

HTA Board meeting, 5 December 2024

Agenda item	2.3 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: Regulation Risk 2: Sector Risk 3: Staff Risk 4: Financial Risk 5: Digital
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

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 2

3. During Quarter 2, we have continued to progress our regulatory and related activities, sought to progress the 24/25 business plan, and responded to matters arising.
4. Over the summer, the HTA alerted all PM establishments that we would be embarking upon a number of unannounced inspections as part of our core inspection programme. This is part of our evolving approach to regulation as described to the Board at the September meeting. We completed eight unannounced inspections in September, another four in October and two more in November during the first stage of the initiative. This approach will run for the remainder of the business year, alongside a limited number of announced inspections. We had targeted these inspections based on the outcome of the Evidential Compliance Assessment (ECA) programme undertaken in Quarters 1 and 2.
5. The HTA continues to participate at a senior level in cross-Arm's Length Body work. This includes contributing to development of a report published by HSSIB (Health Services Safety Investigations Body) in September entitled '*Recommendations but no action: improving the effectiveness of quality and safety recommendations in healthcare*'¹, covering how to improve the landscape of patient safety recommendations. The HTA is continuing to participate at a senior level in follow-up workstreams, so far covering the proposal to develop a 'Recommendations Repository'. Since the September Board meeting, members of SMT and their teams have also engaged with HSSIB on a range of subjects and shared experiences including IT, the Cyber Assessment Framework, issues of information security and EDI. In September, I also attended the most recent meeting of the Small ALBs Group, for DHSC organisations.

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HTA 27-24

6. On the Living Organ Donation front, the HTA has continued to receive a steady stream of referrals under the new regulations requiring certain clinicians to report all organ transplants that take place outside the UK and any reasonable suspicions of transplant-related offences. The current flow of these cases is at a rate of approximately 3-4 per month.²
7. The Stakeholder Engagement event on 20 September 2024 was well attended and I am grateful for the very positive comments from Board members. We have also received positive feedback from those Designated Individuals (DIs) present and establishments which were represented. The event was an opportunity to launch our Annual Review for 23/24 and to answer questions on that and more generally from the diverse audience. We are now considering our stakeholder engagement activity going forward, as part of the development of our business plan for 25/26.

Current Issues

8. We continue to fully support the work of the Fuller Independent Inquiry. I attended a Phase 2 evidence session in October, following which, at the Inquiry's request, I submitted a detailed paper providing an update on current arrangements for regulation and oversight, including the legislative basis and the HTA's role in assuring security measures. The paper also outlined areas for the Inquiry to consider in respect of future ideas for improvements to support safeguarding, supplemented with extensive annexes on licensing arrangements, the role and function of the Designated Individual (DI) and the enhanced assurance activities we have progressed recently in the Post Mortem sector. I also attended a seminar in November on similar themes, which was recorded and is expected to be made available on the Inquiry's website in due course.
9. As an action from the 2023/24 Board Effectiveness Review, members met informally on 4 November 2024 to consider the findings. The Board had a discussion reflecting on relationships and corporate effectiveness and how it might focus its activity to add most value to the organisation, given the emerging priorities of the new Government in respect of health and regulation. A note of the meeting has been shared.
10. The HTA contributed to Lord Darzi's recent Review of the NHS in England which reported in September. The HTA highlighted the impact of previous underinvestment in mortuary facilities as identified through shortfalls against

² The Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024 <https://www.legislation.gov.uk/ukxi/2024/262/made>

the HTA's standards and wider regulatory activity. Looking forward, we are keen to offer the HTA's support to continuing to ensure the core principles of dignity and consent remain at the forefront of the use of human tissues and cells. In that regard, we have been preparing a response, as an Arm's Length Body (ALB) of DHSC, to the NHS 10-year plan currently in development.

11. In addition, Phase 1 of the Dash Review, which looked at the operational effectiveness of another ALB, namely the Care Quality Commission (CQC), was published in October.³ As discussed with the Board previously, there is merit in us looking at the parameters against which another health regulator has been assessed and seeing how we measure up against those yardsticks which are relevant to us. **Annex 1** provides a brief overview of the HTA's high level self-assessment against the issues identified in Phase 1 of the Dash review.
12. Throughout the year, we have continued to progress the Digital & IT Strategy. In Q3 we have been finalising the development of our Regulatory Insight Model and Index (RIMI) for user acceptance testing in Q4. The availability of RIMI as a minimum viable product is a key foundation in the development and automation of data processes, which are helping with our decision-making. The early version of this helpful tool, which will continue to evolve, provides visualisation of risk indicators and allows users to interrogate themes and trends over time, by sector or at an establishment level. We are working towards go-live of the RIMI model from 2025/26, subject to successful user testing.
13. In October, I attended the Health & Social Care Regulators Forum and the most recent DHSC Senior Leaders meeting for ALB Chairs and CEOs. In November, I accompanied the Chair to meet Baroness Merron, the HTA's new Minister. The discussion included how we can assist the Department with the new 10-year NHS plan and the Health Mission; where the HTA can help to promote growth and innovation, not least, in Human Application and life sciences; and our efforts to be more proportionate and risk-based, whilst demonstrating efficiency and effectiveness. The Minister asked me to pass on her thanks to all our staff (which I have relayed) for their dedication and hard work. The Minister also emphasised the vital role played by the HTA in maintaining public confidence in the safe and consented handling, use and storage of human tissue.
14. Katrina Leighton-Hearn is joining the HTA in December as our new Director of

³ Independent Review into the operational effectiveness of the Care Quality Commission: Available at: <https://www.gov.uk/government/publications/review-into-the-operational-effectiveness-of-the-care-quality-commission-full-report> [Link accessed 20 November 2024.]

HTA 27-24

Finance & Resources (DoFR). She has over 30 years of finance experience in the NHS, local government and the third sector. Katrina will have a handover with our current DoFR, Tom Skrinar, in December as he moves to work full-time for our colleagues in the Human Fertilisation & Embryology Authority (HFEA). In welcoming Katrina to the HTA, I express my thanks to Tom for his hard work and wish him well for the future.

Recommendation

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

Annex 1 - Chief Executive's Report: HTA high-level self-assessment against 2024 Dash Report

High-level self-assessment by the HTA against the 10 topics under which the Dash Report's conclusions are summarised.¹

Dash Report topic	HTA self-assessment
1. Poor operational performance	<ul style="list-style-type: none"> • Fully recovered operationally post-Covid and doing more regulatory assessments than before the pandemic - up by 50% on previous targets • Introduced a wider range of regulatory assessments, including a universal Data Collection Exercise (2023/24), Evaluated Self-Assessments (Research) and Evidential Compliance Assessments (Post Mortem) to better understand and address risks across different sectors
2. Significant challenges with the external provider portal and regulatory platform	<ul style="list-style-type: none"> • IT Strategy actively improving the HTA's IT systems over the next 3 years to 2026/27 • Currently moving our core case management system to a more modern and secure platform
3. Delays in producing reports and poor-quality of reports	<ul style="list-style-type: none"> • Not an issue - long-standing practice of providing draft reports to establishments within 4 weeks of an inspection and establishments then have 2 weeks for factual accuracy checking • Inspection reports published promptly once completion of that process • All establishment staff involved in an inspection are invited to complete a feedback questionnaire • Feedback is mostly positive and is always treated as constructive
4. Loss of credibility within the health and care sectors due to the loss of sector expertise and wider restructuring	<ul style="list-style-type: none"> • Expertise is a core value of HTA with sector expertise embedded throughout regulatory functions • Many HTA frontline Regulation Managers (RMs) are drawn from sectors in which they have worked • All RMs undergo notable sector specific induction training and undergo formal assessment by the relevant Head of Regulation of their capability to lead inspections in a sector

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HTA 27-24 ANNEX 1

<p>5. The Single Assessment Framework (SAF) and its application</p>	<ul style="list-style-type: none"> • HTA’s assessment approach is derived from statutory Codes of Practice and Standards (the Assessment Framework for Organ Donation and Transplantation) • The standards used to assess establishments are sector-specific • Our approach has evolved over the lifetime of the HTA • The current Codes were developed through extensive consultation. Similarly, updates to the related guidance to the Codes have been made following consultation • The Codes and Standards, and our exception-based methods of reporting our assessments against these standards, are widely accepted and understood across our sectors
<p>6. Lack of clarity regarding how ratings are calculated and concerning use of the outcome of previous inspections (often several years ago) to calculate a current rating</p>	<ul style="list-style-type: none"> • Little relevant comparison to the HTA’s exception-based reporting, which records (and classifies by criticality) any shortfalls found against licensing Standards. • HTA Standards are publicly available in statutory Codes of Practice and supported with guidance to assist establishments understand the practical application of the Codes Regulatory assessments based on assessment at point in time, however, an establishment’s regulatory and licensing history informs risk profiling and HTA’s response to identified shortfalls
<p>7. CQC’s assessment of local authorities’ Care Act duties</p>	<ul style="list-style-type: none"> • Not applicable to HTA
<p>8. Integrated Care System (ICS) assessments</p>	<ul style="list-style-type: none"> • Not applicable to HTA
<p>9. Supporting providers to improve quality across the health and care sector.</p>	<ul style="list-style-type: none"> • HTA takes active steps to drive up standards and embed good practice through the evolution of its Codes of Practice • HTA takes its role of providing advice and guidance seriously and has provided extensive guidance to its sectors over the years, including standalone documents and a regular professional

	<p>newsletter as well as further development and elaboration of the guidance to its standards and broader guidance it provides to sectors and individual establishments.</p> <ul style="list-style-type: none"> • HTA actively engages stakeholders to ensure it remains well-connected to the regulated sectors • HTA works constructively with those we regulate to encourage improvement, particularly in sectors where innovation is driving new activities, such as HA and ODT • HTA is well-connected with other healthcare and related regulators with whom it frequently collaborates to support improvements in quality and address novel issues.
<p>10. The sponsorship relationship with DHSC</p>	<ul style="list-style-type: none"> • HTA has close working relationship with its sponsoring Department, DHSC, with positive and productive engagement. Sponsorship team are supportive whilst constructively challenging.

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