

Minutes of the Human Tissue Authority Board

Date: 18 September 2025

Time: 10.00 – 12.00

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

Meeting: 113

Attendees:

HTA Board Members

Lynne Berry, HTA Chair
Mhairi Anderson
Ellen Donovan
Helen Froud
Andy Greenfield
Nicole Lappin
Dave Lewis
David Lock
*Gina Radford
Steve Stanbury
David Stanton

Apologies for Absence

Jessica Watts (Board Member)
Katrina Leighton-Hearn, Director of Finance and Resources

*Attending remotely

HTA Senior Management Team

Colin Sullivan, Chief Executive
Louise Dineley, Director of Data, Technology and Development
Nicolette Harrison, Director of Regulation
John McDermott, Deputy Director of Performance and Corporate Governance

HTA Staff

Richard Mabbitt, Private Office Lead *minutes*
Debra Morgan, EA, Private Office

HTA Observers

Zuzana Reid, Head of Finance.
Jakob Stenkist, Policy Manager

Government observers

*Rowan Carbury, Quality & Nursing Directorate, Welsh Government
Jacky Cooper, Head of Ethics of Consent and Human Tissue Policy DHSC,
*Janice Sheppey Women, Children and Organ Donation Unit, DHNI

1. Opening Administration

Item 1.1 – Chair's introduction

1. Lynne Berry welcomed all attendees. Nicole Lappin was attending her first meeting having recently been appointed as a Board member by the Minister for Health in Northern Ireland.
2. Members' pre-meeting observations on papers had been shared with the Senior Management Team, who would address the main points raised under

appropriate agenda items.

Item 1.2 – Apologies for absence

3. Jessica Watts had apologised for her absence but had provided some comments on meeting papers to the Chair and CEO. Katrina Leighton Hearn had also apologised for her absence.

Item 1.3 - Declarations of interest

4. Members noted Jessica Watt's declaration of an interest in the University of Cambridge. However, this did not relate to any part or function of the University falling under the HTA's regulatory remit, and the Board was content that public registration was not necessary.
5. Members noted David Lock's continuing role as an expert adviser to DHSC providing short-term remunerated policy advice for DHSC on matters not directly or specifically related to the HTA.
6. No new interests were declared by Members, and no conflicts of interest in relation to matters under discussion were raised.

Item 1.4 - Minutes of meeting of 6 March 2025

7. The Board AGREED the minutes of the previous Board meeting (HTA 22-25).

Item 1.5 - Actions Log

8. The Board noted good progress against actions logged in paper HTA 23-25.

2. Assurance / Reporting items

Item 2.1 - Chair's Report

9. Lynne Berry reported that Nicole Lappin's term had formally started on 12 September, with public announcement and internal HTA announcements shortly afterwards. She thanked DHNI officials for overseeing an efficient and effective appointment process. The longstanding vacancy for a Northern Ireland Board Member had now been filled and the Board was at full complement. The role was analogous to that of Ellen Donovan (as the member appointed by the Welsh Government), with the role holder bringing special experience of the Northern Ireland context to HTA's work, and in all other respects acting as a 'full member of the Board' for Board decision making and

Committee and Panel work. A similar programme of induction to that arranged for Members arriving earlier in the year would be provided by staff.

10. With a full Board membership, Lynne Berry would now be able to discuss Committee membership and other roles with chairs and members. She thanked Steve Stanbury for filling one of the current vacancies on ARAC. On wider Board effectiveness issues, Lynne Berry noted that Private Office was canvassing for a date in November for an informal online meeting to discuss Board effectiveness and the developing policy and delivery landscape.
11. Lynne Berry reported that the DHSC Permanent Secretary had written to Chairs and CEOs of DHSC ALBs to alert them to the Duty of Candour set out in The Public Office (Accountability) Bill (the “Hillsborough Law”).

Item 2.2 - Audit and Risk Committee (ARAC) Chair’s Annual Report

12. David Stanton, as the new Chair of ARAC, provided a short report (paper HTA 24-25). He summarised his handover from Gary Crowe. He looked forward to working with Committee members, staff, and internal and external auditors, with whom a forward programme of meetings had been arranged. He was also attending a GIAA workshop on ARAC effectiveness on 30 September.
13. The next ARAC meeting was scheduled for 14 October and would include consideration of GIAA’s new audit offering for smaller organisations. A report would be provided to members after the meeting.

Item 2.3 - Remuneration Committee (RemCo) Chair’s report

14. Ellen Donovan, Chair of RemCo, spoke to paper HTA 25-25 summarising the RemCo meeting of 5 September.
15. Under the Committee’s decision-making role, and further to the previous RemCo meeting’s decision-making on staff pay, the meeting had agreed pay arrangements for Executive Senior Managerial staff in 2025-26 in line with the pay remit provided by Government. These arrangements had now been implemented.
16. Under the Committee’s advisory role, members had reviewed HR statistics, including headline figures for gender pay distribution, and noted the improving quality of data that it was now sighted on, beyond the headline attrition rate KPIs. The Committee had also been briefed on overall progress against HTA’s People Strategy, a number of initiatives, activities and processes now having commenced. The Committee would continue to advise staff on the prioritisation of the different elements of the plan. RemCo would also continue

to monitor the findings of staff pulse surveys, and actions arising. The Committee had also discussed performance management in more detail. It felt that the proposed upgrade of the IRIS HR system, and development of consistent people and leadership objectives would be a sound basis for building behavioural change and best practice.

17. The Board noted that HTA's staff attrition KPIs remained under target performance but the underlying figures were improving and its overall People risk had remained above tolerance. It was therefore pleased by the continuing oversight of these areas from both RemCo and ARAC.

Item 2.4 – Department of Health and Social Care (DHSC) Sponsor Team report

18. Jacky Cooper reported that:
 - a) The recent Cabinet and ministerial reshuffle had resulted in the appointment of a further DHSC minister, transplant surgeon Dr Zabir Ahmed. His portfolio was being finalised but would include HTA sponsorship and wider human tissue policy areas. The Board noted that Lynne Berry would be seeking an early meeting with the new Minister.
 - b) The cross-government programme board (on which Colin Sullivan sat) advising on the response to Sir Jonathan Michael's Inquiry Phase 2 Report was now established and meeting fortnightly, four meetings having been held. It was considering all recommendations prior to ministers taking a view, with an update to be published in around November. DHSC was grateful for HTA's continuing advice and support. The Board noted the number and complexity of the Inquiry's Recommendations and its potential implications across departmental responsibilities.
 - c) DHSC's restructured senior leadership structure was expected to be in place by late December, as a part of wider departmental transformation. There was likely to be considerable change in staffing and responsibilities at all levels of the department. The Permanent Secretary was keen for sponsor teams to ensure that ALBs remained well-sighted
 - d) The programme of Permanent Secretary meetings with ALB Chair and CEO continued. The next regular Quarterly Accountability Review meeting between senior DHSC officials and HTA staff was scheduled for 2 October.
19. The Board welcomed Jacky Cooper back to her sponsor role after her recent assignment to work on the implications of assisted dying legislation, and noted continuing constructive engagement between HTA and DHSC colleagues.

Item 2.5 - CEO Report

20. Colin Sullivan introduced paper HTA 26-25. He reported that the organisation

continued to perform well against its operational targets, while taking forward additional key activities and remaining responsive to a changing health and life sciences landscape (to be explored further at items 3.1 and 3.2).

21. He noted that supporting HTA staff navigate and align HTA's work within this changing landscape was a priority for the Executive, and underlined the importance of a strong HTA People Strategy. He provided further clarification of the Strategy's MoSCoW rating in the 2025-26 Business Plan. While not a "Must do" compliance requirement, its "Should do" rating indicated that it was a firm and embedded commitment. Training sessions for all staff and line managers on change management were early deliverables. The afternoon briefing session would provide further information to Board members about strategy implementation and impacts.
22. The Board also noted updates on:
 - a) The Q1 Data Collection Exercise.
 - b) CEO's meetings with stakeholders, notably the Health & Social Care Regulators Forum.
 - c) 'Duty to report' cases.
 - d) Board members also noted the recently notified outcome of the LOD approval case that had been referred to the police a few years previously, as referenced in the CEO's report.
 - e) HTA's Annual Report and Accounts which had been laid before Parliament on 17 July.
 - f) HTA's Business Plan 2025/26. Members noted that while this had been formally approved by DHSC, spend controls for ALBs requested by DHSC over the remainder of 2025-26 could necessitate amendments.
 - g) Publication of HTA's Annual Review of 2024/25.
 - h) The Learning Event on 19 September to enable engagement and learning exchanges between the HTA and representatives from each of its regulated sectors. Board members looked forward to the opportunity to participate.
 - i) The pulse survey of staff issued in July. Members noted the encouraging engagement levels and positive responses around line management support, and an ongoing focus on leadership development in response to less favourable returns around decision making and development.

Item 2.4 - HTA Performance Report

23. The Board reviewed paper HTA 27-25 setting out HTA's performance in Q1 of 25/26 against the Business Plan and the objectives and operational delivery targets, along with an indicative report of early performance in Q2.

24. The Board noted RAG performance against HTA's Key Performance indicators. KPI 2 (new licence applications) was rated 'Amber'. The Board noted the demand led nature of the fluctuation in performance here and that the KPI was likely to be met in Q2. KPI 13a and 13b (staff attrition) showed a small improvement but remained rated 'Red'. The Board noted that the rolling annual average calculation for this KPI masked more encouraging performance in recent months. All other KPIs stood at 'Green' or were necessarily nil returns at this point in the year.
25. The Board noted progress reported on 25/26 Projects, and that HTA was on track to deliver all 'Must do' Projects as anticipated.
26. Colin Sullivan highlighted cyber security as a key strategic priority for the HTA to protect sensitive information and maintain public confidence in the Authority. He noted that HTA had worked hard to strengthen its security posture and significant improvements had been achieved, without being complacent about future attacks. He thanked Louise Dineley for the way she had driven this forward with her team.
27. On the Strategic Risk Register, the Board noted that the rating for Risk 3 (Financial) had improved to 'Amber' but remained at 'beyond tolerance'. The rating for Risk 5 (People) had also improved to 'Amber' but remained beyond tolerance. The rating for risk 6 (Security) had improved and now stood at below tolerance. Risk 1 (operational); Risk 2 (Reputational) and Risk 4 (Strategy) all remained at 'at tolerance'.
28. The Board noted the summary Finance report (reported as at 31 July 2025). CS reported that action had been taken in Q1 and Q2 to forestall a projected end year overspend of £300K, which now stood at a more modest £24K. The Board noted the challenges of forecasting spend, including the volatility of staffing costs in a smaller organisation, and that a staffing co-efficient had been built into the forecast, was in place. The Board noted with the improved levels of debt recovery and thanked the Finance team for their efforts here.
29. The Board:
 - a) Welcomed the good progress on IT and cyber security work and the assurances provided.
 - b) Welcomed the effort being put into the People Strategy and the signs of improvement (including good current performance in terms of reduced sickness absences). It noted that staff attrition remained a challenge for the organisation but this was also improving, and felt it important to remain well-sighted on progress here, including via RemCo's advisory role to the executive.

- c) Noted strong social media performance around post mortem issues.
- d) Discussed and were content with progress on the Innovation in Inspection project, including how HTA deal with CAPAs: putting the onus back on establishments.
- e) Discussed and was content with progress on SoHO. While this was on track, the complexity of the issues meant that an 'Amber' rating was justified at this stage. Officers would discuss further with Nicole Lappin and David Lock outside the meeting.

30. The Board thanked the executive for a clear and well-presented report and asked for its feedback to be shared with key staff. **Action: Colin Sullivan**

3. Information Items

3.1 Dignity of the deceased – Making improvements

31. Colin Sullivan and Nicolette Harrison introduced paper HTA 28-35. This provided a summary of the findings from the Phase 2 Report from Sir Jonathan Michael's Independent Inquiry into the issues raised by the Fuller case, and updated the Board on the HTA's work and next steps. Colin Sullivan thanked the many staff from HTA who had supported the work of the Inquiry. He also drew attention to the very positive recognition of the HTA's work highlighted by Sir Jonathan in his Phase 2 report. The Board noted the length and complexity of the Inquiry, with which HTA had been engaged since its outset. It acknowledged the efforts of staff who had worked with DHSC and the Inquiry team to help bring the Inquiry to its conclusion. The Board acknowledged the actions and updates to its wider approach to regulation already undertaken by the HTA (as set out in the paper) to address the additional risks highlighted by Fuller's offending.

32. The Board noted that there were 75 recommendations flowing from the Report to be considered. Most were sectoral or directed at specific types of organisation. A relatively small number of higher-level recommendations were addressed to 'Government'. While just one Recommendation was directed to the HTA (Recommendation 26: that the HTA should amend its guidance concerning the reporting of incidents in the Anatomy sector), the HTA was also mentioned in association with the more general recommendations concerning proposals for regulation of those involved in managing the deceased. Notably, Recommendation 73 proposed that Government should change the Human Tissue Act (2004) to provide for specific and primary legal responsibilities to be applied to the organisation holding a HTA licence.

33. The Board noted:

- a) The very positive assessment, contained within the Inquiry's Final Report, of the HTA's work towards the care of the deceased.
- b) That HTA was able to engage with stakeholders about the enquiry but could not pre-empt Ministerial decisions about the Government's response to recommendations.
- c) In respect of Recommendation 26, that HTA was empowered under the Human Tissue Act 2004 to set further conditions to licences in addition to those set out in the Act. It had made good progress in developing the HTA Reportable Incidents (HTARI) process for the Anatomy sector.
- d) That the HTA was preparing further guidance for those within its regulatory remit on its approach to managing activities to protect the security and dignity of deceased. This was also likely to be of relevance to other organisations involved in managing and caring for deceased people.
- e) That HTA had committed to determine in 25/26 how to review, and if necessary, revise, its current statutory Codes of Practice, that are required to provide practice advice to practitioners and incorporate the mandatory licensing Standards, where relevant. The HTA was also mapping the Inquiry's findings and recommendations against HTA's Codes of Practice, Standards, and Guidance to inform this process.
- f) That HTA continued to provide support where relevant to DHSC and other officials who were advising Ministers on the Government's response.

34. The Board felt that at this stage it was not possible to determine how HTA and its work would be directly or indirectly affected. It felt it important that Government considered in the round the funding implications of any increase in regulatory scope (particularly in respect of the Funeral sector) by HTA or other new or existing entities. In the meantime, the Board noted and was content with ongoing work by the HTA to further improve how establishments within its remit protected the security and dignity of the deceased in their care, and it was keen that these efforts were maintained. It asked for its comments to be noted by the executive. **Action: Nicolette Harrison**

3.2 Strategic Change

35. Louise Dineley spoke to paper HTA 29-35 which set out various reforms and initiatives in the health sector and more widely across government, aiming to drive growth, promote innovation, increase responsiveness, and reduce costs as set out in the paper. The paper also set out the five interconnected themes that the executive had identified as shaping the HTA's strategic response (Reform and Modernisation of Regulation; Digital-First Regulation; Proportionate and Risk-Based Regulation; System Integration; and Organisational Change).

36. The Board felt that the priorities set out in the HTA's 2024-27 Strategy aligned well with much of this emerging reform agenda. It noted that work

responding to these strategic changes was proceeding in parallel with the established planning process to develop HTA's 26/27 Business Plan. The Board noted that while it was not yet feasible to prioritise these areas of focus against each other, proposals directly impacting the HTA would be considered by the executive and presented to Board for consideration, using the business planning cycle as the vehicle for implementation.

37. The Board also discussed:

- a) HTA's positive progress, relative to peer regulators, in developing more digital processes and automating HTA and establishment practices. Nonetheless, there remained significant resource and cultural challenges for HTA and its sectors to overcome.
- b) The extent to which Government's approach to exploring learning from regulatory sandboxes for emerging technologies was applicable to the HTA's regulatory role. The Board noted that although the HTA's legislative framework had not been tested in this respect, the current review of the legislative log was considering previous interpretations of the legislation in the light of changes to HTA's activities and emerging technologies.
- c) Whether specific feedback from the sector, particularly life sciences, indicated that HTA's regulatory model was inhibiting business development and innovations. It noted the importance of good quality insight, and data sharing. HTA's learning exchange event of 19 September with stakeholders was important in this regard.
- d) The specific identification of "Failure to keep pace with innovation, growth and reform" as a Strategic Risk. The Board also welcomed HTA's work on horizon scanning, stakeholder surveys, and scenario planning exercises to test its responsiveness to different change trajectories. It noted the importance of continuous dialogues with government and was pleased at the good working relationship with the sponsor departments.

38. Overall, the Board was content with the work being undertaken to respond and adapt to the various changes. It asked for its comments to be taken into account by the executive and to be kept aware of developments through regular reporting. **Action: Louise Dineley**

4. Closing Administration

Item 4.1 - Forward plan

39. The Board noted the Forward Plan of corporate meetings and related activity (HTA 30-25). Private Office were seeking to convene a November informal meeting.

Item 4.2 - Any Other Business

40. Lynne Berry outlined the informal development and briefing sessions that were scheduled for the afternoon and welcomed, as usual, further feedback on meeting content and handling over the lunchbreak. With a full Board now in place, she asked for additional time to be set aside before and after meetings for more structured member-only discussion and feedback. **Action: Private Office**
41. Board members thanked all staff who had contributed directly and indirectly to the meeting. With no further items raised, the meeting closed. The next formal meeting of the HTA Board was scheduled for 4 December 2025.

Minutes agreed by the HTA Board at its meeting of 4 December 2025