

Site visit inspection report on compliance with HTA minimum standards

Ipswich Hospital NHS Trust

HTA licensing number 30017

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**

23 January 2013

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.

Ipswich Hospital NHS Trust was found to have met all HTA standards.

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

The establishment was provided with advice and guidance about areas that could be improved further. The areas of good practice included refresher training for clinicians involved in consent as well as training for hospital porters involved in admitting bodies into the mortuary.

The HTA's regulatory requirements

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

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

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

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA inspects the establishments it licences against four groups of standards:

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

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

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

Background to the establishment and description of inspection activities undertaken

Ipswich Hospital NHS Trust is licensed to carry out post mortem (PM) examinations and the removal and storage of PM tissue for use for scheduled purposes under the Human Tissue Act 2004. The Corporate Licence Holder is Ipswich Hospital NHS Trust, with the Chief Executive as the corporate licence holder contact.

The establishment undertakes approximately 600 PM examinations a year under the jurisdiction of the HM Coroner for Suffolk. Hospital consented PM examinations are rare, with only two being undertaken during 2012-2013. All consented paediatric and neonatal/fetal PM examinations are transferred to another licensed establishment. All cases are risk-assessed by the Pathologist and those deemed to be high risk are transferred to a licensed establishment which has suitable facilities.

The DI, a Pathology Service Manager has oversight of all PM licensable activities. The Histopathology and Mortuary Manager, has oversight of the mortuary practices, and the Senior Anatomical Pathology Technologist (APT) manages the day to day operation of the

mortuary and supervises the APTs. The mortuary has 116 fridge spaces including an overflow storage area with 20 spaces. In addition there are two bariatric spaces that can be converted to provide an additional nine routine spaces should the need arise. There are two freezers with seven spaces for longer storage, where four spaces in one of these can be converted back to normal fridge spaces should the need arise.

A site visit inspection was carried out at Ipswich Hospital NHS Trust on the 23 January 2013. The inspection involved a visual inspection of the mortuary, interviews with a Bereavement Services Coordinator, Senior APT, Histology and Mortuary Manager, Quality Manager for Histology, Cytology and Mortuary, Designated Individual (DI) and a Lead Consultant Pathologist. A Coroner's Officer was interviewed during a telephone interview prior to the inspection.

At the beginning of the inspection, the DI identified an area outside the mortuary where the licensable activity of removing tissue from the body of the deceased takes place. This is the hospital's accident and emergency (A&E) department, where samples may be taken in cases of sudden unexplained infant death. Therefore, as part of the visual inspection, the area in the A&E department where removal of tissue takes place was visited and a brief discussion held with the key clinical area representative, an A&E Consultant. The key clinical area representative demonstrated an understanding of the requirements of the Human Tissue Act 2004 and the establishment's governance systems, and the HTA was satisfied with the arrangements in place covering this activity.

The inspection also included traceability audits of bodies in storage and tissue taken during Coroner's post mortems. An audit of three bodies in fridge storage was carried out. Two bodies had a similar sounding name and both fridge doors and ID bands were flagged with 'orange stickers' in accordance with documented procedures for same and similar names. Records were checked, including details in the mortuary register and details on the ID tags. The details were also checked on the electronic information management. No discrepancies were found.

There were no organs being retained at the time of the inspection. The Mortuary Register was used to identify three tissue samples retained after a Coroner's PM examination. An audit was conducted and records were traced from the Mortuary Register to the consent records and to the blocks and slides in storage. The number of blocks and slides were checked against the written records as well as the electronic laboratory information management. 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

All applicable HTA standards have been assessed as fully met.

Advice

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

No.	Standard	Advice
1.	C1	Blocks and slides are only retained by the establishment in case re-examination of them might be of use to the family in future. However, the coroner's <i>'retention of specimens taken following post mortem'</i> form does not include this as a reason for retention, but refers to storage of blocks and slides for the purpose of 'clinical audit'. As the establishment does not store PM material for clinical audit or other purposes, the DI is advised to approach the Coroner with a view to amending the wording so that the purpose of retention is clear to the person completing the form.
2.	GQ1	The DI has informal meetings and conversations with staff on a regular basis. The DI is advised to hold more formal meetings, which should also include the Mortuary staff and the Persons Designated/Key Clinical Area Representatives under the licence. These meetings will provide all staff working under the licence with the opportunity to discuss working practices in a formal setting. Relevant action points or matters arising could also be minuted which enables an audit trail of what has been discussed.
3.	GQ2	The establishment carries out regular audits, both vertical and examination based. While there is an extensive and systematic approach to audits carried out by the Quality Manager for Histology, Cytology and Mortuary, the DI is also advised to consider auditing the paediatric PM hospital consent process, as is carried out for the adult PM hospital consent process. This will provide the DI with added assurance that the paediatric consent process is being undertaken appropriately.
4.	GQ4	It was noted during the inspection that corrections to the Mortuary Register are being made using correction liquids. The DI is advised to ensure that errors are corrected by a single 'strike through' line so that any information remains readable following correction as it may be needed for future audit purposes. It is good practice to initial and date corrections made.
5.	GQ8	Whilst the establishment has risk assessments in place covering health and safety risks, as well as risks assessments associated with non-conformance to HTA standards, the DI is advised to consider widening the scope of the establishment's risk assessments. The DI may wish to consider conducting risk assessments of the likelihood of a serious untoward incident (SUI) occurring, using the HTA SUI categories. This will further strengthen the Trust's risk management and governance system. For more information please refer to http://www.hta.gov.uk/db/documents/Guidance_Document_-_SUI_Notification_201112192847.pdf
6.	PFE5	All fridge and freezers in the mortuary are alarmed and connected to the Trust switchboard. However, there is no system in place to test the alarms. The DI is advised to to develop a procedure for testing of the

		<p>fridge/freezer alarm system periodically to assure himself that the freezer alarm system is operating as expected.</p> <p>Mortuary staff manually monitor fridge and freezer temperatures daily but do not record the actual temperatures of the storage units. The records only verify that temperatures are within a certain range. The DI is advised to start recording the storage temperatures and reviewing these on a regular basis, which might help prevent an equipment failure.</p>
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Concluding comments

The DI along with Mortuary staff, Pathologists, Persons Designated and Key Clinical Area Representatives all have a good working relationship. There were several examples of good practice noted during the inspection. For example, the hospital porters are provided with training and are observed by another member of staff before they are deemed 'competent' to engage in any mortuary related activities. These observational audits are also repeated on an annual basis to ensure that porters are following the correct procedures. The Bereavement Coordinators provide regular refresher consent training to clinicians involved in taking consent for hospital PM examinations. The Bereavement Coordinators are also present during the consent process for both adult and neonatal/fetal post mortems and are able to provide support to the family as well as reassurance that consent is being obtained according to HTA requirements. There is training for staff on HTA requirements, and the DI is involved in providing HT Act 2004 training as part of the Trust induction aimed at relevant new starters.

No shortfalls were identified. The HTA has given advice to the DI with respect to testing of the fridge/freezer alarms in the mortuary as well as the method for recording temperatures. Advice has also been given with regards to correction of the Mortuary Register and development of risk assessments. For more information please see Advice Section of the report.

Report sent to DI for factual accuracy: 18 February 2013

Report returned from DI: 4 March 2013

Final report issued: 5 March 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.

- 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 or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
 - 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

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

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

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as

health and safety risks.

- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- Risk assessments include how to mitigate the identified risks; this includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

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

PFE 2 Environmental controls are in place to avoid potential contamination

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

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

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

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

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

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

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

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

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

Disposal Standards

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

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- 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.