Human Tissue Authority

Strategic briefing on the post mortem sector

HTA
Human Tissue Authority

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About the Human Tissue Authority

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About this document

This document aims to provide an overview of the Human Tissue Authority's (HTA) role in the regulation of post-mortem examination. It also aims to provide leaders of services and board members with an overview of the key strategic issues facing mortuaries and of the potential consequences when standards are not maintained.

Who we are and what we do

The HTA is an executive Non-Departmental Public Body sponsored by the Department of Health and Social Care, established by the Human Tissue Act 2004. The HTA was established as a specialist regulator following events in the 1990s that revealed a culture in hospitals of removing and retaining human organs and tissue without specific informed consent.

Our overall goal is to maintain public confidence by ensuring that the removal, storage and use of human tissue and organs are undertaken safely and ethically, and with proper consent.

To achieve this, we:

- license organisations that remove, store and use human tissue for certain activities under the Human Tissue Act 2004. This includes determining the cause of death;
- monitor and inspect organisations to ensure they comply with our standards;
- use our powers to take regulatory action where we identify non-compliance;
- provide information, advice and guidance to the public and professionals about the nature and purpose of activities within our remit.

The HTA regulates, through its licensing and inspections process, establishments which carry out full, limited, and minimally invasive post-mortem examinations. This includes post-mortem examinations undertaken in emergency mortuaries. We refer to these 180 establishments collectively as the post-mortem sector.

Guiding principles

Four guiding principles drive our work and underpin our regulatory framework. They should be followed in dealing with human bodies, tissue and organs.

Consent

and the wishes of the donor (or in some cases, their nominated representatives or relatives) are the primary consideration when removing, storing and using human tissue.

Dignity

is paramount in the treatment of human bodies and tissue.

Quality

must underpin the management of human bodies and tissue.

Honesty and openness

are the foundation of communications in matters pertaining to the use of human tissue and bodies.

Post-mortem examination and our role

Post-mortem examination in all its forms is important for informing relatives, healthcare professionals and other interested parties about the cause of death.

Post-mortem examination in all its forms is important for informing relatives, healthcare professionals and other interested parties about the cause of death. It may also provide information about possible acquired or genetic diseases that may warrant treatment and care of the relatives of the deceased. More generally, post-mortem examination is considered by clinicians to be important in increasing understanding of disease, improving clinical care, maintaining clinical standards, identifying the spread of infectious diseases and supporting research and training.

The vast majority of post-mortem examinations are conducted under the authority of the coroner, when the death is unexpected or sudden, or of unknown cause. The consent of the family is not required in these cases. Occasionally, a post-mortem examination is requested by a clinician or clinical team, who wish to find out more about the illness of the person who has died. These are referred to as hospital or consented post-mortem examinations, because the consent of the family, or the person before they died, is required for the examination to take place.

The HTA's remit is to ensure that post-mortem examinations are undertaken with appropriate consent or under the authority of the coroner and on suitable premises licensed for that purpose, which is a statutory requirement under the HT Act. It is also to ensure that post-mortem examination and the removal and retention of any organs or tissue samples, including those processed into wax blocks and microscope slides, comply with the requirements of the HT Act.

Licensing and Inspection

The Licensing Standards are designed to ensure that establishments comply with the requirements of the Human Tissue Act and are aligned with our guiding principles.

In order to grant a licence the HTA must be assured on a range of criteria, in particular the governance arrangements for the licence and on how the HTA's licensing standards are met.

Governance arrangements

Designated Individuals (DIs) have a key role to play in implementing the requirements of the Human Tissue Act. They are the person under whose supervision the licensed activity is authorised to be carried out. The DI might be a head of department, clinician, scientist or manager. What is important is that it is a person who is in a position to ensure that activities are conducted properly, by people who are suitable to carry out those activities, and that all the necessary requirements are complied with.

Whilst the DI must be an individual, the HTA has a preference for the *Licence Holder* to be a corporate body where possible (e.g. an NHS Trust). The role of Licence Holder does not impose the duties that are expected of the DI; however, it is important to note that they have the right to apply to the HTA to vary the licence. This enables them to substitute another person as the DI and allows the establishment to cover circumstances where the DI is unable to oversee the licensable activities. Consequently, the HTA prefers individual Licence Holders to be more senior than the DI (i.e. Medical Director / Chief Executive).

An establishment can identify *Persons Designated* as a person to whom the authority conferred by the licence extends. Having Persons Designated, for example in particular areas, can be of assistance to the DI in ensuring that HT Act requirements are understood and appropriately managed across the whole of the premises covered by the licence.

Licensing Standards and inspection

The Licensing Standards are designed to ensure that establishments comply with the requirements of the Human Tissue Act and are aligned with our guiding principles. The HTA works with establishments through its inspection process to help them comply with these Standards, which are grouped under four headings:

- **Consent**
  Establishments meeting the consent Standards will be able to demonstrate that their processes for seeking and gaining consent comply with the HT Act and the HTA's Codes of Practice.
- **Governance and quality systems**
  Establishments meeting these Standards will be able to demonstrate that they have a suitable governance framework, underpinned by clear and controlled documentation, effective audit, staff training and organised record-keeping.
- **Traceability**
  Establishments meeting these Standards will be able to demonstrate full traceability for the human material for which they are responsible, from receipt to final disposal.
- **Premises, facilities and equipment**
  Establishments meeting these Standards will be able to demonstrate that their premises and facilities are appropriate for the licensed activities taking place, that they are safe, secure and clean and that there are effective contingency arrangements in place.

The HTA aims to inspect establishments in the post-mortem sector every three years, although the precise timing is driven by an assessment of the risks present at each individual establishment

Potential strategic risks caused by activities related to a post-mortem sector licence

When we visit an establishment, we inspect the premises and we focus on reviewing their records, operational policies, and procedures.

The activities which take place under a post-mortem sector licence should adhere to the HTA's guiding principles and licensing standards. Failures in any of these areas can, and sadly do, cause unnecessary distress to families at what is already a difficult time. In addition, media interest in individual cases of poor practice has the potential to damage the reputation of the establishment. This section outlines some issues which can potentially pose strategic risk.

Offences

The HT Act establishes a number of offences, for which the maximum penalty is three years imprisonment and/or a fine. In relation to the post-mortem sector these offences are:

- removing material from the deceased to determine the cause of death without appropriate consent
- carrying out a post-mortem examination or removing material from the deceased to determine the cause of death, without a licence

Where these offences are indicated, the HTA has a formal procedure for consideration of referral to the police. In 2017/18, two police referrals were considered in this sector: one relating to the removal of tissue without consent; the other, to removal on unlicensed premises.

Inspection findings 2017/18

When we visit an establishment, we inspect the premises and we focus on reviewing their records, operational policies, and procedures. We also conduct interviews and round-table discussions with a range of staff at the establishment. By examining these areas, we are able to identify any shortfalls against our licensing standards.

We grade shortfalls against our licensing standards as 'minor', 'major' or 'critical' and we work with the establishment to identify the measures that need to be taken to address any areas of underperformance we find through a corrective and preventative action (CAPA) plan.

In 2017/18, shortfalls were identified in 95% (55 of 58) of routine inspections in the post-mortem sector. 510 shortfalls were identified in this sector in total, which corresponds to an average of 8.8 shortfalls per inspection. Of these shortfalls, 351 (69%) were minor, 151 (30%) were major and eight (2%) were critical. Major shortfalls were identified at 39 establishments (67%) inspected in this sector. Critical shortfalls were identified at five establishments (9%) inspected in this sector.

The largest total number of shortfalls in this sector in 2017/18 were for the Governance and Quality (GQ) and Premises, Facilities and Equipment (PFE) groups of standards. The prevalence and severity of shortfalls for PFE standards highlights the importance of site visit inspections in this sector.

Potential strategic risks caused by activities related to a post-mortem sector licence

Since 2010, HTA-licensed establishments in the post mortem sector have been required to notify the HTA of any reportable incidents, including near misses, within five working days of the incident being discovered.

Critical shortfalls

The eight critical shortfalls in the sector were across five establishments:

a. One establishment had three critical shortfalls, which related to disposal practices, traceability and auditing of retained tissue.

b. One establishment had one critical shortfall relating to tissue not being disposed of as soon as reasonably possible, once it has been identified as no longer required.

c. One establishment had one critical shortfall as a result of a number of major shortfalls against their premises.

HTA Reportable Incidents (HTARIs)

Since 2010, HTA-licensed establishments in the post mortem sector have been required to notify the HTA of any reportable incidents, including near misses, within five working days of the incident being discovered. There are 17 categories of HTARIs that must be reported to the HTA.

In 2017/18, 137 HTARIs were reported to the HTA, 47 related to accidental damage of a body, 11 related to release of the wrong body to a funeral director, 9 related to the viewing of the wrong body and 10 to a major equipment failure.

Tissue held for criminal justice purposes

In an unexplained death, post-mortem tissue samples may be taken as part of the investigation for evidential purposes and to find out the cause of death. In some cases these samples have to be kept for significant periods of time to support any criminal investigation and fulfil legal requirements. Where human tissue is taken under police powers at post mortem examinations in suspicious death and homicide cases, it is deemed under the Human Tissue Act to have been taken 'for a criminal justice purpose' and is outside of the scope of the Act. Such samples will, however, often be stored on HTA licensed premises.

Historical cases where such material has been held for longer than necessary do come to light. When this happens the HTA works with police forces, local authorities, and the health service to provide advice and guidance and to ensure that families are informed as appropriate and supported as required.

Discovering that the samples of loved ones are still in storage will clearly be upsetting for the families affected and of concern to the wider public. These cases can generate media interest and result in reputational damage for the organisations involved.

Potential strategic risks caused by activities related to a post-mortem sector licence

Contingency arrangements should ensure the condition and dignity of the deceased, traceability of bodies and security are not compromised.

Other insights

We also receive data from all 180 establishments in the post mortem sector to provide insights into the sector as a whole. Recent findings include:

Staffing – 13% of establishments said staffing levels were insufficient and 16% had Anatomical Pathology Technician (APT) vacancies at the time of submission. These concerns were reflected in other responses, for example staffing shortage was the main reason given for audit schedules not being maintained. There is some evidence that problems also occur as a result of training for staff from outside of the mortuary who are involved in receipt, release and viewings of bodies.

Premises – 42% of establishments had concerns about their premises, with storage capacity being the main concern. This has been evidenced on inspection in the increased number of findings for Premises, Facilities and Equipment standards. Winter can be an especially challenging time of year for health services. For mortuaries, higher numbers of deaths can pose problems if inadequate numbers of refrigerated storage spaces are available. Establishments should therefore have documented contingency plans explaining what to do if the mortuary body store is nearing full capacity, or if the post mortem suite is temporarily unavailable. In particular, storage of bariatric or infectious cases, and deep freeze arrangements, should be considered.

Contingency arrangements should ensure the condition and dignity of the deceased, traceability of bodies and security are not compromised. Appropriate contingency measures may include:

- making reciprocal arrangements with other HTA-licensed mortuaries to use their facilities;
- installing temporary racking in the mortuary, or in an adjacent building, for storage of bodies;
- use of 'chiller blankets' (if suitable refrigerated storage cannot be found);
- arranging with local funeral directors to store bodies at their premises.

Long-term storage – approximately half of establishments stated that the average length of time the deceased were in their care has increased. Inspection findings indicate that establishments do not always have documented procedures or sufficient capacity for long-term storage.

Further information and resources

HTA Code of Practice A: Guiding principles and the fundamental principle of consent

HTA Code of Practice B: Post-mortem examination

Post-mortem examination Standards and guidance

Find an establishment licence or inspection report

Guidance on HTA Reportable Incidents

HTA
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Human Tissue Authority

151 Buckingham Palace Road
London SW1W 9SZ

Telephone: 020 7269 1900

Email: enquiries@hta.gov.uk

www.hta.gov.uk

@HTA_UK

/HumanTissueAuthority