

## **Site visit inspection report on compliance with HTA minimum standards**

### **West Suffolk Hospital**

**HTA licensing number 12242**

**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**

**19 January 2017**

### **Summary of inspection findings**

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

Although West Suffolk Hospital (the establishment) had met the majority of the HTA standards, one minor shortfall was found in relation to consent.

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

### **The HTA's regulatory requirements**

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

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.

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**

This report refers to the activities carried out at West Suffolk Hospital (the establishment). This was its third routine site visit inspection (the previous inspections took place in 2009 and 2013), and included: a visual inspection of the body store, post mortem (PM) suite, viewing area, and histology department; interviews with members of staff; and a review of governance and quality documentation. The Accident and Emergency (A&E) department, where the removal of tissue takes place in cases of Sudden Unexpected Death in Infancy (SUDI) cases, was also visited. The Trust has an agreement with the Coroner and follows documented guidance detailing the types of samples to be taken in SUDI cases.

The Corporate Licence Holder (CLH) is West Suffolk NHS Foundation Trust and the CLH contact is the Trust's Chief Operating Officer. The Designated Individual (DI) under the licence is a Consultant Histopathologist for the hospital. The mortuary is staffed by a Mortuary Manager, a Senior Anatomical Pathology Technologist (APT) and a trainee APT. There are Person's Designated (PD) in A&E, the Intensive Care Unit (ICU), Paediatrics, Histology and the mortuary. There are four Consultant Histopathologists who conduct PM examinations, including the DI.

Approximately 450 PM examinations are conducted each year, including some forensic cases. The majority are on behalf of the HM Coroner for Suffolk and occasionally for Norfolk. High-risk cases are conducted up to category 3. Tuberculosis cases are sent to another HTA licensed establishment. There are a small number of adult hospital consented PM examinations. In these cases, the clinician involved in the patient's care takes consent. All staff must complete the Trust's online consent training before seeking consent.

Perinatal and paediatric cases for PM examination are transferred to Addenbrooke's Hospital. Staff at the establishment seek consent for these using consent forms supplied by Addenbrooke's Hospital, which are based on the SANDS form. Consent forms are checked by an APT for completion and accuracy before making transport arrangements. Addenbrooke's

Hospital emails a release form to the establishment when the body is ready to be returned to the mortuary and the funeral director must present this form to mortuary staff at Addenbrooke's Hospital before the body is released.

The body store has refrigerated space for 86 bodies, four of which are suitable for bariatric bodies. There are four freezer spaces. There is a dedicated fridge bay for products of conception, perinatal and paediatric bodies. All fridges are 24-hour temperature monitored with an audible alarm system, which links to the hospital switchboard and which is tested regularly. Out of hours, the hospital switchboard will phone on-call staff in case of an emergency. Fridges and freezer temperatures are also monitored and documented daily by mortuary staff.

In the event that the mortuary reaches body storage capacity, the establishment has an agreement with a local funeral director who can provide up to ten fridge spaces for contingency storage. It also has an agreement with a local hospital for additional freezer storage.

The main doors to the mortuary are kept locked at all times and staff access is via their ID card, which opens the door.

Bodies are received into the mortuary 24 hours a day. During working hours, porters admit bodies from the hospital, which are brought with a notice of death form that accompanies the body. The porter writes the name of the deceased on the whiteboard against a number before placing the body in a fridge space with the corresponding number. They then place the notice of death form into a locked box in the mortuary.

Out of hours, the coroner's contracted funeral director admit bodies to the mortuary. All coroner's cases are accompanied by a sudden death form. The funeral director staff use an ID card to access the mortuary and phone the porter in charge to let them know when they are coming. They follow the same process for admitting bodies into the mortuary as the porters.

Porters and the coroner's contracted funeral directors are trained by mortuary staff in mortuary procedures. New staff from the coroner's funeral directors will also shadow experienced staff before admitting bodies unsupervised.

At the start of each working day, two APTs check the locked box for notice of death forms or sudden death forms. They also check the whiteboard for new entries. They draw a line through the fridge number on the whiteboard after checking and booking in the body, to indicate that the process has been completed. The fridge number, name of deceased, date of birth, ward/coroner and date/time of death are then recorded onto a daily checklist. For coroner's deaths, the location where the body was found may also be recorded. In the case of same/similar names, APTs will re-write the names in blue marker on the whiteboard. The APTs also record the identification details into a mortuary register and assign each body a unique ID number (see advice item 6).

If a body is brought to the mortuary without identification tags, the APTs contact the relevant hospital staff or the coroner's office. They also report it as an incident on the hospital Datix system.

Bodies are released to funeral directors between the hours of 1:30 pm and 3:30 pm, Monday to Friday. If a body is to be released outside of these hours, this must be arranged with mortuary staff. A member of mortuary staff must always be present during the release of a

body. Funeral directors must present paperwork before release, which is checked by the APT and funeral directors together. A minimum of three identifiers are checked and the APT and funeral director both sign the mortuary register prior to release.

Viewings following a hospital death are arranged by bereavement staff, who liaise with the mortuary. Coroner's viewings are arranged directly between the family and mortuary staff. Before a body is prepared for viewing, two APTs check the identification of the deceased. There are panic alarms for staff who conduct viewings out of hours.

The PM suite has three workstations where PM examinations are carried out. To mitigate the risk of organs being returned to the wrong body, organ buckets are colour coded with corresponding workstations and whiteboards. Tissue taken during the PM examination is cassetted in the mortuary and taken to histology for analysis the same day by mortuary staff. Details of tissue samples are recorded in a central log which is signed by the APT and histopathology staff to aid traceability. This log is kept in the mortuary. After the analysis is completed, tissue is then stored or disposed of according to the wishes of the family.

In the case of an organ retained during a PM examination, a laminated tag that says 'Do not release - tissue/organs waiting to be returned' is attached to the front of the fridge tray to mitigate the risk of releasing the body before the organ is returned.

Audit trails were conducted on three bodies stored in the refrigerators. Body location and identification details on body tags were cross-referenced against the information in the register book. Same/similar name processes were also checked. No discrepancies were found.

An audit trail was also conducted on one hospital consented PM and two coronial cases where histology samples had been retained during the PM examination. Relevant paper records, consent forms, and location of samples in Histology, were checked. Procedures for recording disposal of samples were also checked. No discrepancies were found.

### **Inspection findings**

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

One minor shortfall was found in relation to consent.

Standard	Inspection findings	Level of shortfall
<b>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</b>	<p>There is a consent training presentation which includes the hierarchy of qualifying relationships set out in the Human Tissue Act; however this information is not included in the Trust's consent policy and is important to ensure that consent for post-mortem examination and tissue retention is given by the appropriate person.</p> <p><i>Satisfactory information has been received from the establishment and the HTA considers the shortfall to have been met.</i></p>	<b>Minor</b>

## Advice

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

No	Standard	Advice
1.	C1	The options given on the 'Consent to a Post Mortem on a baby or child' form (Section 1, page 3) are in a different order than on the 'Clinical details for the Pathologists form (Section 2, page 1). The DI is advised to amend one or the other of the forms so that the options appear in the same order and the risk of ticking the wrong box and not acting in accordance with the consent given are mitigated.
2.	C1	When the mortuary receives a 'family wishes form' from the Coroner which indicates their consent for tissue to be retained for use for medical education or research, the DI should ensure that consent was given by the correct person in a qualifying relationship to the deceased so that material is not retained and used without appropriate consent under the HT Act.
3.	C2	During the traceability audit and the review of consent forms, it was observed that the date on which consent for an adult hospital consented PM had been given was not recorded. This date should be clear and easily identifiable on the consent form.
4.	C3	The DI is advised to incorporate regular refresher training for staff who seek consent.
5.	GQ1	The DI is advised to organise regular documented meetings with staff working under the licence to discuss mortuary and licensable activities.
6.	GQ6	When bodies are booked into the mortuary, they are assigned a unique number

		which is written in the register book. When the register book is completed, a new one is started and the numbers begin again from 1. The DI is advised to add the year as a prefix to provide for additional traceability.
7.	GQ6	Toxicology samples are sent for analysis by recorded delivery and staff at the establishment let the receiving laboratory know to expect the samples, but there is no confirmation from the laboratory that the samples have been received. The DI is advised to implement a system whereby mortuary staff receive confirmation of the safe receipt of samples.
8.	GQ7	The Trust's incident policy refers to the need to report serious adverse events and reactions, which relate to the HTA's Human Application Sector only. The DI is advised to include in this policy the need to report mortuary and HTA related incidents.  The DI is also advised to establish a mortuary procedure for HTA reportable incidents, to include: the categories of HTA reportable incidents; the individual(s) responsible for reporting the incident; and the requirement to report these within five days of discovery.
9.	GQ7	Mortuary staff are advised to display contact details in the mortuary of whom to contact out of hours in the case of an incident.
10.	GQ8	There are some risk assessments relating to mortuary procedures, such as misidentification of a body; however, they do not cover all areas. The DI is advised to risk assess the likelihood of an HTA reportable incident occurring.  Risk assessments should include how to mitigate the risks, follow up actions, and who is responsible for these.
11.	PFE2	Mortuary staff are advised to document the weekly cleaning of the fridge room in the mortuary.
12.	PFE5	The DI is advised to ensure that the air ventilation system meets the requirements as set out by the Department of Health recommendation of ten changes per hour. Please see the following link, page 83:  <a href="https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/144029/HTM_03-01_Part_A.pdf">https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/144029/HTM_03-01_Part_A.pdf</a>

### Concluding comments

Many areas of good practice were observed. These included:

- the quality manual is a very high standard and addresses all HTA standards;
- there is a communication board for porters and funeral directors to leave notes to mortuary staff in case they need to inform them of something;
- there appears to be good working relationship between the DI, mortuary, bereavement and other departments involved in licensable activities;
- the establishment immediately acted upon advice given by the HTA during the inspection regarding the fridge alarm settings: and
- during the morning checks of the bodies, last offices are audited and any discrepancies are highlighted immediately with the appropriate ward.

The HTA has given advice to the DI on a range of issues relating to consent, governance and quality systems and premises, facilities and equipment.

The HTA requires that the Designated Individual addresses the shortfall 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 time frames 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 shortfall identified during the inspection.

**Report sent to DI for factual accuracy: 10 February 2017**

**Report returned from DI: 1 March 2017**

**Final report issued: 1 March 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.

<b>Consent standards</b>
<b>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</b>
<ul style="list-style-type: none"><li>• 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.</li><li>• 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).</li><li>• 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.</li></ul>
<b>C2 Information about the consent process is provided and in a variety of formats</b>
<ul style="list-style-type: none"><li>• Relatives are given an opportunity to ask questions.</li><li>• Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event.</li><li>• 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).</li><li>• 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.</li><li>• Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.</li></ul>
<b>C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent</b>
<ul style="list-style-type: none"><li>• 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.</li><li>• Refresher training is available (e.g. annually).</li><li>• Attendance at consent training is documented.</li><li>• If untrained staff are involved in consent taking, they are always accompanied by a trained individual.</li></ul>



## 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:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - 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 draught) 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.