Site visit inspection report on compliance with HTA minimum standards

Countess of Chester Hospital

HTA licensing number 12049

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**

28−29 April 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 Countess of Chester Hospital (the establishment) had met the majority of the HTA standards. Minor shortfalls were found regarding: information leaflets for adult hospital post mortem (PM) examination; documented procedures for research tissue samples; PM traceability records; incident reporting to HTA; and disposal of blocks and slides.

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 (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 Countess of Chester Hospital (the establishment) admits bodies from the hospital and the community. Approximately 500 adult post mortem (PM) examinations, including high risk cases, are conducted each year under the authority of HM Coroner for Cheshire. A small number of adult hospital (consented) PM examinations also take place. Forensic, perinatal and paediatric cases are transferred to other HTA-licensed establishments for PM examination. Sampling of tissues from deceased children in sudden unexpected death in infancy cases is performed in the Emergency Department by consultant paediatricians, with pre-emptive authorisation from HM Coroner.

The establishment uses the Stillbirth and Neonatal Death charity's consent documentation for perinatal and paediatric PM cases. Obstetrics and gynaecology consultants, and speciality registrars, seek consent. They receive annual consent training from staff at the hospital where these PM examinations take place. The establishment uses its own consent form and information leaflets for adult hospital PM examinations (refer to shortfall against C2). Pathologists support clinicians seeking consent for an adult PM examination (refer to advice item 1).

The mortuary has 65 refrigerated spaces, including four spaces in deep freeze and seven spaces for bariatric patients. Perinatal specimens are stored in a stand-alone refrigerator, or on a dedicated tray in an adult fridge, depending on their size (refer to advice item 8). Fridge and freezer temperatures are monitored continuously using a proprietary monitoring system. On-call laboratory staff are alerted if a temperature excursion occurs outside core working hours (refer

to advice item 9). The PM suite has two downdraft tables, one of which can accommodate a bariatric body. Tissues taken at PM examination for histological analysis are processed into formalin-fixed paraffin wax embedded tissue blocks and microscope slides in the histopathology laboratory. Organs are referred to other establishments for specialist examination (refer to shortfall against GQ4).

Blood, tumour and normal tissue samples from living patients with colorectal cancer are stored for use for research under this licence. The samples are stored in a −80 ^{o}C freezer in the Pathology Department (refer to shortfall against GQ2 and advice items 3, 5 and 7).

Donor consent was sought by surgical staff who completed good clinical practice consent training. The project has NHS research ethics committee (REC) approval, providing an exemption from licensing under The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006. This collection is considered to be functioning as a research tissue bank (RTB), as sample distribution to collaborating organisations takes place under material transfer agreements. An application for ethical approval as a RTB has been submitted. Sample collection ceased in 2014 and will re-start if RTB ethical approval is granted.

The establishment has been licensed by the HTA since May 2007. One previous site visit inspection took place in December 2010. This report describes the second, routine, site visit inspection of the establishment. The HTA inspectors met with staff involved with licensable activities and reviewed documentation. Storage locations and identifiers for three bodies were audited. No anomalies were found. Traceability records for three PM examinations (two coronial cases and one hospital case) where tissues and organs were taken for analysis were audited. Although no anomalies were found, some traceability records were difficult to follow (refer to shortfall against GQ4). Research samples from two donors were audited from consent to sample storage. For one set of samples the unique reference number was not written on the donor consent form, making it difficult to identify which donor those samples came from (refer to advice item 5). No other anomalies 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

Consent

Standard	Inspection findings	Level of shortfall
C2 Information about the consent process is provided and in a variety of formats.	The Trust's information leaflets 'Guide to the post mortem examination procedure' and 'A simple guide to the post mortem examination procedure' state that tissue blocks and slides will be kept as part of the deceased person's medical record. The HTA considers relevant material stored as part of the medical record to be storage for use for scheduled purposes, for which valid consent is required. The information leaflets therefore do not comply with regulatory requirements. *(Refer to advice item 1)*	**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.	The 'Use of the research freezer facility in the Pathology Department' (reference DOC1141) standard operating procedure (SOP) describes how to record the disposal of research samples, their transfer to other establishments, and their regular audit. However the processes by which research samples are to be disposed of, transferred to other establishments and audited are not documented. *(Refer to advice item 5)*	**Minor**

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	There are no fields in the electronic 'Specimen Register' to record: • whether an organ was retained at PM examination, and; • if an organ was transferred for specialist examination, its destination, the date it was sent there and the date it was returned; • where, if it has been returned to the establishment, the organ is stored; • the family's wishes for disposal or retention of the organ. There is a potential risk to traceability of organs if such details are not recorded. Auditing is also difficult without more complete information.	**Minor**
GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly.	The HTA guide to reporting HTA Reportable Incidents (HTARIs) has been uploaded to the establishment's quality management software. However, it is not documented who at the establishment can make an HTARI notification. Internal incident reports have not been reviewed to identify potential HTARIs. The inspectors identified one historic incident, and a recent one, that were HTARIs but which had not been reported to HTA. *(Refer to advice item 6)* *The establishment submitted HTARI notifications describing these incidents to HTA immediately after the inspection.*	**Minor**

Disposal

Standard	**Inspection findings**	**Level of shortfall**
D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes.	The timeframe and method of disposal for blocks and slides after coronial authority ends, and a family has not provided their disposal wishes, are not documented.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1, C2, C3	Regarding consent, the DI is advised: • to review the frequently asked questions that the HTA has produced for adult PM examination to inform development of an information leaflet: https://www.hta.gov.uk/faqs/post-mortem-examination---your-choices-about-organs-and-tissue-faq • to separate out the options for retention or disposal of organs from those for blocks and slides on the Trust's 'Consent for post-mortem examination of an adult' form. This will enable families to make separate decisions for disposal or retention for scheduled purposes of an organ, and for blocks and slides; • to consider refresher consent training for pathologists who support clinicians seeking consent for adult hospital PM examinations.
2.	C1	The DI is advised to discuss with HM Coroner for Cheshire whether the form used to record a family's instructions for organs and tissues retained at PM examination could be amended to include all the options set out in the Coroners (Investigation) Regulations 2013. The options are: • disposal of the material by burial, cremation or other lawful disposal by the pathologist; • return of the material to the family; or • retention of the material for medical research or other purposes in accordance with the HT Act..
3.	C1	The patient information sheet (PIS) and consent form for the colorectal cancer research study provide contradictory information on the fate of tissue samples if a donor withdraws consent for storage and use of samples. The DI is advised: • to confirm whether tissue samples are to be retained or disposed of if a donor withdraws consent, and that: • if tissue collection commences again, to ensure the PIS and consent form give consistent information on the fate of samples if consent is withdrawn.
4.	GQ1	Two mortuary SOPs which were authored and authorised by the same person were seen. The DI is advised that SOPs should be reviewed by a second person, not directly involved with that activity, to provide independent scrutiny of content.
5.	GQ1, GQ2	The DI is advised that research sample audits could verify, for example, that: • donor consent forms are completed correctly and consistently; • sample vials are labelled correctly; • details in the traceability register are accurate; • sample storage locations match traceability records.

6.	GQ2	The DI is advised to include in the Pathology Quality Manual: • further information about mortuary quality management, and; • the requirement to report potential HTARIs to HTA and identify the persons who can make an HTARI notification.
7.	GQ4	Research samples were initially stored in a −20 ^{o}C freezer but were later transferred to a −80 ^{o}C freezer. However, the traceability register still records samples as being stored in the −20 ^{o}C freezer. The DI is advised to ensure this register contains correct information on sample storage locations.
8.	PFE3	The DI is advised to put signage on the door of the adult body fridge where perinatal and paediatric cases may be placed, to reduce the risk of an adult body being placed on the designated tray in error. *(The establishment responded to this advice item during the inspection by placing signage on the fridge door clarifying the tray was for babies only.)*
9.	PFE5	Regarding mortuary fridge and freezer alarms, the DI is advised to: • develop a regular schedule of testing and; • consider arrangements for the temporary body storage unit, which is erected as a contingency when additional storage capacity is needed. This unit does not have an alarm. *(The establishment responded to the first piece of this advice item during the inspection by introducing a protocol for regular testing of alarms on each bank of fridges and freezers.)*
10.	D1	The DI is advised that the HTA's guidance on sensitive disposal of pregnancy remains has been published. Relevant Trust policies should be reviewed to ensure these reflect the new guidance on disposal of pregnancy remains. https://www.hta.gov.uk/sites/default/files/Guidance_on_the_disposal_of_pregnancy_remains.pdf
11.	-	The DI is advised to nominate a Person Designated (PD) in the Maternity Ward and to ensure he maintains regular communication with them. This will enable the DI to have better oversight of the seeking of consent for examination of pregnancy remains.

Concluding comments

Despite the minor shortfalls, areas of strength were identified. The DI has good communication with his PDs. The SOP for body identification is clear on the personal identifiers used prior to viewing of a body or release to a funeral director, and for PM examination. As examples of good practice:

- the establishment acted promptly to follow advice given at the inspection;
- the tray number is written on both the outside and inside of the fridge door, reducing the likelihood of the wrong tray being pulled out in error.

A number of areas of practice require improvement, including five minor shortfalls. The HTA has given advice to the DI on a range of issues, including consent documentation, governance and

quality systems, alarm arrangements for fridges and freezers, and the nomination of a PD on the Maternity Ward.

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: 14 May 2015

Report returned from DI: 28 May 2015

Final report issued: 28 May 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: 27 July 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
• 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.

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 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

- 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).

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.