



# Human Tissue Authority

Post mortem sector report – June 2011

*Summary of 2010 self-assessment against HTA standards  
and audit of retained tissue*

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## Introduction

1. The HTA is the regulatory body responsible for implementing the requirements of the Human Tissue Act 2004 (HT Act) in England, Wales and Northern Ireland. We aim to minimise the risk of statutory and regulatory breaches through the application of standards and by providing advice and guidance to stakeholders, in order to ensure and maintain public confidence in the safe and ethical use of human tissue.
2. One of our statutory functions is to license establishments that undertake post-mortem examinations (PMEs) and that store post mortem tissue samples for future use. In summer 2010, when the information contained in this report was collected, there were 211 licensed establishments engaged in these activities.<sup>1</sup>
3. Approximately 111,000 adult and paediatric PMEs are performed each year, by around 1,040 Pathologists and 670 Anatomical Pathology Technologists (APTs). Of these, 7,680 (less than 7%) are consented PMEs, undertaken in discussion with the deceased's family. The vast majority are undertaken at the request of and under the authority of one of HM Coroners, including Home Office cases.
4. Establishments vary in size and in the range of activities they undertake. More than half (125) undertake high risk PMEs – those where the deceased is known or suspected to have had an infectious disease, and which may present a risk to the pathologist and APT. A far smaller proportion, around a fifth, undertake paediatric PMEs. More than three quarters accommodate visiting pathologists, such as Home Office or independent pathologists, some of whom routinely remove tissue for examination at other premises. In fact, the movement of bodies and tissues between establishments is common, and reinforces the importance of good systems of traceability and record keeping, as well as the need for effective communication between pathologists, mortuary staff, coroners and their officers.
5. This report contains a summary of the outcomes of the self-assessment exercise and audit of retained post mortem material which establishments were required to complete in the summer of 2010 in order to check their systems of consent, traceability and disposal.

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<sup>1</sup> As of June 2011, there are 206 licensed establishments in the post mortem sector.

6. One of the primary aims of the exercise was to assess the effectiveness of the HTA's regulation of the post mortem sector and, in particular, to ensure that establishments' operational procedures and practices are successful in preventing the unauthorised retention of post mortem tissue.
7. The information we have gathered shows that the sector continues to have a strong focus on implementing systems that meet regulatory requirements, ensuring that tissue is kept only with the appropriate consent. This has resulted in HTA quality standards being met in a high proportion of cases, and a low incidence of unauthorised tissue retention.
8. There are still improvements to be made in some of the underlying systems supporting the delivery of post mortem services, and we hope the information contained in this report, and any further guidance we issue in the forthcoming months, will be helpful to all those working in the sector.
9. This report was originally due to be published in March 2011. However, the collection and analysis of the data took longer than expected, and it was necessary to go back to a number of establishments for further clarification of the information they had provided. The final report was published in June 2011.

## Findings of the self-assessment exercise

10. This section of the report provides a summary of establishments' self-assessment against HTA quality standards, which were designed with the sector to ensure public and professional confidence that human tissue is used safely, ethically and with consent. It identifies areas of strength and a small number of areas where improvements could be made. It also provides a brief update on Serious Untoward Incident reporting.
11. The overall aims of the self-assessment were: (i) to gather up-to-date information about HTA-licensed establishments' post mortem activities to better understand the profile and dynamics of the sector; (ii) to assess performance against HTA standards in order to assure ourselves of the continued suitability of establishments to be licensed and to inform inspection scheduling based on risk; and (iii) to ensure we have the up-to-date information we need to support the process of continuous licensing, which started in April 2009.

### The self-assessment process

12. Establishments were given a template on which to record a rating of 1 to 4 against each standard and evidence to support it<sup>2</sup>. Examples of types of evidence were provided by the HTA to assist those completing the return. Based on the evidence they provided, the HTA then made its own assessment against each standard to determine each establishment's understanding of the requirement and to ensure consistency in decision making by HTA staff.
13. Around 80% of establishments' self-assessment submissions were subject to slight moderation by the HTA, meaning that an adjustment was made to one or more of their self-assessed scores. The vast majority of these, around 88%, had one or more of their ratings increased by the HTA. For example, some establishments had marked themselves as not fully meeting standard C2 (see paragraph 15) because of the limited formats of consent information available, but the HTA was satisfied from the evidence provided, that consent information provided to patients was sufficient to meet the standard.

### Performance against HTA standards

14. There were overall high levels of performance against all HTA standards (available on the [HTA website](#)), with well over 90% of establishments meeting

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<sup>2</sup> 1 = not met, 2 = partially met, 3 = almost met, 4 = fully met

in full standards relating to governance and quality; premises, facilities and equipment; and disposal, and just under 90% meeting in full standards relating to consent. This may be due to the fact that most establishments had been subject to site-visit inspection by the HTA and had therefore been provided with advice and guidance specific to their needs. In addition, we believe that the sector-wide advice that has been provided via [the revised code of practice on Post-mortem examination](#) and the published '[summary reports](#)' has led to a better understanding of HTA requirements. It is also clear that establishments have worked hard to understand the requirements and make any improvements necessary to meet them.

15. As mentioned above, some establishments assessed themselves as lower than considered correct by the HTA, and ratings were adjusted upwards. This was particularly evident in relation to standards C2 (information about the consent process is provided and in a variety of formats) and C3 (staff involved in seeking consent receive training and support), where the HTA increased establishments' self-assessed score in around 36% of cases. This was usually because, at the time of the submission, establishments' consent documentation (e.g. policies, procedures, information for patients and training materials) was in a cycle of review, but there was a clear plan in place to approve and roll out updated documentation. Where this was the case, checks are made on inspection to ensure the review has been completed and new documentation issued.

16. In a small number of cases, the HTA's assessment was lower than that made by the establishment. This occurred for an average of only three establishments per standard and this information has been considered alongside the submitted audit data in order to inform our risk ratings for scheduling inspections.

### **Areas for improvement**

17. The HTA identified some issues on which establishments may require further support and guidance. In addition, establishments themselves indicated they would welcome further help in meeting specific standards, as listed below:

- 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.
- C2 Information about the consent process is provided and in a variety of formats.

- C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.
- GQ2 There is a documented system of quality management and audit.
- GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.

18. Where the HTA has identified, or an establishment has itself indicated, that extra support is required to meet the standards in full, we will provide targeted support. The provision of advice and guidance remains a core objective for the HTA and we will be considering how best to disseminate advice across the sector to address common areas of difficulty. This will include sharing good practice with the sector. In the meantime, readers are referred to paragraphs 27–55 and 127–166 in the code of practice on Post-mortem examination, the model consent form and communication flowchart, all of which are available on the [HTA website](#).

19. The data on performance against standards will contribute to each establishment's risk score and inform our prioritisation for inspection.

### **Serious Untoward Incident reporting**

20. On 1 May 2010, the HTA implemented a mandatory system of reporting of Serious Untoward Incidents (SUIs, including near misses) in the post mortem sector. Near misses are incidents that had the potential to occur but, because this potential had been identified in time, no incident took place. This information informs the HTA and enables it to share with the sector the learning gained from SUI investigation and the corrective and preventative actions taken in response.

21. From 1 May 2010 to 31 March 2011, 54 SUIs (including near misses) were reported to the HTA, a very small number when considering the 111,000 post-mortem examinations that take place every year, but potentially extremely distressing for those involved, and particularly for the families affected. The HTA has communicated the contributory causes identified by the establishments with the sector, so others can learn and make adjustments to their own systems and help mitigate the risk of similar incidents happening again.

## Findings of the audit of retained post mortem material

22. This section contains summary information about tissue being stored by establishments and the reasons for retention.
23. The aims of the audit were: (i) to understand more about the types and quantities of material stored on licensed premises and the reason for its retention, in order to provide advice and guidance and to inform policy development; (ii) to identify where and why tissue may be being stored without appropriate consent; and (iii) to assure ourselves that licensed establishments have robust and reliable systems of traceability and records management, and identify any that do not, so we can provide support to help them fully meet HTA standards for the safe and ethical use of human tissue.
24. The HTA consulted colleagues from the Royal College of Pathologists and the Association of Anatomical Pathology Technologists in determining the specifications of the audit, to ensure that it was reasonable and proportionate, whilst giving the HTA the necessary assurances that establishments are meeting the consent requirements of the HT Act.
25. Organs and wet tissue (including fetal material) are less likely to be retained for future use, as families often want these returned for burial or cremation. It was therefore anticipated that there would be fewer of these and they would be relatively easy to locate. This is in contrast to the thousands of blocks and slides generated by post mortem establishments each year. It was not considered reasonable or proportionate to require every block and slide to be counted. It was therefore determined that a full inventory of whole organs, wet tissue (including bone) and fetal tissue would be required, but that an audit of a specified proportion of cases where tissue was made into blocks and slides would suffice HTA purposes.
26. Establishments were asked to submit a summary report of the results of the inventory and audit to the HTA by 30 September 2010.
27. A total of 202 establishments were required to complete the exercise<sup>3</sup>. This report summarises information received from 197 establishments. The information received from the remaining five is not included because it remained incomplete at the time this report was written. These establishments have been followed up individually by the HTA.

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<sup>3</sup> Nine establishments storing material on behalf of other organisations, but not undertaking post-mortem examinations themselves, were not required to complete the inventory and audit.

## **Inventory and audit of whole organs, wet tissue and fetal material**

28. Establishments were asked to provide detailed information about the numbers and types of tissue being stored and to state the reasons for storage. The data show that all tissue being stored by HTA-licensed establishments in the PM sector had originally been retained and stored for legitimate purposes with Coroner or police authorisation, or with consent. In one establishment, however, a number of items were found at the time of the audit to have been kept when they should have been disposed of (see paragraph 32).
29. Around 45% of the tissue items were being stored with consent for use for scheduled purposes (e.g. training and education, research or audit). In fact, 85 of the 197 establishments that submitted completed returns stated that at the time of the audit they were storing tissue with consent for use for scheduled purposes. This is encouraging and should reassure the sector about the public's willingness to consent to the retention of tissue for future use.
30. Approximately 36% of the tissue items were being retained under the authority of the Coroner or as evidence in police cases. (The police are currently undertaking a separate audit of retained material, and the HTA will be sharing this report with the Association of Chief Police Officers, who instigated the police audit.)
31. A further 19% of tissue items were being stored pending respectful disposal. Although this might seem a high proportion, the HTA is aware that establishments often work to a cycle of disposal, ensuring that tissue is disposed of appropriately and in accordance with the HTA [code of practice on Disposal of human tissue](#). In addition, special arrangements are made for the sensitive disposal of fetal material in particular, for example burial services, which take place periodically throughout the year. This may account for the relatively large number of items awaiting disposal at any given time. The HTA will review storage pending respectful disposal during its inspections.
32. In reviewing tissue stores and undertaking an audit tracing the material back to the post mortem records, 27 items from six cases were found to have been kept in error by one establishment, which means that they had originally been retained for legitimate purposes, but procedural errors had prevented them from being disposed of. None of these were whole fetuses or items of fetal tissue. The establishment concerned took immediate action to dispose of the tissue appropriately and in accordance with the HTA [code of practice on Disposal of human tissue](#).

33. In 525 cases there was incomplete documentation relating to tissue retention. Around 95% of these cases related to material being stored under the authority of the Coroner. The documentation problems in these cases were caused mainly by communication problems between the establishment and the Coroner and, where relevant, the police, which may have led to tissues being retained for longer than was necessary. Although the material was still being retained legitimately by establishments under the authority of a Coroner, the wishes of the next of kin in relation to disposal were not always provided to establishments in a timely manner following the conclusion of cases. The HTA is working with the Coroners' Society and the Home Office to develop systems which will help resolve these ongoing difficulties. The remaining 5% of cases were hospital post-mortem examinations and in these cases it was the failure of Pathologists to communicate in a timely manner that caused the retention of material for longer than was necessary. The HTA is expecting establishments to dispose of tissue samples as soon as they are able, and we will be checking to ensure that appropriate and timely steps have been taken to resolve these outstanding cases.
34. The inventory and audit of whole organs, wet tissue and fetal material has given establishments the opportunity to review their holdings, check their practices and make improvements where necessary. Importantly, it has indicated that the incidence of inappropriate tissue storage is small in relation to the number of post-mortem examinations undertaken every year. However, we should not be complacent and we encourage all establishments to undertake regular audit of retained tissue to ensure that records are in order, that tissue is only ever kept for a legitimate purpose, and that samples are disposed of as soon as possible when the case is concluded and the wishes of the family have been made known.
35. It is standard practice for the HTA to review establishments' audit activities during site-visit inspections.

### **Audit of blocks and slides**

36. Every year, thousands of tissue samples (usually smaller than the size of a postage stamp) are processed into wax blocks, which are then sectioned for microscopic examination. The HTA did not consider it reasonable or proportionate to require every block and slide to be counted and determined that an audit of a sample of cases where tissue was made into blocks and slides would be sufficient to assess the effectiveness of traceability systems.
37. Establishments were required to review a proportion of cases from the period 1 July 2008 to 30 June 2009. This period was chosen because it was

considered that sufficient time would have elapsed since the commencement of the HT Act for there to be awareness of the consent and traceability requirements, but it was sufficiently far back for most Coroners' cases to have been completed. It was expected that where tissue should have been disposed of, this would be recorded and the blocks and slides would not be present at the establishment.

38. It was agreed that a representative sample of blocks and slides would be audited. Therefore, establishments were required to audit 20% of cases where tissue was made into blocks and slides for the identified time period.
39. The HTA is aware that the number of slides prepared from tissue blocks is not always recorded and that it is not uncommon for slides to be lost or, as they are fragile, broken. Therefore, establishments were asked whether there was full traceability for all (100%), most (75–99%), some (30–74%), few (less than 30%) or none of the slides. (Twenty-two establishments (10.9%) send all tissue off site for processing so this question was not applicable.)
40. Nearly half of establishments were able to account for all microscope slides and over 86% were able to account for more than three quarters of microscope slides. This demonstrates that it is possible to put into place effective systems of traceability, notwithstanding the movement of slides and the varying practices of the Pathologists who are using them.
41. Five establishments indicated they could account for less than 75% of the slides relating to the audit sample. These have been inspected by the HTA since the end of the audit period (1 July 2008-30 June 2009) and the effectiveness of traceability systems was considered during inspection and advice and guidance was provided on improvements that could be made. The HTA is at present satisfied with the traceability systems at these establishments, but will review them again when each is re-inspected.
42. Around 20% of establishments had ongoing cases about which they were waiting for information from the Coroner in relation to the disposal wishes of the deceased's family. Five establishments found blocks and slides on the premises that should have been disposed of. Action has since been taken to dispose of this material.

### **Benefits of the inventory and audit**

43. The HTA appreciates the support of the PM sector in completing the inventory and audit. The exercise has demonstrated the value of audit in ensuring that systems work effectively; where there have been problems, the audit allowed

these to be identified and action to be taken.

44. We consider that our objectives have been met and we will use the results to inform regulatory policy development, the provision of advice and guidance and the prioritisation of inspections.

45. The exercise has brought the following benefits:

- Establishments are aware of and able to rectify shortfalls in their systems that may prevent them from keeping accurate information about the nature and quantity of PM tissue they are retaining and the reasons for its retention.
- Any inappropriate retention of tissue has been identified and addressed.
- Tailored advice and guidance can be provided to individual establishments in order to improve systems relating to consent, traceability and disposal.
- Common areas of difficulty will inform HTA regulatory policy ensuring clarity about our expectations relating to the application of quality standards.
- Learning can be shared across the sector, which will help establishments better meet HTA quality standards.
- The public can be confident that regulation of the post mortem sector is effective and that the HTA is working with establishments within its remit to ensure that tissue is not being retained or used where consent has not been given.

46. As part of an ongoing action plan of activity in relation to the sector, we have been in direct contact with a small number of establishments that were identified as being at higher risk of falling short of HTA standards, and have worked with them to identify and implement improvements.

## Next steps

47. In addition to identifying individual establishments that need support, the audit has identified a number of sector-wide issues, on which the HTA will provide guidance in the forthcoming months:

- The level of traceability of tissue blocks and slides is reasonably encouraging; however there is room for improvement. The information we now have will enable us to provide clarification to the sector on acceptable levels of traceability, taking into account operational realities in the sector, whilst still striving to ensure full traceability wherever possible.
- Some establishments continue to obtain consent for retention of tissue as part of the medical record, without fully explaining to families the potential for that material to be used for scheduled purposes and seeking appropriate consent.
- There is an indication that items of tissue may be being held for a period of weeks, or perhaps months, awaiting disposal; this is particularly the case with fetal material. From our knowledge of the sector, this is most likely because of the special arrangements that are made for the sensitive disposal of this tissue, but we will look further into this.
- Some establishments are not being proactive in ensuring that tissue is disposed of in a timely manner when it is no longer required for Coroner or police purposes. This may relate to systems of communication between key parties, and establishments are advised to consult the [HTA codes of practice](#) for practical guidance.

48. Input will be sought on these issues from the Histopathology Working Group, which is made up of HTA staff and representatives from key professional and stakeholder groups including the Royal College of Pathologists, the Association for Anatomical Pathology Technologists and the Coroners Society of England and Wales. In this way, we can engage with the sector in the development of regulatory policy in the forthcoming months. In addition, as mentioned elsewhere in this report, the HTA will be taking all necessary steps to ensure that tissue is disposed of where appropriate, in line with HTA guidance.

49. The HTA is grateful to colleagues working in the sector for their co-operation in providing the information requested. It will help us focus our regulatory

activity on the small number of establishments at most risk of failing to meet standards fully, ensuring public and professional confidence in the delivery of post mortem services.

## Appendices: Information for Designated Individuals and staff working in licensed establishments

### Appendix 1. Information on the movement of bodies and tissue

The following data were collected as part of the performance update, and may be of interest to those working in the sector:

- 171 establishments send bodies to other establishments for PME.
- 190 send whole organs or tissue (including blocks and slides) to other establishments for analysis.
- 183 have organs or tissue being taken off the premises by independent Pathologists, researchers or tissue retrieval teams.
- 133 receive bodies from other establishments for PME.
- 83 receive tissue (including blocks and slides) from other establishments, including for laboratory analysis and examination.
- 59 store whole organs or tissue (including blocks and slides) on behalf of other establishments or individual Pathologists.

### Appendix 2. Performance against HTA quality standards

HTA standard	Proportion of establishments meeting HTA quality standards		
	Standard fully met	Standard almost met	Standard partially / not met
Consent	88%	9%	3%
Governance and quality systems	94%	5%	1%
Premises, facilities and equipment	97%	2%	1%
Disposal	97%	3%	0%

In reviewing the data provided, the HTA found that in a small number of areas further clarification on HTA requirements was required. Therefore, at the conclusion of the assessment phase, the HTA reviewed the examples of evidence looked for on HTA inspection and made some very minor amendments. The revised examples can be found on the [HTA website](#).

**Appendix 3. Serious untoward incidents and near misses reported to the HTA, 1 May 2010 to 31 March 2011**

<i>Category of incident<sup>4</sup></i>	<i>Number of incidents</i>	<i>Number of near misses</i>
Accidental damage to a body before or after a post-mortem examination	6	1
Discovery of an organ or tissue following post-mortem examination and release of body	7	1
Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services	1	0
Loss of an organ	1	0
Major equipment failure	2	3
Post-mortem examination conducted was not in line with the consent given or the post-mortem examination proceeded with inadequate consent	4	0
Post-mortem examination on the wrong body	1	0
Release of wrong body	8	0
Serious security breach	3	1
Disposal or retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family	1	0
Any incident that could result in adverse publicity that may lead to damage in public confidence	11	3
<b>TOTAL</b>	<b>45</b>	<b>9</b>

<sup>4</sup> Descriptions of these categories are available on the [HTA website](#)

## **Summary of shortfalls which resulted in serious untoward incidents**

Root cause analyses of incidents undertaken by the establishments themselves and subsequently reviewed by the HTA identified a number of contributory factors. These are shown below, along with the corrective actions that were taken to prevent reoccurrence.

### ***Contributory factor 1: Procedures not followed correctly and poor record keeping***

In the majority of incidents, standard operating procedures (SOPs) were in place but were not followed correctly, for example when checking consent, releasing a body from the mortuary or checking the identification of a body before post-mortem examination. In one or two cases, procedures were found to be too detailed, discouraging staff from following them.

Procedural errors relating to documentation and record keeping were also found to be a contributory factor, making traceability of tissue difficult and increasing the risk of tissue being kept without consent, misplaced, or stored and simply forgotten about. Examples are documentation identifying the deceased, e.g. the death notice form or tissue retention forms not being completed correctly.

#### *Corrective actions taken by the establishment*

- Refresher training for mortuary staff.
- Review and modification of existing procedures.
- Introduction of new procedure.
- Audit of compliance against procedures.
- Review of funeral director's procedures, leading to recommended improvements.

#### *Additional advice provided by HTA*

- Refresher training should be provided to all relevant staff, including Pathologists and non mortuary staff such as ward staff, porters, Coroners' officers and funeral directors.
- If it does not exist, a document should be created that requires all staff to sign to say that they have read and understood SOPs relevant to their work.
- Where electronic quality management systems are in use, staff should be encouraged not to keep printed versions of policies and procedures, as this can lead to staff working to out-of-date versions.
- New procedures should be informed by a risk assessment of the activity being undertaken.

- Locum or visiting staff should be provided with training, made aware of local procedures, and asked to formally acknowledge that they have read and understood them.

### ***Contributory factor 2: Inadequate systems of traceability***

Incidents relating to the discovery of an organ or tissue following the release of a body can invariably be linked to inadequate systems of traceability and, in some cases, the lack of audits of retained material. A robust system of traceability – recording the journey of tissue from its removal from the body to its final repatriation – disposal or eventual storage is required to prevent such incidents reoccurring.

#### *Corrective actions taken by the establishment*

- Review and modification of systems of traceability.
- Introduction of regular audits of retained material.
- Introduction of a record of tissue transfer when tissue is transferred between departments and/or establishments.
- Use of different containers for different types of tissue.
- PM tissue to be stored in a designated area of the laboratory only.
- Centralisation of PM records.

#### *Additional advice provided by HTA*

- Placing identifiers on the bodies of the deceased when tissue has been retained and needs to be returned to the body before its release for burial or cremation. This can help prevent bodies being released before tissue is returned.
- Audits should result in action plans to address any shortfalls identified.
- Traceability may be enhanced by the use of an electronic or paper record, which tracks the movement of retained tissue from its removal from the body through to its ultimate fate. The record should detail the movement of the tissue, and the staff member responsible for the tissue at any given time.

### ***Contributory factor 3: Failure to use equipment as per manufacturers' instructions/SOP or faulty equipment***

Incidents relating to accidental damage to a body within the mortuary usually resulted from a failure to follow procedures and not using equipment appropriately, in an attempt to take shortcuts, or faulty equipment. Examples are untrained staff moving a body from a high fridge tray, without using the lifting equipment available for that purpose, and faulty fridge trays, both of which resulted in bodies being damaged on removal from the unit.

### *Corrective actions taken by the establishment*

- Refresher training for staff in the use of equipment.
- Warning signs placed on equipment.
- Review and update of risk assessments of practices and premises.
- Minor modifications to premises to mitigate risk of reoccurrence.

### *Additional advice provided by HTA*

- The completion of training should be documented and it should be repeated as necessary.
- Staff should be clear that if they are not trained in the use of equipment such as fridge trays and hoists, they should contact a trained member of staff for help when using it.
- Maintenance of equipment is often the responsibility of a centralised estates or works department, which undertakes checks and keeps reports of maintenance visits. Designated Individuals should keep their own records of maintenance visits and of checks and works undertaken, to ensure that these are undertaken regularly and cover all areas.

Establishments should contact us whenever an SUI occurs so that we can provide immediate assistance and subsequently share the learning gained from investigation.

The HTA will continue to provide further updates on SUI reports on its website and in future publications.