Site visit inspection report on compliance with HTA licensing standards

Doncaster Royal Infirmary

HTA licensing number 12268

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**

11 & 12 July 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 Doncaster Royal Infirmary had met the majority of the HTA's standards, three major and thirteen minor shortfalls were found against the Consent, Governance and Quality systems, Traceability and Premises, Facilities and Equipment standards. These related to the policy and Standing Operating Procedure (SOP) for seeking consent for post-mortem (PM) examination; the written information provided to relatives who give consent; training for seeking of consent for PM examination; SOPs; risk assessments; the use of three identifiers; premises and equipment and body store alarms.

Particular examples of strengths and good practice are included in the concluding comments section of the report.

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI 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 DI 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

Doncaster Royal Infirmary (the establishment) is part of the Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust. This report describes the activities carried out in the mortuaries located at Doncaster Royal Infirmary (the hub site) and Bassetlaw District General Hospital (the satellite site). The mortuary is managed by Cellular Pathology. The DI is a Consultant Histopathologist and the Corporate Licence Holder contact is the Chief Executive of the Trust. The establishment is licensed under the Human Tissue Act 2004 (HT Act) for: making of a post-mortem examination; removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation, and; storage of the body of a deceased person or relevant material which has come from a human body for use for scheduled purposes.

The establishment receives approximately 2300 bodies each year from deaths in the hospital and the community. The establishment performs around 730 PM examinations annually, the majority of which are conducted for HM Coroner for South-East Yorkshire. These PM examinations include high-risk (up to category three) and around two hospital (consented) PM examinations. Paediatric/perinatal PM examinations are transferred to another HTA-licensed establishment. Consent for paediatric/perinatal PM examination is sought at the establishment by clinicians who may have received some training in the seeking of consent and a trained bereavement midwife (see shortfall against C2(a)). Consent for adult hospital PM examinations is sought by senior hospital clinicians with direct support from the DI or, in her absence, another Consultant Histopathologist. However, all doctors receive some training in relation to PM consent seeking as part of their induction in the Trust.

The establishment has 147 permanent refrigerated body spaces, including two spaces for bariatric bodies and eight spaces for semi-bariatric bodies. There is additional temporary refrigerated storage, which increases the total capcity to 158 spaces. Further fridge capacity has been installed since the last inspection to help alleviate increasing capacity issues during busy periods. A dedicated refrigerated unit has recently been purchased for the storage of neonatal bodies, fetuses and pregnancy remains but is not yet in use (see *Advice*, item 18). The establishment do not have any freezer storage at either site but have a documented agreement in place with another licensed establishment, should long-term storage be required.

Swipe card access is required for both external doors to the mortuary, which are covered by CCTV. However, the entrance used by visitors to the mortuary is covered by hospital CCTV which is not readily accessible to staff in the mortuary to visually verify who is requesting access before opening the doors (see shortfall against PFE1 (d)).

Across both sites, service assistants (porters) transfer and admit all hospital bodies. They are also responsible for admitting community bodies at Doncaster Royal Infirmary (DRI) during out-of-hours periods. Hospital bodies are transferred from the wards using a concealment trolley. Upon admission, the mortuary register, body store location whiteboard and fridge door card are completed by the porters using the information in the 'Notification of death' (NOD) form transferred with each body (see *Advice*, item 4). The mortuary staff complete body identification checks as soon as possible on the day, or the next working day if the body was admitted out of hours. Bodies are predominantly released from the mortuary using only one or two identifiers (see shortfall against T1(c)).

Training in mortuary practices and procedures has been provided to portering supervisors who cascade this training to the wider portering team.

The PM suite contains three PM tables each with an associated dissection area. When removing bodies from refrigerated storage, Anatomical Pathology Technologists (APTs) carry out initial identification checks against coronial or consent documentation and again with the pathologist prior to the external examination and evisceration commencing. Pathologists complete each PM examination before commencing the next case to help mitigate against any risk of a mix-up of organs and tissue samples between cases. Each community body is given an additional identification band at PM examination to ensure that two identification bands are insitu. All PM cases are recorded in a dedicated book which includes a record of specimens and if they have been retained for further analysis. All retained PM histology specimens are taken and processed at the histopathology laboratory on site. Specimens are assigned a unique reference number which is recorded on a dedicated PM tissue database which is overseen by the Head Biomedical Scientist (BMS)/Mortuary Manager.

Five Consultant Histopathologists, three of which are based at the establishment and including the DI, fulfil the PM service.

One senior APT, two APTs and one Trainee APT staff the mortuary. A Mortuary Assistant has recently been appointed to help with non-technical duties (see *Advice*, item 7). Mortuary staff work on-call and provide cover for the hub and satellite site during out of hours periods.

The establishment has a maternity unit, where there is a fridge for the storage of pregnancy remains, fetuses and stillbirths. There is a well documented policy in place for the management of these cases. During the inspection, the inspectors were notified that the fridge is no longer used for fetuses or stillbirths; cold and cuddle cots are now used and bodies are transferred to the mortuary as soon as possible. Pregnancy remains are placed in tissue fixative, negating the need for refrigeration (see shortfall against GQ1(a)).

In addition to the storage activities described above, the removal of tissue samples from the body of a deceased child occasionally takes place in the Accident and Emergency

Department. The process and documentation for these cases were reviewed as part of the inspection and found to be compliant with current guidelines.
A traceability audit of bodies being stored at the establishment was undertaken. Body identifiers, storage locations, mortuary register details and associated documentation were reviewed and cross referenced for four adult bodies (one hospital and three community bodies). Two anomalies were found:

- One hospital body that had undergone PM examination had different first names stated on each identification band. Although the name on one of the identification bands was similar to the name on the Coroner's release form, the spelling was different and in addition, the address did not match;

- There was a discrepancy with the age of one body between the two identification bands and the Coroner's release form.

In addition, an audit of four cases where tissue had been retained for histological analysis following PM examination was conducted (two adult hospital consented cases and two Coroner's cases). The inspection team visited the histopathology laboratory to review the retained tissue and associated traceability records. In addition, records of the relative's wishes regarding the fate of the tissue following its analysis were reviewed to determine if they had been acted upon appropriately. No anomalies were found.

Bassetlaw District General Hospital (satellite site)

Bassetlaw District General Hospital (BDGH) is used as a body storage facility only. Although there is a PM room, this has not been used for some time. However, the area is used to house a bariatric storage facility (see shortfall against PFE2(e)). Hospital bodies admitted to the mortuary that require PM examination are transferred to another licensed establishment as this hospital is situated within another Coronial district. The HTA licence is maintained as removal of tissue may occur in the hospital's Accident and Emergency department in cases of sudden unexpected death of an infant or child (SUDIC).

The mortuary at the satellite site has a total of 29 refrigerated body spaces and a storage facility for one bariatric body. BDGH can be used as contingency storage for the hub premises during busy periods but an unlicensed body store within the same Trust would be utilised first.

There is an external access door to the mortuary, for the admission and release of all bodies, which is secured by code lock and monitored by departmental CCTV, which can be reviewed by staff to assess who is requesting access. Portering staff transfer and admit all hospital bodies using a concealment trolley, which is pushed from the main hospital building to the mortuary (see *Advice*, item 20).

The mortuary is staffed by a mortuary assistant who works alone during working hours. The establishment have considered the risks to lone workers at the satellite site and measures are in place to mitigate the risks of working alone.

A traceability audit of bodies being stored at the satellite site was undertaken. Body identifiers, storage locations, mortuary register details and associated documentation was reviewed and cross referenced for the three adult hospital bodies in storage. No anomalies were found.

Description of inspection activities undertaken

The establishment has been licensed by the HTA since May 2007. Previous routine site visit inspections took place in May 2010 and July 2014. This report describes the third routine site visit inspection in July 2018. Formal interviews were conducted with the DI, BMS Mortuary Manager, mortuary staff, hospital porters, Coroner's Officer, Consultant Histopathologist and PM consent seekers (adult and perinatal). A visual inspection of the mortuaries was carried out, including body stores, viewing rooms and the PM suite at DRI.

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
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	The policy 'Consent to Examination or Treatment' (PAT/PA2), which includes information for the seeking of consent for PM examination, refers to an 'appropriate qualifying person' but does not include details of the hierarchy of qualifying relationships as outlined in the HT Act 2004 or the HTA's codes of practice. In addition, the policy refers to the HTA's previous code of practice (Code 3) and is past its review date (April 2018).	**Minor**
b) There is a documented standard operating procedure (SOP) detailing the consent process	The SOP 'Consent for PM Examination' (MOR-SOP-06) refers to an 'appropriate qualifying person' but does not include details of the hierarchy of qualifying relationships as outlined in the HT Act 2004 or the HTA's codes of practice.	**Minor**

c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice	i) The information leaflet 'A Simple Guide to PM Examination' includes the following: • The phrase, 'Next of kin'. This reference should be removed and replaced with information about the person ranked highest in the hierarchy of qualifying relationships who is the most appropriate person to give consent for a PM examination and for the retention of tissues for use for scheduled purposes (page 1); • 'small blocks of tissue may be retained for scheduled purposes…'. This should be clarified so that it is clear that tissue may only be retained if valid and appropriatre consent for the retention is in place (page 2); • 'If organs or tissue had to be retained'. This should be clarified to state 'with consent' for hospital consented cases and 'under coronial authority' for Coroner's cases (page 3). The leaflet 'A guide to a Post Mortem MRI on a baby or child', version 1.1, valid from 01/07/12 is past its review date. The consent form in use for PM MRI examinations states that the leaflet should be version 2.1.	**Minor**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	At both establishment sites, clinicians who seek consent for paediatric/perinatal PM examination may have had some PM consent training as part of their induction in to the Trust and further informal training by senior clinicians, however, there is no evidence they have received any refresher training. In addition, the Bereavement Midwife who has undertaken formal PM consent training, last had training four years ago and no refresher training had been offered or undertaken since. (see *Advice,* item 2)	**Minor**

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

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	Although the establishment has a range of SOPs covering licensable activity, staff are not necessarily following them, some do not reflect current practice, or they require further detail or clarification. Examples include, but are not limited to: • MOR-SOP-5 'Release of a Body From the Mortuary', version 7, states three identifiers are checked on the bodies against paperwork brought by funeral directors. However, this procedure is not being followed. Hospital bodies are predominantly released using the green disposal order, which does not contain sufficient information to check the required three identifiers, one being unique; In addition, decomposed bodies have identification bands placed on them once identification is established. Current practice is to place a cardboard toe-tag on the outside of the body bag to identify the body and not physically check the identification of these bodies when they are transferred or released from the care of the mortuary. • MOR-SOP-17 'Identification and Checklist Procedure Prior to PM Examination', version 5, refers to the checking of identification (name and DOB only) prior to PM examination. However, in practice, three identifers are routinely checked and the external examination is conducted by the pathologist prior to evisceration. The SOP requires updating to reflect current practice (see *Advice*, item 5); • MOR-SOP-7 'Technical Procedures PM', version 11, refers to the checking of identification, as in MOR-SOP-17. In addition, the return of tissues to a body before its release is documented but how this is highlighted to prevent the body being released and how the return of tissues is recorded, is not detailed; • MOR-SOP-8 'Viewing Protocol', version 7, does not state that the identification of the body is checked when the body is being prepared for a viewing, what the identifiers could be and how the identification is verified with the relatives attending for the viewing;	**Minor**

	• MOR-SOP-32 'Same Name Entry Procedure', version 2, refers only to checking surnames; • The policy MSG 55, version 10, 'Guidelines for Pregnancy Loss Second and Third Trimester Including Stillbirth and Neonatal Death' states that a fridge is used for the storage of these bodies at DRI. This does not reflect current practice. When SOPs state that identification should be checked, the identifers should be detailed. All SOPs require review to assure the DI that they contain sufficient detail and reflect the HTA's codes of practice.	
e) There is a system for recording that staff have read and understood the latest versions of these documents	Review of the electronic document control system demonstrated that not all staff are reading and acknowledging SOPs. This presents a potential risk that staff are not fully aware of, or following, the most up to date procedures relevant to their work.	**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	i) Although the establishment has a range of risk assessments in place, accidental damage to bodies has not been considered as a potential risk on the relevant risk assessments. For example, those relating to PM examination and for the transfer of bodies. In addition, the risk assessment relating to the transfer of bodies does not include the checking of the identification of bodies prior to their transfer, as a mitigating step in preventing the release of a wrong body. i) The risk assessment in relation to HTA compliance refers to to the HTA's previous code of practice on 'Disposal'.	**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	Hospital bodies that require Coroner's PM examination may only be checked using two identifiers. It was noted during the inspection that the hospital identification bands do not include the deceased's address, although this is required as per the Trust's 'Patient Identification' Policy (PAT/PS7, version 4). (see *Advice*, item 12) Hospital bodies are released from the mortuary using only one or two identifiers. On occasion, if the green disposal order is not available, bodies are released using verbal confirmation only. (see *Advice*, item 13) When families attend for viewings, only the name of the deceased is checked with relatives. (see *Advice,* item 14)	**Major**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Although specimens that are sent away for specialist analysis are recorded as being sent, the establishment do not currently request confirmation of receipt at the receiving establishment.	**Minor**

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 mortuary premises at DRI are showing signs of age related wear: • Where there is a join in the body store flooring, it is cracking and coming loose; • There are cracks between the tiles of the PM room floor and chipping to the edges of the tiles around the original floor drains; • The seals around the bases of the PM tables are damaged and require re-sealing; • There is damage to walls exposing bare plaster; • The paint on the radiator within the PM room is flaking and it is rusting creating a porous surface.	**Major**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning	Cleaning of the body store fridges at both sites is not documented in the relevant SOP. (see *Advice*, item 16).	**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)	i) The viewing room doors that access the body store at DRI cannot be locked meaning that there is a potential risk that relatives attending a viewing may enter the body store(see *Advice*, item 17). ii) At DRI, staff cannot visually verify or speak to who is requesting access at the visitors entrance. The hospital CCTV covering this area is not available for mortuary staff to readily view. This increases the risk of the door being opened to unauthorised people, potentially causing a security and/or safety issue for staff.	**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	i) The bariatric storage unit at BDGH is not linked to the remote alarm system therefore staff will not be alerted if temperatures deviate from within set ranges. ii) The body store fridge alarms are not formally tested to provide assurance that they trigger should the temperatures deviate from the set ranges.	**Minor**
f) Temperatures of fridges and freezers are monitored on a regular basis	The fridge for the storage of fetuses and neonatal bodies on the maternity unit is monitored daily. However, the records show readings of minus and excessively high temperatures. On investigation this is likely due to the placement of the probe inside the fridge. In addition, the fridge is only locally alarmed. It is unclear if the alarm had been activated at these temperatures or formally tested. Discussions with the maternity unit staff revealed that it is not practice to use the fridge for the storage of fetuses and stillbirths, preferring to use the cold and cuddle cots available on the ward, then transferring straight to the mortuary, including out-of-hours.	**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	i) The wooden head blocks and dissection boards used within the PM room have not been maintained, are damaged and porous meaning they cannot be adequately cleaned or disinfected, posing a potential infection risk. In addition, wooden body measuring sticks are in use within the body stores. All wooden items should be disposed of and replaced with non-porous replacements. ii) The body hoists in use are showing some age-related damage and areas of flaking paint. At DRI, staff have used material and tape to prevent exposed screw heads from scratching coffins when bodies are released. However, this prevents staff from being able to adequately clean and disinfect the body hoist, which is also used within the PM room. iii) Clinical waste bins are metal and showing areas of flaking paint and rust creating a porous surface which cannot be cleaned effectively.	**Minor**
d) Staff have access to necessary PPE	Staff and pathologists have not been face-fitted for the disposable FFP3 masks available for use and are unable to be used if they have facial hair; the use of fully ventilated hoods is required.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(g)	The DI is advised to liaise with the establishment that undertakes paediatric/perinatal PM examinations to assure themselves that they are using the most recent version of the information leaflet given to parents regarding the PM procedure.
2.	C2(a)	In addressing the shortfall identified against standard C2(a), the DI is advised to explore options to help provide reassurance that suitably trained individuals seek consent for paediatric/perinatal PM examinations, or are accompanied by someone who is.
3.	GQ1(a)	NOD forms for hospital deaths are placed on the body store fridge trays with bodies, once identification checks have been completed. The DI is advised to consider developing a procedure through which any risk of damage to these notices through the leakage of body fluids is minimised.
4.	GQ1(a)	The DI may wish to consider implementing a form to be completed for bodies admitted out-of-hours to ensure that information regarding these bodies is communicated efficiently to mortuary staff; for example, when there is a risk of infection. This is especially important as mortuary staff may not receive information for a few days.
5.	GQ1(a)	The DI may wish to consider including a section in the checklist completed prior to PM examination to confirm that the external examination has been completed by the pathologist prior to evisceration taking place.
6.	GQ1(a)	Same and similar sounding names are already highlighted by staff at the establishment; the DI may wish to consider extending this principle to highlight other pertinent information; for example, ‘Danger of infection’, ‘Implant device’ or ‘Tissue retained’.
7.	GQ3(a)	The DI is advised to ensure that the training and competency records for the recently appointed Mortuary Assistant are completed and kept up to date. These will be reviewed during the next inspection.
8.	GQ4(b)	The DI is advised to ensure that mortuary records are appropriately amended/corrected, for example, correcting errors with a single line and initialling the entry rather than using correction fluid.
9.	GQ6(a)	The DI is advised to keep the risk assessment relating to the mortuary register under review as the information contained within the register is not stored elsewhere, and continue to explore options for suitable electronic systems to store this data.
10.	T1(a)	Community bodies are identified using a cardboard toe-tag. The material of these tags presents a risk that the identification details could be lost if the tag becomes wet, soiled or damaged. The DI is advised to consider other, more robust identification labels/bands for these bodies.
11.	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.
12.	T1(c)	In addressing the shortfall identified against T1(c), the DI is advised to liaise with the relevant personnel involved in the current review of the 'Patient Identification' Policy (PAT/PS7) to reiterate the importance of including the address on patient identification bands, in-line with Trust policy.
13.	T1(c)	The DI is advised to consider introducing a standardised release form for funeral directors to be 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 address. The DI may also wish to consider having this form signed by the deceased's relatives.
14.	T1(c)	The DI is advised to consider strengthening the procedure for viewings by introducing a form to be completed by relatives when they attend for viewings. This can include relevant information to check the identification on the deceased, before the viewing takes place.
15.	PFE1(a)	The DI is advised to consider implementing a schedule to monitor the condition of the premises and equipment to provide assurance that areas of concern are highlighted and addressed, especially as the mortuary facilities are showing age-related wear.
16.	PFE1(c)	The DI is advised to include the cleaning of the body store fridges within cleaning records to maintain oversight of when this is done and provide assurance that all fridges are being regularly cleaned.
17.	PFE1(d)	The DI is advised to continue with the plan as part of the refurbishment works, to include lockable doors from the viewing room to the bodystore at DRI to prevent unintentional or unauthorized access to the body store.
18.	PFE2(e)	The DI is advised to connect the newly purchased refrigerated unit for neonatal bodies, fetuses and pregnancy remains to the remote temperature monitoring and alarm system, once it is operational and before any bodies are stored in there.
19.	PFE3(c)	Although the ventilation system is working to the required standard, the report from the company who undertook the servicing recommended that the filters require changing as they are very dirty. The DI is advised to follow this recommendation to provide assurance the ventilation system continues to work to the required standard.
20.	N/A	The DI is advised to consider alternative options for the transfer of bodies from the main hospital building at BDGH to the mortuary. This transfer occurs outside of the hospital building, down a sloped road, overlooked by houses meaning the concealment trolley can be seen in transit. A risk assessment should be considered to assess the risks to the dignity of the deceased and any potential issues that may occur during transfer.

Concluding comments

The mortuary team are experienced and have worked together for a number of years. The DI is supported in her role by a management team who work closely with the mortuary staff, they appear conscientious, enthusiastic and understand the importance of mortuary practices. There are several areas of strength and good practice:

- When viewings are in progress, there is a red light in the body store to indicate this, so staff and visitors are aware to keep noise levels to a minimum;
- Access to the body store is restricted during PM examination sessions as the staff have to transfer bodies between the PM room and the body store area as the fridges are not 'double-ended'. The staff recognize the movement of the trolley could cause contamination in the body store and routinely clean this area after each PM session;
- The staff have recently filmed a training video for hospital staff for the preparation of bodies for viewing to help provide training and assurance that bodies are appropriately presented and documented procedures are followed;
- At BDGH, the individual body store numbers have been replicated on the inside of the body store doors as a visual reminder for staff;
- The maternity unit use pre-prepared document packs to ensure that staff can readily use the correct paperwork depending on the gestational age of the pregnancy remains, fetus or baby;
- The tissue database, the colour-coding system, and the procedure for the follow-up of tissues retained at PM facilitate traceability systems for the retained tissue.

There are a number of areas of practice that require improvement, including three major shortfalls and thirteen 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: 07/08/18

Report returned from DI: 15/08/18

Final report issued: 11/09/18

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: 10/01/19

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 stillborn 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.