Site visit inspection report on compliance with HTA licensing standards

Sandwell General Hospital

HTA licensing number 12131

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**

8 – 9 July 2019

Summary of inspection findings

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

Although the HTA found that Sandwell General Hospital had met the majority of the HTA's standards, fourteen major and eight minor shortfalls were found against the Consent, Governance and Quality systems, Traceability and the Premises, Facilities & Equipment standards.

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

Sandwell General Hospital (the establishment) is part of Sandwell and West Birmingham Hospitals NHS Trust. This report describes the activities carried out in the mortuaries located at Sandwell General Hospital (the hub site) and Birmingham City Hospital (the satellite site). Both sites are licensed for removal of relevant material from the deceased, storage of bodies of the deceased and relevant material for use for scheduled purposes, and the making of a post-mortem (PM) examination.

The mortuaries are managed by the Primary Care, Community and Therapies Clinical Group, following the transfer of Histopathology Services to the Black Country Pathology Services network. The DI is the Group Director of Operations for Imaging and Pathology, and the Corporate Licence Holder contact is the Chief Executive of the Trust.

The establishment receives approximately 1,300 bodies each year from deaths in the hospital and the community. The mortuary practices and procedures are common across both sites, where appropriate.

Across both sites, porters transfer hospital bodies to the mortuary and are responsible for admitting these bodies during out-of-hours periods (see shortfall against standard GQ3(a)). Community bodies are transferred to the mortuary at Sandwell General Hospital (SGH) by the coroner's contracted funeral director during normal working hours. Anatomical Pathology Technologists (APTs) work on-call and are available for assistance and for viewings outside of normal working hours. Identification of all bodies admitted and released from the mortuary is checked by APTs using a minimum of three points of identification.

Sandwell General Hospital

The majority of routine adult PM examinations conducted at SGH are under coronial authority. All cases for coronial PM examination are routinely scanned ('digital autopsy') at a facility external to the Trust and are then transferred to the mortuary at SGH, where an invasive PM examination will be performed, if required. Approximately 100 invasive PM examinations are conducted at the establishment each year. Home Office (forensic) cases are transferred to another HTA-licensed establishment. In 2018, one adult hospital (consented) PM examination was performed at the establishment (see shortfall against standard C2(a)).

The mortuary at SGH has 108 refrigerated body spaces, including 24 bariatric spaces, eight spaces that can be switched to freezer mode and eight permanent freezer spaces. Freezer storage capacity can be increased by a further two spaces within the existing freezer banks, when this is needed. At the time of the inspection, the freezers were near to full capacity (see shortfall against standard PFE2(c)). All fridges and freezers are connected to a remote temperature alarm system that is tested annually.

The PM suite at SGH comprises two PM rooms, containing three PM tables and one PM table, respectively, each with corresponding dissection units. A minimum of three points of identification of the deceased are crosschecked by APTs and pathologists. However, bodies are routinely eviscerated prior to the pathologist examining them (see shortfall against standard GQ1(b)). Pathologists complete each PM examination before commencing the next case to help mitigate against the risk of a mix-up of organs and tissue samples between cases. Any tissues retained during PM examinations are recorded by the pathologist. Mortuary staff record the total number of specimen pots for each case (see shortfall against standard T1(g)).

Birmingham City Hospital

The mortuary at Birmingham City Hospital (BCH) is used as a storage facility for bodies from the hospital only. The PM room has been partly converted into a contingency body storage area, making the total refrigerated storage capacity at this site 89 spaces, including four bariatric spaces. All the permanent fridge units are connected to a remote temperature alarm system that is tested annually (see shortfall against standard PFE2(e)). There is no freezer storage at this site (see shortfall against standard PFE2(c)).

APTs from the hub site routinely work at this site on a rotational basis. The establishment have considered the risks to lone workers and there are measures to help mitigate the risks of lone working.

Consent for paediatric/perinatal PM examination is primarily sought by a trained Bereavement Midwife and a small team of midwives. The PM examination consent forms are based on the Stillbirth and Neonatal Death (Sands) charity documentation for paediatric/perinatal cases. Families are provided with the Sands PM information booklet. The consent forms are provided by the HTA-licensed establishment that conducts the PM examinations. Paediatric/perinatal cases for PM examination are transferred via the mortuary to the other HTA-licensed establishment for PM examination and are then returned to the mortuary at BCH for collection by funeral directors.

In addition to the activities described above, the removal of tissue samples from cases of Sudden and Unexpected Death in Infancy and Childhood (SUDIC) occasionally takes place in the Accident and Emergency departments at both hospitals.

Description of inspection activities undertaken

This report describes the fourth routine HTA site visit inspection of the establishment. The visit included a visual inspection of both mortuaries, including body store areas, viewing rooms and the PM suite at SGH. Formal interviews were conducted with staff.

Traceability audits of bodies were undertaken at both mortuaries. Body identifiers, storage locations, mortuary register details and associated documentation was reviewed and cross-referenced for seven adult bodies (five hospital and two community bodies). Three anomalies were found:

- The mortuary register location for one body was recorded incorrectly in the mortuary register;
- Two digits of the hospital number for one body had been transposed from the wristband and notification of death form to the mortuary register; and,
- The spelling of the name had been transposed from the wristband to the fridge door name plate for one body.

In addition, an audit was conducted of four cases at SGH where tissue had been retained for histological analysis following PM examination (for one adult hospital consented case and three cases conducted under coronial authority). The inspection team visited the histopathology laboratory to review the retained tissue and associated traceability records. Records of the relative's wishes regarding the fate of the tissue were reviewed to determine if they had been acted upon appropriately. No anomalies were found. However, the specimen container for tissue from the adult hospital consented case was labelled with only two identifiers of the deceased (see shortfall against standard T1(c)).

The process for removal of relevant material in the A&E departments in SUDIC cases was discussed and reviewed and was found to be compliant with current guidelines.

Material held for the police

Home Office (forensic) PM examinations have not been conducted at the establishment since 2017. However, the establishment are storing tissue removed from forensic cases conducted at the establishment prior to this date. Under section 39 of HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority contained a recommendation that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process. Therefore, procedures for Home Office PM examinations and management of tissues and organs taken for criminal justice purposes were reviewed by the HTA at this site visit inspection.

Inspection findings

The HTA found the LH and the DI to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
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	The 'Policy for Consent for Hospital Post Mortems, Retention and the Respectful Disposal of Human Tissues' does not fully reflect the requirements of the HT Act and the HTA's codes of practice. Examples include, but are not limited to: • There are references to the 'Next of Kin' that could imply that someone other than the person ranked highest in the hierarchy of qualifying relationships could consent to a PM examination and retention of tissues for use for scheduled purposes; • Sections 7 and 17 of the policy refer to the removal and retention of tissues during PM examination and state that tissue may be taken for diagnostic purposes but the policy does not make it clear that this must be with appropriate consent or under the authority of the coroner. In addition, the policy states that tissues can be retained indefinitely and used for certain scheduled purposes without consent. This could result in a breach of the HT Act if this policy was followed. In addition, the policy refers to numerous external documents, with associated links, that are out of date and only 27 of the 33 pages of this policy could be reviewed in hard or electronic copy.	**Major**

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	The information leaflet for relatives about consent for adult hospital PM examination does not fully reflect the requirements of the HT Act and the HTA's codes of practice. The information in this leaflet reflects the issues in the establishment's consent policy (refer to shortfall against standard C1(a) for details). In addition, the references to sources of information at the end of the consent information leaflet are out-of-date.	**Major**
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	The consent form used to record consent for adult hospital PM examination does not fully reflect the requirements of the HT Act and the HTA's codes of practice. The consent options on this form reflect the issues in the establishment's consent policy and information leaflet (refer to shortfalls against standard C1(a) for details). In addition, the consent form is not document-controlled or dated to show when it was last reviewed.	**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	The Trust Bereavement Nurse who seeks consent and supports senior clinicians in seeking consent for PM examinations completed consent training several years ago but has not completed refresher training since that time. *As a result of this shortfall, standards C2(b) and C2(d) cannot be met.* *See Advice, item 1.*	**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.	Although the establishment has a range of SOPs covering licensed activities, some SOPs do not reflect current practice or do not contain sufficient details of procedures. Examples include, but are not limited to: • SOPs relating to management of bodies with same/similar names are not reflective of current practice; • SOPs that describe the procedures for identification of bodies do not consistently state that a minimum of three identifiers of the deceased should be checked, what those identifiers could be and at what stage of the process they should be checked; • The procedure to identify 'unknown' bodies before they are formally identified is not documented in the relevant SOPs; • The SOP relating to viewing the deceased states that only the full name of the deceased is requested from those wishing to view. This SOP also states that cosmetic adjustments can be made to be the body without prior permission from the family; • The SOP for HTA Reportable Incidents (HTARIs) refers to previous versions of the HTA's codes of practice and does not state the types of incidents that should be reported to the HTA or who is able to report incidents to the HTA. In addition, the Trust policy relating to incidents does not include the HTA in the 'External/statutory reporting summary' section; • The 'rapid release' policy does not describe the procedure to release a body from the mortuary or refer to the SOPs that describe this procedure. The Quality Manual contains limited information and does not contain any information relating to mortuary activities. Although Trust policies are in place relating to licensed activities, the majority of these policies are out of date and/or under review.	**Major**

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	Although under the authority and instruction of the pathologist, APTs routinely eviscerate bodies for PM examination prior to the pathologist examining the bodies.	**Major**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The scope of the audit schedule is limited and does not include sufficient vertical or horizontal audits to check compliance with documented procedures, the completion of records and traceability of bodies or tissues.	**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	i) Training for porters in mortuary procedures is not recorded or refreshed. ii) The senior staff responsible for release of bodies from the mortuary out-of-hours as part of the 'rapid release' procedure are not formally trained in the mortuary procedures relevant to this process, including the procedure for identification of the deceased. The DI cannot be assured that these staff are suitably trained in these activities and that they follow the required procedures when undertaking these activities. *As a result of this shortfall, standard GQ3(c) cannot be met.*	**Major**

GQ4 There is a systematic and planned approach to the management of records		
b) There are documented SOPs for record management which include how errors in written records should be corrected	The establishment do not have an SOP for records management. Errors in mortuary records are corrected using correction fluid. This does not allow for a full audit of these records.	**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	Not all staff who are involved in undertaking licensed activities are aware of incidents that must be reported to the HTA. The inspection team identified several incidents in the mortuary incident log that should have been reported to the HTA. The inspection team also identified one incident that was not recorded in the mortuary incident log and that should have been reported to the HTA. In addition, the establishment could not provide records of the internal investigation of this incident.	**Major**
d) Information about incidents is shared with all staff to avoid repeat errors	Information regarding incidents is not disseminated to all relevant staff involved in licensed activities. This means that opportunities for shared learning from incidents may be missed.	**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	Although the establishment has some risk assessments relating to licensed activities, these do not fully consider the risks to bodies and tissues. For example: • the risk assessment relating to PM examination procedures does not consider the risk of accidental damage to a body; • the risk of viewing of a wrong body has not been assessed; and • the risks of transferring bodies across the BCH site to the mortuary have not been 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	i) Relatives are only required to provide one identifier of the deceased (the name of the deceased) when they attend the mortuary for a viewing. *See Advice, item 5.* ii) Specimen pots for PM tissue are not consistently labelled with a minimum of three identifiers of the deceased.	**Major**

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The mortuary does not record the number of pieces of tissue retained at PM examination. Although they record the number of pots sent to the histopathology department, the pots may contain more than one piece of tissue. Recording the quantities of tissue taken will help to ensure that accurate traceability records are maintained and can be audited.	**Minor**

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	The establishment is storing PM tissue removed under the authority of the coroner and the police from 2007 onwards. Although these specimens are documented, the establishment is not aware of the status or the instructions for this tissue and therefore, may be storing samples where the coroner's or police authority has ended and consent for continued retention has not been given by the family.	**Major**
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	There is no documented evidence of active follow-up with the coroner's office or police for tissue that has been stored for long periods of time.	**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	Although the mortuary at BCH was clean at the time of the inspection, the facility is showing signs of wear and requires some maintenance to remain fit for purpose. For example: • the painted walls in the PM room/body store are flaking in numerous places, exposing bare plaster; • there are multiple areas of damage to walls and doors, leading to exposed, porous plaster and wood in the body store; • the wallpaper in the relatives area in the viewing room is peeling with patches of mould; and, • sections of ceiling coverings are missing in the mortuary office. Exposure of porous surfaces means that these areas are difficult to clean and disinfect adequately.	**Major**

e) Security arrangements protect against unauthorised access and ensure oversight of visitors and contractors who have a legitimate right of access	The roller shutter door cannot always be closed when bodies are being admitted or released from the mortuary at SGH, depending on the vehicle used by funeral directors. The entrance for funeral directors at the mortuary is adjacent to a road and footpath and is also overlooked by houses. This could allow unauthorised access or unintentional viewing of the body store, which could compromise the dignity of the deceased and pose a security risk.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	One bank of fridges at BCH is operating at 8°C, which is higher than the recommended optimum temperature of approximately 4°C. This could compromise the condition of bodies stored in this unit.	**Minor**
c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The establishment does not have sufficient freezer storage capacity for long-term storage of bodies and does not have any contingency arrangements for freezer storage. The inspection team identified two bodies that had not been transferred to freezer storage in line with the establishment's procedure for long-term storage of bodies. The condition of these bodies had deteriorated. In addition, other bodies in refrigerated storage that required freezer storage were identified in the establishment's records. *See Advice, item 7.*	**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	i) The alarm trigger points for the mortuary fridge and freezers are not set at appropriate temperatures to ensure that the alarms will trigger when storage temperatures deviate from ranges that will optimally maintain the condition of bodies. In addition, mortuary staff are not sure of the acceptable temperature ranges or the alarm trigger points and, therefore, they may not recognise any potential temperature deviations. ii) When the PM room at BCH is used for contingency body storage, the room is not consistently temperature monitored or connected to the temperature alarm system. This means that staff will not be alerted to any deviation in temperature of this storage environment from the expected range. *See Advice, item 8.*	**Major**

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	The concealment trolley covers at both sites are damaged and torn in areas. This may allow bodies to be seen whilst they are in transit from hospital wards to the mortuary.	**Minor**

Advice

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

No.	Standard	Advice
1.	C2(a)	The person acting as the Trust Bereavement Nurse is moving to a new role in the Trust and will no longer be able to support and accompany the senior clinicians who seek consent for adult hospital (consented) PM examinations. The DI is advised to consider alternative arrangements that will help to ensure that an appropriately trained person continues to be involved in the PM consent process.
2.	C2(b)	The DI is advised to request copies of the training records for the staff involved in seeking consent for adult and paediatric/perinatal hospital (consented) PM examinations, to provide assurance that their training is up-to-date.
3.	GQ1(g)	The DI is advised to appoint Persons Designated (PDs) in the maternity unit at BCH and the Accident and Emergency departments at both hospitals. This will help the DI to maintain sufficient oversight of licensed activities in these areas.
4.	GQ6(c)	To ensure that significant risks are incorporated into the Trust's organisational risk register, the DI is advised to continue with plans to escalate issues contributing to long-term storage of bodies and the impact on freezer storage capacity at the establishment.
5.	T1(c)	To help to mitigate the risk of viewing a wrong body, the DI is advised to consider options for how staff could request a minimum of three identifiers of the deceased from those wishing to view a body when they attend the mortuary. These identifiers of the deceased should be crosschecked against the identifiers on the body before the viewing proceeds.
6.	T2(a)	The DI is advised that wet trimmings not suitable for microscopic examination can and should be disposed of as clinical waste.
7.	PFE2(c)	The DI is advised to strengthen the procedure for managing long-term storage of bodies by following up cases that have been in refrigerated storage before the end of the establishment's 28 day timeframe. This may help to speed up these processes so that bodies can be released from the mortuary sooner and identify bodies that may require long-term storage. In addition, the DI is advised to record in the existing spreadsheet the date of death and the date that bodies are transferred to freezer storage. This may help mortuary staff to assess the number of bodies requiring freezer storage at any given time.

8.	PFE2(e)	To provide further assurance that the fridge and freezer alarms will trigger when required, the DI is advised to increase the frequency of the alarm tests and ensure that the procedure for responding to the alarms is also tested.
9.	PFE3(c)	The DI is advised to seek clarification on the ventilation records for the PM suite to provide assurance that the gradient of the air pressure is negative.

Concluding comments

There are a number of areas of practice that require improvement, including fourteen major shortfalls and eight 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: 06/08/19

Report returned from DI: 20/8/19

Final report issued: 10/9/19

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 16/3/20

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 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.