

## **Site visit inspection report on compliance with HTA minimum standards**

**Milton Keynes General Hospital**

**HTA licensing number 12201**

**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.**

**27 November 2012**

### **Summary of inspection findings**

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

Milton Keynes General Hospital (the establishment) was found to have met all HTA standards.

The establishment has good systems in place for taking consent for post mortem (PM) examinations. Bereavement services staff provide support to clinicians who take consent and a pathologist is present along with bereavement staff and the treating clinician when taking consent.

Further examples of 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 Paragraph 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**

Milton Keynes General 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 Milton Keynes Hospital NHS Foundation Trust.

The establishment undertakes around 450 PM examinations each year on behalf of HM Coroner for Milton Keynes and fewer than five consented PM examinations. High risk PM examinations and paediatric PM examinations are not conducted at the establishment, although in relation to the latter, midwives take consent. These cases are sent to other HTA licensed mortuaries. Brain and spinal tissue is occasionally removed with consent and sent to Brain Banks.

The mortuary is staffed by three Anatomical Pathology Technologists (APTs), which includes the mortuary manager. It has 102 fridge spaces including four freezer spaces, and a separate refrigerated unit for babies. The temperature of the fridges is monitored daily.

A site visit inspection of Milton Keynes General Hospital was undertaken on 27th November 2012. This was the second inspection of the establishment and included interviews with a consultant pathologist (DI), locum pathologist, mortuary manager, an APT, bereavement service personnel who support staff who take consent for hospital PM examinations and a coroner's officer.

## **Inspection findings**

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

The Coroner's officer faxes authorisation for a PM examination to the mortuary and obtains the wishes of the next of kin regarding disposal of any tissues retained. The coroner's "post mortem and tissue retention form" offers the options of "archive/disposal" of tissue and the HTA has provided advice on this issue (see advice and guidance note 2 below).

APTs receive and register all bodies which are brought to the mortuary by Funeral Directors both during and after working hours. Hospital porters, who have been trained by mortuary staff, bring bodies from the hospital, place them in the mortuary fridges and record their storage location in the "Deceased Movement Record" form. APTs check these bodies each morning and record details in the mortuary register.

Most PM examinations are undertaken by visiting pathologists who are employed by an external pathology service and visiting home office pathologists. Organs and tissues removed during PM examinations are recorded in the Histology form. The numbers of blocks and slides made are recorded in a computer database along with the wishes of the next of kin. Details of slides issued to visiting pathologists, the return of slides, transport of tissues to specialist centres and disposal of organs, tissues and slides are also recorded in the computer database. Tissue blocks and slides from PM examinations undertaken after 2006 are stored on site. Blocks and slides which date before 2006 have been transferred to another HTA licensed establishment for long term storage.

A document review was carried out. The documents reviewed included: standard operating procedures (SOPs) and policies relating to PM examinations; information provided to those who give consent; written records including the mortuary register, consent forms, paper records and computer records used to record PM examinations and track tissues removed during PM examinations; disposal records; incident reports and investigations; audit records; temperature monitoring records; cleaning records; and training records.

An identification audit was undertaken of three bodies stored in the fridges and one stored in the freezer. Records were checked, including details in the mortuary register and details on the identity tags. One body was from the hospital and had several identifiers including the hospital barcode label. One of the bodies had a similar name to another person in the mortuary, which was highlighted by means of a notice on the mortuary white board to alert staff. During the inspection, the inspectors witnessed the checking procedures followed by staff when releasing a body. No discrepancies were noted.

An audit was undertaken of records relating to two PM examinations, one where tissues were disposed of and one where tissues were retained. Consent records relating to an adult consented PM examination was also reviewed. Records were traced from the mortuary register to paper records, disposal/retention of tissue forms, stored blocks and slides, or disposal records as appropriate. The number of blocks and slides were checked against the written records. There were no discrepancies.

The requirement to report serious untoward incidents to the HTA and the form to be used is documented in SOP Gen 101 – Incident reporting in Pathology. Following the inspection, the DI informed the HTA that a local SOP is being drafted to formalise the SUI reporting

procedure within the mortuary. Visiting pathologists will be made aware of this SOP when they come on-site.

### 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.	C1	The DI is advised to consider updating the consent forms used for PM examinations when the forms are next printed. The phone number given on the form is not in use out of hours. The form states a time frame of 24 hours for relatives to inform mortuary staff, should they decide to change their mind and refuse consent for a PM examination; however, the establishment policy states that relatives must inform the mortuary within 48 hours should they decide to change their mind. Until new forms are printed, staff who take consent can make the required changes by writing on the consent form and signing next to the amendments.
2.	GQ1	<p>The Human Tissue Act 2004 requires appropriate and valid consent to be in place when tissues are stored for use for scheduled purposes following a PM examination. During the inspection the HTA was informed by the coroner's officer that following a PM examination, families are informed that, with their consent, tissues can be stored for medical research or in case they are of future use to the family. If the family consents to continued storage, the "archive" option is ticked on the coroner's "post mortem and tissue retention form.</p> <p>The use of the word "archive" introduces the risk that tissues are stored for no purpose and without appropriate consent under the HT Act. Whilst the HTA appreciates that there is a shared understanding between the establishment staff and the coroner's office with respect to the use of the word "archive", there is no documented evidence which clarifies that the coroner's officers' discussions with families includes adequate explanation of consent for continued storage of tissues for scheduled purposes.</p> <p>The DI is advised to review the use of the word 'archive' in the establishment's SOPs and replace it with a phrase such as "storage for use for a scheduled purpose" or "continued storage".</p>
3.	GQ8	The DI is advised to consider undertaking risk assessments against each of the categories of serious untoward incident listed in the HTA's Guidance for notifying the HTA of serious untoward incidents in the PM sector – see <a href="http://www.hta.gov.uk/db/documents/Guidance_Document_-_SUI_Notification_201112192847.pdf">http://www.hta.gov.uk/db/documents/Guidance_Document_-_SUI_Notification_201112192847.pdf</a>
4.	PFE2	The DI is advised to ensure that he has access to records kept by the Trust building services which detail the measurement of air flow within the post mortem rooms. This will help to assure the DI that the maintenance department monitors airflow on a regular basis and takes corrective actions if the rate of airflow is below the recommended ten air changes per hour. The DI is also advised to satisfy himself that the freezer and fridge alarms are checked on a regular basis by equipment maintenance staff or by staff who work in the mortuary.

## **Concluding comments**

The DI, visiting pathologists and mortuary staff work well together as a team. There were several examples of good practice. There is a formalised induction procedure for all new staff and visiting pathologists, which requires them to sign to confirm that they have read key SOPs. There is an alert system whereby a “red band” is attached to the tray containing the deceased to alert staff that the body should not be released, for example, if it is waiting for tissues and organs to be returned. The pathologist and APT sign to confirm that they have checked the identity of the body before each PM examination takes place. Bereavement services staff, labour ward staff and porters follow a “Care for stillbirth, termination of pregnancy and neonatal death after 24/40 weeks gestation” check list, which covers transferring babies to the mortuary, documentation to be provided to parents and steps to be followed when making arrangement to seek consent for PM examinations. The DI, corporate licence holder contact and Mortuary Manager attend quarterly HTA meetings where issues to do with HTA licensed activities are discussed.

There are some areas of practice that require improvement. The HTA has given advice to the DI with respect to assurance provided by the coroner’s office when families give consent to the continued storage of tissues following a PM examination, and the use of the word “archive” in documentation used at the establishment. Advice has also been given in relation to risk assessments.

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

**Report sent to DI for factual accuracy: 24 December 2012**

**Report returned from DI: 4 January 2013**

**Final report issued: 4 January 2013**