Site visit inspection report on compliance with HTA licensing standards

Wycombe Hospital

HTA licensing number 12245

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**

6-7 September 2017

Summary of inspection findings

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

Although the HTA found that Wycombe Hospital had met the majority of the HTA's standards, one major and six minor shortfalls were found. The major shortfall was in relation to testing of the refrigerator and freezer alarm system (PFE2(e)). The minor shortfalls were in relation to: (i) governance meetings (GQ1(h)); (ii)-(v) systems for investigating and reporting HTA reportable incidents (GQ5(a)-(d)); and (vi) systems for communicating with the Coroner's Office (T2(b)).

Advice has been given relating to the Governance and Quality systems, Traceability, and Premises, Facilities and Equipment standards, as well as advice on licence management.

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

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual (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

This report refers to the activities carried out at Wycombe Hospital (the establishment), whose HTA licensing arrangements cover Wycombe Hospital (WH; the hub site) and Stoke Mandeville Hospital (SMH; satellite site). A separate body store is situated at Amersham Hospital (part of the same Trust), which is not subject to licensing as bodies there are held pending release to funeral directors or temporarily, 'incidental to transportation' to WH for post-mortem (PM) examination.

WH was issued an HTA licence in October 2007 and SMH a separate HTA licence in June 2007. Both organisations have had two previous HTA site visit inspections (the last ones for each site took place in November 2012). The two licences were merged into a hub and

satellite arrangement in November 2013. The current inspection was a routine site visit to assess whether the establishment is continuing to meet the HTA's standards.

Both hub and satellite sites are licensed under the Human Tissue Act 2004 for the making of a PM examination, the removal of relevant material from the deceased for use for a scheduled purpose and the storage of a body and relevant material for use for a scheduled purpose.

The DI supervising activities taking place under the licence is a consultant pathologist, the Corporate Licence Holder (CLH) is Buckinghamshire Healthcare NHS Trust and the CLH Contact (CLHC) is the Chief Operating Officer. There are currently three Persons Designated (PDs) working under the licence.

At the hub site, licensed activities occur within Cellular Pathology, which includes the mortuary and Histopathology Department. At the satellite site, licensed activities occur within the mortuary, the Accident and Emergency Department, and the Maternity Unit.

Cellular Pathology is accredited by the United Kingdom Accreditation Service (UKAS) to International Organization for Standardization (ISO) standard 15189 (2012). The last UKAS inspection of this Department was in August 2017.

Cellular Pathology (WH and SMH Mortuaries)

The WH mortuary receives approximately 590 bodies each year and conducts approximately 300 adult PM examinations annually. The SMH mortuary receives approximately 1,300 bodies each year and conducts approximately 280 adult PM examinations annually. Paediatric, perinatal and stillbirth PM examinations are conducted at a separate HTA-licensed establishment. Home Office PM examinations are conducted at SMH.

Most of the PM examinations are conducted under Coronial authority, for HM Coroner, Buckinghamshire. There were nine 'hospital' (consented) PM examinations in 2015 (six at WH, three at SMH). Approximately 10 Home Office PM examinations are conducted at SMH each year.

There are four consultant pathologists who conduct routine PM examinations on both sites. At WH, they are assisted by a mortuary team consisting of two qualified senior Anatomical Pathology Technologists (APTs) and at SMH by one qualified senior APT and one trainee. Both mortuary teams also assist NHS Blood and Transplant (NHSBT) tissue retrieval teams in procuring multiple tissue types for human application; tissue 'procurement' is under the NHSBT human application licence.

Consent for PM cases on both sites is sought by a team including the treating clinician, a bereavement nurse or bereavement officer and a consultant pathologist. A consent form and information leaflet developed from the HTA template are used. Consent for stillbirth and perinatal PM cases is sought by staff in the Maternity Unit (see below). Consenting staff are required to complete the WH consent training programme.

Both mortuaries are purpose built and are located within the main hospital buildings. At

each, the entrance for funeral directors is screened from public view. Entry and exit points are monitored by closed-circuit television (CCTV) and there is electronic access control (key access at the WH mortuary, video phones and swipe card access at the SMH mortuary; see *Advice*, items 13 and 15). Although suitably staffed, lone working on both sites does occur both during and out of hours and there are procedures to cover these activities.

Adjacent to both mortuaries are the viewing facilities, which are well lit, spacious and discreetly decorated.

Body Store and PM Room (WH)

The WH body store contains 42 refrigerated spaces, including six which can be used for freezer storage.

Refrigerator (and freezer) temperatures are recorded manually on a daily basis by mortuary staff and monitored externally via a wired system linked to the hospital helpdesk. If temperatures exceed the set limits, a local audible alarm is sounded and an electronic signal is sent to the hospital helpdesk for action. There is an on-call rota of mortuary staff available to manage callouts and the movement of bodies, when required. The alarm and callout system is not regularly tested (see shortfall against PFE2(e)).

The WH PM room contains two PM tables, each with an accompanying dissection bench, and has adequate working space and good lighting. Ventilation levels were above the accepted range of 10 air changes per hour.

Body Store and PM Room (SMH)

The SMH body store contains 60 refrigerated spaces, including four which can be used for bariatric storage and four which are reserved for the storage of Hazard Group 3 cases. There is a separate bank of six spaces for freezer storage and a separate paediatric refrigerator containing space for stillbirths, perinatal deaths and fetuses of more than 16 weeks gestation. There is one additional external refrigerated storage unit with 16 refrigerated spaces.

Refrigerator and freezer temperatures (including those in the external unit) are recorded manually on a daily basis by mortuary staff and are also monitored externally via a wired system linked to the hospital helpdesk, although the paediatric refrigerator is not connected to the callout system (see shortfall against PFE2(e)). The system monitors temperatures every 15 minutes and temperature archives are stored on a Trust server, although the temperature data is not reviewed for trends (see *Advice*, item 17). As with the WH Mortuary, there is an on-call rota of mortuary staff available to manage callouts. but the alarm and callout system is not regularly tested (see shortfall against PFE2(e)).

The SMH PM room contains two downdraught PM tables and has adequate working space and good lighting. Ventilation levels wre above the accepted range.

There is a separate storage area within the SMH mortuary for formalin-fixed (wet) tissue

specimens retained during the PM examination and held under the Police and Criminal Evidence Act 1984 (PACE).

Clean, transit and dirty areas within each mortuary are clearly delineated and there are wall notices and diagrams clarifying when and how personal protective equipment (PPE) should be worn.

There are clear policies and procedures for cleaning and decontamination and records of cleaning and decontamination are maintained (see *Advice*, item 12).

Refrigerators and freezers on both sites are subject to regular servicing and planned preventative maintenance (see *Advice*, item 21) and there is a contingency plan for disaster recovery and individual plans for additional body storage demand.

Receipt, Storage and Release of Bodies

Bodies arriving from the community are brought in by a dedicated funeral director under a formal agreement with the Coroner. Those arriving from one of the other hospitals within the Trust are brought in by a different funeral director under agreement with the Trust. All bodies from within the hospital are transported by porters.

Upon arrival, information is entered into the mortuary register on each site and the body is given a unique, sequential number (see *Advice*, item 5). Where the deceased requires a PM examination, a separate PM number is also allocated and a record is kept in the PM register. Records from both registers are entered into the Cellular Pathology database, which can be accessed by all Cellular Pathology staff, including mortuary staff on both sites.

The out-of-hours procedures vary between the two sites. At WH, if funeral directors bring in a body, they are accompanied by a member of the mortuary team. If porters bring in a body, they place the body in the most appropriate vacant space and leave the paperwork in the mortuary office. The mortuary team reviews all new cases the next day, marking the refrigerator door labels in black pen to highlight that the body has been checked, and transferring the details into the mortuary register. Surnames which are the same or similar are highlighted, both on the refrigerator door labels (in red pen) and in the mortuary register.

At SMH, if funeral directors or porters bring in a body out-of-hours, they place the body in the most appropriate vacant space and leave the paperwork in the mortuary office. The details of the deceased are entered in black pen on the white board and the mortuary team reviews all new cases the next day, changing the details on the white board to red pen to highlight that the body has been checked. Surnames which are the same or similar are highlighted, both on the refrigerator door labels, on the white board and in the mortuary register.

The details of tissue specimens and organs taken for analysis during PM examination at WH and SMH are recorded on the histopathology request card and on the Coroners ‘Next of kin statement’. These details are then entered into the Cellular Pathology database and on the ‘slide dispatch spreadsheet’ stored on the shared drive (which can be accessed by all Cellular Pathology staff, including mortuary staff on both sites). Bodies which require repatriation of tissue specimens are highlighted in the PM register and on the refrigerator door labels (WH and SMH) and additionally on the white board (SMH).

Wet tissue specimens removed as part of Coronial or consented PM examinations at WH are delivered by mortuary staff to the WH Histopathology Department for histological analysis. Tissue specimens from SMH are delivered to the WH Histopathology Department at by hospital transport.

Body fluid specimens removed as part of Coronial or consented PM examinations at WH are delivered to the WH Biochemistry Department for toxicological analysis or are sent to SMH by hospital transport and then sent externally for toxicological and asbestos fibre analysis. Body fluid specimens from SMH are delivered to the WH Biochemistry Department by hospital transport or are sent externally for toxicological and asbestos fibre analysis. External transportation is by a dedicated courier under agreement.

Wet tissue and body fluid specimens removed as part of Home Office PM examinations are transported by a specific courier company to a separate HTA-licensed establishment for analysis.

Brain tissue/whole brains, and occasionally cardiac tissue/whole hearts, are transported offsite for specialist examination. They are transported by a dedicated courier company from WH under agreement to separate HTA-licensed establishments (see *Advice*, item 9).

Funeral directors collect bodies throughout the day and bring their own documents (either release forms, signed by families, or the relevant disposal paperwork). These documents do not contain enough fields to add the three unique identifiers and some bodies are released using one identifier alone (see *Advice*, item 3). Bodies under Coronial authority are only released when Coronial release documents have been received directly by the mortuary.

Cellular Pathology (WH Histopathology)

The Histopathology Department has dedicated storage areas for wet tissue, tissue blocks and tissue slides. The department uses the same electronic database as the mortuary to record sample details, including consent for the use of samples after determining the cause of death, and the slide dispatch spreadsheet. The specimens may be stored with appropriate consent for use for various scheduled purposes including: (i) obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person); (ii) research (as defined above); and (iii) education or training relating to human health.

A small number of archival blocks and slides are stored offsite at a separate HTA-licensed establishment.

Accident and Emergency Department (SMH)

The Accident and Emergency Department manages approximately five cases of sudden or unexpected death in infants and children (SUDIC) each year. In such cases, specimens (whole blood, urine and cerebrospinal fluid) are removed by paediatric clinicians in a secure area in the department and sent to the WH Biochemistry Department by hospital transport.

There is no PD overseeing activities in this Department (see *Advice*, item 1).

Maternity Unit (SMH)

Consent for stillbirth and perinatal PM cases is sought by Maternity Unit staff using the Stillbirth and Neonatal Deaths (Sands) consent form and information leaflet. Consenting staff are required to complete the WH consent training programme.

The Maternity Unit is secured by key card access and contains one refrigerator for the storage of stillbirths and perinatal deaths. The refrigerator temperature is recorded manually on a daily basis by trained Maternity Unit staff but it is not linked externally. If temperatures exceed the set limits, a local audible alarm is sounded. There are dedicated Maternity Unit staff who liaise with mortuary staff for the movement of bodies, when required. Bodies are transported to the mortuary by mortuary staff. The audible alarm system is currently not tested (see shortfall against PFE2(e)). The refrigerator is subject to regular servicing and preventative maintenance (see *Advice*, item 21). There was one traceability issue with this system (see *Advice*, item 4). There is no PD overseeing activities in this Unit (see *Advice*, item 1).

Gynaecology Department (SMH)

Pregnancy remains up to 16 weeks are transported by hospital transport to the WH Histopathology Department for histological analysis and then transferred to SMH mortuary for burial. Fetuses of more than 16 weeks gestation are transferred to the SMH mortuary by APTs for release to funeral directors for burial or cremation.

Pregnancy remains are considered to be tissue from the living and the establishment has detailed procedures governing the management and disposal of such remains.

Specimens stored under PACE

Home Office PM examinations take place at this establishment. Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, the management of tissues and organs taken for criminal justice purposes were reviewed by the HTA at this site visit 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.

Description of inspection activities undertaken

The timetable for the site visit inspection was developed after consideration of the establishment's previous inspection reports, compliance update information and communications with the HTA. The inspection included a visual inspection of the hub site (Cellular Pathology – Mortuary and Histopathology Department) and satellite site (Mortuary, Accident and Emergency Department and Maternity Unit), discussions and interviews with key staff, and a review of documentation. Interviews were held with: the DI, CLHC, one PD from each mortuary, two APTs (one senior APT and one trainee), the Lead Biomedical Scientist for Histopathology, a consultant pathologist and the the Head of WH Portering Services.

A documentation review and horizontal and vertical audits were carried out.

- At the hub, a horizontal traceability audit was conducted on three randomly selected bodies in the refrigerators. Body location and identification details on wrist and ankle tags were checked against the labels on the refrigerator doors, mortuary register and Cellular Pathology database. There were no discrepancies noted.
- A vertical audit was conducted on the removal of tissue during PM examination from three randomly selected cases (two Coronial and one consentedcase). The specimens had been processed into blocks and slides. Specimen details were checked against the PM register, the histopathology request card, the Cellular Pathology database, the slide dispatch spreadsheet and the families' wishes on the completed Coroner's 'Next of kin statement' or Hospital 'Consent form for adult PM examination', as appropriate. The physical blocks and slides were sought where applicable and the numbers checked against the records. There was full traceability, with no discrepancies noted.
- At the satellite, a horizontal traceability audit was conducted on four randomly selected bodies (two adults in the refrigerators, one adult in the freezer, one stillbirth). There were no discrepancies noted.
- A reverse vertical audit was conducted on the removal of tissue during PM examination from three randomly selected cases (two Coronial and one consented case). There was full traceability in two of the cases and one minor discrepancy in the third (see *Advice*, item 10).

Inspection findings

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

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	There are no meetings where governance matters relating to licensed activities are discussed. Such meetings will be especially important in the light of: (i) a new DI being in place (April 2017); (ii) a new CLHC being in place (June 2017); (iii) new HTA Codes of Practice having been introduced. In these meetings, the DI is advised to consider including items such as standardisation of documents across both sites, changes to standarsd operating procedures (SOPs), audits and their findings, competence and training, management of incidents (including HTA reportable incidents, HTARIs), risk assessments, equipment maintenance and updates from the HTA (e.g. e-newsletter items). The meetings should have an agenda and minutes should be recorded and circulated. The minutes should include timelines for identified actions and there should be a standing agenda item for discussing progress against actions identified at previous meetings. All PDs involved in licensed activities should be invited to attend the meetings, as well as the CLHC. The DI may also wish to consider whether to include representatives from other departments (e.g. Clinical Governance, Information Technology, Estates) to help develop the establishment's working practices.	**Minor**

GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	The establishment has a Trust level policy (Serious Untoward Incident Reporting, CPM POL 2) which: • Refers to the older HTA classification of serious untoward incidents (SUIs) rather than HTA reportable incidents (HTARIs). • Is past its review date and was written and reviewed by the same individual. • An up-to-date SOP is required which contains a full list of the HTARI reporting categories.	**Minor**

b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents	The up-to-date SOP should give details of: • How to report HTARIs and the reporting timeframe. • Who should report them in the DI's absence.	**Minor**
c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed	The up-to-date SOP should give details of: • How follow up actions are identified (i.e. corrective and preventative actions) and completed • The follow up reporting requirements.	**Minor**
d) Information about incidents is shared with all staff to avoid repeat errors	The DI should ensure that information about incidents is shared with all staff to avoid repeat errors and should ensure that all relevant staff have read and understood the document.	**Minor**

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	During the inspection it was noted that the slide dispatch spreadsheet contained approximately 15 Coronial cases, going back over three years, where the wishes of the family was not known. There is no procedure which covers communication with the Coroner's Office to follow up such cases and there is no procedure to determine steps to take if no decision is made by the family.	**Minor**

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 establishment recently reported an incident to the HTA concerning the remote alarm callout system, where routine tests of the paediatric refrigerator in the SMH body store revealed that it was not connected to the remote alarm system. During the inspection it was noted that: • The testing of the remote callout system for body store refrigerators at WH and SMH was not carried out. • The audible alarm system for the refrigerator in the Materity Unit was not routinely tested. • The refrigerator in the Maternity Unit was not linked to the remote callout system. • The establishment had not risk assessed the impact these current arrangements could have on the dignity of the deceased.	**Major**

Advice

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

No.	Standard	Advice
1.	N/A	The DI should appoint a PD in the Accident and Emergency Department and on the Maternity Unit and notify the HTA of their names and positions.
2.	GQ1(a)	The DI is advised to ensure that mortuary premises and practices are included in the Cellular Pathology Quality Management System and the Quality Manual (PATHQM005).
3.	GQ1(a)	The DI is advised to consider implementing a standardised release form for bodies that details the three identifiers required for identification checks on releasing a body, and to update the relevant SOP.
4.	GQ1(a)	During the inspection, a discrepancy in the transfer of one stillbirth from the Maternity Unit to the mortuary was noted. The Maternity Unit had no record of the transfer although it was in the mortuary records. The DI is advised to ensure that the Maternity Unit SOP includes the transfer procedure and that records of transfer from the Maternity Unit form part of the audit schedule.
5.	GQ4(a)	The SMH mortuary register consists of loose pages held in a binder. The DI is advised to consider using a more permanent, bound, mortuary register to prevent loss or damage of pages.
6.	GQ6(a)	The DI is advised to consider risk assessing the following premises for space and security to ensure the dignity of the deceased: • The area in Accident and Emergency Department where removal

		takes place. • The area in the Maternity Unit where storage takes place.
7.	T1(b)	To further strengthen traceability, the DI is advised to consider using the mortuary register number, assigned to each body when the body arrives, to label the refrigerator door, the whiteboard and the wrist and toe tags.
8.	T1(g)	The DI is advised to consider using full names when recording specimens on the histopathology request card to ensure a more robust identification and traceability system.
9.	T1(g)	The DI is advised to consider modifying the SOP for transportion of organs and tissue offsite to include the steps: • the courier signs to confirm receipt when picking up specimens; • the receiving establishment faxes to confirm arrival of specimens.
10.	T1(g)	During the inspection, it was noted that two blocks had been sent offsite for further immunohistochemistry and assessment for asbestos bodies but there were no records of the transfer, the number of slides cut, and the return of the slides. The DI is advised to ensure that the slide dispatch spreadsheet and records of transfer and receipt of blocks and slides from the Histopathology Department form part of the audit schedule.
11.	PFE1(a)	During the inspection, it was noted that the WH PM room wall was damp and the floor had been damaged in some areas. The DI is advised to assess this and to include repairs to the PM room in the regular maintenance programme so it remains fit for purpose.
12.	PFE1(c)	During the inspection, it was noted that the cleaning schedule for the WH Body Store and PM Room was incomplete. The DI is advised to ensure that this schedule is completed on a regular basis.
13.	PFE1(e)	Porters have their own key to access the WH Mortuary out of hours. The DI is advised to ensure that mortuary staff are aware of how porters access the key. For instance, whether it is a single key that is signed out and back in again. The DI is advised to consider documenting this in an SOP.
14.	PFE1(e)	The DI is advised to consider creating a visitor book for the WH Mortuary to be completed by estates staff and other visitors, to ensure protection against unauthorised access.
15.	PFE1(e)	The DI is advised to consider documenting the monthly review of swipe card access logs to ensure protection against unauthorised access to the SMH mortuary.
16.	PFE2(f)	The DI is advised to ensure that the set temperature ranges for the alarm system are documented and are recorded on labels on freezers and refrigerators.
17.	PFE2(f)	The DI is advised to consider initiating a programme by which, at suitable timeframes, the temperature plots from the monitoring system are reviewed. This may help to identify a potential failure of the system before it occurs.
18.	PFE2(f)	The DI is advised to consider placing a maximum/minimum thermometer in the Maternity Unit refrigerator to ensure that temperature deviations outside

		times of manual monitoring are assessed.
19.	PFE3(a)	During the inspection, it was noted that the WH PM room sinks and tables had some damaged 'feet' and there was a small amount of rust and discoloration on the SMH PM tables. The DI is advised to assess this and to include repairs to the PM room equipment in the regular maintenance programme so it remains fit for purpose.
20.	PFE3(c)	The DI is advised to consider keeping records of service visits for the ventilation system locally in each mortuary to ensure that facilities in the PM room are maintained on a regular basis.
21.	PFE3(f)	The DI is advised to consider keeping records of refrigerator and freezer service visits locally in each mortuary and in the Maternity Unit to ensure that facilities in the body store and Maternity Unit are maintained on a regular basis.

Concluding comments

During the inspection areas of strength and good practice were noted:

- The enthusiasm and dedication of the teams in all the Departments and Units inspected.
- There are well lit, spacious and discreetly decorated viewing rooms on both sites.
- The involvement of the treating clinician, a bereavement nurse or bereavement officer and a pathologist in the consenting process.
- The detailed consent training process for adult and paediatric consent.
- The detailed competence training of porters on both sites.
- The use of a spreadsheet for specimens collected during PM examination which is accessible to staff at both sites.
- The SMH mortuary security arrangements, where the hospital's security department holds an electronic record of everyone entering the mortuary premises, which operates via staff identification cards.
- The use of colour coded magnets on refrigerator and freezer doors at SMH and colour coded wristbands to indicate if a specimen has been taken during PM examination and to confirm if the specimen is to to be returned prior to releasing the body

There are a number of areas of practice that require improvement, including one major shortfall and six minor shortfalls. The HTA has given advice to the DI with respect to the Governance and Quality systems, Traceability and Premises, Facilities and Equipment standards, as well as advice on licence management.

The HTA requires the DI 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: 3 October 2017

Report returned from DI: 17 October 2017

Final report issued: 9 November 2017

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: 21 May 2018

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.