the mortuary. The pathologist and APT check the identity of the deceased before the external examination and evisceration of the body. Material retained at PM examination for histological analysis is labelled, documented and packaged in the mortuary before being sent to the histopathology laboratory with a histology request form (see shortfall against T1(g)). Relatives' wishes with regards to the fate of any tissue retained following PM examination are managed by the establishment's secretaries, who complete a spreadsheet which is also accessible by the mortuary and histology laboratory staff.

In the case of stillbirths or perinatal deaths, babies are transferred to the mortuary within a few hours by porters in a dedicated transfer bag (see *Advice,* item 8). The establishment removes relevant material from deceased infants/children brought into A&E under pre-emptive authorisation of HM Coroner.

The establishment's licence also covers storage of relevant material from living patients for use in research. The establishment has a −80 °C freezer in the Pathology Department for the storage of these samples. At the time of inspection, the establishment stated that samples stored under recognised Research Ethics Committee (REC) approval are also stored in this freezer and during the inspection it was stated that only material with REC approval was being stored. However, following the site visit inspection, information provided by the Health Research Authority suggests that, whileappropriate REC approval was in place for this material, the establishment was not identified as a specified site within the project approval. Based on this current information this material would therefore fall under the the remit of the HTA and the licencing standards (see shortfall against C1(g)).

Description of inspection activities undertaken

Traceability audits of body identifiers, storage locations and mortuary register details were conducted for three adult bodies and one baby, these included both hospital and community cases, and from both fridge and freezer storage. The names of the individuals and mortuary identification number were written on the mortuary location wipe board in the body store. There was a white card in each of the fridge doors which also contained the name, date of birth (DOB), unique mortuary identification number and fridge location. No discrepancies were found for any of the bodies audited.

In addition, tissue removed during PM examinations for four cases between 2017 and 2018 were audited for traceability. Material removed is recorded on the PM histology request form and on the histology database which is accessible by mortuary and histology staff. Samples are delivered to histology and signed for upon receipt (see *Advice,* item 7*)*. No discrepancies were found.

Interviews were conducted with: Consultant Histopathologist (the DI) who oversees consent seeking for adult PM examinations; Mortuary Manager; Pathology Quality Manager; Cestrian Ward Manager who oversees consent seeking for perinatal PM examinations; Sisters responsible for overseeing removal of material in A&E from SUDI cases; Charge-hand for the porters; Cellular Pathology Manager; Biomedical Scientist; Research and Development (R&D) lead and Principle Investigator (PI) for research studies. An interview was not conducted with the Coroner's Officer as they were not contactable at the time of the inspection.

Inspection findings

Although the HTA found the Licence Holder, the Designated Individual and the premises to be suitable in accordance with the requirements of the legislation, the number of shortfalls identified is of concern. Advice and guidance was given to the DI to further improve practices following the last inspection in 2015. During the current inspection similar areas for improvement were identified, and are captured in the shortfalls below.
Although the DI was considered at inspection to a be a suitable person to hold the role, the shortfalls identified demonstrate that he has not ensured that there are suitable practices in place for the conduct of the licensed activities.

The HTA will monitor progress of these shortfalls through the Corrective and Preventative Action (CAPA) plan to be completed by the establishment.

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	The SOP for seeking PM consent refers to the 'Next of Kin' giving consent for a PM examination. For consent to be appropriate and valid under the HT Act 2004, consent must be obtained in accordance with the 'hierarchy of qualifying relationships'. This document requires updating to reflect the requirements of the HT Act and the HTA's code of practice on consent (Code A) (see *Advice*, item 1)	**Minor**
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided.	Material collected by a third party as part of a REC approved study is being stored at the establishment. The establishment was not identified on the study as an approved study site. Consent obtained for the use of this material was for use at a specified site with appropriate ethical approval. The establishment did not have assurance of appropriate consent being in place for the use and storage of the material.	**Major**

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	Consent for PM examination is sought by clinicians, who have undertaken basic clinical consent training. However, there is no formal training which addresses the requirements of the HT Act or the HTA's codes of practice for those seeking consent for either adult or paediatric PM examinations. *Standards C2(b), C2(c) and C2(d) could not therefore be assessed.*	**Major**

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.	While the establishment has a number of the required SOPs in place, they lacked the required detail or attention to wording, these include but are not limited to: • SOP MORT089 – contains incomplete sentences and does not refer to the process for obtaining three identifiers of the deceased from visitors wishing to undertake a viewing; • SOP MORT106 – escalation procedures for bodies who have been in the mortuary for extended periods of time, do not detail when a body should be moved into the freezer storage facility; • SOP MORT042 – does not detail the PM examination process i.e. the roles and responsibilities of the APT and pathologist in the procedure; only the technical details such as how to remove the brain etc. There is no documented SOP for the use of the temporary refrigeration unit for the storage of bodies when capacity is reached in the permanent refrigerated bodystore. Local knowledge is relied upon as to when and where to erect this unit and how it should be utilised.	**Minor**

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	The majority of SOPs reviewed were authored and authorised by the same person and hence did not provide the required level of independent review. Furthermore, many of the SOPs contained errors with regards to the version numbers and review dates. For example, there were discrepancies between the date and version on the front page which was different to that in the document footer. In the previous inspection advice and guidance was given for ensuring SOPs were authored and authorised by different people to provide the required independent scrutiny.	**Minor**
e) There is a system for recording that staff have read and understood the latest versions of these documents	The establishment uses a quality management computer software system, however, the system has not been used appropriately. Therefore, updates to SOPs are not being circulated to staff for them to be made aware of or acknowledge changes.	**Minor**

GQ2 There is a documented system of audit		
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	While audits are conducted and recordings are made, there is no record of follow-up actions. This is because non-conformances are listed as observations resulting in no follow-up actions being required or documented.	**Minor**

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	While manual handling training has been implemented for porters as part of their mandatory training, a number of HTA reportable incidents (HTARIs) involving porter activity within the mortuary have been recorded. Porters do not receive training in relation to HTARIs or other activities which they are involved in within the mortuary. Examples include but are not limited to: • Security – porters are not trained on the correct procedure for bringing visitors and non-authorised personnel to the mortuary. • Viewings – how obtaining three identifiers of the deceased should be achieved from those wishing to view the deceased within the mortuary. All training should be recorded and competency assessed. Refresher training should be repeated every two years or earlier if deemed necessary.	**Minor**

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	The HTA guide to reporting HTA Reportable Incidents (HTARIs) has been uploaded to the establishment's quality management computer software system. However, it is not documented who at the establishment can report HTARIs to the HTA via the website portal. Internal incident reports were reviewed by the inspection team which identified a number of incidents in the two years preceeding the inspection that were either near misses or HTARIs, but which had not been reported to HTA. This was identified as a minor shortfall in the previous inspection report.	**Major**

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 risk assessments in place relate to health and safety issues. The risks and hazards associated with HTA reportable incidents have not been risk assessed.	**Minor**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
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	Currently only two identifiers are used by funeral directors collecting community bodies from the mortuary. In addition, release of both community and hospital bodies occurs after the identifiers are provided verbally to the mortuary staff. No written information is obtained from funeral directors in order to check the identity of a body before it is released. This presents a risk of releasing a wrong body.	**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 issues identified with the cleanliness and maintenance of the establishment, including but not limited to: • Hair and tissue debris in the gully underneath the sink/dissection bench; • Bodily fluids and debris in the bottom of body store fridges; • Hair and bodily fluids on the floor outside of the body store fridges;	**Minor**

	• Damaged and exposed areas of wood, the size of a tennis ball, were visible on the doors and door frame leading to the PM suite, resulting in the loss of effectiveness of the protective covering. The damage makes the wood porous, so that it cannot be adequately cleaned or disinfected.	
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	No documented cleaning schedule was available for the body store fridges.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	During the site visit, the inspection team observed the doors to the PM suite from the body store being propped open whilst a PM examination was being undertaken. The doors to the PM suite should be kept closed whilst bodies are on the PM tables or a PM examination is being undertaken. This will help prevent unauthorised or unintentional access or viewing of PM room activities, maintaining the dignity of the deceased. In addition, closing these doors will help ensure the ventilation system can work efficiently, maintaining the required 10 air changes per hour.	**Major**
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	While the alarm system for the fridges and freezers is challenged for functionality on an occasional basis. The alarm system is not challenged as per the SOP which stipulates a monthly challenge is required to provide assurance it will trigger in the event of deviations in temperature from their expected ranges. All alarm challenges should be recorded. Advice and guidance around the manual challenging of the alarm system on a regular basis was given following the previous site visit inspection.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	Critical pieces of equipment were found not to have regular maintenance records, these include but are not limited to: Body hoist – last maintenance record 2014 PM downdraught tables – serviced in 2012 and 2018.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(a)	The hospital consent policy provides a link to the previous HTA codes of practice. It also states the Trust is licenced for 'the storage and used of tissue for specific therapeutic uses.' This implies the Trust is licenced under the Human Application (HA) sector by the HTA. The DI is advised to review the Trust policy and make amendments to the wording and links provided, as required.
2.	GQ1(a)	The Slide and Block Retention Policy (CPPOL018) references the HTA's previous codes of practice. The DI is advised to review this policy and ensure where appropriate, the current HTA codes of practice are referenced, as well as other sources of reference are current and up to date.
3.	GQ1(g)	Currently there is no Persons Designated (PD) in the maternity services department. The DI is advised to appoint a PD in this department to assure himself of oversight of the consent seeking procedure and training for perinatal PM examinations and staff awareness and compliance to the HT Act and the HTA codes of practice.
4.	GQ1(h)	Currently matters relating to HTA-licensed activities are discussed at 'Seniors' meetings on an ad hoc basis. The DI is advised to add HTA matters as a standing agenda item for these meetings and other relevant staff meetings where those who attend carry out HTA-licensable activities.
5.	GQ2(a)	While there is currently a schedule of audits, the DI is advised to review this schedule to assure himself it covers all HTA-licensable activities and on a sufficiently regular basis to identify potential areas of risk/non-conformance.
6.	GQ3(e)	Staff are currently able to attend in-house training, however external training is restricted. The DI is advised that staff attendance at external training courses/conferences are important for shared learning opportunities and therefore should be made available to all staff where appropriate and feasible.
7.	T1(g)	Currently tissue retained from PM examination is placed into cassettes and then into larger containers and delivered to the histology department, where the recipient signs the histology request from to state they have received the material. . The DI is advised to ensure that the number of cassettes is checked against the histology request form at the point of receipt in the histology laboratory to verify records match material received. This will help to ensure full traceability of all PM examination tissue between departments.
8.	T1(h)	No record of foetal material sent to the mortuary is held within maternity. This poses a risk for the loss of traceability in foetuses sent between the maternity department and mortuary. The DI is advised to implement a record system for recording all material sent to the mortuary from maternity to ensure continuous traceability of all foetal material is maintained between departments.
9.	T2(a)	During the site visit the inspection team noted recent disposal records for tissues that had been retained for a number of years post the conclusion of the Coroner's interest. This was due to insufficient information being held regarding the consent wishes of the family for tissues retained during the PM examination due to lack of historical follow up with the Coroner. The establishment has recently implemented regular tissue audits. The DI is advised to continue with these regular audits of retained tissue. This will help to ensure material is disposed of in a timely manner,

		following the conclusion of the Coroners authority or the consented PM examination.
10.	N/A	During the site visit the inspection team met with the Reseach and Development Lead and and Principal Investigator to discuss options for reinstating a collection of relevant material for the scheduled purpose of research. It is advised that a separate HTA research sector licence is obtained as the DI for the HTA PM sector licence is not involved with this department. This would help to ensure sufficient oversight is maintained for the storage and licensable activities associated with the retained relevant material.

Concluding comments

While there are a number of areas of practice that requires improvement, there were areas of good practice observed during the inspection. The establishment demonstrated a commitment to the continual improvement of practices and compliance with the HT Act. Areas of good practice observed include:

- An electronic mortuary register with colour coding entries for same/similar names; risk of infection; do not release and implant which match fridge door magnets. This system also automatically records the number of days a body has been in the mortuary.
- A charge has been implemented for bodies still in the mortuary for more than five days following the end of the Coroner's authority. This charging system has helped to reduce the delay in collection of bodies by funeral directors and has therefore helped to reduce the impact on the storage capacity for the mortuary due to long-stay bodies.

All staff demonstrated a clear dedication to the role they undertake, a conscientious approach to the handling and traceability of relevant material and a compassionate approach to arranging viewings of the deceased at the mortuary. Many of the staff are long serving and very knowledgeable of the role they undertake. There is a good level of interaction and effective communication between the DI and those carrying out licensible activities.

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: 17 October 2018

Report returned from DI: 01 November 2018

Final report issued: 07 November 2018

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 licence 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 theyare 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 forthese 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 neighbouring 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.