Site visit inspection report on compliance with HTA minimum standards

Royal Stoke University Hospital

HTA licensing number 12224

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**

14-15 & 21-22 September 2016

Summary of inspection findings

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

Although the HTA found that Royal Stoke University Hospital (the establishment) had met the majority of the HTA standards, shortfalls were found in relation to aspects of governance systems, particularly procedural documentation and tissue traceability. The HTA has also given advice to the Designated Individual (DI) on a range of issues, including audits, record keeping and personal protective equipment.

Particular examples of good practice observed during the inspection are included in the concluding comments section of the report.

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

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. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The establishment's HTA licence covers premises at two locations, Royal Stoke University Hospital (the hub, for the purposes of HTA licensing) and County Hospital, Stafford (the satellite). The Designated Individual is a Consultant Histopathologist and the Corporate Licence Holder contact is the Deputy Director of Infection Prevention.

The Hub

The mortuary facility at the hub site consists of a body store and two post mortem rooms; the histopathology laboratories are nearby. The body store has a total of 201 storage spaces of which 170 are standard fridge spaces, five are infant/stillborn spaces and four are bariatric spaces; five are set aside for forensic cases and five for high risk cases. There are five freezer spaces and seven additional bariatric spaces provided in an additional permanently maintained temporary storage unit. The establishment informed the HTA that there are plans and funding in place to convert some space within the existing body storage area into a permanent, walk-in bariatric storage facility, which will have racks for storage trays and room to accommodate bariatric bodies on beds.

Fridge and freezer temperatures are manually recorded during normal working hours. In addition, an electronic temperature monitor alarms locally within the storage area should the temperature deviate from the expected range. The expectation is that the alarm would be

heard by portering staff out of hours, who would contact an engineer and if needed, the on-call member of mortuary staff. At the time of the inspection, a new temperature monitoring system within the body store had been installed but was not yet functional. This system will automatically alert an on-call member of staff of temperature deviations out of hours. It will also allow for temperature trend monitoring, which might predict a potential fridge or freezer failure. Advice has been given to the DI regarding temperature monitoring of the storage facility and the use of the new temperature monitoring system (see advice item 10).

Following a death in the hospital, porters bring the deceased to the mortuary and book them in using a dedicated porter booking-in sheet. Mortuary staff review the booking-in sheet for newly received bodies and check the identification details recorded on the label attached to the wrist of the deceased. They also check the condition of the body, complete a mortuary registration sheet and enter the deceased's details onto the establishment's electronic database. Porters do not undertake viewings out of hours or release bodies. If help is needed with a specific case out of hours, the portering staff contact the on-call member of mortuary staff who attends to assist. The on-call mortuary staff always attend to receive forensic cases.

Porters receive training in handling the deceased and booking deceased into the mortuary. Only after this training has been completed are they given access to the mortuary. During the inspection we spoke with the head porter at the hub premises who confirmed that training is undertaken and recorded for all porters working with the deceased or in the mortuary.

Adult post mortem examinations, including forensic cases, are undertaken at the hub under the authority of the Coroners for North Staffordshire and South Staffordshire. Where the cause of death has been certified but there is medical interest in a case, the establishment may undertake an appropriately consented hospital post- mortem examination; however, there have been none of these in recent years.

During the inspection, the HTA inspectors were informed that consent for adult hospital post-mortem examinations is sought by the clinician who was treating the deceased, with the support of a member of the bereavement services team who has received training in the appropriate seeking of consent and use of the consent forms. Bereavement staff can answer any questions that the person giving consent may have about the procedure. It is understood that there have been changes to staffing within the bereavement team following a recent structural re-organisation at the Trust and the role of bereavement staff in the consent seeking process may have changed. Advice has been given to the DI regarding reviewing the consent procedures relating to adult post mortem examinations to ensure that staff are aware of their role in the seeking of consent (see advice item 1).

Earlier in the year, the lack of availability of pathologists to undertake coronial post-mortem examinations resulted in delays between the deaths being reported to the Coroner and post mortem examinations taking place. The establishment has since engaged locum pathologists to help reduce the backlog of cases and reduce delays.

In the weeks prior to the inspection, the establishment had also stopped undertaking post-mortem examinations on community deaths for the South Staffordshire Coroner, with the exception of bariatric cases, which are brought in by funeral directors who have been trained to book them in out of hours. Community cases from this jurisdiction are now taken straight to the nearby public mortuary for post mortem examination and this arrangement has helped to reduce the time taken to complete PM examinations.

The establishment has been undertaking around 800 post-mortem examinations a year; this number is likely to reduce following the reasons set out above. In addition, it undertakes around 15 defence (second) and around 30 forensic post-mortem examinations per year. The establishment does not undertake paediatric post-mortem examinations; these are

transferred to another HTA licensed mortuary. Consent for infant post-mortem examinations is, however, sought by medical and midwifery staff at the establishment.

The main post mortem room has four post mortem tables, one of which is suitable for bariatric cases. Bodies are transferred into the post mortem room via a set of pass-through fridges. Prior to the examination commencing, two Anatomical Pathology Technologists (APTs) undertake an identity check of the body; a second check is conducted by the pathologist against the coronial paperwork. Once the identity has been confirmed and the pathologist has carried out an external examination of the body, they authorise the APT to eviscerate the body. Details of the deceased are recorded onto a wipe-clean sheet, which is taken into the mortuary so that the original paperwork cannot be contaminated. These sheets are retained for a period of 30 days and are then wiped clean and reused. Since the details on the sheet are used in the identification process, advice has been given to the DI about maintaining a copy of these sheets permanently as a record of the examination process (see advice item 6).

The mortuary at the hub has a separate dedicated high-risk post mortem room for high-risk cases, including hepatitis B, hepatitis C, tuberculosis and HIV. Personal protective equipment (PPE) is available for staff to use; however, during the inspection it came to light that the masks which are available to staff are not suitable for staff with facial hair, as an appropriate seal cannot be made. Personal respirators are also available, but at the time of the inspection it was not clear if these were functional. Advice regarding PPE has been given below (see advice item 9).

Any tissue retained during post-mortem examination for further analysis is sent to the laboratory located close to the mortuary for processing into blocks and slides and review by the pathologist. As well as recording the details of the deceased, the wipe-clean sheets are used to record details of retained tissue (advice item 6 also includes advice on this issue).

Once the slides have been examined by the pathologist, the blocks and slides are stored in a dedicated deceased tissue block and slide store pending receipt of the family's wishes from the Coroner and the end of Coronial authority. Monthly audits of retained tissue are undertaken by the laboratory staff in order to reconcile retained tissue with any wishes of the family and notification that the Coroner's authority has ended. Once notified by the Coroner that that their interest in a case has ended, the establishment acts upon the family's wishes and either sensitively disposes of the tissue, returns the samples to the family or stores them in the archive. One of the Coroners offers a two-year retention period on the family's wishes form. The monthly audit includes a review of all retained tissue and the period for which it should be retained. Where tissue has reached its maximum retention period, the establishment disposes of the tissue.

The maternity department at the hub premises may store the bodies of stillborn babies in cold cots prior to them being transferred to the mortuary so that, where appropriate, parents have the opportunity to spend time with them on the ward. Longer term storage does not take place within the maternity department and the bodies are transferred to the mortuary for storage prior to release to the family or for post-mortem examination.

Consent for infant post mortem examinations, which are undertaken at other HTA licensed premises, is sought jointly by a member of the department's medical staff and a member of the midwifery staff who has been trained in the seeking of consent. Eight midwives have been trained in the consent seeking process by the establishment which undertakes the post-mortem examinations. Training includes the use of the consent forms and supporting information, in addition to observation of an infant post-mortem examination. The training helps to assure the DI that appropriate and valid consent is being sought and enables the midwives to answer any questions that the parents may have. Regular refresher training on

consent is provided to midwifery staff, giving them an opportunity to review their practice and be made aware of any changes to the procedure and associated paperwork.

In cases of sudden unexpected death of infants or children (SUDIC) where deceased children are brought to the hospital or die in the accident and emergency (A&E) department, removal of various tissue samples from bodies of the deceased may take place. The removal takes place in a dedicated room located in the A&E department, which provides a private area for the sampling to take place. Paperwork detailing and recording the samples taken is available to staff within the department. Most sampling in SUDIC cases is undertaken by a paediatrician; however, it can also be undertaken by other medical staff under the guidance of a paediatrician. The Coroner has given authority for sampling to take place in SUDIC cases and is therefore not contacted prior to sampling but alerted to all such cases by the establishment's bereavement staff.

At the time of the inspection the DI had not nominated a member of staff in the maternity department, A&E department or bereavement services to act as a Person Designated and oversee the licensed activity of removal or the seeking if consent for infant or adult post mortem examinations (see advice items 3 and 11).

The Satellite

The establishment's satellite site consists of a body store located at the County Hospital in Stafford. The body store consists of 32 body storage spaces, four of which can operate as a freezer if required. There is an additional fridge with capacity to hold three bariatric bodies. As at the hub premises, the temperature of the fridges and freezer is recorded manually during normal working days. The storage facility is also monitored by two separate remote monitoring systems. This is as a result of the implementation of a new temperature monitoring system, which is the same as the newly-installed monitoring system at the hub premises. At the time of the inspection the new system was not fully operational. A second, existing temperature monitoring system already exists at the satellite premises and will remain in operation until the new system is fully commissioned. The new monitoring system will contact the on-call mortuary staff if the storage temperatures deviate from the expected range. The existing monitoring system alarms at the hospital's switchboard whose staff alert the on-call mortuary staff. Advice has been given to the DI regarding testing the remote temperature monitoring systems at both the satellite and hub premises (see advice item 10).

At the satellite premises, the procedures regarding body receipt mirror the procedures at the hub premises. The porters bring bodies to the mortuary and record the details on the porter booking in sheet. Mortuary staff review the booking in sheet, view the bodies that have been brought to the mortuary and complete a mortuary registration sheet prior to entering the details onto the electronic records system. Bodies from the community which are due to have a post-mortem examination are transferred directly to the public mortuary from the satellite site, with the exception of bariatric cases which are sent to the hub premises. Following the post-mortem examination, bodies are returned to the satellite site for storage prior to being released to the funeral director. Traceability of bodies being transferred is achieved through use of the mortuary registration form, which is used to record details of the body transfers.

Porters at the satellite site do not release bodies out of hours but they do conduct viewings of bodies during these times. The establishment reported that the porters have received training to do this and have had their competency assessed. Records of this training were not reviewed as part of this inspection and the inspectors did not speak with the head porter at the satellite.

During the inspection of the hub premises, staff within the maternity department informed the inspectors that no consent for post mortem examinations of infants is sought at the establishment's satellite premises. Should consent be sought in such cases, this would be undertaken by staff at the hub premises. As a result, the maternity department at the satellite

premises was not visited during the inspection. Additionally, while inspecting the satellite premises, the HTA met with senior medical staff in the A&E department, who confirmed that no sampling in relation to SUDIC cases is undertaken at the satellite premises, bodies being transferred to the hub site.

The Inspection

The establishment has been licensed since May 2007 and this was its third routine site-visit inspection to assess whether it continues to meet the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's last self-assessed compliance information as well as pre-inspection discussions with the DI and review of the previous inspection findings. During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment staff, one of the Coroners and staff from the second Coroner's office were undertaken. There have been multiple changes in staffing and procedures at the establishment over the 18 months prior to the inspection and during the site visit, the HTA felt that in order to fully understand these changes and how the establishment is working, more time was needed. With the agreement of the DI and establishment staff, the inspectors returned the week after the initial visit to undertake further interviews and reviews of documentation.

It was noted during the inspection that the significant changes in staffing included staff with senior roles within the mortuary. These changes have resulted in some elements of the establishment's quality management system not functioning as it should and many procedures have passed their review dates, are out of date and do not reflect current practice. Some documentation had been updated within the previous twelve months; however, again as a likely consequence of the staffing changes and subsequent changes in procedures, this documentation does not always accurately reflect the practices taking place within the mortuary. Although the DI and the establishment's senior management team have recognised the difficulties that have resulted from the changes to staffing and have brought in staff from elsewhere in the Trust with expertise in quality management, there is still significant work to be done. A major shortfall has been identified in relation to procedural documentation and some aspects of the quality management systems.

During the inspection, an audit of bodies stored at both the establishment's hub and satellite premises was undertaken. At the hub premises, three bodies were selected at random and details including name, date of birth and hospital number on the body's wristbands and the physical location of the body were cross checked against the details on the paperwork received from the ward, the mortuary registration from and the electronic mortuary database. No anomalies were found.

At the satellite premises, three bodies were selected at random and details including name, date of birth, hospital number and, in the case of one body received from the community, the address, on the body's wristbands and the physical location of the body were cross checked as above. One discrepancy was found between the details in the electronic database and the paperwork with the body, whereby the month in the date of birth was recorded as August in the electronic system and September on the paperwork. Advice to conduct audits between the paper records and the electronic system has been given to the DI (see advice item 4).

A tissue traceability audit was also undertaken. Four coronial post- mortem examination cases, two each from the North and South Staffordshire Coroners' jurisdictions were chosen at random. In all four cases the information contained in the establishment's electronic laboratory information management system (LIMS) was reviewed, the physical blocks and slides sought and the coronial family wishes form reviewed. In the first of the four cases that were audited, there was no record of the tissue which had been processed into blocks and slides in the establishment's LIMS. For this case, the form which is used to inform the Coroner that tissue had been taken and retained following the post mortem examination,

including details of the tissue types that were taken for further analysis, was sought and also reviewed. The number of physical blocks correlated with the number expected from the Coronial paperwork however, four of the six expected slides were not present in the slide store and it was thought that these had not been returned to the laboratory by the pathologist who may have still required them for analysis purposes.

The remaining three cases that were audited did have details of the tissue retained in the LIMS and the physical numbers of blocks and slides correlated to these records. In one of the three cases, a family had not returned any wishes to the Coroner and, in accordance with the Coroner's and establishment's usual procedure, the retained tissue had been sensitively disposed of. Records of the disposal of the tissue were reviewed.

In summary, one of the three cases had no details relating to retained tissue recorded in the establishment's LIMS and four of the slides from that case could not be accounted for, although it was thought that they would still be with the pathologist. During the audit, a general review of the establishment's traceability systems was also undertaken and it was found that there was a subset of cases where, as a result of the monthly audit of cases and retained tissue, that some blocks and slides could not be located. It was thought that the missing tissue could have been misfiled or remained with the pathologist. During the inspection, a review of the missing tissue was undertaken by establishment staff and some of the missing blocks and slides were located. Although some tissue had been found, a number of slides remained unaccounted for. Without being able to locate all tissue taken during post mortem examinations, there is a risk that a family's wishes may not be able to be acted upon appropriately.

In addition, there was a small subset of blocks and slides from four post mortem examinations which had been retained with appropriate consent, for use in education and training. It had been decided that due to the nature of the pathology of these samples they should be retained separately from other retained tissue and used for information sharing and training with pathologists who may not have seen similar cases. Some tissue that had been retained for training purposes had been retained prior to the Human Tissue Act 2004 (HT Act) coming into force and was therefore, not subject to the consent requirements of the HT Act. Other tissue had, however, been taken more recently and was from cases where consent for retention was for a fixed period of time from the date of the post-mortem examination. Although at the time of the inspection, no tissue had been retained past the time period for which consent had been given, the establishment has no system in place to review the tissue held in the teaching files and the relevant consent to ensure that tissue is not retained for longer than it should be.

Inspection findings

The merger of the two hospitals in 2014 resulted in significant reorganisation across the Trust. The mortuary service has experienced substantial disruption and changes in staffing at management level. During this time, the current team, including the DI who has only been in the role since March 2016, have worked hard to bring some stability to the mortuary and on making improvements.

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	During the inspection it was found that many of the establishment's procedural documents had passed their review date and had not been updated to reflect changes in practice. Additionally, recently updated procedures did not accurately reflect practice as they referred to incorrect documentation such as 'mortuary ledger' and previous procedures such as an out of date same/similar name procedure. As the establishment has experienced significant changes in staffing and has brought in locum staff to help with workloads, it is important that accurate documentation is available for staff to be trained in and follow.	**Major**
GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	During an audit of tissue taken and retained during post-mortem examinations, it was found that there is some tissue that could not be accounted for and therefore, traceability has been lost (see advice item 8) Additionally, there are no procedures relating to the 'teaching set' of tissue to ensure that tissue is not retained for longer than to the consent allows. No tissue has been stored for longer than it should have been; however, the lack of an appropriate procedure to keep this tissue under review, creates a risk that this may occur in the future.	**Major**

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The establishment does not have a specific standard operating procedure (SOP) relating to adverse events/incidents that require reporting to the HTA. The establishment should have documented procedures in place that specify what type of adverse event/incident is reportable to the HTA, how it is reported, who is responsible for reporting it, who reports it in their absence and within what timeframe it should be reported. Although the establishment has reported incidents to the HTA in the past, the lack of a formally ratified document to use in training new and existing staff increases the risk that an incident may not be recognised as reportable to the HTA.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to review the procedure for seeking consent for adult post mortem examinations and associated documentation to assure himself that it remains appropriate following changes to the staff roles within the bereavement team following a recent structural re-organisation. He should also ensure that it continues to reference the appropriate supporting information which is given to the person giving their consent. Additionally, the DI is advised to version control the consent form, so staff can be assured that they are using the most up to date version of the documentation.
2.	C3	The establishment reported that it has not undertaken an adult hospital consented post-mortem examination for around three years. The DI is advised to undertake refresher training for staff involved in seeking consent for adult post-mortem examinations to ensure that they are aware of the correct procedure and associated documentation.
3.	C3	The DI is advised to appoint a Person Designated who is involved in seeking consent for adult and infant post mortem examinations. This will help ensure they are made aware of any issues that arise in relation to this activity and enable them to better disseminate any licensing updates or information to staff relating to this activity. In addition, the DI is advised to periodically involve staff responsible for supporting the seeking of consent for adult and infant post-mortem examinations in the establishment's governance meetings, so that they can benefit from information shared about post-mortem examination or related matters.

4.	GQ2	Evidence of audits taking place at the establishment was reviewed during the inspection. The DI is advised to continue with this audit activity as it has proved helpful in identifying areas requiring improvement. In addition, once updated and accurate SOPs describing the establishment's procedures are put in place, the DI is advised to introduce process/observational audits of establishment staff in relation to the new procedures. This will not only help to assure the DI that the new SOPs are being followed properly but that they accurately reflect practice and do not require further amendment. The DI is also advised to audit the establishment's electronic database which contains identity details of the deceased. During the inspection, a discrepancy between the details held on the electronic system and the paperwork was found; regular audits will help the DI to determine how frequently such discrepancies arise and if any corrective action is required.
5.	GQ3	Some staff reported that regular appraisals have not been taking place. This is likely to be as a result of the changes occurring at senior levels within the mortuary over recent months and the subsequent changes in the line management structures. The DI is advised to ensure that all staff at the establishment have regular appraisal, so that that they have an opportunity to review their performance and discuss any training and development needs with their managers.
6.	GQ4	The establishment uses a wipe-clean sheet in the post mortem room to record the details of the deceased and any tissue retained. These sheets are only stored temporarily until tissue has been recorded on other documentation such as histopathology request forms and has been received by the laboratory. The DI is advised to consider maintaining this information, perhaps as a scanned version, so there is a permanent record which may be reviewed at a later date if necessary.
7.	GQ4	The establishment monitors the temperatures of the storage fridges and freezers daily and records this data on a wipe-clean sheet in the mortuary. Recently staff have started to scan the data from these sheets onto the establishment's computer system to maintain it as a permanent record. The DI is advised to update the document procedure to reflect this additional step and to audit the process to assure himself that it is being carried out.
8.	GQ6	Currently, the DI has no effective way of knowing when tissue slides are being used by the pathologist and therefore not present in the storage area. They should consider how best to ensure that full traceability is achieved and that the whereabouts of all samples is known.
9.	PFE2	Personal protective equipment (PPE) is available for staff; however, during the inspection it was found that the masks which are available to staff are not suitable for staff with facial hair as an appropriate seal cannot be made. Personal full face respirators are also available, but it is not clear if these are functional. The DI is advised to review the PPE available to staff undertaking post-mortem and high risk post-mortem examinations and ensure that appropriate equipment is available and used by staff. Face-fitted masks are recommended.
10.	PFE3	The DI is advised to press ahead with implementation of the newly-installed remote temperature monitoring system, which will alert staff of temperature deviations away from the expected range at both the hub and satellite

		premises. In addition, once operational, the DI is advised to implement a procedure to verify that the alarm system is operating as expected, contacts the on-call member of mortuary staff and that the on-call staff respond appropriately to the alarm alert.
11.	General	The DI is advised to appoint a Person Designated who is involved in the removal of samples from the bodies of deceased infants and children in the A&E department and who can make them aware of any issues that arise in relation to this activity and who will in turn, be better able to disseminate any licensing updates or information to staff relating to this activity. In addition, the DI is advised to periodically involve staff responsible for overseeing this licensable activity in the establishment's governance meetings so that information can be more easily shared.

Concluding comments

Despite the shortfalls identified during the inspection, areas of good practice were observed. For example, the work undertaken by staff in the maternity department at the hub premises, who have reflected upon the processes surrounding the seeking of consent for infant post mortem examinations and specifically occasions when the person giving consent does not have English as their first language. The establishment has access to appropriate interpretation services; however, the midwifery staff felt that some bespoke training to increase the understanding and awareness of interpreters about the particular sensitivities surrounding this type of consent, the language and terms used, would be beneficial. As a result, they developed awareness training for interpreters which will help to facilitate the seeking of valid and appropriate consent.

There are a number of areas of practice that require improvement, including two major shortfalls and one minor shortfall. The HTA has also given advice to the Designated Individual on a range of issues.

The HTA requires that the Designated Individual addresses the shortfalls by submitting a completed corrective and preventative action (CAPA) plan 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 / subject to compliance with the additional conditions applied to the licence.

Report sent to DI for factual accuracy: 31 October 2016

Report returned from DI: 18 November 2016

Final report issued: 28 November 2016

Completion of corrective and preventative actions (CAPA) plan

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

Date: 22 November 2017

Appendix 1: HTA standards

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

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

Governance and quality system standards
GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process
• Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include: o post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases o record keeping o receipt and release of bodies, which reflect out of hours arrangements o lone working in the mortuary o transfer of bodies and tissue (including blocks and slides) to other establishments or off site o ensuring that tissue is handled in line with documented wishes of the relatives o disposal of tissue (including blocks and slides) *(Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)* • Policies and procedures are regularly reviewed (for example, every 1-3 years). • There is a system for recording that staff have read and understood the latest versions of these documents. • Deviations from documented SOPs are recorded and monitored.
GQ2 There is a documented system of quality management and audit
• There is a quality manual which includes mortuary activities. • Policies and SOPs are version controlled (and only the latest versions available for use). • There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits). • Audits include compliance with documented procedures, records (for completeness) and traceability. • Audit findings document who is responsible for follow up actions and the timeframe for completing those actions. • Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why. • There is a complaints system in place.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
• Staff are appropriately trained/qualified or supervised. • Staff have annual appraisals. • Staff are given opportunities to attend training courses, either internally or externally. • Attendance by staff at training events is recorded.

- There is a documented training programme for new mortuary staff (e.g. competency checklist).

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

- 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.
- There are documented SOPs for record management.

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outline responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- 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.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person’s

family.

- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

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.