Site visit inspection report on compliance with HTA minimum standards

Craigavon Area Hospital

HTA licensing number 12042

Licensed under the Human Tissue Act 2004 for the

- **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**

20 May 2015

Summary of inspection findings

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

Craigavon Area Hospital (the establishment) was found to have met all HTA standards.

Since the last inspection, the DI has changed and the establishment has ceased to carry out post mortem (PM) examinations, these now being referred to other HTA licensed establishments.

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

The HTA's regulatory requirements

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

The statutory duties of the Designated Individual are set down in 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

The HTA licensing number 12042 covers licensable activities carried out at two hospitals within Southern Health and Social Care Trust (SHSCT), Craigavon Area Hospital and its satellite site (for the purposes of HTA licensing), Daisy Hill Hospital.

No post mortem (PM) examinations take place at either site. Both hospitals are licensed for removal of relevant material for use for a scheduled purpose and the storage of a deceased body or relevant material for use for a scheduled purpose. Removal of tissue takes place in cases of sudden unexpected death in infancy (SUDI), and may take place in Accident and Emergency departments and within the maternity, neonatal and paediatric wards on both sites. In addition, storage of relevant material in the form of blocks and slides retained with consent following previous PM examinations, takes place at Craigavon Area Hospital.

PM examinations under the jurisdiction of the Coroner for Northern Ireland take place at the State Pathologist's Office, Belfast. Perinatal, paediatric and adult hospital post mortem examinations are sent to the regional referral centre, licensed by the HTA.
For hospital PM examinations, consent is taken by trained members of hospital staff, generally consultants or registrar medical staff, in accordance with a policy issued by Northern Ireland's Health and Social Care Department, and using similarly approved consent forms and family information booklets. The establishment also uses the two stage regionally approved consent training programme consisting of an e-learning package and face to face training for those involved in taking consent.

Staff involved in taking samples in SUDI cases follow a regional protocol. SUDI cases are subject to a blanket authority given by the Coroner, with staff informing the Coroner in advance of taking samples for investigation. This activity takes place primarily in the Accident and Emergency departments, but may also occur, rarely, in the maternity, neonatal or

paediatric departments. The HTA licence has been extended to cover these areas. There is no storage of products of conception, fetal material or stillbirths other than that taking place within the mortuary at both sites.

Bodies and tissue samples, including large surgical specimens for disposal as well as products of conception and placental material, are received into the mortuary on both sites and given a unique mortuary number which is then used to trace bodies and tissues through the mortuary. As no PM examinations are carried out, the mortuaries function only as body stores. The body store at Daisy Hill Hospital has space for six bodies, and that at Craigavon Area Hospital for nine, with one bank of fridges at the latter being suitable for bariatric cases. Two freezer units there are used for storage of products of conception and surgically resected tissues awaiting appropriate, sensitive disposal. Mortuary staff work across both sites, following identical procedures at both.

Although limited storage is available, bodies are retained in most cases for only a few hours or a day before being transferred elsewhere for PM examination, burial or cremation, as the local practice is for burial within three days of death. The storage fridges and freezers are serviced twice annually, are alarmed, temperature readings are recorded and trended monthly and there is a robust contingency plan in place for equipment failure or capacity overflow.

This was the establishment's second HTA inspection and comprised a visual inspection of the body stores on the Daisy Hill Hospital and Craigavon Hospital sites, the Emergency department at Daisy Hill Hospital and the Paediatric department at Craigavon. Key staff acting under the licence were interviewed.

An audit of traceability was carried out:

- At Daisy Hill Hospital, the details on body transfer forms relating to two bodies were compared with those details entered into the electronic mortuary register and recorded on porters transfer logs.
- At Craigavon Hospital, the only body being held in store was viewed and the patient details recorded on the identification wristband compared with paper and electronic records held in the mortuary.
- The identity details for one product of conception were traced to the consent for hospital cremation.
- Two sets of tissue blocks were located within the archive store and the consent for continued retention was reviewed. The electronic laboratory records were also accessed to confirm that the information recorded was consistent.

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.	GQ1	The DI is advised to consider incorporating the regionally approved protocol "Sudden death in infancy pack" into the establishment's document control system. This will allow for a periodic review of this document and help to ensure that any changes to the document are circulated to relevant staff. By incorporating the document into the establishment's system, it will also be possible to make any amendments necessary to reflect local practice, such as the sending of some samples to local laboratories, rather than to those in Belfast.
2.	GQ2	The DI is advised to ensure that the schedule of audits carried out at the establishment includes an audit of consent forms to check that those taking consent are listed on the register of staff who have received training in consent, particularly as staff carrying out consented PM examinations at other centres will have no ability to confirm this themselves. The HTA notes that the relevant policy and procedure detail the need for consent to be taken by trained staff, and the checklist attached to the consent forms requires the consent taker to confirm this, but such an audit will help to ensure the robustness of the current practice. The DI is further advised to ensure that there is an audit of the completeness of information recorded in the "Body transfer form", particularly to ensure that porters moving bodies from the wards to the mortuary are signing where required. This will aid traceability.
3.	GQ6	The DI is advised to ensure that porters sign the "Porters admission form" when they have placed a body from the ward into the body store. The HTA notes that it is possible to trace the porters who have moved a particular body by reference to work logs held by the portering department, but considers that ensuring signatures are appended will make investigation of any incident of damage to a body in transfer much easier, as traceability records will be more robust.
4.	PFE5	The DI is advised to risk assess the current practice of using some mortuary equipment made of porous materials, being head blocks and measuring sticks.
5.	N/A	The HTA notes that the DI is advised of any incidents occurring within areas covered by the HTA licence, has Persons Designated in areas covered by the licence and has regular contact with staff working within the mortuary and laboratories, on an informal basis and during governance meetings. The HTA advises the DI to periodically attend the Quality and Safety meetings for staff in the paediatric department, which Persons Designated in that area attend, so that he remains fully informed of the licensable activity taking place in relation to SUDI cases.

Concluding comments

The HTA saw various examples of good practice during the inspection. The establishment uses identical mortuary procedures at both sites, helping to minimise the risk of staff error. The electronic quality management system is used to control documentation, schedule audits and risk assessments, record training, manage incident reporting and investigation and to share learning, and is available to staff at all locations.

The establishment has taken the decision to combine all relevant mortuary procedures in one document, the Mortuary Manual, which means staff need refer only to it to carry out day to day operations within the mortuary.

Mortuary staff scan documents such as consent forms, transfer paperwork and death certificates into individual electronic records for each patient, ensuring that all documentation and relevant information is retained in one location accessible to all staff working throughout the department.

The HTA has given advice to the Designated Individual with respect to meetings, audit of consent documentation, document control, and modification of some forms used for traceability. Advice has also been provided in relation to the use of head blocks made of porous materials.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Report sent to DI for factual accuracy: 12 June 2015

Report returned from DI: 26 June 2015

Final report issued: 26 June 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.

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 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).

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.
- 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.