Site visit inspection report on compliance with HTA licensing standards
Inspection date: **8 – 10 October 2019**

Whiston Hospital

HTA licensing number 12043

Licensed under the Human Tissue Act 2004

Licensed activities

Hub and satellite site rows denote whether the site is licensed to carry out an activity; the rows below the hub and satellite rows denote whether or not the activity is currently carried out in that area.

Area	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	Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Hub site **Whiston Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology laboratory	-	-	*Carried out*

Satellite site **Southport and Formby District General Hospital**	Licensed	Licensed	Licensed
Mortuary	-	-	*Carried out*
Accident and Emergency (A&E) department	-	*Carried out*	-
Satellite site **Ormskirk District General Hospital**	*Not licensed*	*Licensed*	*Licensed*
Mortuary	-	-	*Carried out*
A&E department	-	*Carried out*	-

Summary of inspection findings

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

Although the HTA found that Whiston Hospital (the establishment) had met the majority of the HTA's standards, four major and six minor shortfalls were found against standards for Consent, Governance and Quality, Traceability and Premises, Facilities and Equipment.

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.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
a) There is training for those responsible for seeking consent for post-mortem examination and tissue retention, which addresses the requirements of the HT Act and the HTA's codes of practice	Not all staff who seek consent for post-mortem (PM) examinations are trained in this process. • Clinical staff at Whiston Hospital who seek consent for adult hospital PM examinations are not trained in this process. The policy for seeking consent does not state that staff need to be trained. • Consent for PM examination is sought in the neonatal intensive care units at Whiston Hospital and Ormskirk District General Hospital. It is not known who undertakes this task or if they have undertaken any training in seeking consent for PM examination.	**Major (cumulative)**
b) Records demonstrate up-to-date staff training	Clinicians and some bereavement midwives have undertaken training in seeking consent for PM examination in the maternity units at Whiston Hospital and Ormskirk District General Hospital. However, the training occurred over two years ago or it is not clear when the training occurred or what the training involved. In addition, the DI has not been provided with these records to provide assurance that staff have been appropriately trained.	
c) If staff are involved in seeking consent, they are always accompanied by a trained individual	The procedure for seeking consent for adult PM examinations at Whiston Hospital does not require clinicians to be accompanied by an appropriately trained individual.	
d) Competency is assessed and maintained	Clinicians responsible for seeking consent for adult PM examinations at Whiston Hospital are not competency assessed.	

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.	Some standard operating procedures (SOPs) do not contain sufficient detail to help ensure they can be followed or reflect current practice. • The SOP for viewing bodies does not include the process to be followed when relatives request a viewing. The SOP refers to checking a minimum of three identifiers of the deceased but is not clear what those identifiers could be and what they are checked against when preparing the body for viewing. The SOP does not detail that a minimum of three identifiers of the deceased should be used to check the identification of babies for viewings. • The policy for recording and learning from incidents does not include the requirement to report HTA Reportable Incidents (HTARIs) to the HTA. The SOP for HTARIs includes a previous version of the list of HTARI categories.	**Major**
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	The hospital site managers are responsible for liaising with relatives and facilitating viewings out of hours at Whiston Hospital. However, they have not received any training in the procedure and this task is often delegated to the portering staff. The DI cannot be assured that the correct procedure is being followed to mitigate the risk of viewing a wrong body out of hours.	**Major**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	The procedure for viewings does not require a minimum of three identifiers to be obtained from relatives when they make an appointment to view a body. Only the name of the deceased is requested. The other two identifiers of the deceased are obtained from mortuary documentation.	**Major**

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
a) There is a documented policy which governs consent for post-mortem examination and the retention of tissue and which reflects the requirements of the HT Act and the HTA's Codes of Practice	The policy for seeking consent for a hospital PM examination does not make it clear that consent must be sought from the person ranked highest in the hierarchy of qualifying relationships. There is a risk that consent for PM examination and the removal and storage of tissue could be obtained from someone other than the person ranked highest in the hierarchy of qualifying relationships.	**Minor**
g) the establishment uses an agreed and ratified consent form to document that consent was given and the information provided	The inspection team's audit of consent forms for PM examination found that one form had not been completed correctly.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although there is a documented schedule of audits, audits of tissue and traceability of bodies have not been regularly undertaken. Where an audit has occurred, representative numbers of bodies or specimens have not been reviewed.	**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 inspection team identified two near-miss incidents from 2018 that should have been reported to the HTA. The DI is required to retrospectively report these incidents to the HTA.	**Minor**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
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)	Staff cannot visually identify who is requesting access to the mortuaries at Whiston Hospital and Ormskirk District General Hospital. This poses a risk of access being granted to unauthorised people.	**Minor**
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	The body store trays at Ormskirk District General Hospital are damaged in multiple areas. Attempts have been made to repair the sharp edges with adhesive tape. The damage presents a risk of sharps injury to staff and a risk of damage to bodies. In addition, the damage and tape prevent staff from being able to adequately clean and disinfect the trays.	**Minor**

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.

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

Number	Standard	Advice
1.	T1(g)	There may be occasions when mortuary staff are required to package and send toxicology specimens for analysis. The DI is advised to ensure that confirmation of arrival of specimens is received from the receiving laboratory.
2.	PFE3(c)	The DI is advised to ensure that the ventilation system of the PM room at Southport and Formby District General Hospital is serviced and tested, if there is a requirement in the future to utilise this site for PM examinations.

3.	PFE3(f)	The DI is advised to formally review the daily temperature records of the fridges and freezers more frequently at each site, in addition to the scheduled temperatures review/mapping. This may help to help identify any potential issues with the equipment before they occur.

Background

Whiston Hospital has been licensed by the HTA since May 2008. This was the fourth site visit inspection of the establishment; the most recent previous inspection took place in April 2016.

In March 2018, Southport and Formby District General Hospital and Ormskirk District General Hospital became satellite sites of Whiston Hospital; both of these sites were last inspected in July 2016.

Following this inspection, the activity of removal of relevant material from the body of a deceased person was added to the licence for Ormskirk District General Hospital.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection

All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation

The inspection included a review of the establishment's governance documentation relating to licensed activities covering all three sites. This included policies and procedural documents relating to licensable activities, cleaning records for the mortuaries and PM rooms, contracts for servicing of equipment and records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents, and staff training records.

The establishment had planned revisions to the consent policy and procedure at Whiston Hospital. However, at the time of inspection, these documents had not been updated to reflect the proposed changes.

Visual inspection

The inspection included a visual inspection of areas covered by the licence at the hub site and both satellite sites including the mortuary body stores, PM rooms viewing rooms and the pathology laboratory at Whiston Hospital. The process for the removal of specimens in sudden unexpected deaths in infants and children (SUDIC) cases was discussed with relevant staff. The A&E departments at Southport and Formby District General Hospital and Ormskirk District General Hospital were not visited.

Audit of records

An audit of body identifiers, storage locations, mortuary register details, mortuary database details and associated documentation was carried out for seven bodies at Whiston Hospital and Southport and Formby District General Hospital (two adult community deaths and five adult hospital deaths), including two bodies in frozen storage. There were no bodies in storage at Ormskirk District General Hospital at the time of the inspection. One minor discrepancy was found at Southport and Formby District General Hospital in relation to a transcription error of a name on a fridge doorplate.

Audits were conducted of tissue removed during PM examination for four cases between 2018 and 2019 (three Coroner's cases and one hospital consented case). The audit included details of tissue type, number of blocks and slides retained, review of consent forms, other associated documentation and electronic database records. No discrepancies in traceability were identified.

Meetings with establishment staff

The inspection included interviews with the DI and staff carrying out processes under the licence across all sites, including Anatomical Pathology Technologists, pathologists, pathology laboratory staff, porters, midwives and A&E department staff.

Report sent to DI for factual accuracy: 6 November 2019

Report returned from DI: 13 November 2019

Final report issued: 25 November 2019

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: 03 March 2020

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

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

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

Its programme of site visit inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

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

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

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 Human Tissue Act 2004 (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 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:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities

- Additional conditions being proposed
- 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 Codes of Practice, 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 review or at the time of the next 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. Establishments 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 routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.