Site visit inspection report on compliance with HTA licensing standards

Royal Bolton Hospital

HTA licensing number 12035

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**

13 & 14 June 2018

Summary of inspection findings

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

Although the HTA found that Royal Bolton Hospital had met the majority of the HTA's standards, thirteen shortfalls were found against the Consent, Governance and Quality systems, Traceability and Premises, Facilities and Equipment standards. These related to the policy which governs consent for post-mortem (PM) examinations; standard operating procedures (SOPs); audits; risk assessments; the use of three identifiers; storage practices; capacity for storage; contingency storage; temperature alarms; alarm testing; security of premises and personal protective equipment (PPE).

Particular examples of 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 Bolton Hospital (the establishment) has been licensed by the HTA since May 2007. This report refers to the activities carried out at the establishment. The establishment is licensed for the making of a post-mortem (PM) examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes. The Designated Individual (DI) is a Consultant Histopathologist and the Corporate Licence Holder contact is the Medical Director for Bolton NHS Foundation Trust. The mortuary is run by the Mortuary Manager and is staffed by two full-time Anatomical Pathology Technologists (APTs) and one part-time Assistant Technical Officer.

The establishment receives approximately 2000 bodies each year from the hospital and community and performs around 600 post-mortem examinations annually, the majority of which are carried out under Coronial authority. The mortuary conducts high-risk PM examinations; forensic PM examinations are transferred to a nearby HTA licensed establishment. Adult hospital (consented) PM examinations are rare at this establishment with only one being conducted in the year prior to the inspection. Consent for adult PM examination is sought by the Designated Individual. The consent form for adult hospital PM examinations is based on the HTA's model consent form. Post mortem examinations for prenatal, perinatal and paediatric cases are undertaken by another HTA licensed establishment, however, trained bereavement midwives seek consent for these cases, which is recorded using consent forms from Royal Bolton Hospital. The consent form and information leaflet used for paediatric/perinatal PM cases is based on the Stillbirth and Neonatal Death (Sands) charity documentation. Both adult and paediatric/perinatal forms used to record consent are compliant with statutory and regulatory requirements.

Removal of tissue from deceased children in cases of sudden unexpected death in infancy (SUDI) is not routinely performed in the Accident & Emergency (A&E) department, the protocol does however state that if a metabolic disorder is identified as potentially contributing to the cause of death, the SUDI consultant would liaise with the Coroner for time-dependent specimens to be taken in A&E.

The mortuary has 52 refrigerated body storage spaces which includes four freezer spaces and four bariatric spaces. There are three dedicated fridge spaces within the mortuary for paediatric cases. There is a fridge on the maternity ward used for storage for foetuses and babies. Temperatures are monitored twice daily by nursing staff, the alarm sounds locally and is not connected to a remote monitoring system (see shortfall against standard PFE2 (e)). The establishment has three temporary refrigerated storage units. At the time of the inspection, one was located in the body store where there is limited space for access using the mortuary trolleys and one at the end of the PM suite. The third unit is erected (when required) in the PM suite immediately adjacent to PM tables. While the temperature of all the refrigeration units are monitored daily by mortuary staff (see shortfall against standard PFE2 (f)), the monitoring is manual and the probes are not yet connected to a remote monitoring system which the mortuary are in the process of installing.

The establishment has no formalised contingency arrangements for storage of the deceased (see shortfall against standard PFE2 (i)). At the time of the inspection the establishment had been storing deceased patients at the base of the refrigeration units on trays but not on the racking (see shortfall against standards PFE2 (a) & (b)). Though the establishment maintains the dignity of the deceased and all bodies are fully shrouded, the current storage capacity is not sufficient for the level of mortuary activity and also pose a potential health and safety risk to staff through manual handling. The establishment is dependent on the use of its temporary storage units which are intended for use during periods of peak activity as contingency storage; however, because the mortuary does not have adequate refrigerated storage capacity, they have been in near constant use for extended periods.

Swipe card access is required for both external doors to the mortuary, in addition to standard key locks. There are no video-intercom systems to allow mortuary staff to confirm who is requesting access (see shortfall against standard PFE1 (d)). In addition, there is no hospital CCTV coverage of the access doors to the mortuary or any coverage within the mortuary itself.

Portering staff are responsible for the transfer of bodies from hospital wards to the mortuary. On arrival to the mortuary, portering staff place bodies in an available refrigerated body space, together with the 'Notice of Death' (NOD) form. Porters then complete the mortuary register and update the body store location whiteboard with the name of the deceased. The coroner's contracted funeral directors transfer all community bodies to the mortuary and mortuary staff are on-call to admit these bodies and complete the relevant mortuary documentation. All community bodies arrive with an orange wristband, stating a unique identification code, which is added to the deceased by the police before arrival at the mortuary. All deceased patients are logged onto an electronic mortuary register where a unique mortuary identification number is generated.

Mortuary staff perform body checks of hospital bodies the next working day, verifying the identification band details on the bodies against the NOD form and making sure they are appropriately shrouded. The bereavement team work closely with the mortuary staff and will raise any recurrent issues via training for ward staff.

Mortuary staff carry out daily visual checks of the fridges, noting details of any patients with same or similar names. Establishment staff place an asterisk on the location whiteboard against same/similar names and place a pink wristband on the deceased and a further laminated pink same/similar name notice on the tray where the deceased is located, to act as a further visual aid.

Coroner's bodies are released from the mortuary using a release form sent from the coroner's office. Hospital bodies are released using the Certificate for Burial and Cremation (Green disposal form). Mortuary staff will facilitate out-of-hours body releases, when

required, for example, religious reasons. Babies over 24 weeks are transferred to the mortuary by a member of the portering staff accompanied by a midwife and are always released from the mortuary. Babies under 24 weeks for hospital cremation are transferred to the histopathology laboratory or if the family are making their own funeral arrangements, the laboratory liaise with the mortuary and maternity unit regarding release of these bodies.

The mortuary operates an appointment system for viewings which generally take place during working hours and are discouraged outside of working hours however mortuary staff will accommodate viewings at all hours if there is a particular requirement. Mortuary staff work with the bereavement team with regards to organising and conducting viewings of the deceased (see shortfall against standard T1 (c)).

The PM suite at the establishment has four downdraft tables and dissection of organs takes place on dedicated dissection units located over each PM table. In addition, there is a dissection bench for the preparation of tissue samples. PM examinations take place one at a time to help minimise the risk of organ and tissue mix-up. The identification of the deceased is always checked by the pathologist and an APT prior to evisceration and the 'Post Mortem Body Risk Assessment' form is completed for all PM examinations. Mortuary staff have access to the necessary PPE (see shortfall against standard PFE3 (d)) within the PM room and body store area and there is demarcation of clean and dirty areas within the mortuary.

Material retained at PM examination for histological examination is appropriately labelled in the mortuary and assigned a unique PM number and transferred to the histopathology laboratory for analysis. Tissue samples may be kept, if appropriate consent has been given for retention or for use for scheduled purposes but the establishment does not routinely store samples for use for research. Blocks and slides are stored in the laboratory and the mortuary uses paper and electronic registers to record sample details, including storage location and family's wishes for the fate of the samples (see shortfall against standard GQ2 (c)).

Description of inspection activities undertaken

This was the third site visit inspection of the establishment with the previous inspection taking place in 2014. The inspection team carried out a visual inspection of the body store, PM room, viewing area and the histopathology laboratory.

Interviews with key members of staff, a review of the establishment's governance and quality systems documentation and traceability audits were also undertaken. Audits were conducted for four bodies in the establishment's body store; two bodies were from deaths in the community and two from deaths in the hospital. Body location and details on the identification bands were cross-checked against the information recorded in the mortuary register; associated documentation and the body store location whiteboard. One discrepancy was found for one of the community bodies in storage; the body store location whiteboard and community death record had been updated with the new storage location but the

mortuary register had not been updated. The establishment records the fridge location for bodies on multiple pieces of documentation and have a ‘Relocation Check List’ to help provide assurance that the fridge location for each body is updated. Due to storage capacity issues, especially during peak times, mortuary staff have to frequently move bodies which poses a risk to traceability.

In addition, one hospital consented PM examination and three PM examinations performed under the authority of the coroner where tissue was retained following the PM examination were audited. The audit included details of tissue type, blocks and slides retained, consent forms, and associated paperwork. No anomalies were found.

Inspection findings

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

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
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 establishment's consent policy does not fully reflect the requirements of the HT Act 2004 and the HTA's Codes of Practice. While much of the required information is contained within this document, it needs to be updated to remove the few instances where the term 'Next of Kin' (NOK) has been mentioned and replace with the details of who the most appropriate person is to give consent. The HTA code of practice on disposal is also referenced in this policy; this code of practice is no longer current and any references to it should be updated to reflect the new codes of practice (please refer to the codes of practice published on the HTA website dated April 2017).	**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.	Many of the SOPs do not accurately reflect current practice and do not contain sufficient detail for staff regarding the procedures that must be followed. Particular examples include but are not limited to: - SOPs describing identification of the deceased do not include details of the minimum three identifiers that must be checked and what they must be checked against; - Relevant SOPs do not reference body store temperature alarm settings and do not detail the acceptable temperature ranges; - There is no SOP relating to lone working in the mortuary; this should be developed in line with the Trust's lone working policy; - The SOP relating to HTA reportable incidents (HTARIs) does not include all of the HTARI categories; The 'PM cross-sectional imaging of the body of a deceased person included an invasive procedure for which consent had not been given' is not referenced within the SOP. This is not an exhaustive list of the amendments required to SOPs, and to fully address this shortfall, the establishment should review all SOPs relating to mortuary activities to ensure that they are accurate and contain sufficient detail of the procedures. **see, *Advice*, item 4**	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The establishment do have an audit schedule in place however the schedule does not include sufficient procedural audits to help provide assurance for the DI that SOPs and policies are being followed by all staff working within the mortuary and that the SOPs remain an accurate reflection of practice. In addition, the sample sizes of some of the audits that are being undertaken are too small to provide a sufficiently robust data set, for example, for the patient/location audit, mortuary staff are currently only auditing one body in storage.	**Minor**
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	The establishment are not currently auditing the disposal or retention of tissue samples to verify that they have been undertaken in accordance with family's wishes and that the tissue remains traceable. These audits should review tissue from the point when it is removed through to its storage or disposal.	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	The establishment has risk assessments in place which relate to health and safety matters, licensed activities and the potential risks to the deceased and tissue. The risk assessments however do not consider the risk of all licensed activities listed under standard GQ1(a). The risk assessments should also include more examples and detail for example: - The risk assessment for the 'removal and return of fridge trays' states there is a risk of bodies being 'lodged' if too big but does not state the risk of damage to bodies. - The risk assessment for major equipment failure has been given a risk rating of three (low) but the fridges are currently not connected to a remote monitoring system and only alarm locally. - Although there is a risk assessment in place for staff who carry out viewings out-of-hours, this does not include procedures that could be implemented to help mitigate the risk to staff. In addition, the risks to staff who attend out-of-hours to admit bodies in to the mortuary are not considered. **see, *Advice*, item 8**	**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	Three identifiers are not being requested or used to identify bodies: Families are not being asked to provide three identifiers when attending the establishment to undertake a viewing of the deceased and often, only the name of the deceased and date of birth (DOB) or address is requested. In addition, only the name and DOB are checked when preparing the body for viewing; Hospital bodies are released from the mortuary to funeral directors using the 'Green disposal order' form only, which does not contain the required three identifiers to sufficiently check the identification of a body prior to release; The establishment only checks two identifiers prior to post-mortem examination, these being the deceased's name and DOB or address. The release form sent from the coroner's office only contains two identifiers that can be checked against the identification bands of a body on release. The use of less than three separate identifiers when identifying bodies presents a risk of misidentification and potentially the viewing, PM examination of or release of the wrong body. *During the inspection the coroner's office agreed to include a third identifier on the release form that could be used by the mortuary staff to release a body. This was implemented and seen by the inspection team.* **see, *Advice*, items 11, 12 & 13**	**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	While the premises were regularly cleaned, some of the areas of the body store and PM suite contained porous wooden items, there was also damage noticed to the unit top in the PM room and the wooden doors. Wood cannot be effectively decontaminated.	**Minor**
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)	There is no mortuary or hospital trust CCTV within or at access points to the mortuary. Staff are only able to verify who has arrived by opening the entrance doors to the mortuary. This could pose a potential risk to the security of staff and premises, especially out-of-hours for staff working alone.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	The mortuary are currently having to store bodies at the base of the refrigeration units underneath the racking, due to a lack of permanent storage. Although the establishment maintains the dignity of the deceased by fully shrouding bodies and placing them on trays, this should not be a permanent storage arrangement. In addition, storage of bodies in this manner poses a potential risk of damage to the bodies while putting bodies into and out of the fridges as the establishment's trolleys cannot be lowered enough to access this level.	**Major**
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	The mortuary does not currently have sufficient refrigerated body storage capacity. Two of the three temporary refrigerated units intended for use during busy periods only, are in constant use.	
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 establishments mortuary fridges and freezers are alarmed which currently sounds locally. At the time of inspection, the mortuary had connected some of the fridges to a remote temperature monitoring system however this system was not yet activated. All of the refrigeration units within the mortuary, including the temporary stores need to be connected to the remote monitoring system. An alarm that sounds locally provides no assurance that if the fridges were to fail that mortuary staff would be made aware in time, which poses a risk to the deceased in storage. In addition, the fridge on the maternity unit for storage of foetuses, is alarmed but again only sounds locally and may not be heard by staff. Alarm trigger points were also set at temperatures that could pose a risk to the integrity of the bodies in storage if the units were to fail. *During the inspection the mortuary staff arranged for maintenance staff to set the alarm trigger points within recommended temperature ranges.* **see, *Advice*, items 14 & 15**	**Major**
f) Temperatures of fridges and freezers are monitored on a regular basis	Temperatures for all refrigeration units are monitored manually on a regular basis however, these records are not reviewed for trends meaning that an opportunity to identify any potential issues may be missed.	**Minor**

i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods	There is no documented or formalised contingency plan in place which poses a risk to the deceased. **see, *Advice*, item 16**	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
d) Staff have access to necessary PPE	The establishment performs high-risk PM examinations. While FFP3 facemasks are available for mortuary staff and pathologists to use, it has been some time since staff have been face-fitted for these. In addition, staff with facial hair cannot be face-fitted and require fully ventilated hoods, which were not available.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(a)	The consent form used for adult hospital PM examinations references the HTA code of practice on disposal, this code is no longer in circulation. This information is now contained within Code B - 'Post-mortem examination' (April 2017). In addition, Part 2 of the consent form, 'Retention and future use of tissue samples' states that only one option can be selected. The DI is advised to consider amending the form to offer all the available options with regards to any retained tissue so that relatives are not restricted to one.
2.	GQ1(a)	DI is advised to reference the SOP for same/similar names in other relevant SOPs, for example, SOPs for viewings, receipt and release of bodies.
3.	GQ1(g)	Although the removal of time-critical metabolic samples in A&E is a rare occurrence, the DI is advised to appoint a Person Designated (PD) in the A&E department to help provide oversight of the activities in this area.
4.	GQ1(h)	The DI is advised to have meetings with Persons Designated under the licence in order to help maintain oversight of licensable activities which are taking place in other areas of the hospital under the post-mortem licence, such as the maternity and A&E departments.
5.	GQ5(a)	The 'mortuary procedures for porters' card which is given to porters following their mortuary training help to remind porters of mortuary procedures. The DI is advised to include what to do in the event of an incident (particularly with reference to relevant HTA reportable incidents such as accidental damage to a body) on this card to help remind porters of the requirements with regards to reportable incidents.

6.	GQ6(a)	In addressing the shortfall that was identified against standard GQ6(a) the DI is advised to consider reviewing the HTA's publication 'Regulation of the Post Mortem Sector: What we have learned' (October 2016) which provides guidance and information in relation to risk assessments. This is available on the HTA's website.
7.	GQ6(b)	The DI is advised to re-assess the risk to staff who attend the mortuary out-of-hours and consider measures that could be implemented to help mitigate the risk to staff who may be working alone. For example, contacting security when they arrive and leave or the use of a personal alarm that will notify security in the event of an issue.
8.	T1(b)	The DI is advised to consider amending the 'relocation checklist' which staff use to record body traceability by including an additional column for recording when the mortuary register has been updated.
9.	T1(c)	In addressing the shortfall identified under this standard the DI is advised to consider ways to strengthen the procedure for undertaking viewings. The DI may wish to consider the introduction of a form to be completed by relatives when they attend for viewings. This form could include relevant identification information so that three identifiers on the deceased may be checked before the viewing takes place.
10.	T1(c)	DI is advised to consider creating a form for funeral directors to complete and bring with them to the mortuary so three identifiers can be reviewed and used to identify the deceased during release.
11.	T1(c)	During the inspection it was noticed that the mortuary location whiteboard has the surname of the deceased only (a christian name is added when deceased shares a same/similar name). The unique Lab Centre number could be added to the whiteboard and mortuary register as a further traceability check. Potentially a further wristband with the unique ID could be added to the deceased so there are three points of ID.
12.	PFE2(e)	In addressing the shortfall identified against this standard the DI is advised to consider how the new body store temperature monitoring could be tested to ensure the system is adequately monitoring the fridge temperatures and triggers the alarm when required, also to consider how this testing will be documented.
13.	PFE2(e)	The DI is advised to make sure the fridge on the maternity ward is connected to a monitoring system that alerts the nurse's station when it is going outside of normal parameters.
14.	PFE2(i)	In addressing the shortfall for PFE2(i) the DI is advised to have a documented Service Level Agreement (SLA) in place as a contingency arrangement for when the mortuary is reaching maximum capacity. There is currently a verbal agreement in place with another hospital but the DI is advised to formalise this agreement.
15.	N/A	All mortuary staff regularly work additional hours as well as working on-call for extended periods. The DI is advised to continue with the plan to employ a trainee APT to assist the existing staff and help continue to provide safe and effective services and avoid having to employ locum staff.

Concluding comments

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

All staff involved in the inspection demonstrated a sensitive approach to their work and dedication to providing dignity to the deceased and high levels of care. A range of positive feedback cards given to the mortuary staff from families of the deceased were seen. Mortuary staff also take pride in preparing mementos for family members if the family express this is something they would like to receive.

The communication between the mortuary and bereavement office is very good, particularly with regards to dignity checks of the deceased. The bereavement team ensure that if ward staff are not preparing the deceased appropriately before transfer to the mortuary that this is addressed in subsequent training exercises. There is also a good working relationship between the mortuary staff and the Coroner's Officers.

The body store doors have fridge numbers on the inside of the doors, this is a good visual aid when placing the deceased within fridges to assist with traceability, helping to make sure each patient is placed in to the correct space.

The hospital death record sheets are colour coded in blue for A&E deaths, white for ward deaths and green for community deaths, this corresponds with the pen colour used on the mortuary location whiteboard which again assists with traceability of bodies. The establishment have already submitted a business case for increasing storage capacity within the mortuary. They have taken a proactive approach to try and address known issues.

The establishment have a documented escalation procedure in place for 'long stay' bodies within the mortuary. Mortuary staff contact patient services for hospital deaths and the coroner's office for community deaths when a body has been cleared for release for more than ten working days. This system helps prevent bodies being stored for longer than necessary.

The mortuary have issued all trained porters with an information card which offers an overview of the necessary forms to complete when transferring deceased patients to the mortuary and the placement of bodies within the body store, as well as important security arrangements.

There are a number of areas of practice that require improvement, including three major and ten 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: 11 July 2018

Report returned from DI: 2 August 2018

Final report issued: 15 August 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: 10 April 2019

Appendix 1: HTA licensing standards

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

Consent

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

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

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

Guidance

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

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

Guidance

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

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

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

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

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

Guidance

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

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

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

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

Guidance

Refresher training should be available (for example annually).

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

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

d) Competency is assessed and maintained.

Governance and quality systems

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

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

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

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

iii. practices relating to evisceration and reconstruction of bodies;

iv. systems of traceability of bodies and tissue samples;

v. record keeping;

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

vii. lone working in the mortuary;

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

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

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

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

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

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

xiv. contingency storage arrangements.

Guidance

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

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

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

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

Guidance

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

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

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

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

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

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

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

g) All areas where activities are carried out under an HTA 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.