

Site visit inspection report on compliance with HTA minimum standards

Warrington and Halton Hospitals NHS Foundation Trust

HTA licensing number 12024

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**

4 October 2012

Summary of inspection findings

Warrington and Halton Hospitals NHS Foundation Trust (the establishment) was subject to a themed inspection focusing on consent, quality management and prevention of major equipment failures.

Although the HTA found that the establishment had met the majority of the HTA standards in these areas, some shortfalls were found. A major shortfall was identified in relation to the monitoring of body store fridges over weekends and bank holidays and the absence of a procedure or training on how to deal with fridge failures out of hours. Minor shortfalls were identified in relation to paediatric consent documentation and staff training, the content of standard operating procedures (SOPs), particularly around identification of the deceased, and risk assessment of procedures where serious incidents could occur.

During the inspection, it came to light that relevant material in the form of blocks and slides is being stored on premises that are unlicensed. Storage of relevant material for use for the purposes set out in the HT Act is unlawful without the necessary licence from the HTA. Whilst this material has not and is not being accessed for use for scheduled purposes, the potential

for such use remains. The HTA is working with the Designated Individual (DI) to ensure the licensing requirements are met as quickly as possible.

The DI and the Licence Holder were assessed and found to be suitable in accordance with the requirements of the legislation at the establishment's previous inspection in April 2009. However, the discovery of blocks and slides on unlicensed premises has called into question their understanding of the requirements of the Human Tissue Act 2004 and the HTA strongly advises the DI to undertake again the HTA's e-learning programme.

Since the last inspection the establishment has continued to comply with the majority of HTA standards; in addition, areas for improvement previously identified have been addressed. Particular examples of strengths and good practice 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 Paragraph 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.

A themed inspection may be carried out at establishments which have been found previously to represent a lower risk of regulatory non-compliance. Themed inspections focus on standards against which the HTA has identified common shortfalls across the post mortem sector and areas of risk identified from analysis of serious untoward incidents reported to the HTA. The themes selected for 2012/13 business year are outlined in the table below.

Themes	HTA Standards
Appropriate consent is in place for post-mortem examinations not under the Coroner's jurisdiction and in the event that tissue is to be retained for future use. Where there is no consent for retention, tissue is disposed of.	
Consent is obtained in accordance with the requirements of the Human	C1

Tissue Act 2004 (HT Act) and as set out in the code of practice.	
Information about the consent process is provided and in a variety of formats.	C2
Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	C3
Governance and quality systems promote robust traceability systems, reducing the risk of serious untoward incidents.	
All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process.	GQ1
There is a documented system of quality management and audit.	GQ2
A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	GQ6
There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	GQ7
Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	GQ8
Fridges and freezers safeguard the integrity of the deceased.	
There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.	PFE3

In addition to the standards listed above, the HTA will follow-up on any other issues that have arisen since the establishment's last inspection.

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

Warrington & Halton Hospitals NHS Foundation Trust carries out approximately 550 post-mortem (PM) examinations each year, the majority of which are coronial cases, with only a small number of consented hospital PM examinations. Forensic and paediatric cases are transferred to other HTA licensed establishments for PM examination. Staff at the establishment obtain consent to non-coronial paediatric PM examinations, but the form and

patient information booklet used are provided by the hospital to which the cases are transferred. The establishment's operating theatres are also licensed for removal of tissue from the deceased, which is occasionally necessary when an organ donor is found to be unsuitable for transplantation but consent has been given to use the tissue for research.

The themed inspection comprised interviews with members of staff, a review of relevant documentation and visual inspections of the following departments: theatres, mortuary, body store and histology laboratory tissue storage area. An audit was carried out in the body store, during which the details on the wrist bands of two of the deceased were compared with corresponding details in the mortuary register. No anomalies were found.

Through discussions with the DI, the HTA learnt that blocks and slides pre-dating the Human Tissue Act 2004 are being stored at an unlicensed offsite facility. The HTA informed the DI that the blocks and slides must be stored on licensed premises and a satellite licence application was immediately submitted.

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

Consent

C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	Staff taking consent for adult hospital PM examinations have recently received training, which is documented. Staff responsible for obtaining consent for paediatric PM examinations have not received consent training in recent years and no record of staff training was available for review.	Minor
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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.	The establishment has a good range of SOPs, which cover all licensable activity; however, some of the SOPs relating to mortuary activities do not go into sufficient detail. In particular, SOPs which require the identification of the deceased to be checked do not specify, what details are checked and who is responsible . The lack of detail in the SOPs increases the risk of inconsistent practice and may result in errors.	Minor
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment has carried out a number of risk assessments on the premises and processes that relate to health and safety. Risks of non-compliance with regulatory requirements and risks to the safety and security of bodies and tissue samples, such as loss of traceability, have not been considered.	Minor

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	The body store is divided into sections, each of which has two compressors to chill the space, so if one unit were to fail, the second would continue to try to maintain the temperature. Staff check the fridge temperatures and record these on a daily basis, except over weekends and bank holidays. The temperature monitoring system is situated in a corridor off of the body store and displays a red LED light when the temperature is outside of specification; however there is no audible alarm and no other alert system to ensure fridge failures are dealt with in a timely	Major

	<p>manner. Porters bring bodies to the mortuary out of hours, but do not check temperatures or the display to ensure the fridges are working appropriately, nor have they received instructions on what to do if they discover a problem with the fridges.</p> <p>An undiscovered fridge failure, particularly over bank holiday weekends, could result in decomposition of the deceased and compromise the outcome of PM examinations.</p>	
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Advice

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

No.	Standard	Advice
1.	C3	The DI is advised to encourage staff who have received consent training, but not yet obtained consent themselves, to observe the process being carried out (with the agreement of the families involved). Consent for adult PM examinations is predominantly being obtained by one individual and therefore it would be advantageous for other staff to gain experience for times when this individual is not available. The DI is further advised to encourage staff to view a PM examination, so that if they are asked questions by relatives they are sufficiently informed to answer.
2.	GQ4	The DI is advised to ensure any errors made on paper records are corrected by drawing a line through and then re-writing the information, rather than the using correction fluids.
3.	GQ6	Stickers are placed on the whiteboard to make staff aware that there is more than one individual with the same or similar name. The DI is advised to ensure staff also place these stickers on the shroud or wristband of the deceased, so that the prompt remains even when the body has been moved into the PM examination room.
4.	GQ8	The DI is advised to use the HTA serious untoward incident notification list as a basis for risk assessing processes where serious incidents could occur.
5.	PFE3	The Estates Department is responsible for setting up contracts with equipment maintenance companies and ensuring routine maintenance visits are carried out. The DI is advised to ensure that the temperature probes for the body store fridges are regularly checked and calibrated as part of the maintenance visit and that information on the outcome or any work completed by engineers during their maintenance visits is provided to local members of staff. Monitoring of recurrent maintenance problems with the same or different refrigeration systems may enable staff to identify issues at an earlier stage and plan contingency arrangements.
6.	D2	The DI is advised to ensure when recording the disposal of tissues that all samples are accounted for.

7.	-	The DI is advised to revisit the HTA e-learning training to ensure he is fully aware of HTA licensing requirements.
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Concluding comments

A number of strengths and areas of good practice were noted during the inspection and examples are given below.

The DI has implemented a thorough training course for obtaining consent to an adult hospital PM examination. Attendance at this course is recorded. The PowerPoint presentation is available for staff to refer to, but the DI also runs refresher courses to ensure staff are confident in carrying out the procedure.

The establishment has a dedicated Quality Manager who has implemented a schedule of audits and created an audit template that sets out the areas that should be covered as part of specific vertical and horizontal audits. This template also includes details of relevant CPA standards to ensure that areas where compliance is required to maintain accreditation are reviewed in detail.

Good systems of traceability were noted during the inspection.

- When organs are found to be unsuitable for transplantation and removed for use in research, a computerised record is maintained that details the recipient organisation of each organ so that the family can be informed of the outcome of the donation.
- A record of signing out and signing in samples is made when transferring samples between the mortuary and histology.
- A sophisticated database in histology records the number of blocks and slides created from the samples, including slides with special stains, and details the option selected by the bereaved for retention, repatriation or disposal of the samples.

The previous inspection highlighted issues with the lack of traceability of slides and procedural audits, which have been addressed and are now managed particularly well. However, there are a number of areas of practice that require improvement, including one major shortfall and four minor shortfalls. In addition, the storage of relevant material in the form of blocks and slides on unlicensed premises must be addressed without delay. The HTA has given advice to the DI on a range of issues, including with respect to staff gaining experience in obtaining consent, the use of same/similar name stickers, increasing the scope of risk assessments and ensuring that fridge maintenance incorporates the calibration of temperature probes.

The HTA requires that the DI 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.

Report sent to DI for factual accuracy: 25/10/12

Report returned from DI: 06/11/12

Final report issued: 06/11/12

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: 04 January 2013

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
<ul style="list-style-type: none">• 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
<ul style="list-style-type: none">• Relatives are given an opportunity to ask questions.• Relatives are given an opportunity to change their minds and it is 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
<ul style="list-style-type: none">• 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:
 - 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.

<ul style="list-style-type: none"> 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
<ul style="list-style-type: none"> 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
<ul style="list-style-type: none"> 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 or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded: <ul style="list-style-type: none"> material sent for analysis on or off-site, including confirmation of arrival receipt upon return to the laboratory or mortuary number of blocks and slides made repatriation with a body return for burial or cremation disposal or retention for future use. 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
<ul style="list-style-type: none"> 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
<ul style="list-style-type: none"> 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.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
 - Disposal records include the date, method and reason for disposal.
 - Tissue is disposed of in a timely fashion.
- (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)*

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.