

# Draft Minutes of the Human Tissue Authority Board

---

**Date:** 19 September 2024

**Time:** 10.00 – 12.10

**Venue:** Wandle 40/41, 2 Redman Place, London E20 1JQ

**Meeting Number:** 109

---

## Attendees:

### HTA Board Members

David Lock (chairing)

Mhairi Anderson

Tom Chakraborti

Gary Crowe

Helen Dodds *items 3 to 6*

Ellen Donovan

Andy Greenfield

Dave Lewis

Jessica Watts

### Apologies

Lynne Berry, HTA Chair

### HTA Executive

Colin Sullivan, Chief Executive

Louise Dineley, Director of Data, Technology & Development

Nicolette Harrison, Director of Regulation

John McDermott, Deputy Director of Performance and Corporate Governance

Tom Skrinar, Director of Finance and Resources

### HTA Supporting officers

Richard Mabbitt, Private Office Lead (minutes)

Debra Morgan, EA Private Office

### Department of Health and Social Care

Jacky Cooper, Policy Lead, Human Tissue Policy and Ethics of Consent

Ria Mukherji, Senior Policy Adviser, Human Tissue Policy and Ethics of Consent

*A number of members of the public also observed the meeting remotely via Teams, and were able to pre-submit questions to the Board*

## 1. Opening administration

### Item 1.1 – Welcome and apologies

1. David Lock welcomed attendees. He was chairing the meeting, in line with Standing Orders, as the nominee of HTA Chair, Lynne Berry, who was unable to attend through illness. Members expressed their best wishes to the Chair.
2. David Lock noted the value that HTA placed on transparency about its role

and that periodically holding Board meetings in public supported such transparency on the organisation's strategic decision-making. On behalf of the HTA, he therefore welcomed members of the public who were observing the meeting remotely and thanked them for their interest.

3. With the exception of Lynne Berry, all members were attending. Helen Dodds had been held up due to train delays but would join for the latter part of the meeting.

#### **Item 1.2 – Declarations of interest**

4. No new interests were declared by members. Jessica Watts noted that she would shortly be registering a new employment role. No potential areas of conflict in relation to registered interests were raised by members.

#### **Item 1.3 – Minutes of 7 March 2024**

5. Minutes of the meeting of 26 June 2024 (HTA 16-24) were **AGREED** by the Board as an accurate record of the meeting.

#### **Item 1.4 – Matters Arising**

6. The Board reviewed the log of actions arising from previous meetings (HTA 17-24) and was content with progress as reported.
7. Further to the completed Action 7 from the meeting of 7 December ("Fees Review"), Tom Skrinar reported that discussions had now taken place with the Devolved Administrations in Wales and Scotland in relation to fees to be set for 2024/25. Discussions in respect of Northern Ireland would take place shortly.

## **2. Assurance and reporting**

#### **Item 2.1 - Chair's Report**

8. The Board was content for this update to be deferred, and for Lynne Berry to provide any updates to members by correspondence after the meeting.

#### **Item 2.2 - DCHS Sponsor Team Report**

9. Jacky Cooper provided background on the remit of Baroness Merron, Parliamentary Under-Secretary of State at the DHSC, under whose ministerial responsibility HTA fell. She also reported that Tom Riordan, former Leeds City

Council Chief Executive, had been appointed as the Department's Second Permanent Secretary.

10. DHSC officials continued to work on the Autumn spending review and were grateful to the HTA Finance team for its contributions to this process. The Public Bodies Review (PBR) provisionally scheduled for 2025 had been paused pending Cabinet Office steerage on the new Government's approach to PBRs.
11. Board members noted a busy workload for the DHSC Human Tissue Policy and Ethics of Consent Team, including work related to the departmental responses to Lord Darzi's Independent Investigation of the NHS in England, and Dr Penny Dash's Independent Review into the Operational Effectiveness of the Care Quality Commission.
12. Board members welcomed the update and looked forward to continuing its constructive working relationships with DHSC.

### **Item 2.3 - CEO Report**

13. Colin Sullivan introduced paper HTA 18-24, comprising a narrative report on HTA activity in the last quarter, and summary of current issues. The Board noted in particular:
  - a) Continuing engagement with Phase 2 of Sir Jonathan Michael's Inquiry into the Offending in a Hospital Mortuary by David Fuller. HTA would be giving formal evidence to the Inquiry in October. HTA continued to develop its approach to assessing compliance with regulatory obligations in the Post Mortem sector, and this work would be covered further at item 3.1.
  - b) Working closely with DHSC to update guidance on the disposal of pregnancy remains following pregnancy loss or termination. This guidance was published earlier in September 2024.
  - c) Ongoing work with DHSC to understand the impact for the UK, and in particular for Northern Ireland, of the proposed EU Substances of Human Origin Regulations (SoHO)<sup>1</sup>, thus covering many areas included in the Human Tissue Act 2004. These are proposed EU Regulations which will repeal the [Blood Directive](#) (Directive 2002/98/EC) and [Tissues and Cells Directive](#) (Directive 2004/23/EC) and merge them into one single EU law, applying across the whole of the EU (but not directly apply to the UK). The HTA have been working with DHSC to understand the scope and effect of the proposed Regulations and their likely impact in the UK, as well as next steps to assist with work planned for this area.
  - d) The additional work for HTA arising from the Human Tissue Act 2004

---

<sup>1</sup> See <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=COM:2022:338:FIN&from=EN>

(Supply of Information about Transplants) Regulations 2024, on which a progress report was provided at item 4.1.

14. Colin Sullivan provided general information about the results of the HTA's June all-staff survey. Board members noted that this had covered themes of purpose; enablement; inclusion and wellbeing; reward and recognition; and leadership and management. The results were mixed with some variance across teams. There had broadly been more favourable responses relating to organisational purpose, roles, and line management, and less favourable responses around leadership and communication. The high response rate was very encouraging. Staff engagement sessions were now being held, together with a proposed Staff Forum staff forum. Colin Sullivan assured the Board that the senior management team was committed to learning from the outcome of the survey and working out what steps could be taken to address the issues that had been raised. The results of the staff survey would influence and inform the HTA's People Strategy. Colin Sullivan hoped to be able to report progress on the strategy to the Board in December 2024.
15. The Board welcomed HTA's Innovation in Inspection work. It was pleased that staff were monitoring initial recommendations from the Dash report for insight into how HTA might innovate or refine its approaches further. The Board was also assured that, having provided its own insight into the performance of the NHS as part of the Darzi review, staff were considering whether any of that review's wider considerations could be applicable to the HTA. Board Members acknowledged that the impact and resourcing of NHS regulation was only a small part of this wide-ranging report. Although the report had cited a significant rise in regulatory staff across the sector, HTA's front line staff (covering six sectors in four nations) made up less than 1% of the current total number of staff involved in NHS regulatory functions.

#### **Item 2.4 - HTA Performance Report**

16. Colin Sullivan spoke to paper HTA 19-24. The Board welcomed the thorough report, noting narrative Quarter 1 updates on Regulation; Policy and Development; ICT; Communications and Stakeholder Engagement; Corporate Services; Finance; Audit and Risk; and HR. The Board noted that the overall Business Plan RAG rating for Quarter 1 was 'Amber', but with an improving picture during the first part of Q2.
17. The Board discussed staff capacity, which they felt was a recurrent theme in the report. Board members noted pressures arising from the new "Duty to Report" under the Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024; ongoing work related to Sir Jonathan Michael's Inquiry; the increase in (and evolution of) Post Mortem sector

activity; and the new Cyber Assessment Framework.

18. Board members asked that the Portfolio Management graphic for projects includes clarification of whether un-started projects are consciously planned to start later or whether they have slipped **Action: John McDermott** to add to the graphic accordingly.
19. Board members reflected more generally on the extent to which mitigating risk actions could deliver more acceptable risk levels, and noted that there could be instances where HTA had to accept resource constraints and manage down its ambition accordingly. The Board:
  - a) Noted that a deep dive into the currently over-tolerance Risk 5 (Failure to make use of available digital, data, and technology) was anticipated at the October ARAC meeting.
  - b) Looked forward to reviewing the People Strategy, given the above-tolerance rating of Risk 3 (Inability to progress core activities due to staff capacity and capability) and a still-high, though improving, attrition rate. The Board asked for more clarity in future reports about how expired fixed-term contract (FTC) roles were factored into the attrition rate calculation. It recognized that FTC roles could be an appropriate and financially responsible way of managing resource challenges but Board members encouraged the Executive to be judicious in using FTCs.
  - c) Noted that Risk 4 (Insufficient or ineffective management of financial resources) has moved above tolerance due to vacancies in the Finance team. It asked to be kept aware of developments regarding the Director of Finance and Resources role. The Board was content that efforts to recover outstanding debt were proportionate and duly prioritised and noted that advice was being sought from DHSC sponsors on potential further recovery action, including through NHS Resolution, if required.

The Board was content that its Audit and Risk Assurance Committee continue to monitor and advise the executive here, and felt that further specificity in the timelines for and effectiveness of risk mitigation would be helpful in determining acceptable risk levels.

### **3. Decision items**

#### **Item 3.1 - HTA activities to increase protections for the dignity of the deceased**

20. Nicolette Harrison introduced paper HTA 20-24 which outlined the context to HTAs work developing and strengthening its approach to regulation in the Post Mortem sector and other related sectors that manage the deceased. It highlighted the work that is ongoing and planned, including support for the

work of Sir Jonathan Michael's Inquiry.

21. The Board endorsed and **APPROVED** work being progressed to improve the HTA's approach to regulation of the pm sector and related sectors, in particular to enhance protections for the dignity of the deceased.
22. The Board asked to be fully sighted on future work arising from the Inquiry's Phase 2 recommendations. **Action: Nicolette Harrison** to bring a table of recommendations, when published, and related HTA actions to Board as part of ongoing reporting.
23. Board members also discussed the effectiveness of the HTA's trials in Wales of advisory inspections for unlicensed hospital body stores, linked to inspections of licensed hospital premises. The Board welcomed this pilot work undertaken with the support of the Welsh Government and Health Boards. It felt that it had been a useful test of the wider applicability of HTA approaches and standards and that potentially advisory inspections could be a useful supplementary to mandated regulatory activity. It noted the appetite from the sector to continue with this type of approach. However, the Board agreed that the pressure on HTA resources meant that HTA's primary focus should be on its statutory obligations and that where HTA staff were asked to provide support outside our statutory remit, this should usually be on a cost neutral basis with the costs being met by the requesting organisation.
24. The Board further discussed the proposal made by the HTA to the Michael Review to consider a specific legal obligation on anyone dealing with the deceased or part of the deceased to act with dignity (based on the Canadian Penal Code). There was strong support for the general concept but Andy Greenfield raised a specific issue about how such a duty would interact with research activity in the UK. The Board noted that the regulation of organoids used for research fell outside the remit of the HTA as set out in the Human Tissue Act 2004 and that the HTA had no formal role in the ethical approval of research. Nonetheless, given the potential for policy and legislative changes arising from Sir Jonathan Michael's Inquiry, the Board felt it would be helpful to explore early the potential consequential impacts of such a scope extension. The Board therefore agreed that a small group (Tom Chakraborti, David Lock and Andy Greenfield, with Nicolette Harrison, Louise Dineley and specialist staff, as required) should discuss and bring back their thoughts to the Board. This could be shared with the DHSC, the Inquiry or both if this important issue were to become part of their policy remit. As noted in para 23 above, the HTA has to be careful not to exceed its own remit and would need to limit activities to framing the issues based on the HTAs experience with implications for others to consider. **Action: Nicolette Harrison** to convene a small group to look at potential implications for the HTA of dignity-based

protections for tissues derived from the living.

### Item 3.2 - Police Referral and Warrants Policy

25. Nicolette Harrison introduced paper HTA 21-24 which sought Board approval for reviewing and updating the HTA's Policy for managing and referring potential criminal breaches of human tissue legislation ("Police Referral and Warrants Policy"). The Executive proposed to bring a revised policy to Board for formal consideration in Spring 2025.
26. Board reviewed the proposed areas for revision, noting the changes to the policy and operational environment since the last update, particularly in respect of aspects of the HTA's work in Organ Donation and Transplantation. In particular, the Board noted the body of experience of working with the clinicians and the police and other relevant authorities on complex cases of living organ donation or transplants, and the importance of ensuring that criteria for referrals, and processes were proportionate and risk-based, and decision making was appropriately delegated.
27. The Board **AGREED** that the Executive review and propose changes to the Board's police referral and warrants policy, bringing revisions to the March 2025 Board meeting, The Board noted that the nature of engagement on referrals tended to vary with different Police Forces, and that it was important that the revisions were informed by due consultation with those stakeholders

## 4. Information items

### Item 4.1 – 'Duty to report' update

28. Nicolette Harrison spoke to paper HTA 22-24 which provided an overview of reports received by the HTA since new Regulations came into force, covering the period 1 April 2024 – 31 August 2024. The Regulations imposed a statutory duty on certain clinicians to report certain transplants or suspicions of transplant-related offences to the HTA. A full report would be brought to the Board when the regulations had been in place for 12 months.
29. The Board reflected on HTA's early experience of working under the new Regulations, and were pleased by the collaborative approach taken by staff to this issue. Board members acknowledged that this was an early snapshot of progress and that the evidence base in this area was not yet well enough developed to draw any firm conclusions about recurrent problems or trends.
30. Board members noted early indications of a variance in in the quality of initial

information and communications in the cases reported to HTA. It suggested that HTA's initial communications about the requirements of the regulations clinicians and their professional bodies may need further embedding. How this was done would need to be informed by further intelligence about where reports were coming from, and potential reporting gaps. Board members were pleased that HTA staff were looking into this, including using web analytics and other feedback from the sector. The value of in person engagement (conferences etc.) was also noted.

31. The Board noted the resourcing requirements of the 'duty to report' including the complexity and elongated timescales of some cases and agreed that the matter should be brought back to the Board once the duty has been in place for 12 months, and that a review should be provided to the Board at that time looking at the impact, effectiveness and resource implications of the duty. The Board thanked staff for their work on this issue and looked forward to the 12-month report in due course.

## **5. Governance items**

### **Item 5.1 - Remuneration Committee (RemCo) Report**

32. Ellen Donovan, RemCo Chair, reported on the RemCo Meeting of 6 September 2024. She welcomed the input from new members Tom Chakraborti and Mhairi Anderson.
33. RemCo had discussed the staff survey, and had considered it robust and helpful in surfacing and elevating staff concerns. RemCo supported the Executive's proposed next steps; had provided advice here; and had asked for the opportunity to feed back on the forthcoming People Strategy.
34. RemCo had also discussed the challenges faced in transitioning to outsourced HR provision and had provided advice to the Executive. Overall RemCo felt that good progress was being made, and had asked to be kept sighted on progress as working arrangements developed. Tom Chakraborti had provided additional advice to the Director of Finance and Resources.
35. RemCo had been briefed on the staff pay remit process. With the departmental pay remit having been received and considered by the executive the previous week, RemCo would meet extra-ordinarily on 20 September to review and approve HTA's submission to DHCS on pay arrangements.
36. RemCo had been kept aware of developments regarding the Director of Finance and Resources role (currently shared with HFEA) and was pleased that a recruitment reflecting the new arrangements was in hand.



## **Item 5.2 - Audit and Risk Assurance Committee (ARAC) Report**

37. Gary Crowe HTA highlighted the ARAC annual report for 2023-24 (HTA 23-24 which had also been circulated to members after the Board meeting of 26 June 2024. Jessica Watts had since joined ARAC as a member.
38. He noted that there had not been an ARAC meeting since the Board last met. At its October meeting and going forward, ARAC would continue to develop its effectiveness, including appropriate pre- and post-meeting engagement to ensure agendas and discussion remained informed and strategic. It would continue to review the organisation's control and risk management processes, and how existing good practice could be further embedded. ARAC would reflect further on Board Member commentary in previous items relating to the Strategic Risk Register.

## **6. Closing administration**

### **Item 6.1 - Pre-submitted questions from observers**

39. David Lock reported that a two-part question had been received from a meeting observer as follows: "Are you aware that people are taking samples using equipment provided by funeral homes, and often using commercial DTC DNA sampling kits, for DNA analysis? What is your approach to educating funeral homes about the legal protocols around taking samples with the intention of obtaining a DNA profile to compare with others?"
40. Receipt of the question had been acknowledged and it had been passed to specialist staff to consider and provide a substantive response which would be made public (in anonymised form) after the meeting.

### **Item 6.2 - Board forward Plan for 2024-25**

41. The Board noted the high-level Forward Plan at paper HTA 24-24 and that Private Office would shortly be canvassing members availability for dates in 2025-26.

### **Item 6.3- Any Other Business**

42. No other items of business were raised.

### **Item 6.4 - Board reflections**

43. David Lock thanked members for their contributions. The Board would reconvene in the afternoon for joint development sessions with the HSSIB

Board. The next formal meeting of the Board would be held on Thursday 5 December at 2 Redman Place, Stratford

44. Board members thanked David Lock for stepping in to chair the meeting and SMT and staff for their support.

DRAFT