Site visit inspection report on compliance with HTA minimum standards

Kettering General Hospital NHS Foundation Trust

HTA licensing number 12096

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**

26 March 2015

Summary of inspection findings

This inspection was conducted jointly with assessors from the United Kingdom Accreditation Service (UKAS), who assessed the mortuary against selected 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 Kettering General Hospital NHS Foundation Trust (the establishment) had met the majority of the HTA standards. One major shortfall was found in relation to body storage arrangements. Minor shortfalls were found in relation to documented procedures and risk assessments.

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

Approximately 500 adult post mortem (PM) examinations are conducted each year in the mortuary at Kettering General Hospital NHS Foundation Trust ('the establishment'), the majority of which are performed under the authority of HM Coroner for Northamptonshire. A small number of adult hospital (consented) PM examinations also take place. Perinatal and paediatric cases, and forensic cases, are transferred to other HTA-licensed establishments for PM examination. The establishment uses the Stillbirth and Neonatal Death charity (Sands) consent documentation for perinatal and paediatric PM cases, and HTA's model consent form for adult hospital cases.

The mortuary has capacity to store up to 49 bodies in refrigeration, with an additional five spaces for bodies in deep freeze. Refrigerators have a local alarm and will also ring through to the hospital switchboard if normal working temperatures are exceeded. In addition to these permanent spaces, bodies that have undergone PM examination and are to be released to a funeral director are stored in a temporary refrigerated unit within the PM suite (refer to shortfalls against standards GQ8 and PFE3). This temporary unit can store up to sixteen bodies. Pregnancy remains above twelve weeks gestation are stored on dedicated trays in the main body fridges; there is a stand-alone refrigerator for storage of pregnancy remains below twelve weeks gestation (refer to shortfall against standard PFE3).

Tissues taken at PM examination for histopathological analysis are processed into formalin-fixed paraffin wax blocks and microscope slides at the establishment. Organs and fluid samples for toxicological analysis are referred to other HTA-licensed establishments. With valid consent, PM tissue blocks and slides are stored for use for scheduled purposes.

Sampling of tissues from deceased children in sudden unexpected death in infancy (SUDI) cases is performed by consultant paediatricians, with pre-emptive authorisation from HM Coroner (refer to advice item 14).

This establishment has been licensed by the HTA since August 2007. Previous routine site visit inspections took place in October 2007 and August 2011. This report describes the third routine site visit inspection of the establishment, which was conducted jointly with the United Kingdom Accreditation Service (UKAS). UKAS assessors inspected the mortuary and 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 three bodies, and traceability records for two coronial PM examinations where tissues were taken for histology, were audited. In the body audit, a minor anomaly was noted in the spelling of the deceased person's first name on their wrist band; the name had been written incorrectly at the scene of the death in the community, but was written correctly by the establishment's staff into the mortuary register from other documents (refer to advice item 8). No anomalies were found in the tissue traceability audit.

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

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. As examples: • 'LP-MOR-SOP-Identification of bodies for PM examination', 'LP-MOR-SOP-View body' and 'LP-MOR-SOP-Release of bodies' do not specify which points of identification, such as the deceased person's name, their date of birth or hospital number, will be used when carrying out these procedures. These SOPs also do not clarify what actions to take if a discrepancy is found in identification details; • the acceptable temperature limits for refrigerators and the temporary unit for adult body storage are not documented either in the 'LP-MOR-SOP-Refrigeration failure' SOP or the charts used to record daily temperatures; • the temperature at which refrigerator alarms will ring locally, and to switchboard, if a bank fails are not documented. To meet this shortfall, all SOPs should be reviewed to ensure these contain an appropriate level of detail. *(Refer to advice item 2)*	**Minor**

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	Documented risk assessments of the establishment's practices and processes do not provide assurance that all key risks have been identified and are being satisfactorily mitigated. For example: • risk assessments do not always describe the risk controls in place, and often cite SOPs as a risk control measure. • they do not identify additional measures which may be taken to further mitigate risks, persons responsible for their completion and timeframes; • the establishment's robust process for highlighting deceased persons in storage with the same, or similar sounding, names is not listed as an existing control measure in risk assessments; • the temporary refrigeration unit for adult body storage, which is in continual use but does not have an alarm, is not documented as being a risk. Risk assessments need to set out all risk control measures, which should then be used to inform writing of SOPs. As identified in the shortfall against standard GQ1, some SOPs contain insufficient detail on local practice.	**Minor**

Premises, Facilities and Equipment

Standard	Inspection findings	Level of shortfall
PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues, cells, consumables and records.	Several issues regarding storage were identified: • the temporary refrigeration unit for bodies following PM examination is in continual use. Its temperature is logged on weekdays by mortuary staff. As the unit is located in the PM suite, it is accessible only to mortuary staff. This unit does not have a local, or remote, alarm and is not checked out of hours. Should a breakdown occur at a weekend or over a bank holiday period, it could be undetected for some days, which may lead to bodies stored within it deteriorating; • a stand-alone refrigerator used solely for storage of pregnancy remains below twelve weeks gestation has its temperature logged on weekdays by mortuary staff. This refrigerator does not have a local or remote alarm; • remote testing of refrigerator alarms is not performed to a regular, documented, schedule. Cumulatively, these deficiencies are considered to represent a major shortfall against this standard as they present a significant risk to the integrity of bodies stored by the establishment.	**Major**

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 consider discontinuing use of the information leaflet provided by the referral centre where perinatal and paediatric PM examinations are performed. The establishment uses the Sands consent form and information leaflet. Use of a second information leaflet may potentially confuse persons giving, and seeking, consent; • to discuss with HM Coroner whether the form used to record the family's instructions for tissues taken at PM examination could be expanded to provide details on the purposes for which tissues may be held in the medical record when coronial authority ends, such as for the future benefit of the family, clinical audit,

		research or education and training. This would facilitate use of tissues for such purposes without having to seek consent again from the family; • to provide additional information on use of Sands documentation in the perinatal PM examination consent training presentation; • to schedule refresher consent training for staff seeking consent for adult, perinatal and paediatric PM examinations, and; • to maintain a current list of obstetrics and gynaecology consultants who have been trained to seek consent and to periodically check this against consent training records. This will assure the DI that any potential risk of consent being sought by someone who hasn't completed local consent training is minimised.
2.	GQ1	Regarding SOPs, the DI is advised: • to add to the 'LP-MOR-SOP-Performing an autopsy' SOP the steps to be taken if, during the course of a coroner's PM examination, a suspicion was raised that might merit re-consideration of the case as a Home Office case, and; • that any variations in working practice between pathologists are described in all relevant SOPs.
3.	GQ1	The DI is advised to include further information about mortuary quality management in the Pathology quality manual.
4.	GQ1	The DI is advised that the HTA's guidance on sensitive disposal of pregnancy remains was published in March 2015. Relevant Trust policies should be reviewed to ensure these reflect the new guidance. https://www.hta.gov.uk/sites/default/files/Guidance_on_the_disposal_of_pregnancy_remains.pdf
5.	GQ2	One example was seen where a non-conformity form was not completed following an audit where a non-conformance was found. This is at variance with the Directorate policy for managing non-conformances. The DI is advised to ensure all non-conformances identified in audits are managed in accordance with Directorate policy.
6.	GQ2	The DI is advised to modify the form used for vertical auditing of the PM examination process ('QF-GEN-Vert Aud') to follow more closely steps in the relevant SOP. This audit could also include auditing of traceability of tissues taken at PM examination.
7.	GQ3	Regarding portering staff training, the DI is advised to ensure that: • competency assessments provide objective evidence of competence, and; • training and competence records cross-reference the relevant SOPs.
8.	GQ6	The DI is advised that where an error on a wrist band is noted, this should be corrected on the band.
9.	PFE2	The DI is advised to seek assistance from the Trust's infection control team to assess potential contamination risks in the mortuary. For example, some cracks in the flooring of the body store were visible which could, potentially, trap biohazard material. The DI should also assess whether cleaning of the PM suite is hampered by the presence of the temporary body storage unit situated there.
10.	PFE3	The DI is advised to ensure the establishment's routine practice of shrouding the head of a deceased person is applied to all bodies. It was noted that for two deceased persons in the temporary storage unit, the patient's face was not fully covered by their shroud.

11.	PFE3	On a daily basis, mortuary staff report to senior Trust colleagues the number of bodies in storage. This has highlighted recent periods of exceptionally high demand for storage space, such that maximum capacity is reached. The DI is advised that body storage capacity should be included as a significant risk on the Trust's Risk Register.
12.	PFE5	The DI is advised to maintain local copies of records of equipment maintenance visits by the Trust Estates Department or its sub-contractors.
13.	D1, D2	Regarding disposal, the DI is advised: • to specify the timeframe within which PM tissue blocks and slides must be disposed of once notification of the end of coronial authority is received and the family's instructions were for disposal. The establishment's standard practice is for pathologists to dispose of tissue as soon as possible under such circumstances. However, without a documented timeframe within which disposal is performed, there is a risk that practice may vary between pathologists; • the HTA endorses the DI's plans for a more structured approach to auditing of disposal of tissue blocks and slides.
14.	-	The DI is advised to nominate a consultant paediatrician as the Person Designated (PD) overseeing sampling of tissues from deceased infants in SUDI cases. The PD who oversees SUDI removal in these cases currently is not directly involved in this activity.

Concluding comments

Despite the shortfalls, aspects of strength were identified. Staff are very knowledgeable about local practice, and are committed to providing a high level of service to deceased persons and their families. In particular, at periods of high occupancy, mortuary staff have been proactive in managing capacity issues, and reporting these within the Trust. There is a good working relationship with HM Coroner's Office, which contributes to effective working practices.

A number of areas of practice require improvement, including one major and two minor shortfalls. The HTA has given advice to the DI with respect to consent training and documentation, strengthening documented procedures and competence assessments for portering staff, mortuary premises and equipment, and disposal of tissue blocks and slides.

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: 18 April 2015

Report returned from DI: 29 April 2015

Final report issued: 30 April 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: 15 September 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).

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.