HTA Initial advice to the Secretary of State for Health & Social Care

15 December 2021

1. Background: the HTA's regulatory remit and approach

The HTA was created by the Human Tissue Act 2004 and has a wide remit in regulating specified purposes for which human tissue may be taken, stored and used, including post mortem examination (referred to throughout as the Post Mortem sector), Public Display, Research, Anatomical Examination (for medical training), Organ Donation and Transplantation and Human Application (use of human tissue in treatment).

The HTA's remit in the Post Mortem sector is restricted to premises where tissue is stored or removed for the purpose of 'determining the cause of death' ie post mortem examinations in mortuaries and related areas, such as pathology laboratories.[1] The HTA does not regulate other premises, which may commonly be called mortuaries, where bodies are stored such as hospital body stores or the premises of Funeral Directors.

The HTA's regulation is based on establishments being granted a licence, which is not time-limited and which depends for retention on continuing to meet the HTA's licensing Standards. Compliance is verified through periodic site inspection and data collection exercises and through the formal requirement that certain specified incidents must be reported to it.

The HTA's licensing Standards are set out in statutory Codes of Practice. Code of Practice A (Consent and Guiding Principles) applies to all the sectors that are regulated by the HTA. Code B is specific to the Post Mortem sector.

The 72 licensing Standards for the Post Mortem sector are organised under four headings: Consent (C), Premises Facilities and Equipment (PFE), Governance and Quality systems (GQ), and Traceability (T). The Annex provides further information on these Standards and details the five that will be the immediate focus for the HTA's short-term activity.

The HTA's statutory Codes of Practice are supplemented with formal guidance to help licensed establishments understand what they have to do to meet these requirements. The HTA also publishes more general advice for the sector on topics relating to its regulatory remit, for example dealing with winter capacity pressures. Guidance is issued through various means such as professional newsletters and via our website.

[1] Human Tissue Act (2004) Schedule 1, Part 1, paragraph 2

The HTA regularly responds to enquiries and requests for advice from individual establishments.

The HTA's remit in relation to the Post Mortem sector covers England, Wales and Northern Ireland. The HTA licences 145 NHS mortuaries (plus 67 satellite sites, often smaller local hospitals within a larger Trust) in England, 12 NHS mortuaries in Wales and 5 NHS mortuaries in Northern Ireland. The HTA's remit also extends beyond the NHS to public mortuaries where post mortem examinations are carried out. Public mortuaries are provided under a statutory obligation by local authorities in England, and by the Department of Justice in Northern Ireland, for the reception and storage of bodies and the provision of post mortem examination facilities.[2] The HTA licences 23 public mortuaries in England and one public mortuary in Northern Ireland.

2. Background to the provision of advice

The HTA was asked by the Secretary of State to provide advice on its regulatory framework following the conclusion of the murder trial of David Fuller and the public revelation of his sexual offending against bodies in a hospital mortuary at Maidstone and Tunbridge Wells NHS Trust (MTW).

3. Scope and timing of advice

The requested advice from the HTA is one aspect of the system-wide response to crimes committed at the Trust. It is anticipated that the HTA's advice, along with actions commissioned by NHS E / I and the Trust, will inform the Independent Inquiry. We anticipate further requests for advice may be made to the HTA as the timetable, scope and terms of reference of the Inquiry are confirmed. The HTA stands ready to support the Independent Inquiry and any other relevant reviews of policy or practice.

This initial advice is based on what is known in the lead up to sentencing and precedes the Inquiry. The advice is presented as actions for the short, medium and longer term and the actual times will depend on the inter-connected and interdependent work being undertaken by the Trust, other Regulators and the Independent Inquiry:

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[2] Under the Public Health Act 1936, s198(1), 'Provision of mortuaries and post-mortem rooms'

(1)A local authority or a parish council may, and if required by the Minister shall, provide—

(a)a mortuary for the reception of dead bodies before interment;

(b)a post-mortem room for the reception of dead bodies during the time required to conduct any post-mortem examination ordered by a coroner or other duly authorised authority;

and may make byelaws with respect to the management, and charges for the use, of any such place provided by them.

short term – this is likely to focus on clarifying and strengthening existing HTA guidance for licensed mortuaries in the Post Mortem sector;

medium term – this is likely to focus on advice about any changes we may consider necessary to clarify and strengthen the statutory Codes of Practice and licensing Standards, plus operational activity to reinforce and gain assurance on compliance with updated guidance and any revision of the Standards; and

longer term – this is likely to relate to more complex or significant changes that may, by then, be considered necessary, such as changes to the HTA's remit and legislative framework (to strengthen powers or reinforce the scope or obligations of statutory roles) or other system-wide change in the health regulatory framework.

4. HTA Advice

This initial advice is high level and set out under four themes.

a) Regulation of the Post Mortem Sector

The HTA has carefully considered its 72 licensing Standards for the Post Mortem sector to identify those that appear particularly pertinent to the issues identified by this case. One of the HTA's guiding principles is the vital importance of dignity and therefore maintaining the dignity of the deceased is a significant factor in how our Standards and guidance should be applied. The HTA will review the wording of, and guidance associated with, five specific licensing Standards concerning effective control and monitoring of access, storage arrangements that maintain the dignity of the deceased, and oversight of visitors and contractors.[3]

Short term action

The HTA will review and strengthen its own guidance associated with these licensing Standards to ensure it is sufficiently explicit, for example relating to expectations of how access should be effectively controlled and monitored.

The HTA will also provide support and advice to other regulators responsible for setting and updating building and security standards (including the use of CCTV) in hospital and public mortuaries. The HTA's role will be to provide expert input to any such reviews to ensure that security considerations are addressed and the dignity of the deceased is protected. The HTA is already supporting NHS E / I on its planned revisions to Health Building Notes (HBN) 16-01 Mortuary Facilities and will do likewise with any other relevant authority.

[3] The HTA has identified three Governance and Quality Standards, GQ1(a), GQ3(g) and GQ6; and two Premises, Facilities and Equipment Standard, PFE1(d) and (e), and PFE2(g), that will be its focus.

Any changes to the HTA's own guidance referring to CCTV will be considered in line with this activity and any amendments to the HTA's guidance and Standards will be made in the context of maintaining the dignity of the deceased. Given the HTA's broad remit in relation to human tissue, this work will be planned to align with activities being led by other regulators and stakeholders, including the Devolved Administrations.

Medium to longer term

The HTA will follow-up changes to guidance with a range of targeted operational activity. The HTA will continue to use the full range of regulatory tools available to it and ensure that any changes to Standards and guidance are effectively embedded through changes to operational practice in licensed mortuaries. These will include clear communication about expectations, education and engagement, as well as assurance checks and inspection.

The HTA will also formally review its statutory licensing Standards, as set out in the relevant Codes of Practice, to identify any updates or amendments that may be needed. Changing the Standards requires extensive consultation across our licensed sector and with other relevant stakeholders, such as professional bodies and Coroners, as well as with the Devolved Administrations. Advice and recommendations will be put to the HTA's Board for approval, followed by formal submission to DHSC, and if accepted will be lodged in Parliament for approval by negative procedure.

b) Review of the regulatory framework in connection with the management of the deceased

Medium to longer term

The HTA is aware that work is being undertaken by other authorities to consider whether changes are needed to the guidance for NHS employers on employment checks and screening arrangements for people whose work may give them access to the deceased. The HTA will contribute its sector expertise as appropriate to any such discussions and will consider if and how it may wish to refer to any new guidance in its own Standards and guidance.

The HTA licenses premises that remove, use and store tissue and bodies of the deceased across the NHS, public and private sectors. Whilst storage may be for determining cause of death, bodies may be stored for other reasons such as for medical training in anatomy departments of university medical schools. Bodies are also stored in settings outside of HTA regulation, for example by funeral directors.

The HTA would be happy to contribute its expertise to any wider consideration of the regulation of settings in which the deceased are managed, including any consideration of how HTA licensing Standards and guidance may be adopted as good practice in other settings dealing with the deceased, especially those not otherwise regulated.

c) Wider regulatory contributions

Medium to longer term

The HTA recognises that it plays a part in a wider stakeholder, regulatory and standards-setting system involved in managing the tissues and bodies of the deceased. The HTA will use its role within this system to strengthen the understanding of its licensing Standards and, as appropriate, encourage other authorities and regulators with oversight and governance responsibilities to seek assurance that legislative requirements are being met.

In the longer-term, the HTA aims to provide advice about how it might constructively enhance and contribute to any system-wide regulatory effort arising from the circumstances of this case to strengthen working across regulatory boundaries.

d) Legislative framework

Longer term

From the information about this case that is available so far, the HTA has not identified any fundamental inadequacies in our legislation in relation to the Post Mortem sector. Therefore, this interim, early advice assumes there would be no change to this part of the Human Tissue Act or related legislation.

If, however, it is considered that the HTA should acquire regulatory oversight of other settings in which the deceased are managed, or if other proposals emerge to regulate this sector in some other way, this would be likely to require legislative change.

Once the HTA has had the opportunity to consider the outcomes of its own reviews and those of others, including the Independent Inquiry, it will consider whether any other legislative changes, such as to the HTA's powers, may be needed.

Any legislative review would be a long-term commitment and could provide an opportunity for changes to strengthen and update the HTA's approach to regulation, and to modernise the HTA's legislation. Such changes would seek to support the Government's wider life sciences and innovation strategies as well as its commitment to maintaining public confidence and patient safety and the principles of dignity and respect.

With colleagues in other regulators and authorities, the HTA will keep these considerations under review, acknowledging that any advice to Ministers on this would be expected to emerge in the longer-term.

5. Next steps

Over the coming weeks and months, the HTA will be focused on taking forward the work outlined in this advice. Our initial priority will be on progressing the short-term actions whilst exploring and planning longer-term activity. The HTA supports, and will actively contribute to, the health system response to the events at Maidstone &

Tunbridge Wells NHS Trust and will address any lessons that can be learned through the findings of the Independent Inquiry.

6. Annex: Licensing Standards and guidance

The HTA has produced a Code of Practice for the Post Mortem sector (Code of Practice B) that sets out the statutory licensing Standards.

It has also published a standalone document (Code B Standards and Guidance) document that provides additional guidance for many of the Standards, so that establishments know what they need to do to meet the HTA's expectations.

The HTA has identified three Governance and Quality Standards, GQ1(a), GQ3(g) and GQ6; and two Premises, Facilities and Equipment Standard, PFE1(d) and (e), and PFE2(g), that will be its focus for short-term action.

The following pages provide extracts from the Code B Standards and Guidance document for each of these five Standards.

These set out the Standards itself (often comprising multiple specific elements) and the official guidance for that Standard.

The Standards and guidance document, covering all 72 licensing Standards, can be accessed at the link below.

<https://content.hta.gov.uk/sites/default/files/2020-11/Code%20B%20standards.pdf>

The HTA will keep all Standards and guidance under review as the inquiry and other activities progress.

Governance and quality systems

GQ1 All aspects of the establishment's work are governed by documented policies and procedures

[Focus: guidance on GQ(1)(a)]

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath. These include:
   i. post-mortem examination, including the responsibilities of Anatomical Pathology Technologists (APTs) and Pathologists and the management of cases where there is increased risk;
   ii. practices relating to the storage of bodies, including long term storage and when bodies should be moved into frozen storage;
   iii. practices relating to evisceration and reconstruction of bodies;
   iv. systems of traceability of bodies and tissue samples;
   v. record keeping; vi. receipt and release of bodies, which reflect out of hours arrangements;
   vi. lone working in the mortuary;
   vii. viewing of bodies, including those in long-term storage, by family members and others such as the police;
   viii. transfer of bodies internally, for example, for MRI scanning;
   ix. transfer of bodies and tissue (including blocks and slides) off site or to other establishments;
   x. movement of multiple bodies from the mortuary to other premises, for example, in the event that capacity is reached;
   xi. disposal of tissue (including blocks and slides), which ensures disposal in line with the wishes of the deceased person's family;
   xii. access to the mortuary by non-mortuary staff, contractors and visitors;
   xiii. contingency storage arrangements.

Guidance

Documented policies and procedures should reflect the requirements of the Human Tissue Act and the HTA's Codes of Practice. They should also reflect other relevant legislation and guidance. This includes the Health and Safety Executive's document: 'Managing infection risks when handling the deceased' (HSG283, published 2018).

Individual policies and SOPs for each activity are not required. Some policies and SOPs will cover more than one activity.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks

[Focus: guidance on GQ3(g)]

a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.

Guidance

This should include all staff who undertake mortuary activities, for example, portering staff, site managers and funeral directors who may carry out mortuary activities out of hours. APTs should be trained in reconstruction techniques to ensure that the appearance of the deceased is as natural as possible.

Staff should be encouraged to obtain vocational and educational qualifications relevant to their work.

b) There are clear reporting lines and accountability.
c) Staff are assessed as competent for the tasks they perform.

Guidance

This should include for all staff who undertake mortuary activities, for example, portering staff, site managers and funeral directors who may carry out mortuary activities out of hours. Assessment of competence should include the standard of APTs' reconstruction work.

d) Staff have annual appraisals and personal development plans.
e) Staff are given opportunities to attend training courses, either internally or externally.

Guidance

Attendance by staff at training events should be recorded.

f) There is a documented induction and training programme for new mortuary staff.
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.

Guidance

The qualifications of locum staff should be checked prior to them commencing work in the mortuary and their competency to undertake each task should be assessed.

Contractors, visiting and temporary staff and funeral service staff bringing bodies out of hours should be required to read relevant SOPs and sign to confirm their understanding.

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored

[Focus: guidance on GQ6]

a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.

Guidance

Risks to the dignity and integrity of bodies and stored tissue should be covered. The HTARI categories provide a good basis for risk assessments. Risk assessments should be reviewed at regular intervals, for example every 1-3 years or when circumstances change. Relevant staff should be involved in the risk assessment process and should be aware of the risks associated with the activities they undertake.

b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.

Guidance

Relevant staff should have knowledge of risks and the control measures that have been taken to mitigate them.

c) Significant risks, for example to the establishment's ability to deliver post mortem services, are incorporated into the Trust's organisational risk register.

Guidance

This includes to the relevant Trust, Health Board or Local Authority, and should include appropriate risk mitigation measures.

Premises, Facilities and Equipment Standards (PFE)

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue

[Focus – guidance on PFE1(d) and (e)]

a) The premises are clean and well maintained.

Guidance

Floors, walls and work surfaces should be of non-porous construction and free of cracks and chips. The premises should be subject to a programme of planned preventative maintenance, which ensures that the premises, facilities and equipment remain fit for purpose.

b) There is demarcation of clean, dirty and transitional areas of the mortuary, which is observed by staff and visitors.
c) There are documented cleaning and decontamination procedures and a schedule of cleaning.

Guidance

There should be records of cleaning and decontamination.

d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access).

Guidance

This includes body storage units in areas outside of the mortuary, for example, temporary storage units and storage facilities in maternity departments.

Relatives who visit for a viewing should not be able to access the body store area. Security systems and lone working arrangements should take into account viewings which take place out of hours.

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.

Guidance

Swipe card access lists should be reviewed regularly. Staff and authorised visitors and contractors should be aware of the establishment's security arrangements.

PFE2 There are appropriate facilities for the storage of bodies and human tissue

[Focus – considering providing guidance on PFE2(g)]

a) Storage arrangements ensure the dignity of the deceased.

Guidance

Storage temperatures should be appropriate to ensure that the condition of bodies is preserved. Refrigeration of bodies should be at a temperature of approximately 4 degrees Celsius. The optimal operating temperature for freezer storage is around -20 degrees Celsius. The Health and Safety Executive's document: 'Managing infection risks when handling the deceased' (HSG283, published 2018) includes guidance on storage of bodies.

b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.

Guidance

Capacity should be regularly reviewed, particularly if contingency arrangements are used regularly or for extended periods. Where storage capacity is identified as an ongoing issue, this should be escalated to the relevant Trust, Health Board or Local Authority.

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs.

Guidance

There should be sufficient frozen storage for the long-term storage of bodies; the HTA advises that bodies should be moved into frozen storage after 30 days in refrigerated storage if there is no indication they are soon to be released or further examined, or before, depending on the condition of the body. Bodies in long-term storage should be checked regularly; this should include confirmation of their identity and the reason for their continued storage.

Where there is insufficient freezer storage to meet needs, there should be arrangements with other establishments, or other contingency steps, to ensure that bodies can be stored appropriately. Where storage capacity is identified as an ongoing issue, this should be escalated to the relevant Trust, Health Board or Local Authority.

d) Fridge and freezer units are in good working condition and well maintained.
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range.

Guidance

This includes storage units in which bodies or tissues are stored under the HTA licence in other areas, for example in maternity departments.

The HTA advises that storage units in areas that are not permanently staffed should have a remote alarm system to alert staff to temperature deviations out of hours.

Temperature alarm trigger points should be set to ensure that alarms will trigger in the event that the storage temperature deviates from an acceptable range to ensure that the condition of bodies and tissue is appropriately preserved. Staff should be aware of the acceptable temperature ranges and temperature alarm trigger points.

Alarm tests should include call out procedures and should be recorded.

f) Temperatures of fridges and freezers are monitored on a regular basis.

Guidance

This includes storage units in which bodies or tissues are stored under the HTA licence in other areas, for example maternity departments.

Temperature monitoring should enable the establishment to identify trends and the extent of any variations in storage temperatures.

g) Bodies are shrouded or in body bags whilst in storage.
h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.
i) There are documented contingency plans in place should there be a power failure or insufficient numbers of refrigerated storage spaces during peak periods.

Guidance

Where contingency arrangements involve the transfer of bodies to other premises, these should be assessed to ensure that they are suitable and that traceability systems are of the required standard.

Practices such as placing more than one body on a tray or storing bodies in unrefrigerated storage should not take place.

Establishments should have documented agreements with any funeral services that they may use for contingency storage. Consideration should be given to whether the funeral service provides contingency storage for other mortuaries.

SOPs should address issues such as risk assessments and same/similar name systems.

The hire of temporary storage units should not be the sole contingency arrangement for an establishment. Establishments should put in place other formally agreed arrangements for contingency storage. Where the hire of temporary storage facilities forms part of establishments' contingency arrangements, consideration should be given well in advance and steps taken to ensure availability of funds, and of units for hire.

Establishments should consider entering in to Mutual Aid Agreements with neighbouring organisations in order that they can provide and obtain support during periods of capacity shortages.