

Human Tissue Authority Board Meeting

Date: 7 December 2023

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Agenda item: 5

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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.
3. The HTA Board is asked to approve the in-year changes to the 23/24 Business Plan, as highlighted at Annex 1.

Update on Quarter 2

4. At the end of Q2, as shown in our more detailed Performance Report, we are meeting all of our operational KPIs (with one minor exception). This is a positive outcome but the picture is more mixed in respect of the delivery of our portfolio of projects, where we have had to push out some completion dates of lower priority activity in order to accommodate other pressures.
5. These pressures have arisen most notably due to implementation of a recent policy change, and a further planned policy change. In light of the introduction of section 32a in July 2022 which prohibited (for most UK residents) the purchase and sale of organs outside the UK, and the conviction this year of three people for the trafficking of a man to the UK for the purpose of removing an organ without consent, DHSC is planning to clarify the responsibilities of clinicians in sharing information about transplants which take place outside the UK, as well as when they have a reasonable suspicion that an offence under human tissue or modern slavery

legislation has taken or will take place. DHSC would like this information to be sent to the HTA, who would then decide whether to refer it to the police.

6. Other pressures are due to vacant posts being unfilled for several months impacting on delivery.
7. In response to these in-year pressures, the Portfolio SMT meeting at the mid-year point considered progress against the 23/24 Business Plan (which was approved by the Board and DHSC in March 2023) and has proposed reprioritised project activity. In some cases, this means pushing back activity into the next business year, and which will need to be included in the 24/25 Business Plan. This will come to the Board and then DHSC in March 2024.
8. Whilst full details are provided at Annex 1, the primary areas being pushed back are:
 - Insight Network was to have been in place by March 24. Completion will extend into 24/25.
 - Phase 2 of the Review of Inspections will be earmarked for funding from within 24/25 resources, as the costs are not affordable in 23/24.
 - LOD approval project activity – we are only able to progress the original, more limited scope of the project without additional investment.
 - Completion of our Review of Tissues and Cells will be pushed back by one Quarter - to be completed in 24/25, although work will need to be progressed on it in 23/24.
 - Our review of performance management and development of a new people strategy will be delayed.
 - Regulatory Insight Model & Index (RIMI) - commence work as intended in 23/24 but acknowledging that bandwidth on Duty to Report will require completion of RIMI to now extend into 24/25.
9. As regards the Duty to Report work, in discussions with DHSC, we have pulled together policy, regulation and project management experience and have been preparing for possible implementation. The pausing/delaying of lower priority work from our Business Plan reflects the lack of any additional resource to resource the DTR activity in-year.
10. Work to develop and embed our new evaluated self-assessments (ESAs) continued in Q2, with a total of 13 ESAs carried out in the Research sector during the quarter. This work is a good example of 'in-house' innovation to increase our regulatory reach and efficiency. We are now working to a total of 30 ESAs to be completed (within our enhanced target of 222 annual inspections) by the end of March 2024.
11. The HTA also played its part in changes to the burials at sea requirements which were announced publicly by the Marine Management Organisation (MMO) on 28th September 2023. The changes allow for DNA extractions from the deceased to take

place prior to burial at sea so that any body parts subsequently washed up ashore can be matched and identified, saving HM Senior Coroner and the police from having to obtain DNA from the families of those recently buried at sea, to identify the body parts and potentially mount a suspicious death inquiry. Staff from our Post Mortem (PM) sector team have been involved in ongoing engagement with the Missing Persons Unit to advise on licensing requirements. HTA support has also extended to presentation of HTA consent training to funeral directors to facilitate these changes in a way that is compliant with the Human Tissue Act.

12. Following our own investigation into concerns about the removal and storage of tissue obtained during surgical procedures, we referred a complex case to the police in April 2020. Circle Health Group Limited (formally BMI Healthcare) were fined £100,000 in October at Worcester Crown Court after pleading guilty in July 2023 to the unlawful storage of human tissue, contrary to the Human Tissue Act 2004. We supported the police during their criminal investigation, providing expert advice as it progressed. It is the first case HTA has referred to the police which has resulted in a successful criminal conviction under the Human Tissue Act. The successful conclusion to this case sends out a strong message that establishments wanting to use human tissue must follow the law and we will involve the police where we think the law has been broken.

Current Issues

13. Winter Pressures - the Post Mortem (PM) sector and Communications and Engagement Team have been working collaboratively on proactive engagement to support the sector and minimise risks associated with winter pressures ahead of quarters 3 and 4. The busiest time of the year for mortuaries is traditionally December to February and we have worked to distribute a focussed engagement package to the sector by way of a Regulatory Update, General Directions, a Director's blog followed by a webinar; with a further stakeholder engagement forum planned in mid-December to ensure advice and guidance is ongoing.
14. Taking steps to build greater resilience has been a key theme for us throughout 2023/24 and remains a "live" issue. For small and medium sized organisations such as HTA, there is a heightened risk of disruptive gaps in roles or skills required to deliver key functions due to limited potential cover in the organisation, in effect creating a greater proportion of Single Points of Failure (SPOFs). On occasions having just a few staff absent from key posts can have a disproportionate impact. As mentioned in the Audit & Risk Committee (ARAC) report, this risk was explored in a deep dive exercise at the committee's October meeting in which each potential SPOF was considered. It was a helpful review of the different and varied strategies we have for dealing with such pressure including:

- managing pressures within teams,
- recruitment and retention strategies,
- ensuring our budget is sufficient to support in-year pressures, and
- the pooling or sharing of support functions with other public bodies.

15. As regards our progress on the HR shared services front, our new shared service offer continues to roll out with the Care Quality Commission (CQC). Last month, the data transfer was successfully progressed. CQC are now in possession of the HTA personnel files following completion of the Data Protection Impact Assessment (DPIA), and we are working with CQC to make sure they are complete and correct. Loss of our internal HR service has impacted our ability to manage the transition at pace and has delayed some aspects of our new HR service commencing (mainly transactional HR services, including contractual changes and HR management information) but that tail of activity has been prioritised and is being progressed. The new service is being developed and improved by CQC as it is being delivered, with KPIs and more detailed service arrangements being firmed up.
16. The HTA continues to explore other opportunities for sharing support functions. Interestingly, the greater use of shared services for efficiency and resilience, with DHSC working with its ALBs to scope the merits of shared service functions, is one of 19 recommendations in the recently published public body review of the Human Fertilisation & Embryology Authority (HFEA). I was interviewed as part of the review process. The HTA, which has several shared finance staff with HFEA, is referenced specifically in some detail. The report recommends the HFEA should be retained as a separate ALB. It notes that whilst there are some synergies between HTA and HFEA, the two bodies “regulate within discrete and specialist areas with little overlap. A merger would be unlikely to yield a cost saving that would outweigh the well documented risks and could drive additional costs in the short to medium term.” Other recommendations include how HFEA can enhance its effectiveness and efficiency, changes to legislation to assist the HFEA’s work and how accountability might be improved. We are studying the recommendations to see which of them might be usefully applied to HTA. We will come back to the Board in more detail later.
17. The Independent Inquiry into the issues raised by the dreadful offending by David Fuller in the mortuary at Maidstone & Tunbridge Wells NHS Trust was established by the then DHSC Secretary of State, Sajid Javid MP, in November 2021. Over the last two years, the HTA has been fully supporting the work of the Independent Inquiry. We have provided evidence and much detailed background information. Phase 1 of the Inquiry covering matters relating to the events in Maidstone & Tunbridge Wells NHS Trust, was laid in Parliament on 28 November with DHSC Minister, Maria Caulfield MP, issuing a written ministerial statement in response. The HTA recognises the notable work undertaken by the Inquiry team resulting in the Phase 1 report. Alongside DHSC officials and partners across the health sector

and more widely, we are carefully considering the findings and recommendations to determine the implications for the HTA and the wider group of interested parties. We are committed to playing our part to improve practice and guard against anything similar happening again. Meanwhile, we continue to support Phase 2 of the Inquiry.

18. Xenotransplantation – You may recall last November, the HTA attended a roundtable discussion about the UK’s approach to Xenotransplantation (the use of tissue from other species in humans). DHSC has now asked that a formal group is constituted to provide a set of recommendations, within the next 18 months. We have been invited to join the group alongside other relevant parties and the first meeting is in early December. Co-Chairs for this work are Professor John Iredale (Chair of Experimental Medicine at Bristol University) and Anthony Clarkson (Director of Organ Donation and Transplantation at NHSBT).
19. Forecast Expenditure (after Q2). In-year financial forecasts are improving. At the end of Q1 we were looking at a potential overspend of around £100,000. Whilst we did not bring in a recruitment freeze, we have been wary about any new in-year spends. This is another reason for reprioritising the business plan. Based on current activity levels and work on the Fuller Inquiry, that we agreed to progress at risk, we are now forecasting a slight overspend (as at end October), but there is still some uncertainty about our resource needs as we move into the second half of the year, in particular, in relation to some elements of the business plan yet to commence and potential pressures, such as DTR. This position will continue to be monitored very closely.

Recommendation

20. The HTA Board is asked to note and comment on the issues raised.
21. The HTA Board is asked to approve the in-year changes to the 23/24 Business Plan, as highlighted at Annex 1.