

**From the Chair,  
Lynne Berry CBE**

Sir Jonathan Michael  
Chair of the Inquiry  
Independent Inquiry into the issues raised by the David Fuller case

29 April 2024

Dear Sir Jonathan

**Re: Phase 2 - the wider range settings for care of the deceased**

The HTA welcomes and supports the aims of your Inquiry as it now focuses on the wider issues beyond Maidstone & Tunbridge Wells NHS Trust and on overall improvements in the standards of care for bodies, organs and tissue after death.

Our experience as a regulator provides strong support for the view that the present legal framework does not provide sufficient protection for dead bodies and human remains. We believe that there is a strong case to increase protection and thus ensure the dignity of the deceased is maintained at all times.

The HTA's role includes regulating settings, premises and operational practices relating to the management of locations which handle human tissue mainly within the health sector, medical schools, life sciences companies and local government (including health research, mortuaries for post mortems and public display museums). We have no remit to regulate funeral directors or any other persons outside of scheduled purposes covered by legislation.

Nonetheless, as the Inquiry considers the wider range of settings for care of the deceased, we felt it may be helpful to offer insights from the HTA's nearly 20 years' experience of regulating under the Human Tissue Act and specifically in managing the deceased in post mortem establishments (please see **Annex A**). This includes experience of the issues that can arise at the intersection between regulated and unregulated settings and the ways in which regulation might improve those transitions.

The regulatory framework we have imposed on those we regulate and those who have some responsibility for handling dead bodies or human remains is underpinned by the principle that cadavers must be treated with dignity at all times. Whilst the HTA seeks to uphold this principle in the areas where we regulate, UK law does not impose any general legal duty on those handling human corpses or human remains to ensure they act in a way that maintains the dignity of the deceased.

In contrast, a variety of other countries have recognised this as an area which should be covered by a clear legal framework and have imposed legal obligations which have the general effect of upholding the dignity of the deceased after death.

I would thus invite your Inquiry to reflect on whether, learning from other jurisdictions, the creation of a legal duty on anyone involved to maintain the dignity of the deceased would be one appropriate way to provide an effective legal framework to meet societal needs to protect dead bodies or human remains. We enclose a short introductory paper prepared for the HTA by one of its non-executive Board Members, David Lock KC, at **Annex B** to this letter which sets out this thinking.

It explores how a combined criminal law and civil law duty could create an enforceable legal framework. We would also propose that, as part of any framework, the relevant Secretary of State should be entitled to publish guidance to explain to both professionals and the public what is required to comply with the duty to treat dead bodies or human remains with dignity. A UK criminal statute, with the addition of a civil wrong, as explained in the paper, may present the most appropriate way to meet legitimate concerns that our current system does not offer proper safeguards in this area.

The HTA recognises that it is for the Inquiry to consider these matters and to make any recommendations it sees as appropriate and then for government to determine what statutory regulatory frameworks should exist and how those are implemented. However, we would ask the Inquiry to seriously consider this proposal.

Although the funeral sector aspect of your Inquiry is beyond our current statutory remit, we remain available to assist the Inquiry with any information or further input, as may be appropriate.

Yours sincerely



**Lynne Berry CBE**  
**Chair of the Human Tissue Authority**

## Annex A

### The HTA and the wider range of locations where care of the deceased occurs

#### 1. Introduction

This paper captures the experiences and interfaces the HTA has had and continues to have with a wider range of locations where care of the deceased occurs. We hope the points raised will be of interest to the Inquiry as it takes evidence about the care provided and the oversight of these settings.

#### 2. Regulation

The HTA actively contributed to the Competition & Markets Authority (CMA) investigation of the funerals sector in 2018/19. The resulting report strongly recommended that regulation of funeral care settings and practice was required, as well as better transparency of costs and pricing.

In making its recommendations for regulation of this sector, the CMA had reviewed and discussed with the HTA the potential applicability of our kind of framework, in particular an adaptation of our standards for the Post Mortem sector, whilst not making any specific recommendation about how and by whom any such regulation might be undertaken.

The CMA report strongly recommended mandatory, statutory regulation of the funerals sector. The Government response, for which Ministry of Justice (MoJ) is in the lead, was to give the sector an opportunity to develop self-regulation.

The HTA has had ongoing engagement with the MoJ over this and related matters, including contributing to the draft proposed framework for assessing the effectiveness of self-regulation in the funeral sector. Whilst there is no date set for that consultation, it will undoubtedly provide useful evidence and insight.

#### 3. HTA engagement with Funeral Directors

The HTA has had constructive engagement with the two main trade bodies in the funerals sector to support their development of self-regulation.

- ***The National Society of Allied and Independent Funeral Directors (SAIF)*** approached the HTA concerning their proposed approach to self-regulation. We reviewed and responded to their proposals, providing constructive advice on the next steps SAIF may wish to consider in developing this further. We found their work to be at an initial phase, pre-public consultation, and we have indicated we are available to continue to support in an advisory capacity, when requested.
- We have also had regular engagement with the ***National Association of Funeral Directors (NAFD)*** and their self-regulation body, the ***Independent Funeral***

**Standards Organisation (IFSO)**, on their development of a self-regulatory model. This incorporates some aspects of HTA-style Standards for premises and practices and a combination of self-assessment and inspection by IFSO. NAFD continues to keep the HTA updated on their wider policy proposals, and we continue to provide informal advice, when requested.

#### **4. Inquiry's published video seminars in Manchester and London**

The Inquiry's recently published seminars reflected the HTA's experiences of the current state of the sector, the effectiveness of self-regulation and opportunities for further development to improve the care of the deceased.

The HTA noted the indications of significant support for regulation to tackle the inconsistent quality of practice and improve the safety, dignity and care of the deceased in funeral care settings.

The seminars also highlighted the issues arising from the absence of a defined and coherent risk assessment methodology or standardised approach to setting and assessing standards, as well as the complexity of causes of issues in maintaining the dignity of the deceased through increasingly lengthy and complex post-death systems.

The lack of a statutory framework, and a coherent and consistent framework of standards and superintendence was clearly a cause of concern to the participants in these seminars. This is consistent with the HTA's experience.

The HTA's standards and guidance are of course much broader, more detailed and more systematically underpinned by proactive and reactive regulatory tools than the current voluntary frameworks or the minimum standards being introduced in Scotland, although it is worth noting there is some helpful high-level alignment in all these approaches.

The HTA notes that several seminar participants commented on the clearly described and defined assessment requirements of HTA's approach whilst others reflected on their experience and the potential relevance of CQC-style inspection. Whilst the HTA may be considered to have directly relevant experience in regulating settings involved in managing the deceased, we do not advocate any specific organisational solution for the funeral sector, but whilst noting that a consistent approach would be preferable and beneficial.

The ongoing absence of mandatory regulation for this sector and with approximately 25% of the sector not current members of any trade association, and hence outside the scope of national self-regulation, presents an ongoing risk and concern to the HTA, given the practical significance of the intersection between the funeral sector and our licensed sector in managing the deceased.

Considering the current role of regulators and scope of regulatory tools available to ensure minimum standards are achieved in safeguarding the security and dignity of

the deceased, there is potential benefit and opportunity to avail of existing expertise to support the sector.

## **5. HTA providing support in an advisory capacity:**

The HTA has set out below examples of work we have progressed in an advisory capacity to assist those involved in managing the deceased who are currently outside our remit.

### **5.1 Advisory inspections of unlicensed body stores in healthcare settings linked to licensed establishments**

The HTA is supporting the Welsh Government in undertaking advisory inspections of six unlicensed body stores in hospitals within Health Boards. This pilot programme follows the Welsh Government advice to Health Boards that unlicensed body stores should adhere to relevant HTA standards (November 2022).

The HTA will be evaluating this process, with Welsh Government and Health Board officials, to assess its usefulness and practical considerations for any wider adoption of this approach, in Wales or other nations within the HTA's remit.

The final report includes commentary on the advisory aspect of the process. It's currently at the review stage and will be available shortly; the HTA will be happy to share this with the Inquiry.

#### **a. Scottish Government: statutory regulation of funeral directors**

The HTA has had contact with the Scottish Government's HM Inspector of Funerals and notes that the draft Code of Practice for funeral directors in Scotland uses a similar, albeit less detailed and high-level, framework to the HTA's Code of Practice and Standards. We continue to constructively engage with Scottish Government on their proposed statutory regulation and inspection regime for funeral directors.

#### **b. NHS England (NHSE)**

The HTA has had extensive ongoing interaction with NHSE since the disclosure of Fuller's offending in Maidstone & Tunbridge Wells NHS Trust (MTW). This has informed the approach adopted by NHSE since that time, for example their emphasis on adherence to HTA standards, effective governance and senior management oversight, and their assurance exercises on key aspects of security.

The HTA also contributed significantly to NHSE's overhaul of the formerly defunct Health Building Note on mortuaries (now published as HBN-016).

The HTA now participates in the NHSE-led Joint Strategic Oversight Group for the South East, which (amongst other matters) provides some aspects of scrutiny and assurance on the implementation of changes at MTW following Fuller's conviction.

The HTA continues to have constructive and mutually supportive engagement and dialogue with senior managers at NHSE responsible for leading on their Fuller response. This has provided a productive route for exploration of opportunities for mutual advice and support, including consideration of unlicensed body stores on NHSE sites throughout England to ensure consistency and transparency.

**c. HTA ability to undertake work to support other public bodies in the UK in carrying out their functions**

The HTA has statutory powers (under s42 of the Human Tissue Act 2004) to not just assist other public authorities in carrying out their functions but also to recover our costs for doing so, making this a viable route to providing support to other public bodies where this may be considered beneficial.

The HTA is interested in exploring whether this might provide a helpful means of providing practical advice and operational support to public bodies who may wish use our expertise to assist them in setting, assessing compliance with and gaining assurance on relevant standards in premises and settings that would otherwise be outside our remit. These could range from assisting NHSE (and equivalent bodies in the other nations) with oversight of unlicensed body stores to assisting Local Authorities with oversight of funeral directors premises for whom they may have licensing or public / environmental health functions. It might also underpin advice and collaboration with other Regulators such as CQC with an interest in such inspections.

The Inquiry may also wish to note that s14 of the Human Tissue Act 2004 allows the Secretary of State for Health and Social Care to amend our remit 'by order'.<sup>1</sup>

**d. Local Authorities and public mortuaries**

Under our statutory remit, the HTA licenses approximately 20 public mortuaries managed by local authorities in England. We've actively consulted on and have been involved in advising on (from a regulatory perspective) significant re-development work in local authority run public mortuaries, which they have found invaluable.

Our expertise has provided insight and supported local authorities managing settings that care for the deceased beyond our remit, such as the urgent expansion of facilities during the Covid pandemic, which we assisted with the creation of additional body storage (in excess of 20,000 spaces).

We continue to have constructive engagement with officials at the Department for Levelling Up, Housing and Communities (DLUHC) and Ministry of Justice (MoJ) in supporting local authorities:

- At the time of the Fuller trial, the DLUHC Minister of State for Building Safety and Fire (Lord Stephen Greenhalgh) wrote to all local authorities to highlight the

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<sup>1</sup> S14(4) HT Act 2004: 'The Secretary of State may by order amend this section for the purpose of adding to the activities within the remit of the Authority.'

<https://www.legislation.gov.uk/ukpga/2004/30/section/14>

importance of adhering to HTA standards and guidance, particularly concerning security and access requirements.

- Presently, the HTA is assisting DLUHC, MoJ, with DHSC (following the recent incident at a Hull funeral directors), in supporting local authorities to undertake visits to funeral homes, by providing and signposting sections of our Post-mortem guidance relating to traceability and premises, and highlighting process and procedure considerations, such as recording outcomes and escalation.

We continue to expand our understanding of the particular risks and issues the sub-sector faces by working with relevant representatives of local authorities to explore the scope for joint development work in support of the sector.

**e. Applicability of HTA Codes of Practice and licensing Standards in other settings**

The HTA notes that the standards developed by the Scottish Government and the voluntary code developed by NAFD/IFSO have closely mirrored HTA's standards, albeit at a higher level.

The HTA has **four** overarching standards in its Codes of Practice, with specific sub-standards relevant and applicable to the circumstances of specific sectors, including those involved in the management of the deceased (such as the Post Mortem, Anatomy and Public Display) . These are tailored to the needs of our sectors with specific sub-standards defined: for example, there are **74 standards for the Post Mortem sector**.

The **four areas** for these standards are **Consent (C); Premises, Facilities and Equipment (PFE); Traceability (T); and Quality and Governance (GQ)**.

The standards for Premises, Facilities and Equipment (PFE); Traceability (T); and Quality and Governance (GQ) are those of more obvious direct relevance to other settings not currently subject to the HTA's remit, including hospital body stores and Funeral Directors, although there is the potential for introducing standards relating to Dignity.

The Consent (C) requirements relate to specific statutory obligations for gaining assurance that there is appropriate consent under the Human Tissue Act (2004) for specific activities. Whilst these are less likely to be relevant in other sectors, the underlying principles of documented clarity of approval or authorisation for activities undertaken could be adapted for other settings.

Whilst only a sub-set of these standards would be applicable in those settings, relatively minimal amendment would be required to identify which might be suitable (please see below) and to alter them to be suitable for application in those other settings.

Adoption of such standards could be on either a statutory or good practice/advisory basis. Updating them could be aligned with the HTA's process of review and revision for the HTA's Post Mortem standards.

## **7.1 Applicability of HTA Standards for PM to other settings (Code B)**

Code of Practice and Standards B, (Post Mortem), licencing standards and guidance documents are available on our website:

- [Code B – Post-mortem examination.pdf \(hta.gov.uk\)](https://www.hta.gov.uk/sites/default/files/2017-06/Code%20B%20-%20Post-mortem%20examination.pdf)
- [Microsoft Word - Post-mortem examination licencing standards and guidance version 3 \(hta.gov.uk\)](https://www.hta.gov.uk/sites/default/files/2017-06/Microsoft%20Word%20-%20Post-mortem%20examination%20licencing%20standards%20and%20guidance%20version%203.pdf)

We also regularly publish guidance and regulatory updates to assist licensed establishments.

The specific standards, noted below, are **a small illustrative list of some standards that could be directly applied, or applied with relatively little modification, in other settings such as Funeral Directors premises.**

[Note: This does not include all the guidance text that accompanies the extracted standards, as it is extensive. The full text is available in the link, as referenced above.]

### ***Governance and Quality:***

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

*(c) Procedures on body storage prevent practices that disregard the dignity of the deceased.*

#### *Guidance*

*Practices such as placing more than one body on a tray, placing bodies unshrouded on trays, or storing bodies in unrefrigerated or unsecured storage areas should not take place.*

### ***Traceability***

*T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail.*

- Bodies are tagged/labelled upon arrival at the mortuary.*

#### *Guidance*

*The condition and labelling of bodies should always be checked and recorded, and their identity confirmed. Identification labels should be attached to the body. Body bags and shrouds should not be labelled in place of labels attached to the body.*



- b) *There is a system to track each body from admission to the mortuary to release for burial or cremation (for example mortuary register, patient file, transport records).*

*Guidance*

*Body receipt and release details should be logged in the mortuary register or the electronic database, including the date and name of the person who received/released the body and, in the case of release, to whom it was released.*

- c) *Three identifiers are used to identify bodies and tissue, (for example post-mortem number, name, date of birth/death), including at least one unique identifier.*

*Guidance*

*This licensing standard aims to ensure that identification procedures are robust.*

**Premises, Facilities and Equipment**

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

- 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*

*Security arrangements should be robust, with effective mechanisms to strictly control access.*

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

*Guidance*

*Levels of oversight, particularly surrounding mortuary access and mortuary activities undertaken, should be clearly defined and take into account risks to the dignity of the deceased.*

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

*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.*

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

*Guidance*

*Capacity should be regularly reviewed, particularly if contingency arrangements are used regularly or for extended periods.*

*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.*

*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.*

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

*g)Bodies are shrouded or in body bags whilst in storage*

*Guidance*

*Shrouding practices should preserve the dignity of the deceased, including during release and transportation. Shrouds should be clean and appropriate for use and checked regularly.*

*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*

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

## Annex B

### **A note on the extent to which the law protects (or should protect) a dead body or parts of a dead body.**

In 2004 Parliament passed the Human Tissue Act 2004 in the wake of the scandal involving the retention of human body parts from children at Alder Hey hospital. The system of licensing of those handling human body parts now provides an appropriate level of control and supervision for medical professionals who have to handle human tissue as part of their activities, including tissue belonging to the deceased.

The underlying public policy justification for this regulatory system was captured by Dr Imogen Jones<sup>1</sup> of Leeds University in her paper “*A grave offence: corpse desecration and the criminal law*”

*“In the context of human corpses, whilst individuals may be influenced by personal religious or spiritual beliefs, this ‘sacredness’ can be areligious. This is because the corpse is universally viewed as an important symbol of the previously living person. Corpses are also vital, yet painful, reminders of the vulnerability of human life. Subsequently, whether we adhere to religious, cultural or personal practices, many people have strong views about the treatment of the dead. These are often specifically directed at how the body is treated prior to disposal. It is predictable therefore that we have a strong emotional response when we hear that something unpleasant has happened to a corpse, especially where it is that of a loved-one. Whatever our personal beliefs, we have in common the feeling that it is a serious wrong to behave with disrespect towards human remains”*

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<sup>1</sup> See <https://deadbodiesandthelaw.wordpress.com/> Her website summarises the position saying “Sometimes, people can do things to deceased bodies which are, or at least seem, disrespectful. A common assumption is that the criminal law is equipped to respond to these incidents. However, my research has found the opposite to be true”. This appears an accurate statement of the law.

However, the HTA regulatory system does not provide any protection for human tissue from a deceased person outside regulated settings. Further, as the above paper from Dr Jones explains, there is no systematic or comprehensive protection offered by the criminal law to prevent a person doing acts which disrespect a dead body or parts of a dead body.

There are a number of other countries which have criminalised offensive activity towards a dead body. Perhaps the most useful is article 182 of the Canadian Criminal Code which provides:

*“Every person is guilty of an indictable offence and liable to imprisonment for a term of not more than five years or is guilty of an offence punishable on summary conviction who*

*(a) neglects, without lawful excuse, to perform any duty that is imposed on him by law or that he undertakes with reference to the burial of a dead human body or human remains, or*

*(b) improperly or indecently interferes with or offers any indignity to a dead human body or human remains, whether buried or not”*

This provision has the following features:

- It imposes obligations on anyone who comes into contact with a dead body or human remains, whether in a professional, healthcare or personal capacity
- It sets an objective duty to treat a dead body or human remains with “dignity” (or more accurately criminalises treating a dead body or human remains with indignity) and can thus apply to a myriad of different factual situations.
- It does not require anyone to be offended at the time the act is done and thus can cover acts done in private but which objectively amount to indignity
- It specifically recognises that a person who has a duty towards a dead body (i.e. within sub-paragraph (a)) is required to carry out that duty. That would cover anyone involved in a post-mortem but also an undertaker.

There are more limited provisions described in Dr Jones' helpful paper and website applying in France and Germany. In Queensland, Australia it is a criminal offence to "interfere" with a dead body<sup>2</sup>.

### **A civil wrong?**

A criminal offence punishes those responsible for reprehensible behaviour but does not provide compensation to anyone whose feelings have been substantially injured by the conduct of a person who failed to treat a dead body or human remains with respect. The "loss" is not suffered by the deceased, but by the feelings of someone who knew the deceased.

Applying the model under the Protection from Harassment Act 1997, it would be possible to create a legal obligation to treat a dead body or human remains with respect which amounted to both a criminal offence and a civil wrong, actionable at the suit of anyone who had a pre-existing significant relationship with the deceased and suffers a significant level of distress as a result of the actions of the defendant. That person could be a relative but (adopting the model from s4 of the Mental Capacity Act 2005) the category of people would not be limited to blood relatives.

A UK statute modelled on the Canadian statute, with the addition of a civil wrong as set out above, may present the most appropriate way to meet legitimate concerns that our present system of law does not offer proper protection to maintain the dignity of a dead body or human remains.

David Lock KC

28 April 2024.