Site visit inspection report on compliance with HTA licensing standards

Whittington Hospital

HTA licensing number 12099

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**

18-19 December 2017

Summary of inspection findings

This report describes the first inspection of this establishment against the revised HTA licensing standards, which came into force on 3 April 2017.

Although the HTA found that Whittington Hospital (the establishment) had met the majority of the HTA's standards, two major shortfalls were identified; one was in relation to the numbers of identifiers used to identify the deceased, and the other was in relation to fridge and freezer temperature monitoring. In addition, 14 minor shortfalls were found across the Consent, Governance and quality systems, and Premises, facilities and equipment standards.

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

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

Whittington Hospital (the establishment) has been licensed since July 2007. The establishment is licensed for the making of a post mortem (PM) examination, removal of relevant material from the deceased, and storage of bodies of the deceased and relevant material for use for scheduled purposes.

The mortuary has four members of staff: three Anatomical Pathology Technologists (APT), one of which is the lead APT (Mortuary Services Manager), and a Mortuary Administrator.

The establishment carries out approximately 400 adult PM examinations each year, most of which are coroner's PM examinations. The majority of these are performed under the authority of HM Coroner for Inner North London. Paediatric and perinatal cases are transferred to another HTA-licensed establishment for PM examination. A small number of forensic PM examinations are also undertaken on site. The establishment has a PM Computed Tomography (CT) scanning service, which is utilised both for local cases and for cases transferred from other establishments. The body is returned to the mortuary after scanning. If the cause of death cannot be determined based on the scan report alone, a PM examination is conducted as per the instructions of HM Coroner. Any additional samples, for example for toxicology screening, are taken in the mortuary.

A small number of adult hospital consented PM examinations take place at the establishment. Consent is sought by the Mortuary Services Manager, a senior APT, or the DI. The consent forms in use are based on the HTA's model consent forms and are broadly in alignment with the HT Act (see shortfall against C1(a)) and *Advice* items 1 and 2). For perinatal cases, a bereavement midwife seeks consent. The Stillbirth and Neonatal Death (Sands) charity's PM consent package is used. Consent for paediatric cases is sought by paediatricians (see shortfall against C2(a)).

The mortuary is accessible via key lock. Closed Circuit Television (CCTV) covers the visitors' entrance to the viewing room, and the body store entrance. The body store entrance has two shutter style doors, which are opened and closed one at a time when trolleys or funeral director's vehicles are entering the loading bay. This ensures that the body store area remains closed off from view while a vehicle or trolley is entering the mortuary from the outside (see *Advice,* item 15). There is a storage area for stillborn and neonatal deaths at the labour ward. This area consists of a fridge and a logbook to ensure traceability of the deceased. The storage area is not secured from access by the public (see shortfall against PFE1(d)).

The mortuary has 48 standard adult fridge spaces for bodies, five spaces for bariatric cases, and six freezer spaces. There is also a fridge with six trays that is used for paediatric cases; this can be converted to a five-space standard adult fridge if required. The establishment has

a contingency plan in place, which provides additional storage space with local funeral directors (see *Advice*, items 16 and 18).

The temperature of the fridges and freezers is monitored remotely by the hospital Estates department. Temperatures are not regularly monitored for trends (see shortfall against PFE2(f)). In addition to a local audible alarm, the system is connected to an external alarm that alerts the Estates department in working hours, and the hospital main switchboard out of hours. The Mortuary Services Manager also receives an alert to their phone when the alarm is triggered. The alarm is not tested on regular basis (see shortfall against PFE2(e)).

The deceased are transferred to the mortuary from the main hospital by portering staff. There is no formal training programme in place for portering staff (see shortfall against GQ3(a)). Bodies are brought in from the community by funeral directors contracted by HM Coroner, both in hours and out of hours. Both portering staff and funeral directors sign a daily log book with the details of the deceased, and mortuary staff check the identity and enter details into the mortuary register the following day. Perinatal cases are transferred to the mortuary by mortuary staff.

The mortuary uses paper registers to ensure traceability of deceased persons and samples. There are separate registers for adult, foetal/perinatal and forensic cases. There is also a separate register for bodies that are brought from other establishments for PM CT scanning. It could not be evidenced during the inspection that the mortuary routinely uses three identifiers when confirming the identity of the deceased (see shortfall against T1(c)).

The PM room has three separate working spaces, each with a sink and a dissection space. Clean and dirty areas are clearly separated. Personal Protective Equipment including boots, gloves, protective clothing, cut-resistant gloves and face fitted masks with respirators for high-risk cases are available.

Tissue samples in formalin are stored temporarily in the preparation room within the PM suite prior to transfer to the Histopathology department for processing. Tissue samples that have been analysed by the Histopathology department are held in a dedicated sample room in the mortuary. Samples taken during PM are recorded in a log book in the mortuary office. This documents when the sample is transferred to the Histopathology department, or off site for specialist analysis. The return of tissue samples to the mortuary is also recorded, as well as disposal of tissue where appropriate.

Samples for determining the cause of death in sudden unexpected death in infancy (SUDI) are taken in the Accident and Emergency (A&E) department and in the neonatal intensive care unit (NICU) (see shortfalls against GQ1(a) and (g)).

Description of inspection activities undertaken

This report describes the third, routine HTA site visit inspection of Whittington Hospital. The inspection team interviewed staff involved with licensable activities, reviewed documentation and conducted visual inspections of the mortuary facilities, including the body store, viewing room and PM room. The inspection team also visited the Histopathology Laboratory, the A&E department, NICU, and the Labour Ward.

A traceability audit was conducted for three adult bodies and one perinatal case. These audits included checks of identifiers recorded in the mortuary register against identification details on bodies in fridge and freezer storage. No discrepancies were found.

The establishment was not storing any whole organs or wet PM tissue at the time of the inspection. Audits of traceability were conducted for tissue blocks and slides from seven PM cases (six coroner's cases and one hospital consented case). This included checks of the consent documentation for storage of samples and disposal records where consent had not been given for storage or use of samples after the end of the coroner's authority. No discrepancies were found.

The consent form for one adult hospital PM examination were reviewed. The consent form had been filled in indicating that consent for storage of tissue had been given, but also gave instructions for disposal (see *Advice*, item 1).

Inspection findings

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

Two major and 14 minor shortfalls were identified.

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		
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.	While the current SOP for taking consent includes the hierarchy of qualifying relationships, it does not accurately reflect the relationships listed in the HT Act; half-brother and half-sister have been left out. This constitutes a risk that the person giving consent may not be the person in the highest qualifying relationship with the deceased, which would be a breach of the HT Act.	**Minor**

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	The establishment does not currently provide training to consent seekers for paediatric cases, or keep a log of who seeks consent for these cases. Although there had not been any such cases recently, this constitutes a risk that consent may be sought in a way that is not in line with the requirements of the HT Act.	**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.	A number of the establishment's procedural documents need revisions to ensure they are in line with the revised HTA standards, for example: • SOPs for release, viewing and PM do not contain sufficient detail on how identification of bodies take place (refer to shortfall against T1(c)). • The list of qualifying relationships in the establishment's consent policy (POL/CL/0169, v.2) is not in line with the HT Act (refer to shortfall against C1(a)). • A number of documents refer to the previous versions of the HTA's Codes of Practice. • The establishments HTA Reportable Incident (HTARI) reporting SOP (MP MOR 500 012) does not include the current full list of HTARIs that need to be reported to the HTA. • There is currently no up-to-date protocol for removing relevant material in A&E. This means the establishment cannot be assured that procedures are undertaken in a consistent manner and in line with the requirements. The list above is not exhaustive and, to fully address this shortfall, the DI should ensure that all SOPs relating to licensed activities are reviewed to ensure that they are accurate and contain sufficient details of procedures.	**Minor**
e) There is a system for recording that staff have read and understood the latest versions of these documents	While mortuary staff record that they have read and understood relevant procedures, the consent seekers for perinatal and paediatric cases are not aware of the current overarching consent SOP. This poses the risk that some staff may not be aware of the procedures they must follow, including updates to procedures, and may not carry out their duties in accordance with the requirements.	**Minor**

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	The DI does not currently have full oversight of activities under the licence outside of the mortuary; there is no PD in the A&E department, and the DI was unaware that removal of relevant material from the deceased takes place in the neonatal intensive care unit (NICU). There are currently no formal meetings to discuss matters relating to the HTA licence where areas outside of the mortuary are included, and staff in non-mortuary areas were not aware of procedures that are relevant to them such as the consent SOP. There is therefore a risk that staff carrying out activities under the licence may not be working to the correct procedures and may not be aware of the requirements under the HT Act. See also *Advice*, item 3.	**Minor**
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	While meetings with the DI and mortuary staff had been occurring regularly in the past, these have not taken place since early 2017. These meetings have not covered areas outside of the mortuary, such as the Labour Ward. See also *Advice*, item 4.	**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	Training for portering staff carrying out duties in the mortuary is not formalised or recorded. See also *Advice*, item 6.	**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	While the establishment has covered a number of licensed activities in their risk assessments, the assessments focus on the risk to mortuary staff or contracted funeral directors rather than the risk to the deceased or the deceased's family. There is therefore no assurance that risks to the deceased or their family have been considered or mitigated against. Risk assessments for activities in the Labour Ward were not appropriately graded, and it is therefore not clear whether the mitigating actions have reduced the risks to an acceptable level.	**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	It could not be evidenced during the inspection that the establishment routinely uses three identifiers when confirming the identity of the deceased. For viewings, only one identifier is requested from the person requesting to view the deceased. The SOPs describing procedures for identification of bodies do not include details of the minimum number of identifiers that should be used, what these should be, how the identification checks should be performed and the procedures to follow in the event of discrepancies being identified. This constitutes a risk of misidentification of the deceased. See also *Advice*, items 8, 9 and 10.	**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	The PM suite has a book rest and a step-over bench, which are made from wood. Porous materials are hard to decontaminate and impair effective cleaning. The stands that hold fridge trays during PM examinations were not cleaned appropriately and appeared sticky, thereby attracting dust and dirt. There were minor areas of rust on some equipment. See also *Advice*, items 12, 13 and 14.	**Minor**
d) The premises are secure (for example there is controlled access to the body store area(s) and PM room and the use of CCTV to monitor access).	The storage area on the Labour Ward is not secure. Neither the fridge, nor the room where the fridge is kept, are locked. Although the Labour Ward is secured by swipe card and intercom access, a number of members of the public who attend the Labour Ward, as patients or family members, would be able to access the storage area. This presents a risk of unauthorised viewing of the deceased, and a risk to the dignity of the deceased.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
d) Fridge and freezer units are in good working condition and well maintained	There is rusting of the floor on the inside of the fridges between fridge sections A and B. This makes the area difficult to clean which presents an environmental risk, as well as a risk to the dignity of the deceased.	**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 alarms of the fridges and freezer units in the mortuary are not tested on a regular basis. For the fridge on the labour ward, alarms are tested but this is not being recorded. This constitutes a risk to storage conditions and dignity of the deceased.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
f) Temperatures of fridges and freezers are monitored on a regular basis	Temperature records for fridges and freezers are not routinely monitored for trends. This is the case both in the main mortuary and in the storage area on Labour Ward. There is no oversight of temperature records in the mortuary, as records are held by the Estates department. Temperatures are not being recorded on a regular basis in the Labour Ward. This means that any deterioration in function of the units may not be discovered until the units malfunction completely, which constitutes a risk to storage conditions and dignity of the deceased. See also *Advice*, item 17.	**Major**
g) Bodies are shrouded or in body bags whilst in storage	One body was observed to not be fully shrouded, with the face and feet left uncovered. This is not in line with standards for dignified storage of the deceased.	**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	Maintenance of fridges and freezers is done on a reactive basis only; in combination with the shortfalls against PFE2(e) and (f), this means that there is no regular oversight of the functioning of the units. This presents a risk to storage conditions and the dignity of the deceased.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(d)	The establishment is advised to update the consent form for PM examination to ensure that it is clear that when consent for storage is in place, the section on disposal should not be completed.
2.	C1(f)	The establishment's process for seeking consent for PM examination includes giving a "cooling off period" for the deceased's family to change their mind. The length of the cooling off period is decided on a case by case basis in agreement with the deceased's family. To further strengthen this practice, the DI is advised to include a minimum length of the cooling off period in the establishment's procedural documents.
3.	GQ1(g)	The DI is advised to update the list of PDs under the licence to include A&E and NICU, and to arrange regular meetings with PDs in these areas as well as the Labour Ward to ensure full oversight of licensed activities.
4.	GQ1(h)	The DI is advised to ensure that governance meetings happen on a regular basis and are minuted.
5.	GQ2(a)	While the current audit schedule covers relevant activities, the level of detail included is not sufficient to understand, for example, the method and sample size included in the audit. The establishment is advised to write clear standards for each audit, and to make it clear what sample or time period has been included in the audit as well as what evidence has been reviewed to arrive at the conclusions made.
6.	GQ3(a)	The DI is advised to develop a standardised training package for porters carrying out work in the mortuary, and to work together with the portering services to ensure that this training is recorded.
7.	GQ5(a)	The establishment's overarching serious incident policy (POL/COR/0002, v.3) refers to out-of-date terminology and methods of reporting HTARIs to the HTA.
8.	T1(c)	The establishment is advised to include a step in the viewing and release procedures where at least three identifiers are collected from the person seeking to view the body, or the funeral director collecting the body. These can then be verified against the details of the deceased, to ensure that the correct person is prepared for viewing or release.

No.	Standard	Advice
9.	T1(c)	To address the shortfall against standard T1(c), the DI should ensure that a minimum of three identifiers, including at least one unique identifier, are used to identify bodies. SOPs that set out the procedures for checking the identification of bodies should describe, as a minimum: • what records or information are required for the identification check; • the minimum number of identifiers that must be used and what these identifiers are expected to be, including for cases where the identity of the deceased is not known at the time of admission to the mortuary; • how the identification check should be performed, including what records the identification tag on the body should be checked against; and • the actions to take in the event of any discrepancies in the identifiers.
10.	T1(c)	The establishment is advised to include a unique identifier for babies; this is currently in place for adults.
11.	T1(f)	The establishment is recommended to document the criteria for when a deceased person is moved into long-term storage.
12.	PFE1(a)	The establishment is advised to replace or remove porous materials. If that is not possible, the DI should consider treating surfaces with sealing products that will allow appropriate cleaning.
13.	PFE1(a)	The establishment is advised to conduct a thorough clean of the stands that hold fridge trays during PM examinations and include these in cleaning schedules.
14.	PFE1(a)	The establishment is advised to monitor equipment for signs of rust and take action if this is deemed to impair the ability to appropriately clean or utilise equipment in the PM room. The establishment should consider longer-term plans for upgrading or replacing the mortuary facilities and if required, include these in their business plan.
15.	PFE1(e)	The establishment is advised to include, in their SOPs, a requirement for the inner shutter of the loading bay to be closed while the outer shutter is open. This is to ensure that there is no unauthorised access to, or unwanted viewing of, the mortuary.
16.	PFE2(c)	While demand may be sufficient at the moment, it was noted that the mortuary was almost completely full at the time of the inspection, including the freezer storage and that this was not unusual following weekends and bank holidays. The establishment is advised to consider the future need for further fridge and freezer storage, and to include this in business planning if deemed necessary.
17.	PFE2(f)	The establishment is advised to review temperature records for trends on a regular basis, for example monthly. Records held by the Estates department should be requested for this purpose, and records should be kept on the Labour Ward. This review should be recorded and any actions required documented and followed up.
18.	PFE2(i)	There is currently no trigger point for invoking the establishment's contingency plan. The establishment is advised to consider whether this would be a useful tool in managing capacity.

Concluding comments

This report describes the third site visit inspection of Whittington Hospital. Despite having shortfalls against the HTA's licensing standards, the HTA observed a number of strengths and areas of good practice at this establishment:

- The mortuary provides a good service to bereaved families. This is achieved by including bereavement care, and managing the issuing of death certificates, within the department;
- The establishment has arrangements in place for burying blocks and slides in a dignified way when these are no longer required for scheduled purposes;
- There appears to be good communication with others, both within the hospital and externally with, for example, the Coroner's office;
- The establishment has provided training for Coroner's officers in mortuary procedures to help further their understanding;
- The establishment has limited the number of consent seekers for adult hospital PM examinations to a small team, which helps ensure that consent is sought appropriately;
- It was evident from speaking to staff that they are committed to ensuring the dignity of the deceased.

There are a number of areas of practice that require improvement, including two major shortfalls and 14 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: 12 January 2018

Report returned from DI: 26 January 2018

Final report issued: 13 February 2018

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: 01 August 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 injuries 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 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 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.