

Draft Minutes of the Human Tissue Authority Board

Date: 27 June 2024

Time: 10.00 – 12.00

Venue: Wandle 40/41, 2 Redman Place

Meeting Number: 108

Attendees:

Board Members

Lynne Berry, HTA Chair

Mhairi Anderson

Tom Chakraborti

Gary Crowe

Helen Dodds

Ellen Donovan

*Andy Greenfield

Dave Lewis

David Lock

Jessica Watts

HTA Executive

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

Tom Skrinar, Director of Finance and Resources

HTA Supporting officers

*Morounke Akingbola, Head of Finance

*Mathew Atkinson, Head of IT (item 4.2)

Richard Mabbitt, Private Office Lead

Debra Morgan, Executive Assistant

Department of Health and Social Care

Amanda Davies, Deputy Director

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

HTA Observers

Victoria Askew, Policy Officer,

*Sam Mortimer, Project Manager ,

*Attending remotely

1. Opening administration

Item 1.1 – Welcome and apologies

1. The Chair welcomed all to the 108th HTA Board meeting. All Board Members and members of HTA's Senior management team were present. Ria Mukherji and Amanda Davies were attending on behalf of DHSC.
2. The Chair welcomed Debra Morgan and Richard Mabbitt (who had recently

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joined HTA to strengthen the organisation's Private Office function) and HTA staff observers Victoria Askew and Sam Mortimer.

Item 1.2 – Declarations of interest

3. The Chair reported that the HTA's register of members interest had now been published on the HTA website. Members were reminded to declare any new interests as they became apparent.
4. No new declarations were made by members additional to those already registered. No conflicts were identified in respect of matters to be discussed.

Item 1.3 – Minutes of 7 March 2024 (Paper HTA07/24)

5. Minutes of the meeting of 7 March 2023 were AGREED by the Board as an accurate record of the meeting. Due to the pre-election period of sensitivity, the minutes would not be published on the HTA website until after the General Election on 4 July 2024.

Item 1.4 – Matters Arising (Paper HTA 08/24)

6. Tom Skrinar provided an update on discussions with the Devolved Administrations on Fees Review (Item 7 from the Board meeting of 7 December 2023 refers). He reported that a request for payment at a level rolled over from the previous year had been issued to the Devolved Administrations. Board noted that further discussion was needed to clarify the nature of the ongoing service supported by the fee payments, especially in respect of Wales and Northern Ireland, in parallel to a light touch review for 2024/25 in England and Wales.
7. The Board was content that other actions had been completed satisfactorily and could be removed from the log.
8. Colin Sullivan reported that a role specification for the vacant Northern Ireland Board representative post had been drafted and agreed some time ago, but that an appointment process was not yet underway. Board noted that HTA would continue to monitor and chase progress from the Department of Health in Northern Ireland, but a new appointee was unlikely to be in place for a matter of months.

2. Assurance and reporting

Item 2.1 - Chair's Report

9. The Chair reported that she had now approved the final Board Effectiveness Review outputs and the proposed action plan from consultants RSM. She had

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set in place arrangements for monthly updates on progress via Private Office and would relay progress to the Board as required. She further reported that she had seen and was supportive of the finalised training plan for 2024/25, and Board members would benefit from the first instalment of training immediately after the meeting.

10. The Chair reported that with the CEO and Committee chairs, she had completed the process for assigning new and established members to Committees, and other roles for 2024/25. Jessica Watts had now joined Dave Lewis and Helen Dodds as members of the Audit Risk and Assurance Committee, Chaired by Gary Crowe. Tom Chakraborti and Mhairi Anderson joined herself and David Lewis as members of the Remuneration Committee, chaired by Ellen Donovan. She would look to David Lock, and Andy Greenfield (who were not assigned to Committees) for specialist Board-level advice on the Fuller Inquiry and on Life Sciences regulation, respectively. She had also taken advice from DHSC about options for identifying in advance of need a named member to deputise for her and would discuss this further with members in the private session after the meeting.
11. The Chair reported that DHSC had agreed her own work objectives, bar those relating specifically to the delivery of the Business Plan.
12. **Action: Chair** to cascade her objectives to members and CEO when finalised.

Item 2.2 – Update from DHSC Sponsor Team

13. Amanda Davies provided an oral report on:
 - a) General election-related issues. She thanked HTA for deferring published material and the Board's stakeholder due to the pre-election period of sensitivity. Departmental preparations for the incoming government were in hand, but no immediate additional briefings on HTA related activities were anticipated at this stage. DHSC was grateful for HTA's continued constructive engagement on spending review preparations. The Public Bodies Review of the HTA, currently deferred to 2025-26, was unlikely to be brought forward. DHSC hoped to re-establish a regular schedule of Ministerial meetings with ALB Chairs and CEOs Minister/Chairs.
 - b) The current position of the Fuller review, where HTA's contribution had been valuable. Responses to the phase one report and published updates on phase two had been delayed until the Autumn due to the election and potential change of government by election.
 - c) Other key policy priorities for the DHSC Sponsor team. These included the new Duty to Report on organ transplantation, introduction of new EU Substances of Human Origin regulations; work (led by the Ministry of

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Justice), on the regulation of the funeral director sector (prompted by serious concerns relating to practices at Legacy Independent Funeral Directors); and infected blood, where policy leadership had reverted to the team following the final report of the Infected Blood Inquiry.

14. Board members noted the report and welcomed the continuing constructive and open relationship with DHSC as HTA's sponsor department and the anticipated continuity in the sponsor team itself.

Item 2.3 – Chief Executive's Report (Paper HTA 09/24)

15. Colin Sullivan (CS) introduced the Chief Executive's Report which provided updates on regulatory and related activities and contextual updates on a range of current issues including:
 - a) HTA's engagement on the Fuller Independent Inquiry and in response to its wider impact on the sector;
 - b) HTA's Data and Security Protection Toolkit assessment achieving the intended 'Moderate' assurance rating;
 - c) HTA's deferral and scaling back of external communications activity due to the pre-election sensitivity period;
 - d) the coming into effect in April 2024 of the Human Tissue Act 2004 (Supply of Information about Transplants Duty to Report) Regulations 2024 and a consequent increase in reports for consideration by the HTA;
 - e) Provision of technical advice and guidance in support of development of the Substances of Human Origin regulations.
16. Board received further clarification from SMT on the following:
 - a) Staffing levels, where the current attrition rate of 30% was targeted to reduce to 20%. In support of this target there had been an all-staff survey distributed which had received an 85% response rate, the data from which was currently being collated and would form part of the ongoing strategy for staff recruitment and retention to reduce associated risks for resourcing. DHSC were also seeking to arrange a secondment to HTA. Board members were pleased at the direction of travel but felt that staffing levels and retention remained a risk to the organisation. These matters would be considered further by Remuneration Committee at its September meeting.
 - b) Cyber security, in the light of clinical impacts of the ransomware cyber-attack perpetrated against Synnovis earlier in June. SMT briefed further on HTA's proactive monitoring and remedial activities in place to mitigate cyber risks, alongside the work under way with HTA third party suppliers and DHSC.
 - c) HTA's Proactive engagement with the Fuller Inquiry, preparation for likely contributions to phase 2 and other relevant engagement relating to a

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potential general duty of respect.

- d) HTA's work to assure quality given the increased number and sophistication of regulatory assessments.

Item 2.4 – HTA Performance Report (Paper HTA 10/24)

17. Colin Sullivan spoke to this report which set out HTA's performance against objectives and operational delivery targets in Quarter 4 of 2023/24, and an early indication of initial performance in Quarter 1 of 2024/25. He spoke to the outturn position for the Business Plan, noting the KPI RAG position at year end (8 Green, 1 Amber and 2 Red) and the number of successfully delivered projects 7 of the cohort of 10, with the 3 always intended to run into the following year's plan. He referenced the 222 assessments stretch target and the new risk-based approach to this area of work. He also drew members' attention to the successful testing of HTA's CIRP / BCP arrangements in April. He referenced recently completed audits in which Reportable Incidents received substantial assurance, Portfolio Management received moderate assurance and Health & Safety received limited assurance.
18. Board members reviewed the report and discussed the following:
 - a) The table of Debtors at 31 March 2024, and proportionality thresholds for debt recovery from other public sector bodies. Board members noted that officers tracked debt on a rolling basis and were content that HTA's approach here be guided by government policy on debt recovery from public sector bodies.
 - b) Concern around the reported training underspend. Board members were pleased that this was now priority focus for SMT, with training needs analysis having been undertaken for the new year.
 - c) Concern related to the 'Limited' assurance rating for Health and Safety within the organisation. They welcomed that work was under way to remedy the areas baselined as not in compliance with H&S regulations, with priority on reinvigorating a staff forum; embedding management reporting of issues; and registering Health and Safety concerns as a strategic risk.
 - d) Initiatives to support the better interrogation of Resources management information and the recruitment of a new Business Manager within the Resources Directorate.
19. The Board was otherwise content with overall progress as reported, and thanked officers for their efforts.

3. Items for decision

[no items specifically for decision were brought to the Board at this meeting]

4. Items for discussion

Item 4.1 – HTA Strategic Risk Register (Paper HTA 11/24 and HTA 11a/24)

20. Tom Skrinar spoke to the Strategic Risk Register (SRR) and covering paper. The SRR format and content had been updated to reflect steerage from the ARAC meeting of 12 June and was now presented to Board for information and review. The SRR would continue to be presented to the Board at each meeting as an annex to the Performance Report. Once a year it would be presented as a dedicated item for discussion.
21. Gary Crowe, as ARAC Chair, confirmed ARAC's endorsement of the new approach and format as providing consistency of presentation and a good platform for engagement with ARAC on 2024/25 strategic risks. It was noted that the number of risks had been narrowed with clearer setting-out of the appetite for each item and mitigating actions and trajectories.
22. The Board reviewed the report and SRR and:
 - a) Was supportive of the overall clarity and consistency of the SRR and felt that risks and mitigations had been captured appropriately.
 - b) Suggested that, at Risk 1, compromise of patient safety needed elevation.
 - c) Reflected on the importance of baselining and validating risk scores, with smartness about when mitigations would take effect. The degree to which HR-risk related mitigations were embedded was cited. Board members noted that the SRR was discussed at PSMT monthly meetings where risks were collectively reviewed and calibrated to prepare responses to organisational risks.
 - d) Discussed cyber security risks. Given ARAC discussion of cyber risk and the feedback loops to Board through ARAC minutes and chairs reports the Board felt that identifying cyber security as a standalone risk was not necessary but asked officers to keep this under review in maintaining the SRR.
23. **Action: Tom Skrinar** to take into account Board feedback on the presented SRR, including amending Risk 1 effects column in line with Board suggestion patient safety; and working with all risk owners to make all of the mitigations more SMART.

Item 4.2 – HTA Digital Strategy Update (Paper HTA 12/24)

24. Louise Dineley introduced this paper which summarised HTA's Digital Strategy. It set out the four strategic priorities and themes (1: "Protection through

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Prevention”; 2 “Availability through Reliability”; 3: “Transformation through Automation”; 4: “Innovation through Collaboration”) supported by a delivery roadmap. The full strategy would be circulated to members after the meeting. Louise spoke to the changing technological landscape, explaining that this was a forward-looking document and approach designed to respond to that. Louise referenced agreeing the Strategy and a detailed Implementation Plan with SMT during the last month, with items to be factored into our formal Business Plans, accordingly over coming years.

25. Gary Crowe spoke to ARAC endorsement of the Strategy and approach more widely, noting the resource challenges that will impact on the practicalities of delivering some of the ambitions set out .The Board noted ARAC’s scrutiny and of and support for the strategy. ARAC had also highlighted the importance of capacity and resourcing to ensure the strategy was taken forward effectively. The Appointment of a permanent Head of ICT was an important milestone here. The Board also noted the value of training such that the strategy was understood, bought-into, and reinforced to ensure that protocols were followed, and the importance of timely auditing of usage and user permissions.
26. The Board reflected on the behavioural elements to cyber security, both as risks and mitigations. It felt that the approach of both mandatory training modules, and informal reminders and reinforcement through team and all-staff meetings was sound. Board members’ own behaviours here were important, and their attention was drawn to advice circulated before the meeting on handling suspicious email correspondence.
27. Board members flagged the risks around third-party suppliers and were satisfied that the strategy recognised this and that control arrangements within the supply chain were in place.
28. Board members noted that while a case would be made for additional funding to implement the strategy through any upcoming spending review HTA was likely to need to use funds from existing budgets. Potentially, working in collaboration with CQC or in a blended-delivery model (work in-house, with partnering where specialist skillsets were required) could provide some mitigation.
29. The Board noted the risks and opportunities around AI around and flagged the issue as a topic for which further strategic discussion would be welcomed.
30. The Chair thanked discussants and asked officers to circulate the Strategy to interested Board members: **Action: Louise Dineley.**

Item 4.3 – Living our organisational values: Reflections on recent reports into managing the personal impact of regulatory decisions and actions (Paper HTA 13/24)

31. Nicolette Harrison introduced this paper which set out context and assurance to Board that the Executive had considered the lessons learned from the Inquiry into the Ofsted inspection which led to the tragic Ruth Perry case. HTA Officers had developed a prioritised list of actions to take forward through business-as-usual processes over the remainder of the year.
32. She reported that after careful consideration, officers had concluded that the risk that our inspection and regulatory processes could trigger an issue of this nature was very low. Nonetheless the report highlighted the need to avoid any complacency and improve where we can, guided by our values, to reduce and mitigate the likelihood of unnecessary adverse personal impacts. Next steps had been identified as (1) Staff training and awareness; (2) Internal guidance; external guidance and (3) improvements to the inspection feedback process.
33. Board members:
 - a) Welcomed the values-based thinking demonstrated in the report and its emphasis on how HTA regulated as well as what it did.
 - b) Reflected on reporting by exception, and how to capture excellent practice. Board noted that, based partly on stakeholder feedback, current reporting formats had been streamlined to make the reports a clearer and more straightforward assessment of compliance. However, while the narrative section of reports was less substantial, good practice was now collected in the round and shared collectively with stakeholders.
 - c) Noted HTA's engagement with other regulators to cross-check good practice and the importance of ongoing feedback from stakeholders across the piece.
 - d) Noted the importance of training to recognise any likelihood of people involved in assessments disproportionately responding to criticism in a personal way. Board members agreed that while assessment findings needed to be delivered with empathy and proportionately, clarity in terms of how compliance, and in how HTA was discharging its statutory duties had to be maintained.
 - e) Felt that risks relating to regulatory capture were minimal at this stage, noting that there was no intention for the HTA to ever move to single word assessments.
34. The Board welcomed and supported the findings of the report.

5. Governance items

Item 5.1– Committee updates

35. Gary Crowe gave an oral update on the ARAC meeting of 12 June 2004, which the Chair had observed. Minutes would be circulated to members shortly.
36. Board members noted recent internal audit reports completed, the external audit process and approval of the Annual Report and Accounts, the quarterly update on the Cyber Security updates, the annual DSPT exercise, the Strategic Risk Register, and reporting on past internal audit recommendations. Board members noted the GIAA annual rating of 'moderate' and agreed that in effect, this represented a positive rating for the year. The Board felt that this reflected well on the executive.
37. The Chair thanked Gary Crowe and ARAC members for their engagement and support.
38. The Board noted that Remuneration Committee had not met since the previous Board meeting. The next Committee meeting would take place on 6 September 2004.
39. Board members reflected on the roles of non-executives in terms of seeking information and assurance, and raising with officers matters of strategic concern, and the risk of blurring of executive and non-executive functions. The Chair would discuss this further with members in the private session after the meeting.

6. Closing administration

Item 6.1 - Forward plan (HTA14-24)

40. The Board noted the current forward plan and looked forward to its amplification as the year progressed and the new Private Office staff redeveloped their outputs.

Item 6.2 - Any other business

41. With no further formal items of business having been raised, the Chair thanked all participants and HTA staff who had been involved in writing papers and otherwise supporting SMT and closed the meeting. The next Board meeting was scheduled for 20 September and would be held in public.

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42. The meeting would be followed by a closed session for Board members and the CEO only, and then Board member training sessions led by staff (Post Mortem sector update, and Living Organ Donation training).