

“**[redacted]**”
By email

Tel 020 7269 1960
Web www.hta.gov.uk

Date 17 April 2014

Dear “**[redacted]**”

Freedom of Information request

Thank you for your request for information dated 10 April 2014, which we received as follows:

“I would be indebted if you could help with the following information. In 2010 to 2012 the Human Tissue Authority required hospitals to conduct an audit.

1. What was the background to the authority deciding that audit was required?
2. As regards the county of Worcestershire what were the audit's findings?
3. Did you specify any requirements for the audit, in terms of standards and procedure?”

Response

In December 2009, the HTA issued a regulatory alert to Designated Individuals (DIs) following review of site-visit inspections, which indicated that there was lower than expected compliance with standards relating to consent and traceability, and that the practice of storing tissue blocks and slides without appropriate consent under the Human Tissue Act 2004 (HT Act) continued, despite repeated guidance issued by the HTA. In addition, since April 2008, the HTA had been notified about several incidents involving the storage without consent of a brain following release of the body for burial or cremation after a forensic post-mortem examination. The regulatory alert put DIs of establishments where post mortem examinations are conducted on notice that the HTA would be issuing General Directions in April 2010 requiring them to undertake an inventory and audit of relevant material from the deceased stored on the premises after the commencement of the HT Act on 1

September 2006, the results to be submitted to the HTA in writing in September 2010.

It was not the intention of the HTA to use the results of the audit to target establishments for regulatory action, but to use the information gathered from post mortem sector establishments to:

- a. provide tailored advice and guidance to individual establishments on tissue retention;
- b. identify establishments that required support in reviewing their systems governing consent, traceability and disposal, in order to achieve full compliance with HTA standards;
- c. inform the advice and guidance provided to the post mortem sector as a whole on common areas of difficulty;
- d. provide information to the HTA on the issues facing post-mortem sector establishments to inform the continued development of HTA policy affecting the sector.

At the time of the audit, the HTA licensed three establishments in the post mortem sector in Worcestershire, two of which were required to complete the exercise. Their findings are set out below:

Worcestershire Acute Hospitals (HTA licensing number 12079)

Inventory of whole organs and wet tissue

- One whole organ was being stored at another HTA-licensed establishment and one whole organ was being retained; both were awaiting repatriation with the body
- 35 items of wet tissue and 80 fetuses or items of fetal tissue were being retained
- Of the total of 116 items stored on the premises, 8 items were being retained under coroner or police authority; the remaining 108 items were being retained awaiting disposal or collection for burial/cremation
- There were no cases for which the documentation relating to retention indicated that the hospital should not have been retaining the organ/tissue.

Audit of tissue blocks and slides:

- 700 tissue blocks were generated from the audited cases

- There were 39 audited cases where blocks and/or slides were still being retained
- The establishment was able to trace 100% of the slides during the audit.
- There were no cases for which the documentation relating to retention indicated that the hospital should not have been retaining the tissue.

Alexandra Hospital, Redditch (HTA licensing number 12424)

Inventory of whole organs and wet tissue

- 28 whole organs and 26 items of wet tissue were being retained awaiting disposal or collection for burial/cremation
- 136 whole organs and items of wet tissue, whole fetuses or items of fetal tissue were being retained under coroner or police authority
- There were no cases for which the documentation relating to retention indicated that the hospital should not have been retaining the organ/tissue.

Audit of tissue blocks and slides:

- 445 tissue blocks were generated from the audited cases
- There were 9 audited cases where blocks and/or slides were still being retained
- The establishment was able to trace 100% of the slides during the audit.
- There were no cases for which the documentation relating to retention indicated that the hospital should not have been retaining the tissue.

The HTA worked with the Royal College of Pathologists to define the specification of the audit exercise, helping ensure that it was proportionate whilst giving the HTA the necessary assurances of compliance with the requirements of the HT Act. The Directions applied to all establishments that were licensed by the HTA for 'the making of a post-mortem examination'. They did not apply to establishments licensed for storage only. In addition to the completion of an inventory and audit of whole organs and wet tissue, they were required to undertake an audit of a representative sample of cases in which tissue blocks were made from relevant

material removed from deceased persons. Templates and instructions for use were provided.

The audit exercise gave establishments the opportunity to review their holdings, check their practices and make improvements where necessary. Overall, it indicated that the incidence of inappropriate tissue storage was small in relation to the number of post mortem examinations undertaken every year. The HTA is not complacent, however. We expect all establishments to undertake regular audits of retained tissue to ensure that records are in order, tissue is only ever kept for a legitimate purpose and that it is disposed of as soon as possible when the case is concluded and the wishes of the family have been made known. We check this as a matter of course during inspections of post mortem sector establishments.

If you are unhappy with the way the HTA has handled your request for information in this case, you may in the first instance ask us for an internal review by writing to us at the above postal or email address. If you remain dissatisfied with the handling of your request or complaint, you have the right to appeal directly to the Information Commissioner for a decision, at the address below:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire SK9 5AF

Telephone: 08456 30 60 60
 or 01625 54 57 45
Website: www.ico.gov.uk

There is no charge for making an appeal.

Yours sincerely

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