Site visit inspection report on performance against HTA quality standards
Pathlinks
HTA licensing number 12310

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**

18 October 2011

Executive Summary

A site visit inspection of Pathlinks (the establishment) was carried out by the HTA on 18 October 2011.

The establishment was found to meet the majority of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment and disposal. Two minor shortfalls were found, in relation to the consent standards. Examples of strengths or good practice are included in the concluding comments section of the report.

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.

All 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

Pathlinks currently holds three HTA post mortem (PM) sector licences covering three hospital sites at Diana Princess of Wales Hospital in Grimsby, Lincoln County Hospital and Pilgrim Hospital in Boston (licensing numbers 12310, 12314 and 12316 respectively).

During the month prior to the scheduled inspection of all three sites, post mortem examinations at Pilgrim Hospital ceased and the mortuary PM suite mothballed. Bodies requiring PM examination are now sent to other licensed establishments and only a body store remains at Pilgrim Hospital. Since bodies requiring PM examination are usually transferred within 24 hours (and always within a week), the storage of these bodies is considered to be incidental to transportation and is therefore outside the HTA licensing framework. As a result, the premises at Pilgrim Hospital were not inspected.

The report refers to the activity taking place at the Diana Princess of Wales Hospital where both coronial and hospital (consented) PM examinations are carried out, including known high risk cases such as HepB, HIV and TB. The establishment has a dedicated high risk PM suite for undertaking known high risk PM examinations. Paediatric PM examinations are not performed here and are transferred to other licensed premises.

Tissue taken during PM examination is transferred via Pathlinks' dedicated courier to the Lincoln County Hospital for processing into blocks and slides, examination by the Pathologist and storage for future use for scheduled purposes (if this has been consented to).

This was the second site-visit inspection of the establishment and was a routine inspection to assess whether the establishment is continuing to meet the HTA's standards. The timetable for the site visit was developed in consideration of the establishment's recent self assessment compliance information and audit of stored material, as well as pre-inspection discussions with the Designated Individual (DI). During the site visit, a visual inspection of the premises, review of documentation and interviews with establishment staff were undertaken.

An audit of three bodies in the body store was undertaken. Identification details contained on body tags were checked against details in the mortuary register and on the mortuary fridge doors; no anomalies were found. All bodies admitted into the establishment are assigned a unique mortuary number (CP number). This number is recorded in the mortuary register by adding a pre-printed adhesive label with the mortuary number into the mortuary register. The mortuary number is added to the same column in which the hospital's 'A' number (patient identification number) is recorded. In some cases the sticker covered the hospital number which could no longer be read. Advice on the use of the adhesive labels has been given below.

The DI confirmed that removal of tissue from the deceased does not take place in other areas of the hospital, such as the accident and emergency department; hence the inspection focussed on the mortuary PM suite and body store.

Meeting the HTA's licensing standards

The HTA developed its licensing standards with input from its stakeholders, in order to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA expects licensed establishments to meet these standards.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a licensing standard is not met, the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor' (see Appendix 3: Classification of the level of shortfall).

Unless otherwise advised, the establishment is required to inform the HTA within 14 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the improvements are addressed. A template for this purpose is provided as a separate Word document.

HTA standards not met

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.	Prior to the inspection, during the establishment's routine audit cycle, an audit was undertaken of compliance with its consent process. As a result of the audit findings, the DI has drafted new training programs for those training others in taking consent and for those who will be seeking consent. In addition the DI has also developed a new consent form. These new processes and documentation were still in draft form at the time of the inspection. Currently, the establishment uses the out of date Department of Health (DH) consent form which states that tissue taken during PM examination will automatically be retained in the deceased's medical record. The wording on the consent form should reflect the requirement of the Human Tissue Act 2004 (HT Act) that tissue may only be retained for use in scheduled purposes with appropriate and valid consent.	**Minor**
C2 Information about the consent process is provided and in a variety of formats.	The establishment also uses the out of date DH supporting information about the PM examination process, which states that tissue taken during PM examination will automatically be retained in the deceased's medical record. The wording in the supporting information should reflect the requirement of the HT Act that tissue may only be retained for use in scheduled purposes with appropriate and valid consent.	**Minor**

Advice

Below are matters which the HTA advises the DI to consider.

No.	Standard	Advice
1.	C1 C2	The DI is advised to liaise with the paediatric department where consent for perinatal and paediatric PM examination is taken by the consultants locally, and to nominate a person designated (PD). Although the consent procedure, patient information and consent form are from another licensed establishment where the PM examination takes place the DI has a responsibility to ensure that the consent seeking process meets the requirements of the HT Act. By nominating a PD, the DI will have a link to staff seeking consent and be able to be updated of changes to the procedures in addition to being able to disseminate information to the staff seeking consent. The DI is advised to hold regular meetings with the PD to facilitate the transfer of information. The coronial family's wishes form refers to tissue retention in the deceased's medical record as one option. The DI is advised to liaise with the coroner to amend the wording so that it is clear to those giving consent what the potential scheduled purposes are that tissue might be used for, such as for further review in the future in light of new medical information. The establishment has a clear consent policy which details who may seek consent, from whom, and the procedure to follow. However, its standard operating procedure (SOP) does not include the full list of who may give consent to a PM examination. This list should include the deceased prior to death and a nominated individual as well as the hierarchy of qualifying relationships.
2.	C3	Currently, consultants seek consent from the families of the deceased for PM examination. Clinicians receive training in the seeking of consent for PM examination as part of their hospital induction. Following the establishment's audit of the consent procedure, the DI recognised that although all new clinicians receive the training at induction the documenting of consent training is difficult. The DI has developed a new procedure where key members of staff will be trained to give training to those who may wish to seek consent for a PM examination. This 'just in time' training of clinicians wanting to seek consent ensures that they all receive training in line with the establishment's procedures. The DI is advised to implement the new process (which is still in development) so that he may ensure that all seekers of consent receive appropriate training. In addition, the DI is advised to amend the training slides for clinicians to reflect the people who may consent to a PM examination. Importantly the deceased may have given consent prior to death or nominated an individual to consent on their behalf, this should be reflected in the training package.
3.	GQ1	The DI is advised to ensure that a written authorisation for the release of bodies to the funeral directors is received from the coroner prior to their release. This will reflect the establishment's documented procedure. Currently the establishment releases bodies with verbal consent from the coroner over the telephone. Additionally, some SOPs reviewed during the inspection, did not match current practice. For example, in the 'Tissue Retention/Disposal' document it states that 'the department will take no further action in respect to tissues or organs retained in the absence of the family's instructions'. This is not the case and the establishment does have a well established system to establish the family's wishes. The DI is advised to review SOPs to ensure that they fully reflect current practice. It is understood that the establishment are embarking on a large scale review of both the content and number of SOPs used within the establishment. This review will assist the DI in ensuring that SOPs reflect current practice.

4.	GQ3	The DI is advised to ensure that all staff working under the licence receive regular appraisals in line with the establishment's documented policy.
5.	GQ6	When bodies with unknown identities are brought to the mortuary the establishment books them into the mortuary register as 'Unknown'. The DI is advised to also include the unique CP number to the body identification tag so that there is a unique identifier on every body of an unknown person. When adding the assigned CP number to the mortuary register the CP number sticker is at times placed over the hospital's 'A' number. The DI is advised that the CP number sticker should be added to the mortuary register in a space so that the 'A' number can still be read and used for traceability if needed.
6.	GQ7	The establishment has a documented procedure covering the reporting of serious untoward incidents (SUIs) which includes reporting to the HTA. The DI is advised to ensure that all staff working under the licence are familiar with what constitutes an SUI, how to report it and who to report it to.

Concluding comments

Areas of good practice were observed during the inspection, some examples of which have been included below.

The establishment has a good range of risk assessments of both the premises and practices covering health and safety risks in addition to the risks posed to the tissues and bodies themselves.

The establishment has well developed systems covering the cleaning of the mortuary supported by an SOP. Log sheets recording when cleaning takes place are on display within the mortuary, which capture the cleaning of the various areas of the mortuary and the frequency with which the cleaning takes place. Cleaning of different areas takes place either daily, weekly, monthly or quarterly as defined in the SOP, depending upon how dirty an area may become.

Report sent to DI for factual accuracy: 9 November 2011

Report returned from DI: No factual accuracy comments received

Final report issued: 20 December 2011

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: 01 June 2012

Appendix 1: HTA inspection process

The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, transplantation, and education and training. The legal requirements for establishments which carry out such activities are set out in the Human Tissue Act 2004 and The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

We license establishments in England, Wales and Northern Ireland that carry out these activities, and inspect them to make sure legal requirements are met.

Inspections

We use the term 'inspection' to describe when we:

- visit an establishment to meet with staff, view premises and facilities, and review policies and procedures (a site-visit inspection); or
- assess written information we have requested from an establishment (a desk-based assessment / inspection).

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that:

- other staff working under the licence are suitable;
- suitable practices are used when carrying out the activity; and
- the conditions of the licence are met.

We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

After every site visit inspection, we write a report documenting our findings. Where we find a particular standard is not fully met, we will describe the level of the shortfall as 'Critical', 'Major' or 'Minor'. In most cases, it will be the responsibility of the DI to seek the HTA's agreement on how they will address the identified shortfalls. More information about the classification of shortfalls can be found in Appendix 3.

The majority of our site-visit inspections are announced. If we have concerns about an establishment, we can also undertake an unannounced site visit inspection.

You can find reports for site visit inspections which took place after 1 November 2010 on our website.

Appendix 2: HTA standards

Standards which are not applicable to this establishment have been highlighted.

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
• 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
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it 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
• 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.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.

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 3: 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.

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.

Follow up actions

A template corrective and preventative action plan is available as a separate Word document. 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.