Site visit inspection report on compliance with HTA minimum standards

Queen Alexandra Hospital

HTA licensing number 12237

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**

10 July 2014

Summary of inspection findings

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

Although the HTA found that Queen Alexandra Hospital (the establishment) had met the majority of the HTA standards, two minor shortfalls were found in relation to the consent standards. Consent for adult hospital post mortem(PM) examinations and perinatal PM examinations is sought by clinicians and midwives, many of whom have been trained to seek consent. However there is no system to ensure that all staff who seek consent have received training. In addition, the standard operating procedure (SOP) for seeking consent does not include who can take consent, the process for taking consent, or the training which they must have undertaken to enable them to seek consent.

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

Queen Alexandra Hospital is licensed to carry out PM examinations and the removal and storage of PM tissue for use for scheduled purposes under the HT Act. The corporate licence holder is Portsmouth Hospitals NHS Trust, and the corporate licence holder contact is the Director of corporate affairs and business development.

The establishment undertakes around 1,200 PM examinations each year, including 40 perinatal PM examinations. Almost all of the adult PM examinations are undertaken on behalf of the coroner for Portsmouth and South East Hampshire; only three consented adult PM examinations have taken place this year. Two pathologists based at the hospital undertake adult PM examinations; one of the pathologists also undertakes perinatal PM examinations. Four external pathologists also provide PM services to the mortuary. No forensic PM examinations are undertaken.

The mortuary is staffed by a Mortuary Manager, four Anatomical Pathology Technologists (APTs), one trainee APT and one Medical Technical Officer. APTs also undertake activities on behalf of other HTA licensed establishments, including retrieval of eyes for corneal transplantation and removal of brain tissue for research. High risk PM examinations take place in a dedicated PM suite. Staff are trained to handle such cases and are provided with appropriate protective equipment.

On receipt into the mortuary, staff check bodies using at least three points of identification, complete the ‘mortuary register’ and log details of the deceased in the customised mortuary database. The database is used to track bodies, identify same or similar names and record any updates relating to the deceased, since it is checked before bodies are released or prepared for viewing by relatives. A card is placed on the body if a same or similar name is identified or if tissues are removed during a PM examination.

Hospital porters arrange for supervised access to the mortuary when bodies are delivered out of hours. Porters receive induction training in the mortuary and all portering activities are logged and can be checked. APTs come into the mortuary when viewings take place out of hours. Release of bodies is always undertaken by a member of staff and the funeral director after checking and confirming the paperwork and identity of the deceased.

The establishment has 139 fridge spaces, including three bariatric spaces, four isolation spaces and four freezer spaces. The storage area also has a ‘baby’ fridge where babies are stored. The fridge and freezer temperatures are monitored and linked to local alarms and to the central switchboard. The establishment has access to a portable modular body storage system which can be set up in another room if required.

The Coroner’s officer faxes authorisation for a PM examination to the mortuary. The pathologist and an APT independently check the identity of the deceased before external examination and evisceration takes place. The pathologist is responsible for ensuring that all tissues and organs removed are documented on the ‘tissue retention form’. All tissues removed during PM examinations are sent to the histopathology laboratory on site for examination.

The Coroner’s ‘wishes of the next of kin’ form has the option to return tissues and organs to the body or to the family, but does not include the option for continued retention of tissues by the establishment (see advice and guidance item 9 in the section below). The Laboratory Manager has taken on the role of ensuring that tissues are disposed of when the Coroner’s authority ends and uses a separate tissue database to track tissues and review the status of cases; the establishment plans to link this database with the customised mortuary database. There are procedures in place to ensure that all blocks and slides are accounted for and are returned to the laboratory, including slides issued to external pathologists. The establishment uses a separate tracking system for disposal following pregnancy loss. Consent is sought from mothers regarding disposal of these tissues by cremation, irrespective of the gestation period.

The site visit inspection of Queen Alexandra Hospital took place on 10 July 2014. This was the second inspection of the establishment and included interviews with the Clinical Director for Pathology (DI), pathologists who undertake adult and perinatal PM examinations, consultants who takes consent for adult and perinatal PM examinations, a coroner’s officer, Mortuary Manager and a Trainee APT.

A document review was carried out. The documents reviewed included standard operating procedures (SOPs) relating to PM examinations, seeking consent for PM examinations, reception and release of bodies, viewing and identification of bodies, mortuary access, paediatric PM examinations referred to other hospitals and use of the mortuary database. The inspection team also reviewed policies, computer records of bodies booked into the mortuary, and disposal records, as well as paper records of tissues removed during PM examinations, the mortuary ‘error log’ incident reports and investigations, audit records and verification of the mortuary ventilation system. The inspection did not include a review of records relating to transportation of tissues for specialist examination or training records.

An audit trail was undertaken of two bodies stored in the mortuary. Details in the mortuary register were checked against the mortuary database, and the location of the bodies and their identity tags were checked; no discrepancies were found. The inspection team observed the release of a body to a funeral director.

Computer and paper records relating to a coroner's PM examination, a perinatal PM examination and an adult consented PM examination were traced from the mortuary register, consent form (if appropriate), tissue retention records, written and computer records and records of stored blocks or disposal records as appropriate. The number of blocks was checked against the paper and computer records. One block in one of the cases could not be accounted for. It was noted that in two cases, the section in the consent form for perinatal PM examinations relating to communicating with the establishment in the event that the consent giver changes their mind, was not completed (see – compliance with HTA standards - in the following section of this report). There were no other discrepancies.

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
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.	The SOPs 'Consenting for Post Mortems' - MORPROT038 and 'Perinatal Hospital Consented Post Mortems' - MORPROT035 do not reflect the process for seeking consent for adult and perinatal PM examinations and do not include details such as who can seek consent and the training they should receive. In 2011, following the previous HTA inspection, the establishment drafted a 'Consent to Post Mortem Examination Policy; which included more detail. However, it is unclear whether this policy was ever issued, as the current procedure is not in line with its contents. The checking procedure for completed PM consent forms is not sufficiently robust. It was noted that the section 'Changing your mind' in the consent form for perinatal PM examinations (where the consent seeker records a deadline for the parents to communicate with the establishment in the event that they change their minds) was not always completed. There is the risk that parents are not given clear guidance or the opportunity to change their minds as required by the HTA's Codes of Practice on consent and post mortem examination.	**Minor**

Standard	Inspection findings	Level of shortfall
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	The DI is not able to assure himself that staff who seek consent for PM examinations have received formal training in seeking consent. Some clinicians and midwives have received training in seeking consent for PM examinations but this has not been documented, nor is the mortuary aware of the names of staff who have attended training. Hence pathologists who undertake PM examinations are not assured that staff who seek consent, or staff who support them, have received training as required by HTA's Codes of Practice on consent and post mortem examinations. The training requirements for consent training have not been formalised or documented.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1	The DI is advised to consider providing a list of trained consent seekers or staff who can provide support to clinical staff who seek consent, to the mortuary which is updated regularly. This will enable pathologists and mortuary staff to assure themselves that consent has been taken by trained staff. The consent taker can be supported by another trained member of staff when seeking consent. If that is the case, the DI is advised to update the consent form to include the name of the person who supported the consent seeker so that the mortuary is aware that they were present when consent was sought.
2.	C3	The DI may wish to provide training in seeking consent for PM examinations to a limited number of staff and to set up a system to ensure that either these members of staff seek consent or are available to support clinical staff who seek consent.
3.	GQ1	The DI is advised to appoint Persons Designated (PDs) in the Accident and Emergency Department and Labour/Gynaecology wards to bring them within the current governance arrangements relating to HTA licensed activities and ensure that they attend governance meetings as required. Governance meetings currently cover the mortuary and histopathology laboratory and external pathologists but do not include staff in other areas.
4.	GQ1	The external pathologists who provide services to the mortuary are familiar with mortuary practices as they are invited to meetings and are provided with meeting minutes. The DI is advised to formalise the current arrangements with external pathologists in order to clarify their roles and responsibilities.

5.	GQ1	The DI is advised to consider updating the following SOPs to reflect current practices: • SOP covering mortuary access - staff are always present whenever maintenance personnel undertake work in the mortuary during working hours and outside working hours. • SOPs which cover receipt and release of bodies and checks undertaken before PM examinations - to state the acceptable minimum three points of identity checks completed by staff, which could include identifiers such as name, date of death, hospital number and address as noted on the wristband. The SOP should also cover the system for identifying bodies with same or similar names and identifying bodies when tissue samples or organs are removed during PM examinations. • The SOP for storage of bodies – to include the time frame for follow up of bodies which have been stored for long periods with the Coroner or other responsible authorities.
6.	GQ1	The DI is advised to review the mortuary 'error logs' in order to identify trends relating to the procedures followed by staff on the ward when preparing bodies for transfer to the mortuary. The DI is advised to feedback if additional training is required for ward staff responsible for care after death.
7.	GQ2	The DI is advised to consider setting up a system to audit consent forms in order to provide assurance that staff who seek consent complete all sections on the consent forms for PM examination.
8.	GQ3	The DI is advised to consider using mortuary staff to provide training to porters who have access to the mortuary. The Head Porter is responsible for training porters. The mortuary is aware that porters are trained to use the hoists and follow procedures when transferring bodies from the wards and providing access to funeral directors out of hours. However, the mortuary does not have direct input into training porters, nor is there assurance that all porters who have access to the mortuary have received training.
9.	GQ8	The DI is advised to undertake a risk assessment of the practice of routinely disposing of PM tissues following the end of the Coroner's authority. There is the risk that the disposal of tissues will not allow re-examination of those tissues in the event that further analysis might benefit the family, for example, in cases where there is found to be a genetic disorder.
10.	PFE2	The DI is advised to set up a system to manually challenge the alarms linked to the fridges and freezers to check if the alarms function as expected and if staff on the switchboard respond by contacting estates and/or APTs as they are required to do. In February 2014, during the annual inspection and re-verification of the ventilation system, it was observed that the air change rate in the main post-mortem room and high risk PM room did not meet target requirements of 10 and 12 changes respectively, as recommended in guidance - Health Technical Memorandum 03-1 specialised ventilation for healthcare premises (HTM03-1). However, the report states that the readings are within the 75% duty permitted levels. The DI is advised to follow up on these findings and act to ensure that the number of air changes does not decrease further and are in accordance with published guidance.

11.	D2	The DI is advised to ensure that the consent form for the disposal of tissues following pregnancy loss is retained by the establishment to maintain an audit trail and provide assurance that disposal was undertaken in accordance with the wishes of the parents.

Concluding comments

The HTA was impressed with the professionalism and dedication shown by staff who work in the mortuary.

The DI, pathologists, Laboratory Manager and staff in the mortuary and histopathology laboratory work well together as a team. Regular meetings are held to update staff and meeting minutes are made available to external pathologists who are kept upto date with any changes to procedures. There were several examples of good practice.

There is an effective system in place when a deceased baby or child is brought into the A&E department, which ensures that paediatricians, the Coroner, and other professionals, are consulted when tissues are removed from the deceased.

The establishment uses a customised mortuary database which is used to track bodies. The 'Mortuary error log' forms are used to record incidents such as when bodies are brought down from the mortuary without proper identification or have not been adequately prepared.There are effective systems in place to track tissues and organs removed during PM examinations. Access to the mortuary for teaching purposes or viewing a PM examination must be authorised by the training department and all visits and visitors are logged. The establishment has a system of audits which cover practices such as management of retained tissue, receipt and release of bodies and preparation and reconstruction of bodies. There are robust systems in place to track tissues from pregnancy loss; disposal options are provided to mothers and the hospital disposes of all pregnancy remains by cremation.

There are a number of areas of practice that require improvement, including two minor shortfalls relating to consent standards. The HTA has given advice to the Designated Individual with respect to the process for taking consent, auditing completed consent forms, updating SOPs, appointing Persons Designated on the licence, formalising the arrangements with external pathologists and training of porters, air flow in the PM rooms and manual testing of alarms.

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 time frames 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: 05 August 2014

Report returned from DI: 18 August 2014

Final report issued: 20 August 2014