Site visit inspection report on compliance with HTA licensing standards

Royal Oldham Hospital

HTA licensing number 12342

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**

10 & 11 January 2018

Summary of inspection findings

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

Although the HTA found that Royal Oldham Hospital had met the majority of the HTA's standards, six major and six minor shortfalls were found against the Consent, Governance and Quality, Traceability and Premises, Facilities and Equipment standards. These related to consent documentation and training, standard operating procedures (SOPs), identification of bodies, premises, security and the storage of long-term bodies.

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

Royal Oldham Hospital (the establishment) is part of the Pennine Acute Hospitals NHS Trust, which has recently become part of the Northern Care Alliance. This report refers to the activities carried out at the mortuary at the establishment. The mortuary is managed by Cellular Pathology. The DI is the Cellular Pathology and Mortuary Services Manager. The Corporate Licence Holder contact is the Chief Executive of the Trust. The establishment is licensed under the Human Tissue Act 2004 (HT Act) for: making of a post mortem examination; removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation, and; storage of the body of a deceased person or relevant material which has come from a human body for use for scheduled purposes.

The establishment receives approximately 3,100 bodies each year from the hospital and the community and performs around 1,700 post-mortem (PM) examinations annually. This figure includes high-risk (up to category 3) cases, forensic adult cases and some adult hospital (consented) cases. The majority of routine adult PM examinations are performed under the authority of HM Coroner for Manchester North. Paediatric/perinatal PM examinations are transferred to another HTA-licensed establishment. Consent for paediatric/perinatal PM examination is sought at the establishment by the Bereavement Midwife or specially trained senior midwives (see shortfall against C2(c)). Consent for adult hospital PM examinations is sought by the Mortuary Manager or the DI who have received appropriate training in the seeking of consent (see *Advice*, item 6). The consent form for adult hospital PM examinations is predominantly based on the HTA's model consent form (see *Advice, items 2 and 3*). The consent form and information booklet used for paediatric/perinatal PM cases is based on the SANDs documentation.

The establishment has 102 refrigerated body spaces including 17 spaces for bariatric bodies. In addition, the establishment has five freezer spaces for the storage of bodies requiring frozen storage (see shortfall against PFE2(c)). The majority of the fridges are 'double-ended' for direct access into the PM suites. There is a dedicated fridge for the storage of perinatal cases and pregnancy remains. The establishment has additional body storage capacity at three unlicensed body stores providing refrigerated storage and one additional frozen storage space. At the time of the inspection, the establishment had installed four temporary refrigerated storage units due to capacity pressures. Two of these units were being used to store bodies at the time of the inspection. These temporary units are housed in a building next to the mortuary (see shortfall against PFE1(e)).

Swipe card access is required for all external doors into the mortuary. There is a camera and intercom system at both doors and electric access gate so mortuary staff are able to verify who is requesting access before allowing entry. Both entry doors are also covered by CCTV. Funeral directors and porters access the mortuary via the access gate.

Porters transfer and admit all hospital and community bodies into the mortuary. The mortuary register, body store location whiteboard and fridge door details are completed by the porters using the information on the 'Notification of Death' form transferred with each body. A 'Body Admittance Form' is completed by the mortuary staff when patient identification checks are undertaken as soon as possible on the day, or the next working day if the body was admitted out of hours. Perinatal cases, pregnancy remains and their associated documentation are transferred to the mortuary by the porters. There is a separate mortuary register for these cases that the mortuary staff complete. All bodies are entered on to the mortuary laboratory information management system (LIMS) and subsequently 'booked out' when released. Bodies may be released from the mortuary using only one or two identifiers (see shortfall against T1(c)).

The mortuary's main PM suite contains five downdraught PM tables, each with an associated dissection unit. The forensic/high-risk suite contains one downdraught table and one dissection unit. APTs carry out initial identification checks of bodies when removing them from the fridges, and again with the pathologist prior to the external examination and evisceration commencing. Pathologists complete each PM examination before commencing the next case to help mitigate against any risk of a mix-up of organs and tissue samples between cases. Both PM suites and the bodystore floors are showing signs of wear despite some repair work (see shortfall against PFE1(a)).

There are currently eight Consultant Histopathologists who conduct routine PM examinations on a rotational basis at the establishment and three Forensic Pathologists who are based at the establishment. Tissue removed during PM examinations is sent to the establishment's histopathology laboratory but can also be sent to other laboratories for specialist analysis if required. Records of traceability are kept by the mortuary for PM tissue sent to histopathology and when tissue is sent to other organisations for specialist examination. The mortuary is staffed by seven Anatomical Pathology Technologists (APTs), which includes the Mortuary Manager. In addition, the establishment also employs a mortuary assistant.

Description of inspection activities undertaken

The establishment has been licensed by the HTA since October 2007. Previous routine site visit inspections took place in January 2010 and November 2013. This report describes the third routine site visit inspection visit in January 2018. Formal interviews were conducted with the DI, Mortuary Manager, mortuary staff, Consultant Pathologists, staff involved in the seeking of consent (adult and perinatal), portering staff and a Coroner's Officer. The inspectors also carried out a visual inspection of the mortuary, including the body store, post mortem rooms and viewing suite. An audit of body identifiers, storage locations, mortuary register details and associated documentation was carried out for four adult bodies (one hospital and three community bodies, including one body stored in the freezer) and one perinatal body. Some minor anomalies were found:

- Three out of the four adult bodies audited, had their names spelt differently between the mortuary white board and the mortuary register;
- Mortuary documentation relating to a body in frozen storage had not been updated to record the body being moved to a different location within the freezer.

In addition, an audit of six cases where tissue had been removed for histological analysis during the PM examinations were conducted. The inspection team visited the histopathology laboratory to review stored tissue and the associated traceability records . In addition, records of the relative's wishes regarding the fate of the tissue following its analysis were reviewed to verify that they had been acted upon appropriately. No anomalies were found.

Material held for the police

Under s39 of the Human Tissue Act 2004, 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, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, police holdings stored at the establishment were reviewed by the HTA during the inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Inspection findings

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

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
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 'Post Mortem Information Leaflet' used to support the seeking of consent for adult PM examination states that blocks and slides will be kept permanently by the hospital, as part of the deceased's medical record. The leaflet does not make it clear that tissue removed during PM examinations can only be retained for use for a scheduled purpose if appropriate and valid consent has been given for this.	**Minor**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
c) If untrained staff are involved in seeking consent, they are always accompanied by a trained individual	Untrained clinical staff have been seeking PM consent for perinatal cases. The inspection team were made aware of two issues during the inspection. (see *Advice*, item 4)	**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.	Not all documented SOPs reflect current practice, examples include, but are not limited to: • 'Assisting at Routine Post Mortem' (MORT-SOP-20). The SOP does not state that identification is checked when bodies are removed from the body store for PM examination. In addition, an identification tag is placed on the body at PM, detailing the full name, mortuary register number and fridge number; however, these procedures are routinely carried out. • 'Long stays' (MORT-SOP-71), states that bodies are placed into freezer storage after one month. However, examples where bodies had remained in refrigerated storage for longer periods were identified during the inspection. • 'Fridge temperatures' (MORT-SOP-53), states that the baby fridge is monitored daily and the body store alarms are tested monthly; however, the establishment is not undertaking regular tests of the alarm. • The lone working SOP (MORT-SOP-72) only includes procedures for those working out-of-hours. However, mortuary staff work alone at the unlicensed body stores during normal working hours. In addition to the above, the establishment's SOPs do not always include details of the identification to be checked when identifying bodies.	**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	Not all funeral directors bring documentation with them when collecting bodies, e.g. the green disposal order, coronial paperwork and/or their own tracking documents. Observation of the body release to funeral directors procedure during the inspection, highlighted a case where the funeral director had requested the release of a body using the deceased's name only which is only one identifier. (see *Advice*, item 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	Although some repairs have been made to the flooring in the PM room, the room's flooring, and the flooring in the body store, are showing signs of wear, including cracking and pitting of the surface. This means the surface of the flooring in these areas cannot be effectively cleaned. Cracking of the PM room flooring was identified during the last inspection. Some repairs have been made to the flooring in the PM rooms but these have not been sufficient to prevent further issues. The mortuary staff will not be able to clean and disinfect these areas adequately.	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	Funeral directors enter the establishment's mortuary compound, to bring and collect bodies to and from the mortuary, via an electronically controlled security gate which opens directly onto a public road. During the inspection is was noted that funeral directors do not always manoeuvre their vehicles sufficiently far into the mortuary compound meaning that a sensor prevents the gate from closing. In addition, the building being used to house the four temporary refrigerated storage units is accessed from the same public road. While bodies are being removed from the temporary storage units the outer doors to this building are not always locked. This is dependent on the vehicle used by the funeral director. Not closing the security gate or securing the external building doors could allow unauthorised or unintentional access to these areas, compromising the dignity of the deceased and placing staff and the premises at risk. (see *Advice*, items 21 and 22)	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The lower and upper alarm trigger points for the fridges in the body store are set at 1°C and 15°C respectively. The upper alarm limit of 15ºC means that a temperature deviation from the advised storage temperature of around 4ºC may not trigger an alarm and therefore alert establishment staff to the deviation within an appropriate timescale. Any delay in alerting establishment staff to a deviation of the storage temperature from the expected range poses a risk to the intergrity of the stored bodies. (see *Advice*, item 23).	**Major**

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	The establishment has five freezer spaces for the long-term storage of bodies and one additional freezer space at one of the body stores. The amount of frozen storage spaces is not sufficient to meet the needs of the service; at the time of the inspection, all freezer spaces were occupied and there were 12 bodies in refrigerated storage that required frozen storage. *Following the inspection, the DI has informed the HTA that there are plans in place to increase frozen storage capacity by an additional 12 spaces at a body store in January 2018.*	**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	The temporary storage refrigeration units are not connected to an alarm system and are located in an area separate to the main mortuary building, meaning that any failure of the storage units would not be detected until the units were accessed by establishment staff. In addition, the establishment's main body store alarms are not routinely tested to verify that they are activated and responded to appropriately should the storage temperatures deviate from expected ranges.	**Major**
f) Temperatures of fridges and freezers are monitored on a regular basis	The establishment has no procedure in place through which it monitors and reviews the temperatures of its storage units. Regular review of storage temperatures may help to identify trends alerting establishment staff to potential equipment failures before they occur.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation provides the necessary tem air changes per hour and is checked and maintained at least annually.	The establishment has not provided the ventilation service records to provide assurance the ventilation system is working to the required standard and is regularly maintained.	**Minor**
f) Key items of equipment, including fridges/freezers, trolleys and post mortem tables (if downdraught) are subject to regular maintenance and records are kept	The establishment has not provided the maintenance records for the fridges and freezers.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(a)	The DI is advised to review the establishment's 'Adult Hospital Post Mortem Consent Policy' (version 4) to ensure the HTA's new codes of practice and licensing standards are referenced.
2.	C1(g)	The DI is advised to consider amending the form used for seeking consent for adult hospital PM examinations to offer the different options for retained tissues and organs separately. This will allow relatives to selectively choose which option(s) they would like and not feel obliged to consent to all options for retained tissues.
3.	C1(g)	The DI is advised to include the option for retained organs to be returned to the relatives in the adult hospital PM examination consent form.
4.	C2(a)	The DI is advised to schedule refresher training for those staff involved in seeking PM consent for perinatal/paediatric cases (at least every two years) as this is soon to be out of date. To further strengthen the process for seeking consent for perinatal/paediatric PM examinations and help prevent untrained clinical staff undertaking this task, the DI is advised to liaise with the Bereavement Midwife and include them and mortuary staff in this refresher training.
5.	C2(a)	Although the consent training presentation informs consent seekers about the hierarchy of qualifying relationships when seeking appropriate consent for PM examination, the presentation also refers to the 'next of kin' (slide five). this introduces a risk that consent could be sought from someone other than the person ranked highest in the hierarchy of qualifying relationships. The DI is advised to remove the term 'next of kin' from the training material.
6.	C2(a)	Although the DI and Mortuary Manager have undertaken PM consent training that is refreshed annually, they are advised to consider undertaking external training as some time has elapsed since their initial training. This may help to assure them that their knowledge is up to date.
7.	GQ1(a)	The SOP 'Office Duties' (MORT-SOP-68) should be amended to stipulate that the baby fridge should be checked daily, ensuring that these bodies are dealt with as soon as possible. In addition, this SOP should make it clear that all bodies with same and similar names are identified as such.
8.	GQ1(a)	The DI is advised to review and revise all SOPs to assure themselves that all SOPs reference the HTA's most recent codes of practice and standards.
9.	GQ1 (a)	The DI is advised to include more detail in the SOP 'HTA Reportable Incidents (HTARIs)' to state who can report the incidents to the HTA; namely the DI and PDs who are registered for the portal via the HTA website. It may be helpful to include a link to the HTA's incident reporting portal within the HTARI SOP.
10.	GQ1(a)	The DI is advised to consider developing a body release form which could be used by funeral directors. The form could be given to and completed by the deceased's relatives at the funeral directors and brought to the mortuary when the funeral directors are collecting the body. This form should contain the required minimum three identifiers (one being unique) that the mortuary staff can use to identify the body, independently to any mortuary documentation. The release form could be used in addition to any other documentation available to the funeral

		director; for example the green disposal order or the Coroner's paperwork, if these documents do not contain sufficient identification information. Developing additional documentation to be used by funeral directors during release of bodies from the mortuary may help to reduce the risk of releasing an incorrect body.
11.	GQ1(c)	Although bodies are routinely shrouded (fully covered) in storage, the DI is advised to implement checks to provide assurance that bodies have not become unwrapped.
12.	GQ1(e)	The DI is advised to develop a system to assure themselves that all staff acknowledge that they have read and understood SOPs and risk assessments distributed to them via the document management system in a timely manner.
13.	GQ2(c)	Although there is a schedule of audits in place at the establishment, the DI is advised to increase the frequency of the audits, as most are carried out annually. Increasing the frequency of audits may help the DI to identifiy any errors or deviations from the expected procedure sooner and therefore reduce the time before measures to mitigate against the risk of similar occurances are developed and implemented..
14.	GQ6(a)	The establishment has a good set of risk assessments that include the risks to the deceased, tissues and traceability. However, the DI is advised to include more detail regarding the control measures that are in place to mitigate against each identified risk. In addition, the DI should include risk assesments of the security of the building housing the temporary refridgerated storage units and the transfer of multiple bodies to off site premises.
15.	T1(a)	The SOP 'Long stays' (MORT-SOP-71) states that identification details of bodies within the freezer are written on the outside of body bags. Although bodies are appropriately labelled using a wrist band, there is a potential risk that the identification details on the bag are used to release a body, rather than checking the identification attached to the body itself. The DI is advised to review this practice and to put in place procedures to assure themselves that only identification details attached to the body are used when identifying the deceased. In reviewing this practice, the DI may wish to cease labelling body bags to remove the risk that the information on the bags is used when identifying the deceased.
16.	T1(b)	The DI may wish to consider using the mortuary register number already allocated to bodies during their admission to the mortuary on: documentation relating to the deceased, the body store whiteboard, fridge/freezer doors and the boxes of perinatal cases. This number could be used as an additional identifier for bodies while in the care of the mortuary and may help with traceability, especially in cases when the identity of bodies is not known at the time that the bodies are being admitted to the mortuary.
17.	T1(b)	The DI is advised to ensure that the mortuary register is completed when a body is released from the mortuary to ensure traceability is maintained. Regular audits of the mortuary register would help identify any omissions.
18.	T1(c)	The DI is advised to ensure that bodies admitted from the community via the contracted funeral director are identified using three identifiers, one being unique, so that indentification details can be cross referenced with documentation sent by the Coroner's Office. Currently, the police log number or officer collar number is used which may not be recorded anywhere else.
19.	T1(c)	The DI is advised to develop a procedure to assure themselves that the relative's wishes relating to tissue removed during PM examination are appropriately documented, especially when there has been a change of decision and the establishment are notified to this verbally.

20.	T1(d)	The mortuary staff are advised to make sure that bodies with same and similar names are consistently identified as per the SOP 'Office Duties' (MORT-SOP-68), including those bodies stored in the temporary refrigerated storage units. In addition, the stamp used in the mortuary register to highlight these bodies could be used on any documentation associated with the deceased and act as a visual cue.
21.	PFE1 (e)	The DI is advised to instruct funeral directors to manoeuvre their vehicles far enough in to the gated area to allow the electric security gate to automatically close. Staff should not release or admit bodies until this area is secure.
22.	PFE1 (e)	In order to help maintain the dignity of the deceased, the DI is advised to develop procedures to assure themselves that the release and admission of bodies from the temporary refrigerated storage units is appropriately secure and activity is not viewable by members of the public using the road adjacent to the temporary store.
23.	PFE2(a)	The DI is advised to ensure fridge temperatures are maintained at approximately 4°C, with appropriate alarm trigger points and time period before the alarm triggers. The optimal operating temperatures for mortuary freezers is -20°C, +/- 4 degrees; the trigger points and time periods for the freezer alarms should allow for this. It is also important that all staff are aware of what the fridge and freezer temperatures should be to recognise any potential equipment failures before they occur.
24.	PFE3(c)	The DI is advised to remind mortuary staff and pathologists who have not been face-fitted for the disposable FFP3 masks being used at the establishment, that they should only use the fully ventilated hoods until they have been face-fitted.
25.	N/A	The DI is advised to consider if it is appropriate to continue storing tissue that is not being used for the purpose for which consent has been sought, for example, teaching or research. The DI may consider that disposal of these tissues after a suitable timeframe would be appropriate. Tissue being stored for any scheduled purposes should be regularly reviewed. The rationale for the disposal of any tissues should be recorded, including the date and method of disposal. Discussions with relatives who wish to consent to tissues being stored for use for scheduled purposes, should include the information that if the tissues are not used for these purposes within a specified timeframe, that they will be sensitively disposed of.

Concluding comments

The mortuary team appear to work well together, appear enthusiastic and dedicated, and received praise from numerous sources during the inspection. They are supported by a DI who recognises the importance of effective mortuary practices and works closely with the mortuary team. There are some areas of strength and good practice:

- The mortuary documentation generated for each body ensures appropriate information is recorded;
- There is a dedicated spreadsheet for the management of specimens taken at PM examination;
- Magnetic signs are used on body store doors to indicate pertinent information, for example 'danger of infection'.
- The consent PM information booklet contains an 'explanation of terms' section to help relatives to understand information and references.

There are a number of areas of practice that require improvement, including six major shortfalls and six 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: 06/02/2018

Report returned from DI: 15/02/18

Final report issued: 27/02/2018

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: 22/04/2020

Appendix 1: HTA licensing standards

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

Consent

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

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

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

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

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

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

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

Guidance

Meeting minutes should be recorded and made available to staff.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits.

Guidance

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

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

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

b) There are clear reporting lines and accountability.

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

Guidance

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

d) Staff have annual appraisals and personal development plans.

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

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

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

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

Guidance

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

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

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

a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.

Guidance

Records include mortuary registers, PM examination records, tissue retention forms and

records of transfer and return of organs/tissue sent elsewhere for examination.

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

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

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

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

Guidance

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

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

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

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

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

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

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

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

Guidance

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

b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Guidance

Relevant staff should have knowledge of risks and the control measures that have been taken

to mitigate them.

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

Traceability

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

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

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

Guidance

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

Fridge/freezer failures that require bodies to be moved temporarily whilst repairs take place

present a risk to traceability. Full identification checks should be made when theyare placed back into normal storage.

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

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

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

ii. receipt upon return to the laboratory or mortuary

iii. the number of blocks and slides made

iv. repatriation with the body

v. return for burial or cremation

vi. disposal or retention for future use.

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

this purpose.

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

d) The method and date of disposal are recorded.

Premises, facilities and equipment

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

a) The premises are clean and well maintained.

Guidance

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

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

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

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

Guidance

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

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

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

a) Storage arrangements ensure the dignity of the deceased.

Guidance

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

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

Guidance

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

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

Guidance

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

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

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

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

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

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

Guidance

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

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

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

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

Guidance

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

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

assessments and same/similar name systems.

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

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

Establishments should consider entering in to Mutual Aid Agreements

with neighbouring organisations in order that they can provide and obtain support during periods of capacity shortages.

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

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

   i. fridges / freezers

   ii. hydraulic trolleys

   iii. post mortem tables

   iv. hoists

   v. saws (manual and/or oscillating)

   Guidance

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

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

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

   Guidance

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

d) Staff have access to necessary PPE.

   Guidance

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

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

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

Guidance

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

Appendix 2: Classification of the level of shortfall

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the HT Act or associated Directions.

1. Critical shortfall:

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the Human Tissue Act 2004 (HT Act) or associated Directions

or

A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

(1) A notice of proposal being issued to revoke the licence

(2) Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.

(3) A notice of suspension of licensable activities

(4) Additional conditions being proposed

(5) Directions being issued requiring specific action to be taken straightaway

2. Major shortfall:

A non-critical shortfall that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or
- indicates a breach of the relevant CoPs, the HT Act and other relevant professional and statutory guidelines, or
- has the potential to become a critical shortfall unless addressed

or

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

3. Minor shortfall:

A shortfall which cannot be classified as either critical or major, but which indicates a

departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based or site visit.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

Follow up actions

A template corrective and preventative action plan will be sent as a separate Word document with both the draft and final inspection report. You must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up site-visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next desk-based or site-visit inspection.

After an assessment of your proposed action plan you will be notified of the follow-up approach the HTA will take.