

HTA Board meeting, 7 March 2024

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| Agenda item | 2.3 (CEO Report) |
| For information or decision? | Assurance / reporting To inform the HTA Board of key or current issues from the CEO's perspective |
| Decision making to date? | N/A |
| Recommendation | The HTA Board is asked to note and comment on the issues raised |
| Which strategic risks are relevant? | Potentially any area of business may be raised in the report or subsequent conversation |
| Strategic objective | Any strategic objective may be covered |
| Core operations / Change activity | Any operational or change activity may be covered |
| Business Plan item | Senior Management Team – strategic direction and leadership of operational delivery across the organisation (including risk management) |
| 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

Update on Quarter 3

1. At the end of Q3 and following the December 2023 Board meeting, DHSC officials confirmed it was a Ministerial intention to introduce a duty on certain clinicians to report all:
 - organ transplants which take place outside the UK, and
 - where a clinician has a reasonable suspicion that an organ donation and transplantation related offence has been (or may be) committed.
2. This confirmed the need to push back elements of the 23/24 HTA business plan (as agreed by the Board on 7 December) to provide essential in-house resource to create a “minimum viable product” by 1st April with which to administer the new scheme.
 1. Following the legislative changes in July 2022 to section 32 of the Human Tissue Act (2004), activity levels for the LOD (Living Organ Donation) team have remained high in Quarter 3, with a continued steady stream of inward referrals to the HTA by clinicians concerned about suspicions of unlawful transplants outside the UK. These new cases, plus the work on cases previously referred to the HTA (including gathering relevant information to assess these for onward referral to the police) continues to place a heavy resource burden on the small Living Organ Donation Team that was not set up or resourced to deal with this volume of complex activity.
 2. Six cases were referred to the HTA in Quarter 3, with three further referrals since. This brings the total number of cases to 20 for those referred to the HTA since July 2022. Additionally, there is ongoing additional scrutiny of all cases involving donors from outside the UK coming to the UK to donate an organ, given the known risk factors. This is in addition to other potentially complex or higher risk living organ donation cases.
 3. The system-wide acute winter mortuary capacity pressures experienced last year have not materialised on a similar scale so far this year. This may in part be attributable to the activity across the system to monitor and manage capacity, reinforced by the HTA's regulatory focus throughout this year on ensuring mortuaries have addressed capacity issues and have suitable contingency arrangements in place. For example, the data collection exercise in the first half of the year included a focus on contingency arrangements in the PM sector with a continuing focus on winter capacity in Quarter 3 including the issue of a Regulatory Update, the issue of Special Directions to the sector and the production of a well-

received webinar, alongside using our access to NHS England's weekly mortuary capacity reports to identify any specific high risk establishments.

Current Issues

4. We continue to progress our response to, and support for, the work of the Independent Inquiry into the offending of David Fuller. Our comprehensive approach includes responding to the findings from the Phase 1 report (published in November 2023 and specifically focusing on the issues found in Maidstone & Tunbridge Wells NHS Trust) and the areas that are currently being considered by Phase 2. Specific activities within our next phase of work includes:
 - developing training for DIs and PDs on identified risk areas,
 - developing evidence-based assurance exercises, and
 - reviewing our approach to overseeing the management of Corrective & Preventative Actions by establishments following inspection findings of shortfalls against licensing standards or in response to incidents reported to the HTA.
5. As we respond to the matters covered in Phase 1 and the issues being considered under Phase 2, we are seeking to be involved increasingly in cross-system working with other regulators or multi-agency oversight groups, providing expert input and support and to help address the system-wide risks and issues found in the post mortem sector.
6. Colleagues across the HTA continue to work collaboratively to prepare for the upcoming Duty to Report (see paragraph 3). This includes close working with DHSC and NHS Blood and Transplant. Given the restrictions on additional resource to support the new duty and definitive delivery date of 1st April 2024, a restricted 'minimum viable product' has been developed to ensure that the HTA delivers the essential activities. These include:
 - Developing guidance for clinicians who are required to report under the duty (with input from NHSBT);
 - Introducing a single route for reporting under the duty and updating the existing process for handling reports; and
 - Notifying key stakeholders of the upcoming duty.
7. The HTA continues to work with DHSC on changes they propose making to the HTA's guidance on the disposal of pregnancy remains, following the release of DHSC's Pregnancy Loss Review last year. In line with a Ministerial commitment

made in 2023, DHSC remains committed to making changes within the HTA's remit this business year.

8. Trafficking for the Purpose of Organ Harvesting: Strengthening the Response - was the name of a conference organised by the Metropolitan Police and held at City, University of London in January. Several HTA staff who have been working with the police attended, along with our Chair, and I gave a short presentation on the HTA's role in relation to Living Organ Donation. We heard from a wide range of speakers including those involved in the recent Operation Manoa case - the first organ trafficking convictions under the Modern Slavery Act (2015). Prosecution Counsel (Hugh Davies KC) and the Senior Investigation Officer (SIO) also presented. Taking a multi-agency approach was recognised as the best way to deal with this complex and challenging issue. Seeking to develop more reliable data is an ambition of all stakeholders involved. There is a clear role for the HTA and the work we have progressed to bolster and protect the legitimate organ donation approvals process should add to the overall response. Further multi-agency discussions are planned.
9. The Audit and Risk Assurance Committee meeting on 7 February 2024 included consideration of a paper on Sector Risk Profiles, which updated the qualitative assessment of regulatory risk for each of our sectors and provided information on the quantitative approaches trialled to assess relative sector risk using regulatory data and insight. A report of this will appear in the ARAC update, which noted that this sector risk assessment is being used to influence our regulation activities in 2024/25, including our proactive programme of compliance assessments on our population of licensed establishments.
10. Empathy in Regulation – The HTA has already started considering the impact of the coroner's findings in the Ruth Perry / Ofsted matter and what this might mean for the HTA in terms of ensuring we approach fulfilling our regulatory remit professionally and with appropriate empathy for those with whom we engage. This was a substantive item at a Regulation Directorate quarterly training day in January, which prompted much reflection and a rich discussion on lessons to be learned from this tragedy. It recognised what we do well, as well as identifying areas in which we might be able to improve. We anticipate bringing this together for a Board discussion later this year.
11. As an Arms' Length Body (ALB) which has direct access to NHS patient data, as part of our Living Organ Donation (LOD) approval process, the HTA is required to complete an annual Data Security & Protection Toolkit (DSPT) self-assessment. This year, 2023 /24, the HTA is required to demonstrate compliance against 108 assertions that are aligned to 10 national guardian standards. DSPT leads within the HTA are working towards the first key milestone to upload our baseline assessment to the NHS portal by 29 February. The date for the audit (conducted by GIAA – Government Internal Audit Agency) is still to be agreed but it is expected to take

place over April and May 2024. The deadline for the final assessment is 30 June 2024.

12. The forecast year-end position, as at the end of Q3, was a deficit of £88k. This represents an overspend of c.1.6% of the HTA's initial expenditure budget. This is largely driven by forecast income receipts being c. £150k below initial budget expectations, of which c. £85k relates to sectoral fee income and £90k relates to a GIA (Grant in Aid) deduction implemented by DHSC off set by surplus of £25k within other income. HTA Finance continues to discuss the GIA deduction with the Department. The HTA's forecast spend is currently £66k lower than the original budget. We have kept DHSC briefed on the position throughout the year, and they have not asked us to undertake any specific corrective action. Additional detail is provided in the finance section of the Performance Report.
13. In recent weeks, we have been in discussion with DHSC officials about the timing of the Public Body Review (PBR) for the HTA. When the most recent round of PBRs was announced in 2022, it was thought the review for HTA might have been conducted in 24/25 but based on the reviews of other DHSC ALBs that are now timetabled, at this stage it is not clear when this will proceed.
14. I should also highlight to Board members that the 2025 Board meeting schedule has been agreed by our Chair to be:
 - 6th March 2025
 - 26th June 2025
 - 8th September 2025.
 - 11th December 2025
15. In addition, the next Board meeting, previously planned for Thursday 27th June 2024 will now be held on Friday 28th June 2024, with a stakeholder engagement event on Thursday 27th June 2024. This year's annual Board meeting held in public will therefore be moved to the meeting convening on 19th September at 2 Redman Place.

Recommendation

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