Site visit inspection report on compliance with HTA licensing standards

Royal Liverpool University Hospital

HTA licensing number 30002

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**

22 & 23 May 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 Liverpool University Hospital had met the majority of the HTA's standards, seven major and nine minor shortfalls were found against the Consent, Governance and Quality systems, Traceability and Premises, Facilities and Equipment standards. These related to the training for seeking hospital (consented) post-mortem (PM) examinations; standard operating procedures (SOPs); audits; risk assessments; sharing of information following incidents; the use of three identifiers; traceability of tissues; security of premises; storage of long-term bodies; alarm testing; documented contingency plans; premises and equipment.

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 Liverpool University Hospital (the establishment) is a large teaching and research hospital. This report refers to the activities carried out at the mortuary of the establishment. The combined Mortuary and Bereavement service is managed by Cellular Pathology which is part of Liverpool Clinical Laboratories (LCL). The DI is an experienced Consultant Histopathologist. The Corporate Licence Holder contact is the Medical Director 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 4300 bodies each year from within the hospital and bodies that require post-mortem (PM) examination predominantly from other hospitals in the area, one of which is part of the same Trust. The establishment performs around 580 PM examinations annually, the majority of which are conducted under the authority of HM Coroner for Liverpool and the Wirral. The total figure for PM examinations undertaken includes high-risk (up to category three), forensic and around five hospital (consented) PM examinations. The establishment does not have a maternity unit, therefore staff do not seek consent for paediatric/perinatal cases. Consent for adult hospital PM examinations is sought by bereavement officers who have received some training in the seeking of consent (see shortfall against C2(a)). The form used to record consent for adult hospital PM examinations and the information for relatives reflects the requirements of the HT Act and the HTA's codes of practice.

The establishment has 80 refrigerated body spaces including five bariatric spaces which are 'double-ended' for direct access in to the PM room. In addition, there are twenty spaces within a 'cold room' which can also be used to store super-bariatric bodies, if required. There are five freezer spaces for the storage of long-term bodies.

Portering staff transfer and admit all bodies from within the hospital using a concealment trolley. All bodies are transferred with a 'Notice of Death' form in addition to the identification bands on the body which are checked by the mortuary staff as soon as possible on the day, or the next working day, if the body was admitted out of hours. The porters complete a 'porters log' form and use an 'asterix' on the bodystore location white board to indicate where the body has been stored. Bodies sent to the establishment for PM examination from the other hospitals are transferred by the Coroner's contracted funeral director. Mortuary staff admit and check these bodies during normal working hours using the Coroner's authorisation for PM examination. The mortuary register, the fridge door and bodystore location whiteboard details are completed by the mortuary staff when identification checks have been completed. All bodies are entered sequentially on to a dedicated database using the mortuary register number assigned to the body on admission (see *Advice*, item 9). In

addition, bodies that require a PM examination are entered into the laboratory's electronic laboratory information system (LIMS). Bodies are released from the mortuary using only one or two identifiers (see shortfall against T1(c)).

Access to the mortuary is controlled by swipe card and there is CCTV and a camera and intercom system at the external roller shutter door so mortuary staff are able to verify who is requesting access).

The mortuary has a large PM suite that contains five tables in the main PM room, each with an associated dissection unit. Adjacent to this room there is a smaller PM room containing two tables with dedicated dissection units and viewing gallery. Within this area there is storage of preserved tissue samples for teaching. These teaching samples were retained and stored prior to the introduction of the Human Tissue Act 2004 (HT Act) and are classed as exisiting holdings which are not subject to the consent requirements of the HT Act but do need to be stored on licensed premises as they are being stored for use for a scheduled purpose (see *Advice*, item 19). In addition to the PM areas described above, there are two further PM rooms, one for forensic cases and one for high-risk (up to category 3) cases, each with a viewing gallery (see shortfall against PFE1(a)). Identification checks at PM examination are carried out by the Anatomical Pathology Technologists (APTs) and the pathologist prior to the external examination and evisceration. Pathologists complete each PM examination before commencing the next case and use the dissection units dedicated to a each PM table to help mitigate against any risk of a mix-up of organs and tissue samples between cases.

There are six Consultant Histopathologists who conduct routine PM examinations at the establishment. However, this number has recently reduced unexpectedly due to ill-health and other absence. The mortuary is staffed by the Mortuary and Bereavement service manager, a senior APT, three APTs and and three Mortuary and Bereavement Assistants.

Tissue removed during PM examinations is recorded in the mortuary's database and entered on to the laboratory's electronic information system (see shortfall against T1(g)). Specimens are 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. Forensic specimens are additionally tagged and sealed when transferred from the mortuary. The storage and disposal of PM tissue that has undergone histological analysis is managed by the histopathology laboratory.

In addition to the activities detailed above, the establishment facilitates surgical skills training in the PM suite by a private company. The import and transport of the specimens to the establishment is organised by the company. The establishment have documented procedures in place for this activity and specimens are disposed of following each training session.

Description of inspection activities undertaken

The establishment has been licensed by the HTA since October 2007. Previous routine site visit inspections took place in May 2012 and February 2016. This report describes the third routine site visit inspection visit in May 2018. Formal interviews were conducted with the DI, Mortuary and Bereavement service manager, mortuary staff, a Consultant Histopathologist, staff involved in the seeking of consent (adult), 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 (excluding the forensic suite) and viewing suites.

An audit of body identifiers, storage locations, mortuary register details, mortuary database details and associated documentation was carried out for four adult bodies. Two anomalies were found:

- the mortuary register number for one case had been incorrectly entered into the laboratory's electronic information system (see *Advice*, item 10);
- The date of birth (DOB) in one case had been transposed incorrectly when entered onto the mortuary database.

In addition, it was identified that one of the bodies audited should have been placed into frozen storage as the person had died three months previously (see shortfall against PFE2(c)).

Audits of four PM examinations where tissue had been removed were conducted (one adult hospital consented case and three Coroner's cases). The consent forms and Coroner's documentation were reviewed for the all cases to establish the relatives' wishes for the tissue that had been retained following PM examination and to investigate if these had been complied with. Two anomalies were found:

- Records of the amounts and types of tissue blocks taken during PM examinations are not kept by the mortuary, only how many pots of tissue are taken. The number and types of tissue blocks is recorded on the histology request form sent with the samples to the histopathology laboratory (see *Advice,* item 14);

- The blocks and slides for one case had not been filed under the 'F' number documented in the laboratory's electronic information system. During the inspection, the inspection team were notified that upon further investigation, the 'F' number had been incorrectly recorded in the laboratory's electronic information system. The blocks and slides were filed under the correct number, accounted for and the system was updated with the correct number.

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 Holder and the Designated Individual to be suitable in accordance with the requirements of the legislation.

Standard	Inspection findings	Level of shortfall
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	Although bereavement staff are knowledgable, aware of the consent requirements of the HT Act and the HTA's code of practice and have received some training, there is no formal provision of refresher training. (see *Advice*, item 1)	**Minor**

GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	SOPs do not always contain sufficient detail or reflect current practices. Examples include but are not limited to: • CP-MOR-SOP-4 'Receiving Deceased into the Mortuary' does not state which identifiers are checked on identification bracelets or what the identifers are checked against. In addition, the procedure for checking same and similar names initially refers to checking only surnames; • CP-MOR-SOP-17 'Release of Deceased from the Mortuary' states that during busy periods a body could be released without the required listed documentation. It is not clear that the funeral director is expected to bring some other documentation with them to help provide assurance of identification and that they are dealing with the funeral; • The SOPs in relation to performing PM examinations on high-risk cases, non-TB and TB cases, does not state which identifiers are checked with the pathologist on the identification bracelet or what the identifiers are checked against. In addition, the SOP states the 'Post Mortem Work Sheet' is provided as an appendix to the SOP but is not.	**Major**

	• CP-MOR-SOP-17 states that mortuary staff place blue oversleeves on bodies that have had organs retained at PM examination as a visual cue for staff to check what the relatives instructions with regards to the retained organs before the body is released. This practice should also be carried out when any tissues are to be returned to a body, not just whole organs and the SOP updated to reflect this. • CP-MOR-SOP-16 'Handling and Transportation of Specimens' does not contain sufficient details of the identifiers used to label histology specimen containers. Specimens sent for toxicological analysis are labelled using only two identifers; name and PM number. • CP-MOR-SOP-35 'Mortuary Storage Body Audits including Transfer of a Body to the Freezer' states the procedure for the management of long-term bodies. However, this is not being followed. The inspection team identified two bodies that had not been moved into frozen storage after 30 days of refrigeration. Although staff stated they carried out condition checks on long-term bodies in refrigerated storage, one body in particular was showing significant signs of deterioration (see *Advice*, item 3). Where identification checks are referred to in SOPs, they should detail what those identifiers could be and what they are checked against.	

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The current schedule of audits does not include sufficient audits relating to licensable activities, documented procedures, audits of bodies or tissues retained at PM examination (see shortfall against GQ2(c)). In addition, the schedule includes 'HTARI assessment audits'. These audits do not contain any auditable information and it unclear what the purpose of these 'audits' are.	**Minor**

b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Audits reviewed as part of the inspection demonstrated that where non-conformances have been identified, they have not always been addressed or there is not documented evidence to demonstrate this. For example: • AUD635 (completed 13/04/18) – non-conformances identified in December 2017 were still open; • AUD638 (completed 20/02/18) – six non-conformances identified were still open; • AUD639 (completed 13/3/18) – relates to the mortuary not having equipment records in December 2017 and were non-compliant against numerous areas in the audit.	**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	Although the histopathology laboratory staff regularly follow-up with the Coroner's office regarding the relatives instructions for tissues retained following PM examination, audits of tissues retained at PM examination have not been carried out. The DI cannot be assured that the processes and procedures in place for the retention and disposal of tissues is robust.	**Minor**

GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
d) Information about incidents is shared with all staff to avoid repeat errors	During the inspection it was highlighted to the inspectors that information about incidents is not adequately shared among staff to help encourage 'shared learning' and mitigate the risk of repeat errors.	**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 carried out some risk assessments in relation to health and safety matters. For those risks that have been assessed, not all risks have been considered. The risk-ratings given to the health and safety activities that have been assessed require review to provide assurance they are proportionate and have been assessed properly. As per the Trust's 'Risk Management Policy' (Ref: 1194), the current risk-ratings indicate all activities that have been assessed require escalation to departmental management, at least. In addition, the policy states that all activities should be risk assessed at least annually, depending on the residual risk score. Risk assessments are currently reviewed by the establishment every two years. The HTARI risk assessments reviewed as part of the inspection do not consider all risks to the deceased, tissue or traceability, have not been risk-rated and do not contain sufficient detail. For example, references to SOPs and departmental forms are not included. (see *Advice*, item 6)	**Major**
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	Some of the risk assessments reviewed state that the the level of risk is not acceptable, even when additional control measures are in place. Where actions have been raised in relation to the level of risk identified and subsequently closed, there is no documented evidence to demonstrate that the activity has been re-assessed.	**Minor**

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

c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	Bodies that require a Coroner's PM examination can only be identified using two identifiers (full name and DOB) to cross reference with the Coroner's authorisation for PM examination, as the Coroner's office do not have a record of the deceased's hospital or NHS number. Hospital bodies are released from the mortuary using the 'green disposal order', which does not contain sufficient identifiers to check the identification of a body to the required standard. Therefore staff are releasing bodies from the mortuary using the full name only. Coroner's bodies may be released from the mortuary using one or two identifiers, depending on the documentation brought by the funeral director or sent to the mortuary by the Coroner's Office, to release a body. (see *Advice*, items 11 and 12) When relatives make appointments for viewings, the bereavement officers record only two identifiers (the full name and DOB) of a deceased on a dedicated form given to the mortuary staff for them to identify and prepare the body for viewing. Relatives are required to complete a form when they attend for viewings for staff to verify the identification of a body, prior to the viewing taking place. However, this form does not contain the required minimum three identifiers. SOPs that state the checking of identification is required, should be updated to reflect the requirement for three identifiers to be checked.	**Major**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The tissue tracability audits could not be fully completed during the inspection as the histology request forms sent with the tissues were not appropriately or accurately filed in the histopathology laboratory. As these forms are currently the only detailed record of tissue retained at PM examination that is held by the establishment (prior to 2018), it is important they are appropriately stored and easily accessible. The establishment is required to locate the histology request forms and provide evidence to the HTA. (It was noted that the histology request forms from 2018 are now scanned and stored electronically). (see *Advice*, item 15)	**Major**

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

a) The premises are clean and well maintained	The PM suite floor within the high-risk and forensic rooms has areas of cracking. This compromises mortuary staff's ability to clean and disinfect the post-mortem suite. There is some damage and marks to the walls and bodystore doors that require attention. Doors within the PM suite and bodystore are damaged exposing porous wood that cannot be adequately cleaned or decontaminated. The premises should be subject to a programme of planned preventative maintenance to help ensure they remain fit for purpose.	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	During the visual inspection it was noted that the roller shutter door at the funeral director's entrance was not always completely closed and left raised when funeral directors were collecting bodies. This practice could allow unauthorized or unintentional access to the mortuary and poses a risk to staff, the deceased and the premises.	**Major**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
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 fridge and freezer units are alarmed but the alarm is not tested to assure the establishment that it is working as expected and will alert establishment staff to temperature deviations from the expected range.	**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	Contingency plans involve the transfer of bodies to the unlicensed bodystore within the Trust or to another licensed establishment. However, this procedure is not documented. (see *Advice,* item 17)	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	The body hoists used within the in PM room are unable reach the top fridge spaces within the bodystore when extended to full height, due to the slope of the PM room floor and have already been identified as requiring upgrading. This poses a health and safety risk to staff and a risk to bodies when removing and replacing them from the bodystore.	**Major**
d) Staff have access to necessary PPE	Although FFP3 masks are available within the PM suite, mortuary staff and pathologists have not been face-fitted for these masks to safeguard against airborne biological hazards.	**Minor**

Advice

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

No.	Standard	Advice
1.	C2(a)	The DI is advised to have the Mortuary and Bereavement services manager (who has been suitably trained in consent seeking for PM examinations), accompany the Bereavement Officers during the consent seeking process, until they are fully trained and assessed as competent. Any training should be recorded and regularly refreshed, for example, every two years.
2.	C2(d)	The DI is advised to develop a procedure through which the Bereavement Officer's competency in seeking consent is assessed and recorded regularly, for example, every two years.
3.	GQ1(a)	The SOP that considers long term storage of the deceased (MOR-SOP-35) states that 'If it is anticipated that the four week threshold will be exceeded, preparations should be started after about two weeks, to allow Bereavement Services time to liaise with relatives where applicable'. The DI is advised to apply this practice for all bodies in their care to help identify those who may need to be transferred to freezer storage. Additionally the DI is advised to add condition checks to the weekly body audit.
4.	GQ1(h)	The DI is advised to include information and feedback following the investigation of incidents within the existing mortuary staff meetings. The minutes of the meetings should be circulated to all staff.
5.	GQ5(a)	The DI is advised to include the HTA in the list of external agencies that should be informed in the event of a HTA reportable incident, in the Trust policy 'Incident Reporting Policy and Procedure' (Ref: 3188), Section 4.10.
6.	GQ6(a)	In addressing the shortfall identified against standard GQ6(a), the DI is advised to assure themselves that all the licensed activities outlined in GQ1 and the HTARI categories are risk assessed to provide a comprehensive set of risk assessments. In particular, ensuring the risks to the dignity and integrity of bodies and stored tissue are included. The HTA's publication 'Regulation of the Post Mortem Sector: What we have learned' (October 2016) provides guidance and information in relation to risk assessments. This is available on the HTA's website.
7.	T1(b)	During the inspection it was noted that names of the deceased are documented surname followed by first name and first name followed by surname. The DI advised to ensure that the names of the deceased are consistently documented wherever they are recorded. This will help prevent confusion and mitigate the risk of bodies being misidentified.
8.	T1(b)	As discussed during the inspection the DI is advised to include a column in the existing mortuary database that will calculate the amount of days a body has been stored. This will assist with identifying and monitoring of bodies that have been in refrigerated storage for extended periods of time, for example, two weeks.
9.	T1(b)	To further strengthen traceability of bodies while in the care of the mortuary, the DI may wish to consider using the mortuary register number of the deceased on the fridge doors in addition to the full name. The mortuary register number is unique to that body, acting as an additional identifier while in the care of the mortuary. This can also be helpful when distinguishing

		between the deceased with same or similar names and bodies of unknown identity.
10.	T1(b)	When input errors have been made entering bodies in to the electronic laboratory information system, the DI is advised to: • have the erroneous record deleted and re-enter the deceased's details under the correct number, or • update all documentation with the number assigned to the deceased in error and do not allocate the number that should have been used for that body. The first option may help to assure the DI that all bodies are entered in to the laboratory system and mortuary database in the correct sequential order and help to mitigate the risk of misidentification of bodies.
11.	T1(c)	The DI is advised to consider introducing a standardised release form for funeral directors that is completed by them prior to arrival at the mortuary and brought in addition to other documentation brought by the funeral director. This form could contain the required three identifiers to release a body; for example, full name, DOB and DOD. The DI may also wish to consider having this form signed by the deceased's relatives. In addition, the DI is advised to liaise with the Coroners' office to request that the relevant three identifiers are included on the release forms sent by them to the mortuary.
12.	T1(c)	In addressing the shortfall identified against T1(c), the DI is advised to liaise with the Mortuary and Bereavement services manager and request placing the date of death (DOD) on the deceased's identification bands during last offices procedures. The care after death policy is currently being reviewed by the Mortuary and Bereavement services manager; therefore, it may be a suitable time to review what procedures are included. This may help identification of bodies by providing another point of identification, which can be used on receipt of the body, prior to PM examination and release of the body from the mortuary.
13.	T1(d)	To further strengthen the procedure for same or similar names, the DI is advised to highlight all bodies with same or similar names in the mortuary register, to act as another visual cue for staff when releasing bodies and include this within relevant SOPs. This may help to further mitigate the risk of bodies with same or similar names being incorrectly identified.
14.	T1(g)	A record of the quantity of tissue blocks retained after the PM examination is recorded on the histology request form that is sent with the tissue to the laboratory. The DI is advised to consider keeping a record of the quantities and types of tissue taken at PM examination in the mortuary, to assist with tracebility audits of tissue from the mortuary to the histopathology laboratory.
15.	T1(g)	The DI is advised to sort and file the histology request forms stored in the histopathology laboratory so they can be easily accessible and audited when required. In addition, the DI may wish to consider scanning the forms that precede 2018.
16.	PFE2(a)	There are two digital displays showing the bodystore temperatures. Although the difference in temperatures were not significant, it was unclear what the purpose of the dual readings were for. The DI is advised to establish which display is showing the correct bodystore temperatures, that these readings are used to record the daily temperatures and assure himself that the bodystore alarms are connected to the correct system.

17.	PFE2(i)	In addressing the shortfall identified against PFE2(i) the DI is advised to include details of: • when the contingency plan would be instigated, for example, when capacity reaches a certain level; • how bodies would be transferred from the mortuary and if Service Level Agreements (SLAs) are required with funeral directors to facilitate this; • the identification checks and traceability records when bodies require transfer to other premises.
18.	N/A	The DI is advised to consider liaising with the Coroner's Office to offer the options for tissue to be stored and used for scheduled purposes (once the Coroner's authority has ended), as separate options on the tissue instruction form returned to the establishment. Currently, the options for medical record and scheduled purposes are given together, meaning relatives cannot opt for, or decline tissue to be used for specific schedules purposes.
19.	N/A	The DI is advised to re-catalogue the collection of preserved teaching specimens stored within the PM suite as this has not been done for some time and it is unclear where the records are located. It would be prudent to carry out regular documented audits of these specimens and check the number and condition of them and the containers they are held in. In addition, the DI is advised to keep the collection under review to determine the need for their continued retention.

Concluding comments

There are a number of areas of practice that require improvement, including seven major shortfalls and nine minor shortfalls. However, there are some areas of strength and good practice, which include:

- Staff receiving praise from service users, internal and external to the Trust;
- Posters within the bodystore area highlighting the danger of accidental damage to bodies if not correctly placed into the bodystore;
- The use of coloured magnets on the bodystore doors and office whiteboard to highlight pertinent information regarding bodies, for example, same and similar names and retained organs;
- Blue over sleeves are placed on bodies that have had organs retained during PM examination to act as a visual cue for staff to check the disposal instructions for the organ, before the body is released, in case it is for return to the body.

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: 21/6/18

Report returned from DI: 13/7/18

Final report issued: 19/7/18

Completion of corrective and preventative actions (CAPA) plan

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

Date: 16/1/19

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.