

HTA Board meeting, 19 September 2024

Agenda item	3.1 Update on HTA activities to increase protections for the dignity of the deceased
For information or decision?	Decision
Decision making to date?	N/A
Recommendation	The HTA Board is asked to approve the approach taken by the Executive to improve protections for the dignity of the deceased
Which strategic risks are relevant?	Risk 1: Regulation Risk 2: Sector
Strategic objective	Approach to Regulation
Core operations / Change activity	Change activity
Business Plan item	Continue to support and respond to the Fuller Independent Inquiry, identify and deliver workstreams
Committee oversight?	N/A
Finance and resource implications	N/A
Timescales	Ongoing and partially dependent on external factor: FII Phase 2 report publication
Communication(s) (internal/ external stakeholders)	N/A
Identified legislative implications	Possible: As yet unknown

Update on HTA activities to increase protections for the dignity of the deceased

Purpose of paper

1. In recent years, the HTA has been developing and strengthening our approach to regulation in the Post Mortem (PM) sector and other related sectors that manage the deceased. This paper outlines the context for this work and highlights the work that is ongoing and planned, including our support for the work of Sir Jonathan Michael's Independent Inquiry.

Action required

2. The Board is asked to **approve** the work that is being progressed to improve the HTA's approach to regulation of the PM sector and related sectors involved in the management of the deceased, as outlined in this paper, in particular to enhance protections for the dignity of the deceased.

Context: Drivers for change

3. In recent years, various internal and external factors have created a context in which the HTA has sought to adapt and develop its approach to regulation, including:
 - the HTA's new strategy for 2024-2027, with its clear focus on continuous improvement in our approach to fulfilling our regulatory functions to ensure the safe and trusted use of human tissue, for example by continuing 'to develop, strengthen and deploy the full scope of our regulatory tools and activities to ensure standards on the safe use of human tissue are embedded; and to 'drive up standards, actively support innovation and address shortfalls in practice';
 - wider regulatory reform, including the need for regulation to be risk-based, proportionate and support innovation in the life sciences.
4. In the PM sector, there has been a particular focus on making improvements to the HTA's regulatory activities that contribute towards protecting the dignity of the deceased. This has come about, in part, as a result of:
 - the HTA's Guiding Principles ('consent; dignity; quality; and honesty and openness') – applicable to all establishments and professionals operating under the HT Act and Regulations, which include specific reference to protecting the dignity of the deceased, for example:

‘Dignity should be paramount in the treatment of human tissue and bodies. This means: a) the dignity of the donor should be respected at all times; b) there should be mechanisms in place to protect bodies and human organs and tissue from harm (Para 13) ¹;

- raised awareness of risks to the security and dignity of the deceased arising from the HTA’s own regulatory activities and from the Phase 1 Report of Sir Jonathan Michael’s Independent Inquiry (**Annex A** provides background to the Inquiry); and
- the HTA’s advice to the Secretary of State of Health and Social Care in December 2021, following the conviction of David Fuller, which set out the HTA’s assessment of the regulatory issues related to this matter and outlined actions the HTA would plan to take in response over the short, medium and longer term.²

Work packages and themes

5. The HTA’s advice to the Secretary of State identified four principle themes to be addressed in response to the revelation of offending against the deceased in a hospital mortuary:

- regulation of the PM sector;
- review of the regulatory framework in connection with the management of the deceased;
- wider regulatory contribution; and
- the legislative framework

6. The HTA has used these themes to inform its work in this space with the strategic aims of:

- strengthening the HTA’s direct effectiveness in fulfilling its core function of superintending compliance with regulatory requirements;
- raising awareness of the importance of protecting and prioritising effective measures to ensure respect for the dignity of the deceased;
- sharing learning and good practice by supporting and assisting, where relevant, other organisations involved in the management of the deceased (directly or indirectly) where our knowledge and expertise may be of assistance; and

¹ ‘HTA Code A: Guiding principles and the fundamental principle of consent’. Para 8 sets out the 4 Guiding Principles and Para 13 defines what dignity means. Available at: <https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice> [Link accessed 20 August 2024]

² See HTA website for update published in May 2022, which includes a link to the Guidance to the Secretary of State for Health and Social Care from December 2021: <[HTA Progress Update on advice to the Secretary of State for Health and Social Care in connection with offending by Fuller in a hospital mortuary | Events | Human Tissue Authority](#)> [link accessed 14 August 2024]

HTA 13-24

- assessing policy issues that may impede the effectiveness of current oversight models or that could strengthen them.
7. Whilst the primary focus here is on activities and changes to the HTA's approach to superintending compliance with regulatory requirements in the PM sector, these are also relevant to aspects of activities in all the HTA's sectors, any one of which may involve direct interaction with the deceased.
 8. Delivery of these aims is being managed through a series of discrete work packages, which fall broadly into four groupings:
 - A. Policy,
 - B. Operational Delivery,
 - C. Wider Sector Engagement, and
 - D. Direct Engagement with and support to the Inquiry.
 9. Further illustrative detail of some of the key activities within each of these groupings is provided below. **Annex B** summarises the activities and work-packages in more detail.

Summary of key activities under each grouping

A. Policy

10. The HTA's advice to the Secretary of State for Health and Social Care (Dec 2021³), noted that significant policy matters, including reviewing the HTA's statutory Codes of Practice and Standards, would have to be considered in the medium to long-term, after the Inquiry concludes.
11. Activity to take forward significant policy matters is anticipated to commence following the conclusion of the Independent Inquiry, whose Phase 2 report is expected to be published later this year.
12. Policy matters likely to be addressed include:
 - changes to the HTA powers (e.g. the ability to levy administrative fines);
 - the role of the DI and whether this is working effectively and as envisaged;
 - whether corporate bodies or senior officials within licensed establishments should have formal or statutory responsibilities in connection with licensable

³ See HTA website for update published in May 2022, which includes a link to the Guidance to the Secretary of State for Health and Social Care from December 2021: <[HTA Progress Update on advice to the Secretary of State for Health and Social Care in connection with offending by Fuller in a hospital mortuary | Events | Human Tissue Authority](#)> [link accessed 14 August 2024]

HTA 13-24

activities; and

- whether there should be a legal duty to respect the dignity of the deceased (as referenced in the letter the HTA sent to the Inquiry in April 2024 – see **Annex C**).

13. With regards to operational policy, the HTA reviewed and revised its guidance relating to licensing standards in PM and Anatomy sectors in 2022/23⁴, clarifying and strengthening expectations around security arrangements, including how licensed establishments should test the effectiveness of their arrangements through their own audits and assurance checks.

B. Operational delivery

14. The HTA has enhanced the scope and depth of its assurance activities. For example, the HTA has:

- increased inspection numbers to increase frequency of attendance, particularly but not exclusively in the PM sector;
- implemented enhanced scrutiny and testing of evidence regarding security systems, including audits, at inspection following updates to HTA guidance relating to licensing standards on security and assurance;
- made changes to its case management system in the PM sector to provide a longitudinal 'at a glance' view;
- conducted mandatory webinars (Spring 2024), focused on PM security standards, for all relevant PM DIs, with confirmed attendance and participation by all 164 relevant DIs;
- published revised guidance for HTA Reportable Incidents (April 2024)⁵;
- expanded its regulatory assessment toolkit with the introduction of Evidential Compliance Assessments (ECAs) in PM sector (Q1 and Q2 2024/25)⁶; and
- developed a trial programme of unannounced inspections in the PM sector, commencing mid-September 2024⁷.

C. Wider sector engagement

15. In relation to this work package, the HTA has carried out, or is in the process of carrying out, the following:

⁴ [Regulatory alerts | Human Tissue Authority \(hta.gov.uk\)](https://www.hta.gov.uk/regulatory-alerts)

⁵ <[Update for Post Mortem Sector Licensees: Revised Incident Reporting Guidelines | Events | Human Tissue Authority \(hta.gov.uk\)](https://www.hta.gov.uk/news-events)>, Published 4 April 2024; [Link accessed 9 September 2024].

⁶ HTA newsletter: issue 92 - April 2024

⁷ [Unannounced inspections for the post mortem sector from September 2024 | Events | Human Tissue Authority \(hta.gov.uk\)](https://www.hta.gov.uk/news-events)

- Engagement and collaboration with other agencies to support an improved system-wide response, including:
 - HTA-led Sector forums and round tables, focusing on specific sector risks or issues, with published outputs from these events⁸;
 - participation in relevant sector forums and events led by others (e.g. Anatomy Sector webinars; Association of Anatomical Pathology Technologists (AAPT) Annual Conference and Consent Training; presentation at the National Association of Funeral Directors (NAFD) Annual Conference and provision of an article on traceability);
 - contributions to other agencies' policies and guidance (e.g. NHSE's Health Building Note (HBN-16 - Mortuary standards));
 - Updating MOUs and information sharing agreements (e.g. with CQC and UKAS);
 - contributing to multi-agency working groups, including Health and Social Care Regulators Forum (and Emerging Concerns Protocol), NHSE Mortuary Oversight Board, and NHSE (SE) Joint Strategic Oversight Board (JSOG);
 - ongoing engagement with Funeral Directors' trade bodies; and
 - supporting Government and Local Authority responses to the problems identified at Legacy Funeral Directors, with practical advice on the potential applicability of HTA standards and undertaking site visits.
- Trial with the Welsh Government and Health Boards of advisory inspections for unlicensed hospital body stores.
 - In this regard, the HTA has undertaken five advisory inspections of unlicensed body stores under the same governance at Health Boards / Hospitals in Wales, linked to the inspection of their licensed premises. The outcomes of these advisory inspections were included as annexes in the published inspection reports of the licensed establishments. Whilst there is an appetite to explore how to continue what was recognised as good work, further considerations are needed to identify what might be a suitable framework, including resourcing, before any continuation or expansion of this activity can be agreed, either with Welsh Government or more widely.

D. Direct Engagement with and support to the Inquiry

16. The HTA Chair wrote to the Inquiry Chair in April 2024 with HTA input for Phase 2, including an annex entitled '*A note on the extent to which the law protects (or should protect) a dead body or parts of a dead body*', prepared by a member of

⁸ <[Introducing our sector-focused stakeholder forums | Blog | Human Tissue Authority \(hta.gov.uk\)](#)> and <[Stakeholder roundtables | Human Tissue Authority \(hta.gov.uk\)](#)>; [Links accessed 9 September 2024]

HTA 13-24

the HTA Board, concerning whether there should be a legal duty on relevant professionals to protect the dignity of the deceased.

17. The HTA has also continued to respond to specific information requests from the Inquiry as it has been progressing through Phase 2.
18. Work is currently ongoing to prepare for HTA participation in providing further formal evidence relating to Phase 2 at any in-person sessions to which the HTA may be invited.

Summary

19. The HTA acknowledges the importance of continuing to improve regulatory practice to ensure those responsible for caring for the deceased take all reasonable and practicable steps to protect their dignity.
20. In the context of the aftermath of the discovery of offending within a licensed establishment and concerns raised in Sir Jonathan Michael's Phase 1 Report, the HTA has instigated a wide range of activities to strengthen and enhance its approach to increase protections for the dignity of the deceased.
21. This paper provides an overview of the steps the HTA has taken, and is continuing to progress, in support of that objective.
22. These activities are broad-ranging and have generated positive responses from across the sectors the HTA regulates. However, the HTA recognises there is always more that can be done and will continue to identify and implement suitable measures to continue to maintain and enhance the focus on dignity of the deceased, including taking forward policy work once the Inquiry's Phase 2 report is published.

Recommendation

23. The Board is asked to **approve** the work that is being progressed to improve the HTA's approach to regulation of the PM sector and related sectors involved in the management of the deceased, as outlined in this paper, in particular to enhance protections for the dignity of the deceased.

ANNEX A:

Background to Sir Jonathan Michael's Independent Inquiry

1. David Fuller was convicted in November 2021 and sentenced in December 2021 for two murders and for sexual offences involving the deceased carried out at his place of work, Maidstone and Tunbridge Wells NHS Trust.
2. Following Fuller's sentencing, Sir Jonathan Michael was asked by the Secretary of State for Health and Social Care to extend his existing confidential internal investigation for the Trust into a national (England-wide) independent inquiry.⁹
3. The Terms of Reference for the Inquiry were finalised on 23 February 2022 and identified two distinct phases; Phase 1 focusing on events at the Trust and Phase 2 considering the wider system involved in managing the deceased.¹⁰ A subsequent addendum was added to the Terms of Reference in May / June 2023.¹¹
4. Sir Jonathan Michael's Phase 1 report was published in November 2023.¹²
5. Phase 2 had been launched in July 2023, with an initial focus on the funerals sector. Phase 2 is continuing and is currently expected to report in 2024.¹³
6. Throughout the period since having been made aware of the allegations against Fuller, the HTA has undertaken a range of activities to review and strengthen our approaches for managing those settings within our remit involved in handling the deceased, primarily but not exclusively in the PM sector.
7. The HTA has also constructively engaged with Sir Jonathan Michael's Inquiry, providing input and evidence into Phase 1 (now concluded) and continuing to do the same for Phase 2.

⁹ <[David Fuller Case - Hansard - UK Parliament](#)> [Link accessed 10 September 2024]

¹⁰ Terms of Reference for Sir Jonathan Michael's Inquiry are available on the Fuller Inquiry website at: <<https://fuller.independent-inquiry.uk/terms-of-reference/>> [link accessed 12 August 2024]

¹¹ The addendum to the Terms of Reference and explanations for this addendum are available on the Fuller Inquiry website at: <<https://fuller.independent-inquiry.uk/announcements/>> [link accessed 12 August 2024]

¹² The Phase 1 report is available on the Fuller Inquiry website at: <<https://fuller.independent-inquiry.uk/wp-content/uploads/2023/11/Fuller-Inquiry-Phase-1-Report-1.pdf>> [link accessed 12 August 2024] and at Gov.UK at <<https://assets.publishing.service.gov.uk/media/6565d4c762180b0012ce82e8/HC310-fuller-inquiry-phase-1-report-web-accessible.pdf>> [link accessed 12 August 2024]

¹³ The Fuller Inquiry website states, in relation to Phase 2: '*The final report, looking at the broader national picture and the wider lessons for the NHS and for other settings, is planned for publication in 2024.*' Link available at <<https://fuller.independent-inquiry.uk/phase-2/>> [link accessed 12 August 2024]

ANNEX B**Activities to increase protections for the dignity of the deceased:****Summary of past and current work-packages**

Work-packages	Status
<p>WP1 Review of Licensing Standards and Guidance</p> <ul style="list-style-type: none"> - Internal review of Post Mortem¹⁴ and Anatomy¹⁵ Licensing Standards and Guidance - Engagement with external stakeholders on proposed additional guidance to Standards to clarify and strengthen expectations around security arrangements and audits / checks of those to provide assurance - Updates finalised 	<p>Status: Complete</p> <ul style="list-style-type: none"> - Published Regulatory Update 001/2022 issued 4 October 2022: updates to Post Mortem Examination Licensing Standards and Guidance - Published Regulatory Update 002/2023 issued 31 January 2023: updates to Anatomy sector Licensing Standards and Guidance
<p>WP2 Fuller Independent Inquiry: engagement and preparation for evidence sessions</p> <ul style="list-style-type: none"> - Engagement with Inquiry Phase 1; themed briefings and responses to on-going and ad-hoc data requests - Phase 1 evidence sessions; preparation - Engagement in Phase 1 report ‘fairness process’ - Phase 1 report publication November 2023; reviewed concerns raised and recommendations to inform current and future work-packages 	<p>Status: Complete</p> <ul style="list-style-type: none"> - Submitted formal briefings on the role of the HTA and its regulatory processes - Responded to data requests within allotted time - Prepared supporting material for evidence sessions - Submitted formal response to concerns raised as part of the Phase1 report fairness process - Phase 1 report publication; reviewed in-full , including concerns raised and recommendations
<p>WP3 Supporting the wider health system response</p> <p>On-going engagement with regulators, government agencies, devolved administrations and wider community of stakeholders:</p> <ul style="list-style-type: none"> - Strengthen relationships and working partnerships to help better identify and manage complex, system-wide risks 	<p>Status: On-going</p> <ul style="list-style-type: none"> - The HTA is represented (as an Observer) on NHS England’s (NHSE) Mortuary Oversight Board Health and is a member of the Health and Social Care Regulators Forum (providing access to the Emerging Concerns Protocol); is active on various multi-agency working groups (such as the Death Investigation

¹⁴ Premises, facilities and equipment: PFE1d), PFE1e), PFE2g). Governance and quality systems: GQ1a), GQ1b), GQ1d), GQ2a), GQ2b), GQ4a), GQ6a)

¹⁵ Premises, facilities and equipment: PFE1, PFE2. Governance and quality systems: GQ1, GQ2, GQ3, GQ4, GQ5, GQ6. Consent standards: C2

HTA meeting papers are not policy documents.

Draft policies may be subject to revision following the HTA Board meeting

HTA 13-24

<ul style="list-style-type: none"> - Publish operational data to increase transparency and help identify trends and opportunities for improvement - Support partners and the wider sector through information sharing, including sharing of good practice - Increase opportunities for stakeholder engagement on sector-focused issues, to consider policy and practice and share insight and intelligence 	<p>Committee, Burial At Sea working group and the Regional Joint Strategic Oversight Group for NHSE (Southeast); and has regular meetings with professional and trade bodies (eg AAPT and NAFD)</p> <ul style="list-style-type: none"> - Finalising MOUs with key partners (CQC and UKAS); expected sign-off October 2024 - Closed incident data dating back to 2020 is published¹⁶ and continues to be updated quarterly. Licence, inspection, inspection shortfall and enquiries data is also published, dating back to 2017, and is updated bi-annually - Access to NHSE’s National Mortuary Capacity data and reports - Shared latest inspection reports, data on HTA licences and relevant sections of the Standards and Guidance to support colleagues in Other Government Departments in their understanding of the issues facing the sector - Intelligence sharing with devolved administrations on systems of regulation and licensing schemes - Introduction of sector focused forums with a Post Mortem forum held in February ‘24 on the impact of recently updated licensing standards and data on reportable incidents
<p>WP4 Governance and planning</p> <ul style="list-style-type: none"> - Maintain suitable governance and planning arrangements to ensure effective management of workstreams. 	<p>Status: On-going</p> <ul style="list-style-type: none"> - Cross-departmental membership confirmed - Terms of reference updated - Risk register and milestones reviewed - On-going adherence to internal governance and reporting processes
<p>WP5 FII Engagement: Phase 2</p> <ul style="list-style-type: none"> - Continued engagement with Inquiry throughout Phase 2 - HTA briefing and preparation for Phase 2 evidence sessions - HTA position brief and statement in response to the Inquiry’s Phase 2 Report 	<p>Status: On-going</p> <ul style="list-style-type: none"> - Responding to data requests within allotted time - Evidence sessions expected October 2024; preparing brief - Publication date of Phase 2 report (expected 2024)

¹⁶ Pre-2020 closed incident data was included as an annex in delivery reports to the HTA Board
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HTA 13-24

<p>WP6 Codes of Practice and Standards</p> <ul style="list-style-type: none"> - Licensing Standards and Guidance initial review - Review of the Codes of Practice and Standards 	<p>Status: Medium to long term activity</p> <ul style="list-style-type: none"> - Published updates to Post Mortem and Anatomy sectors Licensing Standards and Guidance in 2022 and 2023; continue to receive and review intelligence on security measures being implemented to assess impact - A formal review is scheduled following publication of the Fuller Independent Inquiry Phase 2 report
<p>WP7 Operational Activities</p> <ul style="list-style-type: none"> - Enhanced assurance activities; initial focus security standards in the PM sector - Review the inspection approach; review of the CAPA process and pilot programme of unannounced inspections 	<p>Status: Medium to long term activity</p> <ul style="list-style-type: none"> - Updated HTARI guidance published; to assist establishments in deciding whether an incident is reportable - Sessions on security standards¹⁷ delivered for 164 DIs looking at critical areas with known risks; access control, risk documentation and documented policies and procedures relevant to licensed activity - PM establishments were required to submit evidential compliance assessments focused on security standards to capture up-to-date data on states of compliance. The results have been assessed and dependent on the category of compliance, establishments will be integrated into the inspection schedule, or offered further advice and follow-up activities.
<p>WP8 Develop a Longitudinal View: Enhance Sector and Establishment Intelligence: Medium to long-term</p> <ul style="list-style-type: none"> - Effective engagement with regulatory bodies - Risk analysis - Sector insight 	<p>Status: Medium to long term activity</p> <ul style="list-style-type: none"> - Finalising MOUs with key partners (CQC and UKAS); expected sign-off October 2024 - Shared latest inspection reports, data on HTA licences and relevant sections of the Standards and Guidance to support colleagues in other Government Departments in their understanding of the issues facing the sector - Trialled advisory inspections of unlicensed body stores for the Welsh Government - Activities to improve the HTA’s proportionate approach to assessment: on-going review of assessment tools; data collection and analysis; evaluation of trialled operational programmes

¹⁷ Focused on GQ1a), GQ2a), GQ6c), PFE1d), PFE1e)
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HTA 13-24

<p>WP9 Safeguarding</p> <ul style="list-style-type: none">- Maintaining the dignity and safety of the deceased is a regulatory requirement and a guiding principle of the HTA's Code of Practice; any review of legislative and operational frameworks to formally incorporate 'safeguarding the deceased' into existing legal safeguarding frameworks would be a policy matter outside the HTA's control but in which the HTA would be keen to participate and may result in consequent changes to human tissue legislation and may impact a review of the Codes of Practice and Standards.	<p>Status: Long term activity</p> <ul style="list-style-type: none">- Submitted initial considerations from HTA Chair to Inquiry in a letter, April 2024- Future activities to be informed by the Phase 2 Report recommendations and the wider government-led response
<p>WP10 Legislative framework</p> <ul style="list-style-type: none">- Review of the Human Tissue Act (as referenced in the Inquiry's Phase 1 report)	<p>Status: Long term activity</p> <ul style="list-style-type: none">- Potential impact: the HTA in an advisory capacity providing evidence to support recommendations to amend the Act- Future activities to be informed by the Phase 2 Report recommendations and the wider government-led response