Site visit inspection report on compliance with HTA minimum standards

Calderdale Royal Hospital

HTA licensing number 12108

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**

8 May 2015

Summary of inspection findings

This inspection was conducted jointly with assessors from the United Kingdom Accreditation Service (UKAS), who assessed compliance with selected HTA licensing standards on behalf of HTA.

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 Calderdale Royal Hospital (the establishment) had met the majority of the HTA standards. Minor shortfalls were found regarding the information leaflet for perinatal and paediatric post mortem (PM) examination and documented procedures and risk assessment relating to the establishment's activities.

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

This establishment comprises Calderdale Royal Hospital ('the hub') and Huddersfield Royal Infirmary ('the satellite'). Each site's mortuary admits hospital deaths, but no community deaths are received. The establishment ceased performing post mortem (PM) examinations three years ago. All bodies for adult, perinatal or paediatric PM examination are transferred to other HTA-licensed premises, but the establishment retains responsibility for seeking consent for PM examination. Sampling of tissues from deceased children in sudden unexpected death in infancy (SUDI) cases may be performed in the Emergency Department at either site by consultant paediatricians, with pre-emptive authorisation from HM Coroner. A Trust protocol underpins this activity.

The establishment uses the Stillbirth and Neonatal Death charity (Sands) consent form for perinatal and paediatric PM cases (refer to shortfall against standard C2). Consent for perinatal PM cases was, until recently, being sought by bereavement midwives, but is now sought by obstetrics and gynaecology consultants (refer to advice items 2, 3). The establishment has adapted HTA's model consent form for adult hospital PM examinations. Consent can be sought by any clinician who has taken Trust consent training (refer to advice item 4).

The hub and satellite sites have 45 and 50 mortuary body fridge spaces, respectively, with bariatric spaces at each site. Perinatal and paediatric cases are stored on dedicated trays in an adult fridge at the hub; perinatal cases are in individual containers. A bank of fridges at the satellite can be switched to freezer mode if long term storage of a body is required.

The establishment has been licensed by the HTA since June 2007. There have been two previous site visit inspections (November 2007 and September 2011). This report describes the third, routine, site visit inspection of the establishment, conducted jointly with the United Kingdom Accreditation Service (UKAS). UKAS assessors visited the mortuary at each site and the histopathology laboratory, and gathered evidence against licensing standards GQ1-6, PFE1-5 and D1 on behalf of HTA. The HTA inspector met with staff involved with licensable activities and reviewed documentation. Storage locations and identifiers for six bodies (three at each site) were audited. Three minor anomalies in identification details were found, which would have originated on wards (refer to advice item 4). Mortuary records were correct in each case.

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 establishment uses the Department of Health 'A guide to the post mortem examination procedure involving a baby or child' leaflet to support seeking consent for perinatal PM examination. This leaflet pre-dates the Human Tissue Act and has been withdrawn from the DH website. It states that tissue blocks and slides will be retained indefinitely. 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. This information leaflet therefore does 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.	Some standard operating procedures (SOPs) are insufficiently detailed. For example: • the 'Procedure for obtaining consent for non-coronial hospital post mortems' SOP (M20 045) does not state that an information leaflet will be given to the family; • the 'Reception of bodies' SOP (M20 016) does not describe how mortuary staff highlight bodies with same or similar sounding names, or that porters place a head block under a deceased person's head when placing them into a fridge; • the 'Release of bodies' SOP (M20 027) does not state that two people will confirm the deceased's identity prior to release; • the 'Viewing the deceased' SOP (M20 032) does not specify points of identification, such as the deceased person's full name, date of birth or hospital number to be checked when giving access to relatives for viewings during working hours; • the 'Mortuary Bereavement Team' SOP (M20 051) also does not specify points of identification to be used for out of hours viewings and releases; • SOPs M20 027, M20 032 and M20 051 relating to release and viewing of deceased persons do not state what actions are to be taken if details on a deceased person's identity tag and associated paperwork do not match. There is also no documented procedure for testing of mortuary body fridge alarms. *(Refer to advice item 3)*	**Minor**

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The risk assessment of practices, processes and premises (M20 005) does not provide full assurance that key risks have been identified and are satisfactorily mitigated. For example: • the risk of viewing the wrong body has not been assessed; • the minimum points of identification for release and viewing procedures are not set out; • procedures for highlighting deceased persons with the same or similar sounding names are not cited as a risk control measure; • actions that can be taken to further mitigate risks, such as testing of mortuary body fridge alarms, are not listed.	**Minor**

Advice

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

No.	Standard	Advice
1.	C2, C3	Regarding consent for perinatal PM examinations, the DI is advised as follows: • a model information leaflet is available: https://www.hta.gov.uk/policies/sands-perinatal-post-mortem-consent-package • obstetrics and gynaecology consultants should receive refresher training on seeking consent for perinatal PM examination; they previously received consent training in 2008, and; • bereavement midwives play a pivotal role in supporting families experiencing pregnancy loss and seeking consent for perinatal PM examination. The number of bereavement midwives has fallen recently, for a number of reasons, and the DI is advised to discuss within the Trust whether more bereavement midwives can be recruited (see also advice item 7).
2.	C3	The DI is advised to include in the PM examination consent training presentation the following matters: • the hierarchy of qualifying relationships applies only when no decision to consent to, or not to consent to, a PM examination was made by the deceased person whilst they were alive, and there is no nominated representative acting on their behalf to give consent; • if the highest ranked person in the hierarchy of qualifying relationships does not give consent, then consent cannot be given by a person lower down in the hierarchy; • clarify whether 'indefinite retention' of tissues means the retention of relevant material for future use for the family; • reference to the HTA codes of practice on consent, PM examination and disposal. The DI is also advised that the Human Tissue Act 2004 does not require a person in a qualifying relationship to be eighteen years of age, although whenever seeking consent from someone less than eighteen years of age, their competency to consent to the

		activity must be assessed and proven.
3.	GQ1	Regarding documented procedures, the DI is advised: • to archive the 'Post Mortem' SOP (M20 006) as PM examinations are no longer being carried out; • to rename the 'Reporting serious untoward incidents to the Human Tissue Authority' SOP (M20 010) to reflect the current nomenclature of HTA Reportable Incidents (HTARIs), and; • to confirm with mortuary staff whether a minimum of two documents must be presented by a funeral director in order for a body to be released, as stated in M20-027, or whether one document is sufficient to enable release.
4.	GQ7	The DI is advised that a typographical, or other, error found on the death notice or identity tag on a deceased person admitted into the mortuary from a ward should be logged as a non-conformance in Trust systems.
5.	PFE3	The DI is advised to explore whether the upper temperature setting for mortuary body fridge alarms (+15 ^{o}C) can be adjusted downwards. If the alarm temperature can be lowered, then the likelihood of bodies deteriorating if a bank of fridges fails is reduced.
6.	PFE5	The DI is advised to keep local copies of records of maintenance visits for mortuary equipment from the Trust Estates Department or its sub-contractors, so that these are easily accessible for checking or inspection.
7.	D1	The DI is advised that the HTA has published guidance on sensitive disposal of pregnancy remains. Trust policies for the management of pregnancy remains should be reviewed in light of this new guidance: https://www.hta.gov.uk/sites/default/files/Guidance_on_the_disposal_of_pregnancy_remains.pdf
8.	-	The DI is advised that mortuary staff should be informed of the names of obstetrics and gynaecology consultants at this establishment, to facilitate communication with them when perinatal cases are returned there following PM examination.
9.	-	The DI is advised to: • nominate Persons Designated (PDs) to oversee removal of tissues samples from deceased infants in the Emergency Department in SUDI cases, and seeking of consent for perinatal PM examinations, and; • to meet regularly with these PDs, so he can be kept abreast of these activities.

Concluding comments

A number of areas of practice require improvement, including three minor shortfalls. The HTA has given advice to the DI with respect to consent training and documentation, SOPs, the mortuary premises and the disposal of pregnancy remains. The nomination of additional PDs is also advised.

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: 27 May 2015

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 13 June 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: 31 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.