

Site visit inspection report on compliance with HTA minimum standards

Macclesfield District General Hospital

HTA licensing number 12411

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**

11 June 2015

Summary of inspection findings

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

The HTA found that Macclesfield District General Hospital (the establishment) had met the majority of the HTA standards. Three minor shortfalls were found in relation to the post mortem examination consent policy, documented procedures and maintenance of mortuary fridges and freezers.

Strengths and 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 Designated Individual, Licence Holder, premises and practices are suitable.

The statutory duties of the Designated Individual (DI) are set out 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 licenses 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 mortuary at Macclesfield District General Hospital (the establishment) admits bodies from the hospital and the community. Approximately 300 adult post mortem (PM) examinations are carried out each year, the majority being performed under authority of HM Coroner for Cheshire, with a small number of hospital (consented) cases each year. All Home Office, perinatal and paediatric cases for PM examination are transferred to other HTA-licensed establishments.

The pathology services at this establishment and at Leighton Hospital (licensing number 12145) together comprise Cheshire Pathology Services. Pathologists and staff involved in quality management work across both sites. Each hospital's mortuary has two Anatomical Pathology Technologists (APTs), who occasionally attend the other site. Mortuary processes and documentation are site-specific, as local practices vary.

The establishment has adopted HTA's model consent form for adult PM examinations. Consent may be sought by any hospital clinician (refer to minor shortfall against C1, advice item 1). The establishment uses the Stillbirth and Neonatal Death charity (SANDS) consent documentation for perinatal PM examination cases. Consent is sought by obstetrics and gynaecology consultants.

The mortuary body store has 48 refrigerated spaces, including three spaces for bariatric adults and three deep freeze spaces. Perinatal and paediatric bodies are stored on dedicated trays in the fridges. Fridge and freezer temperatures are logged twice-daily during the week, alarms are tested monthly.

The PM suite has three downdraft tables. Wet tissue taken at PM examination for histopathological analysis is cassetted in the mortuary and transferred to Leighton Hospital by a contracted transport company for processing into paraffin wax embedded blocks and microscope slides. Whole organs and toxicology samples requiring specialist analysis are sent to other HTA-licensed establishments. Where appropriate consent has been given, blocks and slides are stored for use for scheduled purposes at Leighton Hospital after analysis is completed.

There is no removal of tissue samples from deceased infants in sudden death cases or storage of tissue samples for use for research or other scheduled purposes under this licence.

The establishment has been licensed by the HTA since February 2007. One previous site visit inspection has taken place (February 2011). This report describes the second, routine, site visit inspection of the establishment. The inspectors met staff involved with licensable activities and reviewed documentation. Storage locations and identifiers of two deceased persons were audited. A minor transcription error was seen in one person's address in the mortuary register. This did not affect traceability, and all other details for this person were correct. There were no errors in the other person's records.

Records for two PM examinations (a hospital case and a coronial case) were audited. While no data anomalies were found in traceability records in either case, the staff member who completed the hospital PM examination consent form with the family had not undertaken consent training, although the clinician who had treated the patient prior to their death was present. This failure to follow internal procedures for seeking consent for hospital PM examination was reported as an internal incident (refer to advice item 1).

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

Consent

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 Code of Practice.	<p>Paragraph 6.8 of the 'Procedure for Consent for a Hospital Post Mortem Examination' suggests a hospital PM examination can be performed at the hospital's instruction without consent either from the deceased, their nominated representative or a person in a qualifying relationship. This is contrary to the consent requirements of the HT Act.</p> <p>In addition, this document does not list the hierarchy of qualifying relationships from the HT Act, or explain what PM examination consent training clinicians must complete and how they are assessed as competent to seek consent.</p> <p><i>(Refer to advice item 1)</i></p>	Minor

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.	<p>The 'Protocol for performing post mortem examinations' (MO.SPA001) and 'Viewing of bodies by relatives' (MO.SPA037) standard operating procedures (SOPs) do not specify which personal identifiers, such as the full name, date of birth or hospital number, will be used to identify deceased persons prior to PM examination or a viewing. The 'Technical training programme and training record' does not list which personal identifiers portering staff will use for out of hours viewings.</p> <p><i>(Refer to advice item 3)</i></p>	Minor

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.	There is no schedule of preventive maintenance servicing visits for mortuary fridges and freezers.	Minor

Advice

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

No.	Standard	Advice
1.	C1, C3	Many PM establishments have a small group of staff with knowledge of the PM examination procedure, the HT Act's consent requirements, and consent documentation, who support clinicians seeking consent for adult hospital PM examinations. Such an approach brings greater consistency to the seeking of consent for adult hospital PM examinations.
2.	C1	'Form 2: consent for the examination of tissue following miscarriage' seeks a mother's non-objection to examination of her pregnancy remains. The DI is advised to amend this form so that a mother's consent for examination of her pregnancy remains is sought, to reflect that giving of consent is a positive act.
3.	GQ1	The DI is advised to archive the mortuary SOP describing disposal of PM tissue blocks and slides. The establishment does not dispose of PM blocks and slides; this is always done at Leighton Hospital.
4.	GQ8	Regarding risk assessments, the DI is advised: <ul style="list-style-type: none">to assess in the 'Post mortem examinations risk assessment' (MO.R001) the potential risk of conducting a PM examination without appropriate consent or coronial authorisation;to ensure all existing control measures, such as the twice-daily checks of fridge and freezer temperatures and regular alarm testing, are listed in risk assessments.
5.	D1	Paragraph 16 of the 'Disposal of organs and tissue' policy states PM tissue blocks and slides will be retained as part of the deceased person's medical record if their family has given permission for retention. The DI is advised that relevant material stored for a deceased person's medical record is considered by the HTA to be storage for potential use for scheduled purposes. This paragraph should therefore state which scheduled purposes PM tissues may be stored, and the requirement for valid consent under the HT Act.

Concluding comments

Despite the minor shortfalls, areas of strength were identified. Porters receive thorough training and periodic competence assessment in mortuary procedures they are required to

perform. Mortuary record keeping is to a good standard. As an example of good practice, staff put green ticks against the name of the deceased on the mortuary whiteboard when doctors have completed death certification checks, and a red tick to indicate when a body can be released for burial or cremation.

Some areas of practice require improvement, including three minor shortfalls. The HTA has given advice to the DI regarding consent training and documentation, documented procedures and risk assessments.

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.

Report sent to DI for factual accuracy: 26 June 2015

Report returned from DI: 01 July 2015

Final report issued: 01 July 2015

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: 28 October 2015

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 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
<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).

PFE2 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.

PFE4 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.