

HTA Board meeting, 26 June 2025

Agenda item	2.5 - Chief Executive's Report
For information or decision?	Information
Decision making to date?	N/A
Recommendation	The HTA Board is asked to note and comment by exception on the issues raised
Which strategic risks are relevant?	Risk 1: Operational Risk 2: Reputational Risk 3: Financial Risk 4: Strategy Risk 5: People Risk 6: Security
Strategic objective	Efficient and Effective
Core operations / Change activity	Core operations
Business Plan item	Senior Management Team – strategic direction and leadership of operational delivery across the organisation (including risk management and seeking opportunities for ALB collaboration)
Committee oversight?	Board only
Finance and resource implications	Various due to the range of items covered
Timescales	Various due to the range of items covered
Communication(s) (internal/external stakeholders)	N/A
Identified legislative implications	N/A

Chief Executive's Report

Purpose of paper

1. To inform the HTA Board of key or current issues from the CEO's perspective.

Action required

2. The HTA Board is asked to **note** and comment on the issues raised.

Update on Quarter 4 of 2024-25

3. The final quarter of a financial year is often a busy period for a public body and that has been true for the HTA this year, but I feel we have achieved the key activities we sought to progress whilst responding effectively to matters arising.
4. Details are provided later in the agenda at the HTA Performance Report, but to summarise, I am pleased to report we have managed to deliver on the bulk of our business plan activities and operational targets for 24/25, whilst also progressing the main activities from the first year of our new three-year HTA Strategy (2024-2027) which was published in August 2024. That work has included:
 - Continuing to reform how we conduct regulatory activity by being more risk-based and proportionate, with a wider range data collection activity and inspection tools, for example, the use of Evidential Compliance Assessments (ECAs) as highlighted later in this meeting.
 - Launching our People Strategy - following presentation of the strategy at the March meeting of the Board, concerted implementation has commenced with a notable number of activities in train, as set out in the Implementation Plan, which was discussed by RemCo in early June.
 - Progressed our programme for IT and digital development, which has included upgrading our CRM system and completion of a project to enable much better use of the data we hold (RIMI - Regulatory Insight Model and Index). This is a significant step forward and we will add further datasets and information sources as we develop the tool.
5. More details of our progress with the HTA 3-year strategy will be provided later in the meeting.
6. In relation to Living Organ Donation (LOD) activity, the overall figures for 2024/25 show that the HTA approved 1115 cases during the year which

compares with a figure of 1119 in 2023/24. Of the 1115 cases approved last year, 26% were approved by the Board, whilst the remaining 74% were assessed and approved by the HTA's Living Donation Assessment team.

7. The HTA has continued to receive a regular flow of cases under The Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024, which require relevant clinicians to report all organ transplants that take place outside the UK, or if they have a reasonable suspicion that an organ donation and transplantation-related offence may have been committed. A total of 39 cases were received in the first year of implementation. We are now able to bring to the Board for discussion our 12-month evaluation of implementation.
8. We continue to support the Inquiry by Sir Jonathan Michael into the issues raised by the David Fuller case. The final report (Phase 2) of the Inquiry, which is considering the system wide approach, is expected to be published soon, and the HTA will work to assist with implementation of those recommendations that are supported by Ministers.
9. In parallel, during Q4 we have continued to roll out, across several work-packages, our programme to improve the dignity of the deceased. I note that the number of shortfalls in the PM sector has increased in 2024/25. We believe this is because we are better at identifying compliance weaknesses and driving consistency through the use of unannounced inspections (UAls). We completed 24 of these in the PM sector during 2024/25 and a review of the shortfalls identified is being completed to determine any common features and trends. As we look to assess how best to review and update our Codes of Practice, the level and types of shortfalls in the PM and other sectors will be have a bearing on any changes proposed.

Current Issues

10. In early April, I accompanied the Chair to meet the NI Minister for Health (Mike Nesbitt, MLA) in Belfast. The discussion included how we can assist his Department to meet its organisational goals, our work to assist the proportionately higher numbers of living organ donations in NI, and the recruitment of a new Board Member for Northern Ireland. Minister Nesbitt thanked us for the work the HTA is progressing to ensure the dignified and safe use of human tissue. Also during April, the Chair had a similar virtual conversation with officials from the Welsh Government. Ellen Donovan, the Board member selected by the Welsh Government, and I accompanied the Chair to this meeting. Going forward, both NI and Wales have agreed to routinely send observers to HTA Board meetings.

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11. We launched a data collection exercise during April to improve and update the data we hold for establishments. We asked establishments in the Anatomy, Post Mortem, Research, Public Display and Organ Donation & Transplantation sectors to complete a short questionnaire with simplified answer options. We also asked for responses in the Human Application (HA) sector. The responses received help inform our understanding of risks and activities within establishments and sectors, and hence our subsequent prioritisation and allocation of assessments. We have already had a very high response rate (over 96% with the deadline for returns in the HA sector not until 30 June). In some sectors, such as PM, the response has been nearly 100% which is testament to the very good engagement we have developed with that sector. Team members have started to analyse the data and information provided.
12. In December 2024, the HTA submitted its baseline assessment against the NHS Cyber Assessment Framework (CAF). The framework replaces the previous Data Security & Protection Toolkit (DSPT) for Arm's Length Bodies. The CAF is made up of 46 standards across five objectives that seek to set and promote expected levels of performance against :
 - Managing Risk:
 - Protecting against cyber-attacks and data breaches;
 - Detecting cyber security events;
 - Minimising the impact of incidents, and
 - Using and sharing information appropriately.
13. A full assessment against the standards is due to be submitted by 30 June. The HTA has been undergoing an internal audit against 12 standards to validate the assessed position and to provide confidence in our assessment and the supporting evidence. We have undertaken extensive work in this space and I am optimistic that the independent assessment will recognise the HTA's overall practices meet the expected levels of performance for 2024/25 and where improvements are needed there are plans in place.
14. During June, work has continued to finalise the draft Annual Report and Accounts (ARA) before they are submitted to the Comptroller and Auditor General (C&AG) at the National Audit Office (NAO) and it is hoped they can be laid before Parliament before recess. This is a significant piece of work and I am very grateful to the Director of Finance & Resources and the Head of Finance & Governance, who have provided great support to me as Accounting Officer. The draft ARA were discussed by the Audit, Risk and Assurance Committee (ARAC) at the 10 June meeting. The Head of Finance & Governance (Morounke Akingbola) will leave the HTA at the end of June for

a new challenge. She is our longest serving member of staff and I am very grateful to her for 18 years of hard work and commitment to the HTA. We wish her every success in her new role.

15. Separate from the ARA, we have been working on an annual review which considers progress in the areas we regulate and provides commentary and analysis of our work over the last year, 2024-25. We anticipate this document will be completed soon and ready for publication during the summer. Quarter 1 of 2025/26 would normally be a time for completing the publication of the 2024/25 data sets but these will now be published in Q2 following the completion and publication of the Annual Review.
16. I continue to attend the National CEOs meeting for Health ALBs and the DHSC-led ALB Senior Leaders Meeting (for Chief Executives and Chairs). In as much as we are aware, we have kept staff briefed on the ongoing changes across the health sector landscape, seeing this as an essential part of good staff engagement, either through the short weekly exchange call led by myself as the CEO or when convening in-person all staff meetings. As an organisation which is committed to learning and improving and is currently implementing ongoing strategic change, we are alive to continuous improvement and responding to further changes as the government's agenda unfolds.
17. In June, the Head of Regulation for the Organ Donation and Transplantation sector was invited to present at the Council of Europe Network of National Focal Points on Travel for Transplantation meeting in Strasbourg. This was to update colleagues on the requirements and implementation of The Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024.
18. The Director of Regulation and Head of Regulation for the Organ Donation and Transplantation sector have also attended meetings held by NHSBT looking at the deceased organ donation process, following implementation of deemed consent legislation across the UK.
19. The Executive welcomes our four new Board Members for England (Helen Froud, Steve Stanbury, Reverend Prebendary Professor Gina Radford and Canon David Stanton) who were announced as new Board Members on 22 May 2025. Activities to support their induction have been ongoing over the last few weeks, prior to their first Board meeting today.
20. In addition, Board Members will wish to note that the competition to recruit a Member selected by the NI Department of Health is ongoing. Applications closed on 9 June. Dr Andy Greenfeld and Dave Lewis have been extended for a three-year period until 1 April 2028. We are grateful to Tom Chakraborti and

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Helen Dodds, who stood down at the end of March and also to Prof Gary Crowe, Chair of ARAC, who will leave at the end of August before our next Board meeting. Our thanks to all for their dedicated service and support to the executive whilst providing the necessary challenge to ensure high calibre governance of public resources and to improve outcomes for the public.

21. The next meeting of the Board is set for 18 September 2025 in Redman Place.