

Human Tissue Authority Board Meeting

Date: 3 November 2022

Time: 10.00 – 12.00 Main meeting including Business Planning discussion
12.00 – 12.30 Board and Chief Executive only session
12.30 – 13.00 Lunch
13.00 – 15.00 Afternoon Board and SMT Session – Horizon Scanning

Venue: 2 Redman Place, London, E20 1JQ

Meeting Number: 102

Protective Marking: OFFICIAL

Agenda

Meeting Administration

1. Welcome and apologies (Oral) (LB)
2. Declarations of interest (Oral) (LB)

Regular Reporting

3. Chairs Report (Oral) (LB)
4. Chief Executive's Report (HTA 30/22) (CS)
5. HTA Performance Report (HTA 31/22) (CS)
Annex C Summary of Strategic Risk Register (HTA 31c/22)
6. Update from DHSC Sponsor Team (Oral)

Items for discussion

7. Fees Proposal (HTA 32/22) (RS). The Fees paper is confidential and not included.

Committee and Working Groups

8. Audit and Risk Assurance Committee Update (HTA 33/22) (GC)
9. Remuneration Committee Update (HTA 34/22) (ED)

Items for information only

10. Minutes of 14 July 2022 (HTA 35/22) (LB)
11. Matters arising from 14 July 2022 (HTA 36/22) (LB)

Business Planning

12. Discussion on Business Planning (Oral) (JMcD)

Any Other Business

13. Any other business (Oral) (LB)

This version 24 October 2022

Human Tissue Authority Board Meeting

Date: 3 November 2022

Paper reference: HTA 30/22

Agenda item: 4

Author: Dr Colin Sullivan

Protective marking: OFFICIAL

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 Q2

3. During Q2, we have continued to progress our regulatory and related activities against the Key Performance Indicators, sought to progress the 22/23 business plan, and responded to matters arising.
4. The DHSC laid the revised Code F part two (amended given the introduction, in Spring 2023, of **Deemed Consent in Northern Ireland**) before Parliament on 5 September 2022. Whilst the new deemed consent law and revised code is not planned to come into force until Spring 2023, the HTA intends to publish the revised Code of Practice, alongside the outcome of the consultation process, following the completion of the 40-day negative lay period, which is due to end on 7 November 2022.
5. The **Organ Tourism** Amendment to the Human Tissue Act 2004, and to the Human Tissue (Scotland) Act 2006, came into effect on 1 July 2022. HTA

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officials from the Policy and ODT (Organ Donation & Transplant) teams have meet on several occasions during Q2 with colleagues from NHSBT, DHSC, Scotland and the National Crime Agency (NCA), to refine the referral process to be followed when there may be potential breaches of the Act in relation to organ tourism. There is now a process in place whereby any concerns identified by clinicians regarding individuals recently returned from abroad who have had a transplant (or who have donated an organ), can be flagged through to the HTA for consideration. The NCA are agreed that these cases will then be routed to them in the first instance for consideration.

6. In addition, there is the possibility of individuals being trafficked into the UK for the purpose of unlawful transplantation, in breach of Section 32 of the Human Tissue Act. The HTA is engaging with relevant stakeholders to address those concerns. For example, we are discussing if there would be benefit in the HTA developing additional guidance material for use in the training of key professionals.
7. The HTA is continuing to participate in exploratory conversations with the Care Quality Commission (CQC) and NHSBT, facilitated by DHSC, to explore the **regulatory framework for the matching and allocation of donor organs** intended for transplantation. This is currently a statutory function of the CQC which it has been suggested the HTA could consider taking on alongside our other functions in relation to organ donation and transplantation.
8. During Q2, meetings held have included supporting the Chair and Board Member for Wales at a meeting with Eluned Morgan, the Health & Social Services Minister for Wales and a discussion with Professor Mike Osborn, President of the Royal College of Pathologists. External meetings also included discussions with colleagues in the NI Department of Health and a meeting of Health Arms Length Bodies (ALBs) chaired by Shona Dunn, the Second Permanent Secretary at DHSC, to discuss the new Secretary of State's priorities. I also attended the British Transplantation Society Annual Congress in Belfast in early September which was an excellent opportunity to meet with many key stakeholders across the ODT sector.
9. Members of SMT attended the **Quarterly Accountability Review** meeting with our DHSC Sponsor Team on 15 September, which we hosted in Redman Place. On the EDI (Equality, Diversity and Inclusion) front, I chaired a further quarterly meeting of the Diversity Collective Forum meeting in July which was attended by each of the Health ALBs located in Redman Place.

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Current Issues

10. During October, I and several other HTA colleagues attended and gave evidence to the **Fuller Independent Inquiry** being held in Maidstone. This was primarily in relation to phase 1 of the Inquiry's work which covers matters relating to the Maidstone & Tunbridge Wells NHS Trust. A number of former employees of the HTA were also invited to give evidence to the Inquiry and the HTA made relevant documentation available to them to enable preparation for their hearings, with suitable arrangements to ensure confidentiality of that material. The HTA continues to fully support the inquiry and we continue to receive direct requests for material from the Inquiry. An internal lessons learned-type review of the HTA activities in response to Phase 1 of the Inquiry will now commence to help us understand how best to prepare for and provide input to the Inquiry as it progresses to Phase 2 and to continue to provide appropriate support to colleagues. We expect that learning from this exercise will be helpful for any other inquiry-type processes in which the HTA may be engaged in in the future.
11. During the summer, DHSC sought a combination of in-year efficiencies, spending reductions and recruitment restrictions. These were ahead of any further **public expenditure** constraints to be announced in the autumn. The challenge of finding suitable recruits to fill advertised posts is having a bearing on our ability to delivery our in-year business plan targets and any public expenditure restrictions for next year and beyond will influence business planning for future years. The Business Planning process for 23/24 has commenced with early engagement with staff and discussion at this meeting of the Board.
12. The work to develop a **shared services** model for the HTA's IT and HR services has continued to be developed in Q2 through engagement with potential partners, preparation of draft specifications and options for the scope of future services and contractual arrangements. Detailed plans and timescales for delivery will be reviewed by SMT during Q3. Delays with the recruitment of key personnel with essential and specific skills has had a bearing on the speed of progress.
13. In preparation for the delivery of the services we have been requested to provide to the **Isle of Man (IoM)** government, a draft Service Level Agreement (SLA) has been developed by colleagues from the Regulation Directorate and the Policy team. The SLA will provide certainty on what level of service we can provide to the IoM and how costs will be recovered. The draft SLA is still in its early stages of development, and we will be seeking legal advice and

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sharing it with DHSC for their review and consideration before finalising the SLA with IoM.

14. Work to review the **HTA Codes of Practice** for minor revisions and/or updates in terms of factual accuracy has been advanced during Q2. These have been shared with DHSC colleagues for their review. When we are ready, we will share the amendments with the Board for review and agreement by correspondence.
15. Working with the HSC Leadership Centre, we have continued to progress the organisational development work previously discussed with the Board and which is included in the 22/23 business plan. This programme is designed to improve our **delivery and organisational effectiveness**. The latest All Staff Day (13th October) focused on identifying and understanding our individual staff and team motivational values, in terms of processes, performance and people. This is invaluable when seeking to review the values and develop the competences required by the authority in order to deliver effectively against our objectives. There was very positive feedback about the exercise and the level of staff engagement. The day also provided an early opportunity to start the process of engagement on next year's business plan. Further all-staff days are timetabled for Q3 and Q4.

Recommendation

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

Human Tissue Authority

Board Meeting

Date: 3 November 2022

Paper reference: HTA 31/22

Agenda item: 5

Author: CEO and Senior Management Team

Protective marking: OFFICIAL

HTA Performance Report

Purpose of paper

1. To inform the Board of the HTA's performance in Quarter 2 (Q2) against our objectives and operational delivery targets.

Action required

2. The HTA Board is asked to note and comment on the performance recorded and the context provided.

Operational Delivery

Regulation

3. **Annex A** provides a summary of the Key Performance Indicators (KPIs) and two Performance Indicators (PIs) presented to the Board each quarter. Most relate to the Regulation Directorate, but Enquiries and Freedom of Information Act requests can arise in any area of the business.
4. Despite external factors (such as the periods of extreme heat and rail strikes) and internal factors (such as staff turnover and other matters impacting staff availability) leading to some re-scheduling and deferral of inspections, we remain on track at the end of Q2 against the significantly increased inspection target for this year.

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5. Other performance indicators show a mixed picture over Q2 and in terms of trends over the first two quarters of 22/23. We continue to actively monitor all amber KPIs to identify and address any underlying issues whilst recognising in this first year of operating in a new inspection mode, the increased inspection target has had an impact on other activities.
6. The KPI target of 210 inspections includes all types of inspection except initial licence assessments. Whilst we continue to carry out unannounced site visits and inspections when required, there have been none during Q2. In the Post Mortem Sector, one establishment was inspected to assess progress against outstanding corrective and preventative actions.
7. Until this year, pre-licensing assessments (often known as Licence Application Assessment Visits or LAAVs) have been counted in the inspection target KPI. The number of pre-licensing assessments over the first two quarters of this year has been significantly higher (20 to the mid-year point) than anticipated (around 10-12 for the whole year) and is much higher than we have previously experienced. This is another factor contributing to demand-led workload, alongside other factors such as an increased number of Regulatory Decision Meetings concerning a variety of technical licensing breaches.
8. One establishment within the Post Mortem Sector received a critical shortfall. Whilst the inspection took place in Q1 (and was thus captured in the last Board report), the inspection report publication date crossed into Q2.
9. Following the provision of written advice to the Secretary of State for Health and Social Care in December 2021, the HTA has now undertaken a review of its guidance in relation to the HTA's Code B Post-mortem examination licensing standards. This entailed an internal review followed by external engagement and feedback to stakeholders. The updated guidance was published on the HTA's website on 19 September 2022. Related to the SoS advice, we have decided to review other relevant sectors, including consideration of the guidance to Anatomy standards.
10. The invitations to tender for the various lots in the Review of Inspections Project have been advertised on the HTA's website and the cross-Government "Contracts Finder" website with a closing date of 24 October 2022.
11. The HTA has continued to support the work being undertaken by DHSC to review the regulatory framework in Northern Ireland (NI) in the context of the Northern Ireland Protocol (NIP) Bill. We organised two stakeholder events on

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behalf of DHSC so that they could engage with Tissue Establishments in NI to discuss possible future regulatory models, should there be changes to the NIP. DHSC officials have noted how useful these events have been.

12. The HTA has also contributed to DHSC's post-implementation review of the 2012 Organ Donation and Transplantation Regulations and has held the first of our reinstated technical liaison group meetings with MHRA.

Finance

Table 1: £k	Year to Date				Outturn			
	Actuals	Budget	Variance		Forecast	Budget	Variance	
	£	£	£	%	£	£	£	%
Income	(5,096)	(4,793)	(303)	6.3%	(5,420)	(5,381)	(39)	1%
Expenditure	2,426	2,615	(189)	(7.3%)	5,118	5,381	(263)	-5%
Net (surplus)/deficit	(2,670)	(2,178)	(492)	22.6%	(302)	0	(302)	%

13. **Table 1** provides a summary of year-to-date income and expenditure to the end of September 2022 (period 6). The large net surplus in income is the result of profiling of our Grant in Aid income and our licence fee income which is above budget. We have now billed all our licence fee income with the last tranche billed at the end of September. Further detail of our expenditure is contained in the expenditure table at the foot of this paper – **Annex B**

Income

14. Licence fee income is currently £145k above budget. The April fees (Human Application) income is £49k above budget with the September fees (other sectors) being £84k above budget. Application fees have generated £12,000 more than predicted. Grant in aid income drawn from DHSC is currently £122,000 higher than budget due to budget profiling.

Expenditure

15. Several vacant posts in the process of recruitment have resulted in a £93k underspend in staff costs for the first half of the year. A further £96k

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underspend against budget arises from non-staff costs and is mainly due to budget phasing.

16. Certain non-staff cost budgets are phased equally across the financial year as the expenditure can be unpredictable, for example: training costs, travel costs, legal and other professional costs and conference attendance.

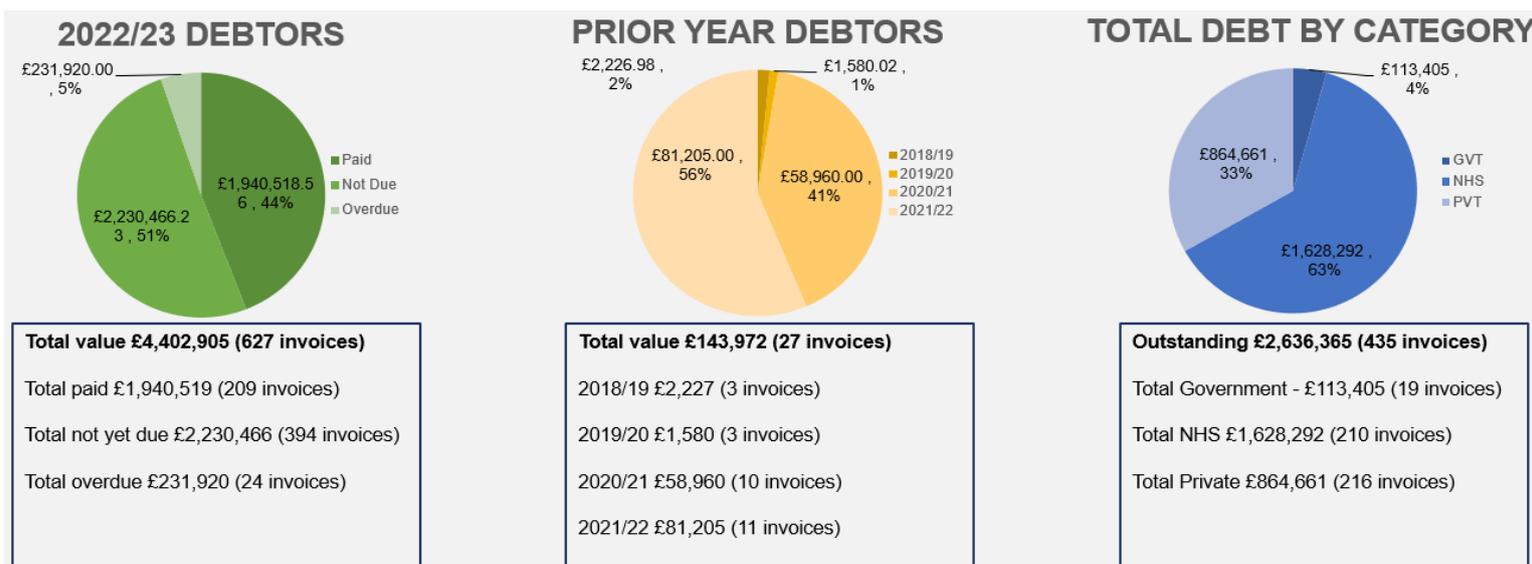
Outturn

17. The current projected underspend is £302k. This arises from significant variances as detailed above. Also included within this underspend is a contingency of £100k which has been earmarked for return to DHSC as part of the in-year savings exercise.

Other key performance indicators

Debtors

18. Outstanding debt from licensing activities is provided below.



19. From left to right: The 2022/23 Debtors pie-chart shows the total licence fee income invoiced in 2022/23. Payment has been received for 86% of the April invoice run and 12% of the September invoice run. Debt collection procedures are ongoing for the remaining 14% of the April debt.

20. Prior year debtors – this shows the debt outstanding from previous financial year(s). £309k (62 invoices) was carried forward from 2021/22 and payment has been received for £165k (35 invoices). The remaining £144k is being

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further chased on an ongoing basis with additional payments already received in October.

21. Total debt by category is shown in the final chart and with the total outstanding debt (all years) by sector. The NHS sector continues to make up almost two thirds of our outstanding debtors.
22. To strengthen the financial management team, a finance officer was recruited in mid-August. This has facilitated significant progress with debt recovery, particularly with the prior year(s) debt, with £113k received since June 2022 (37% of debt carried forward from 2021/22).
23. Payments of £43k (28 invoices) has been received in respect of the April invoices since June 2022 and progress is continuing.

Financial risks and mitigations

24. Financial risk remains low but is above tolerance, with the focus of the Executive on debt recovery and ensuring that agreed plans are in place and are progressed.
25. Work to maximise resource utilisation in order to deliver the business plan and minimise underspends is underway.

People Issues

26. The key strategic issue of note at present on the “people” front is the number of vacancies and the difficulties we have encountered in filling these positions. Q2 has seen a total of 16 vacancies arising either from departures or from a number of new posts and interim roles. 6 of these have now been filled with 10 vacancies remaining open. Alternative channels to market have been established in response to this challenge and to widen the potential talent pool. This approach has resulted in more applications.

27. Other HR Data of note:

Attrition Rates:

- Quarter 2 9%
- YTD 15%

Sickness:

- Quarter 2 0.67%
- YTD 0.98%

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28. Staff Wellbeing – to support our organisational development work and the Employee Assistance Programme (EAP) currently on offer to employees. This service provides a more formal counselling service to employees who may be struggling with significant life events, e.g., Divorce, Financial issues etc that need a more formal intervention such as counselling. The service also offers articles on a range of wellbeing topics. To supplement the service currently on offer, we have purchased and will be implementing the Headspace Application. This is an App which operates in the mindfulness space which employees can access at a time of their own choosing to support any stress/personal issues that they might be experiencing.

29. More detailed People information is made available to and discussed by the Board's Remuneration Committee (RemCo).

Digital, Data and Technology

30. Digital, Data and Technology has been the area most impacted by staffing shortages throughout Q2. These have included some permanent staff turnover along with the conclusion of fixed term contracts. There were 6 vacancies at the end of Q2, increasing by 1 at the start of Q3.

31. Due to the specialist nature of some of these vacancies, there are limited alternative options for backfill internally. Areas impacted include IT, Policy, Information Governance and Project Management and these staff vacancies have impacted Q2 progress against the business plan, as managed by the portfolio management process. Progress that has been made includes:

- Draft specification and scope for IT Shared Services
- Engagement across ALB organisations, exploring the potential for collaboration and/ or a future partnership arrangement for IT
- Revision of Code F Deemed Consent, Northern Ireland successfully laid before Parliament
- Internal review of HTA's legislative framework
- Development and agreement of the high level and detailed improvement plan for the Data Security & Protection Toolkit (DSPT)
- Ongoing delivery of the Comms & Engagement Strategy including preparations for the first roundtable event with Devolved Administrations

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Communication and Engagement

32. Through Q2 we appointed a Communication Officer and Digital Engagement Content Designer with both roles now supporting the continued delivery of the Communication Strategy.
33. Engagement with the media has increased in Q2, from 4 responses provided in Q1 to 12 in Q2. This has enabled us to explain HTA's role and get key messages across on a range of stories. We are working with colleagues to agree a plan to increase proactive messages around our quarterly data releases and inspection reports.
34. Following a pilot in the summer, which showed an increase in engagement with reduced frequency, we have moved the internal newsletter to every fortnight. The stakeholder newsletter is moving to quarterly enabling us to coordinate publication with our quarterly data releases on reportable incidents.
35. Social media activity and engagement has continued to grow in Q2. With an increase in the engagement rate from 2.7% to 4%. The most engaged tweets were in support of Organ Donation week.
36. The stakeholder engagement plan has been agreed with 5 potential executive led events outlined for the remainder of 2022/23. The first is taking place on 8 November. This is with colleagues in the Devolved Administrations and DHSC and will focus on horizon scanning and emerging issues, codes of practice guidance and support from HTA.

Governance

37. The Risk Summary document can be found at **Annex C** (HTA31c-22) to this paper. This was reviewed by ARAC in early October.
38. At its most recent assessment of strategic risks, SMT concluded that 6 of the 7 risks should be rated as above tolerance. Many of these risks are in some measure impacted by the cross-cutting issue of carrying a number of vacancies which is impacting across the Authority and to which we are responding by seeking more ways to increase the pool of suitable candidates for each vacancy.
39. The Portfolio SMT process and monthly review meeting has continued, with detailed reviews of performance and reprioritisation of our activities within our available resources.

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40. We anticipate developing the Board's Performance Report over coming weeks and to share a subset of the Portfolio SMT data to give the Board greater insight into our delivery progress.
41. First ideas for the 23/24 business planning process have been collated from colleagues and will be discussed with the Board in this meeting.
42. A targeted piece of work to review and test our Critical Incident Response Plan has been commissioned and will be concluded by the end of the financial year.
43. During Q2, the HTA received 6 Freedom of Information (FOI) requests. All FOI requests received were dealt with in line with HTA procedures in meeting statutory timeframes. In Q2, no complaints were received by the HTA.

Recommendation

44. The HTA Board is asked to note and comment on the performance recorded and the context provided.

Annex A – Quarterly Board Data Overview

Business Plan KPIs & PIs		<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid green; padding: 2px; text-align: center;">3 On track</div> <div style="border: 1px solid orange; padding: 2px; text-align: center;">8 Amber</div> <div style="border: 1px solid red; padding: 2px; text-align: center;">0 Off track</div> </div>		
		Q1 22/23	Q2 22/23	22/23 YTD
KPI	210 Inspections covering all sectors			103
	At least 90% of draft inspection reports are sent to DI for a factual accuracy check within 20 working days of the substantive completion of the inspection	93% (42/45)	95% (54/57)	94% (96/102) ↑
	At least 90% of inspection/audit reports are published on the HTA website within 10 weeks of the substantive completion of the inspection/audit	89% (42/47)	88% (58/66)	88% (100/113) ↓
	At least 95% of enquiries are answered within ten working days of receipt	94% (320/340)	87% (261/301)	91% (402/434) ↓
	All FOIs d/w in line with HTA procedures and meet statutory timetable	80% (4/5)	100% (6/6)	91% (10/11) ↑
	At least 90% of licence variation request outcomes are communicated within 20 working days	90% (55/61)	72% (41/57)	81% (96/118) ↓
	At least 90% of completed applications are processed within 90 working days of payment	75% (6/8)	80% (8/10)	78% (14/18) ↑
	100% of panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within ten working days	100% (36/36)	97% (58/60)	98% (94/96) ↓
	100% of non-panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within five working days	100% (166/166)	99% (206/207)	100% (372/373) ↓
	PI	At least 90% of Corrective and Preventative Actions (CAPAs) implemented to address major shortfalls are completed within agreed timescales	74% (31/42)	97% (32/33)
A decision is reached on at least 90% of PPDs within 20 working days of receipt of the completed dossier or any additional information requested by the HTA		80% (8/10)	100% (9/9)	89% (17/19) ↑

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Annex B – Detailed Expenditure table

£k	Year to Date				OUTTURN				
	Actuals	Budget	Variance		Forecast	Budget	Variance		
	£	£	£	%	£	£	£	%	
EXPENDITURE SUMMARY									
Staff Costs	1,826	1,919	(93)	-5%	3,794	3,901	(108)	-3%	
Non-Staff Costs	600	696	(96)	-14%	1,324	1,379	(55)	-4%	
Gross Costs	2,426	2,615	(189)	-7%	5,117	5,281	(163)	-3%	
Non-Staff Costs									
Travel & Subsistence	47	72	(25)	-35%	122	144	(22)	-15%	
Training & Recruitment	45	80	(35)	-44%	165	139	26	19%	
Conference & Project Costs	36	71	(35)	-44%	95	123	(28)	-23%	
Post, Stationery & Printing	6	10	(4)	-40%	7	20	(13)	-66%	
Other Costs	13	17	(4)	-24%	34	36	(2)	-8%	
I.T. & Telecommunications	160	187	(27)	-14%	348	370	(22)	-6%	
Legal & Professional	86	55	31	56%	161	109	52	48%	
Consultancy	35	30	5	17%	69	90	(21)	-24%	
Accommodation	159	135	24	18%	294	270	24	9%	
Non-Cash Costs	0	0	0	0%	0	0	0	0%	
Capital Charges	13	39	26	67%	29	78	(49)	-62%	
Total Non-Staff Costs	600	696	(96)	-14%	1,324	1,379	(55)		
Organisational Development Costs				0%				0%	
Contingency				0%	100	100	0	0%	
Total Revenue Expenditure	600	696	(96)	-14%	5,217	5,381	(163)	-3%	

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Latest review date – 20/09/2022

Strategic Risk Register 2022/23

Risk summary: residual risks

Risk area	Strategy link*	Residual risk	Risk owner	Status	Tolerance	Trend**
R1: Failure to regulate appropriately	Delivery (a-d & f) and Development (a-d) objectives	12 – High	Director of Regulation	Above tolerance	10	↓ ↔ ↑ ↔
R2: Failure to manage an incident	Delivery, Development and Deployment objectives	9 - Medium	Director of Regulation	Above tolerance	6	↔ ↓ ↔ ↔
R3: Failure to manage expectations of regulation	Delivery e) and Development c)	8 - Medium	Director of Regulation	Below tolerance	9	↔ ↓ ↔ ↔
R4: Failure to utilise our staff capabilities effectively	Delivery, Development and Deployment (a, c, and d)	12 - High	Director of Resources	Above tolerance	9	↔ ↔ ↑ ↔
R5: Insufficient or ineffective management of financial resources	Deployment (b) objective	4 - Low	Director of Resources	Above tolerance	3	↔ ↔ ↔ ↔
R6: Failure to achieve the benefits of organisational transformation	Development (a-d) objectives	12 - High	Director of Data, Technology and Development	Above tolerance	9	↔ ↔ ↔ ↔
R7: Failure to optimise the safe use of existing and available digital data and technology	Delivery (a-e), Development (a-d) Deployment (a, c and d)	12 - High	Director of Data, Technology and Development	Above tolerance	9	↔ ↔ ↑ ↔

* Strategic objectives 2021-2024:

** This column tracks the four most recent reviews by SMT (Senior Management Team) (e.g. ↑ ↔ ↓ ↔).

R1: There is a risk that we fail to regulate in a manner that maintains public safety and confidence and is appropriate.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
3	5	15 - High	3	4	12 – High
Tolerance threshold:					10 - Medium

Commentary

At tolerance.

We have a good regulatory framework, with moderate assurance on a recent internal audit on the Effectiveness of the Inspection Process in Quarter 4 2021/22 (final report issued 11 April 2022) and previously substantial assurance on an internal audit on key regulatory processes in Quarter 4 2018/19 (final report issued 16 April 2019).

The HTA has set a target of 210 establishment assessments for 2022/23 (a combination of onsite and virtual regulatory assessments) and remains on track to meet this target. This level of assessment is a significant increase on previous years and 50% higher than the coverage in 2021/22. Even if not fully met, this will result in wider reach than in previous years. Our re-introduced KPIs and Portfolio Management Process includes reporting on delivery of our core business and provides visibility at SMT and board level.

We continue to use all other regulatory tools and processes, such as managing and responding to incident reports (Serious Adverse Events and Reactions and HTA Reportable Incidents), whistleblowing / informant information and ongoing engagement with our regulated sectors, with investigations and active regulatory action having continued.

We continue to be notified about and to actively manage and monitor a small number of more unusual regulatory matters with establishments.

SMT believes this risk is now above tolerance given the number and serious nature of some of the incidents we are dealing with, which could lead to an increased likelihood of an impact on public confidence.

R2: There is a risk that we will be unable to manage an incident, event or issue impacting on the delivery of HTA objectives.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	5	20 – Very high	3	3	9 – Medium
Tolerance threshold:					6 – Medium

Commentary

This risk concerns our ability to respond to incidents irrespective of their nature or cause, which could be from matters outside the HTA's remit or control as well as matters for which we are directly responsible. The Executive has therefore set a lower tolerance level on this risk as our ability to respond appropriately is within the HTA's control.

The HTA believes that our incident management response plans have been well tested and found to be robust and effective through their deployment in several different circumstances over the past two years. These have included managing the impact of the pandemic and related restrictions and in their adaptation for use in managing the potential impacts of EU Exit following the end of the Transition Period. During the 2022/23 business year we will undertake a business continuity or critical incident test event to ensure our plans and response is effective.

We also found these arrangements useful and effective in preparing for and managing our response to the public revelation of sexual offending in a mortuary through the trial of Fuller and subsequent actions from Quarter 3 of 2021/22 onwards.

Having increased the risk scoring in July 2021, in anticipation of the prospective Fuller trial, we now believe that the likelihood of this risk materialising has reduced but given continuing uncertainties, we believe it is still above the tolerance level and has remained unchanged from the last review.

We have appointed a specialist consultant to assist with formally testing our Critical Incident Response Plan and anticipate concluding this work by the end of March 2023.

R3: There is a risk that we will fail to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
3	4	12 - High	2	4	8 – Medium
Tolerance threshold:					9 – Medium

Commentary
<p>Below tolerance.</p> <p>We have no indications of any current specific factors that would contribute to this risk. The HTA continues to communicate our remit and advise where appropriate.</p> <p>The HTA is in ongoing dialogue with DHSC (Department of Health and Social Care) and wider stakeholders regarding Sir Jonathan Michael’s Independent Inquiry into offending by Fuller and continues to provide evidence to the Inquiry and to assist colleagues and former colleagues to have suitable access to relevant information in order to enable them to help the Inquiry when called upon to provide input.</p> <p>The HTA has an established Horizon Scanning process and is building its Policy function, including updating our legislative log and preparing to engage on this with DHSC.</p> <p>The HTA is working with colleagues in the Northern Ireland Executive and NHSBT (NHS Blood and Transplant) to ensure there is effective implementation of the recent passing of the deemed consent for organ and tissue donation in Northern Ireland through changes to the Code of Practice F, Part 2.</p> <p>Whilst the recent amendment to s32 Human Tissue Act 2004 by the Health and Social Care Act 2022, to introduce an offence for ‘organ tourism’, is not expected to have any direct operational impact, the HTA continue to engage and support implementation of this change with NHSBT and other relevant stakeholders, including the police, to ensure that a suitable referral mechanism is in place.</p> <p>All these matters are being actively managed.</p> <p>SMT consider this risk to be below tolerance.</p>

R4: Failure to adequately deliver the diverse, capable workforce the HTA requires or needs to fulfil its functions and objectives

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	3	12 - High	4	3	12 – High
Tolerance threshold:					9 – Medium

Commentary
<p>Above tolerance.</p> <p>A significant amount of work was undertaken in 2021/22 to mitigate the risks associated with workforce. Actions included a partial organisational redesign, recruitment of fixed term contracts to a number of significant and standalone roles ensuring the short-term skill and competencies need was addressed and the identification of additional skills required to support agreed activity going forward.</p> <p>The HTA has reframed this risk for 2022/23 to reflect wider workforce issues that need to be considered beyond numbers of staff and vacancies. As we reflect on the past year and look forward the HTA requires a range and changing set of skills, capabilities and capacity to fulfil its functions and objectives. The diversity of our workforce and the adoption of new ways of working will be essential to ensure our approach to regulation remains responsive, proportionate and supportive to the sectors we regulate and the wider functions we deliver.</p> <p>In addition to the general concerns relating staff churn and recruitment workload the DHSC has introduced internal controls on recruitment and have begun conversations with ALBs regarding not filling vacancies to realise in year savings. Should these controls result in the HTA needing to seek departmental approval to fill vacancies we are concerned this could delay or prevent HTA filling posts leading to potential impact on delivery.</p> <p>SMT raised this residual risk to 12 in August 2022 and believe it remains at that level.</p>

R5: There is a risk that the HTA has insufficient or ineffective management of its financial resources

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	5	20 – Very high	2	2	4 – Low
Tolerance threshold:					3 – Low

Commentary**Above tolerance.**

Budgets for 2022/23 have been agreed and delegation letters to Directors issued. Our Grant in Aid (GIA) funding from the Department has been confirmed at previous levels and we have been provided with cover for asset purchases (Capital DEL - £80k) and depreciation and amortisation costs (Ring Fenced RDEL).

Invoicing for licence fees in the HA sector were issued in April 2022, this has increased our overall debtors' figure, but aged debt continues to fall. Following the material underspend that emerged at the end of 2021/22 SMT have agreed to introduce a target of an underspend below 3% for 2022/23 and this will be monitored monthly.

There are no emerging internal financial pressures within the organisation, but DHSC have issued a number of requests over the summer for impact assessment of reductions in our GIA funding in year and for future years. We have offered to return £100k of the additional GIA funding the Department provided for costs incurred in assisting the FII (for 2022/23 only), we believe this is affordable in year and we anticipate further savings requests in the coming weeks.

SMT will be reviewing the financial position monthly with formal quarterly reviews with each Directors feeding on to the portfolio management process to ensure more timely decisions to invest emerging underspends in areas identified in our activity pipeline. We expect to revisit the scoring of this risk following the Q2 finance review and portfolio meeting.

Activity is planned later in this business year to review the current assumptions in our fees model and ensure they reflects any changes in our approach regulation activity or focus.

SMT have agreed that this risk is unchanged.

R6: Failure to identify opportunities and achieve the benefits of transformation and continual change to support modernisation and improvement of the HTA.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	3	12 - High	3	4	12 – High
Tolerance threshold:					9 – Medium

Commentary

Above tolerance.

Following the review of the Development Programme in Q1 2022/23, a paper shared with the Board in July identified a number of projects that would be contributing to the transformational activity to support the modernisation and improvement of the HTA. These projects included the review of inspections, the exploration and move to a shared services model for IT and HR functions and the next stage of development for the Regulatory Insight Model & Index.

At the end of Q2 all identified projects have been subject to review with detailed papers presented to SMT on the review of inspections and the adoption of a shared service model for IT and HR services. In all cases additional (external) resources have been identified to support the next stages of development and delivery in these projects. An outline of the next stage of development of the RIMI is due to be presented to SMT by early November. This outline will set out the potential scope of work and resources requirements which will inform the decision to further progress this work in 2022/23 based on internal capacity and its relative priority against other priority projects identified. Current capacity in the organisation is a constraint that a significant factor in this risk being higher than the identified tolerance level. Actions to address the capacity stretch will assist in reducing the likelihood of opportunities and benefits not being achieved.

SMT believe that some areas of activity are at risk of slipping and this would have impact on anticipated benefit realisation although the extension of timescales on some projects may reduce risk without impacting on the overall output. Oversight of the progress will be maintained by SMT.

R7: Failure to optimise the safe use of existing and available digital data and technology

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	Likelihood	Impact	Residual risk
4	4	16 – High	4	3	12 – High
Tolerance threshold:					9 – Medium

Commentary

Over the last 2 years the HTA has been progressing with the planned development of its digital data and technology (systems and architecture) as part of the Development Programme. The planned development had been incremental based on available resources and aimed to future proof business needs. Following the review of the Development Programme in Q1 2022/23 two projects have been identified to support the use of existing and available digital and technological capabilities. These are the adoption of an IT Shared Services model and the stage 2 development of the Regulatory Insight Model and Index.

The move to a shared service model aims to strengthen resilience and capability in the HTA's systems, capacity and capability aiding future and further developments. In the last quarter exploratory conversations have been held with identified health partners to establish appetite and interest in a future partnership. In addition, a draft specification for a future service model has been developed alongside a timeline and outline of the approach to be taken. Although additional resources have been agreed to support this project, these resources are not currently active which is affecting the HTA's ideal timeline although is not anticipated to negatively impact on the readiness of an organisation for transition. It is anticipated that once the additional resource and capacity identified is available and operational the risk will move back to within tolerance.

The proposal to support the development of the next stage of the Regulatory Insight Model and Index is due to be presented to SMT in early November. Failure to resource this project internally and externally will impact delivery of the next phase of development as well as our current and future use of data. Current capacity is a constraint to the early thinking and commissioning of this work and redeploying existing resources to this has the potential to impact on the pace and progress of other priority projects. The decision to continue with this project in 2022/23 and the allocation of resource and capacity to it will influence the level of risk going forward.

Reviews and revisions

(23/02/22) SMT review March 2022

Risks 1, 2 and 4 were discussed in detail. SMT agreed that the impact score of risk 1 should be reduced as the tools in place continue to work; risk 2 likelihood score was also adjusted down; and risk 4 likelihood has been reduced from 3 to 2 reducing overall rating to 8 as key posts have been recruited to.

(19/05/22) SMT review April/May 2022

The SMT reviewed the current register in light of the finalised business plan and agreed the following:

- Risk 2 to be shortened in the summary leaving the detail to remain in the register itself
- Risk 4 it was agreed to separate this risk into a people risk (risk 4) and a digital risk (risk 7) which is more reflective of the current situation
- Risk 6 it was agreed to re-framed to reflect the fact that it is broader than just the Development programme

(08/09/22) SMT review September 2022

SMT reviewed the register at its meeting on 8 September. The following changes were made to the risk scores:

- Risk 1 it was agreed that the likelihood should be increased based upon recent issues that may materialise, which together would increase its likelihood
- Risk 4 was increased. In part the reason relates to the number of recruitments currently underway and the challenge it continues to be to recruit to certain roles. The SMT believed the likelihood is increasing
- Risk 5 has not changed however, SMT recognise the impact that restrictions on recruitment may pose if there is a change in focus of the DHSC and Cabinet Office
- Risk 6, SMT believe that there is a thread which impacts risks 4 – 6 from the potential savings we are being asked to make. The various pieces of work (IT Shared Services, Inspections Review) will be affected should we be required to make further savings

Strategic Aims

Delivery: Deliver a right touch programme of licensing, inspection, and incident reporting, targeting our resources where there is most risk to public confidence and patient safety.

- (a) Deliver effective regulation of living donation.
- (b) Provide high quality advice and guidance in a timely way to support professionals, Government, and the public in matters within our remit.
- (c) Be consistent and transparent in our decision-making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing firmly and fairly with those who do not comply with our standards.
- (d) Inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them and influence them in matters that are important to us.

Development: •Use data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target resources effectively.

- (a) Make continuous improvements to systems and processes to minimise waste or duplicated effort, or address areas of risk.
- (b) Provide an agile response to innovation and change in the sectors we regulate, making it clear how to comply with new and existing regulatory requirements.
- (c) Begin work on implementing a future operating model, which builds our agility, resilience, and sustainability as an organisation.

Deployment: Manage and develop our people in line with the HTA's People Strategy

- (a) Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money
 - Provide a suitable working environment and effective business technology, with due regard for data protection and information security
 - Begin work on implementing a future operating model, which builds our agility, resilience, and sustainability as an organisation

Criteria for inclusion of risks

Whether the risk results in a potentially serious impact on delivery of the HTA's strategy or purpose.

Whether it is possible for the HTA to do anything to control the risk (so external risks such as weather events are not included).

Rank

The risk summary is arranged in risk order.

Risk scoring system

We use the five-point rating system when assigning a rating to the likelihood and impact of individual risks:

Likelihood:	1=Rare	2=Unlikely	3=Possible	4=Likely	5=Almost certain
Impact:	1=Very low	2=Low	3=Medium	4=High	5=Very High

Risk Scoring Matrix						
IMPACT	5. Very High	5 Medium	10 Medium	15 High	20 Very High	25 Very High
	4. High	4 Low	8 Medium	12 High	16 High	20 Very High
	3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
	2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
	1. Very Low	1 Very Low	2 Very Low	3 Low	4 Low	5 Medium
Likelihood						
Risk score = Impact x Likelihood	1.Rare (≤3%)	2.Unlikely (3%-10%)	3.Possible (10%-50%)	4.Likely (50%-90%)	5.Almost certain (≥90%)	

Risk appetite and tolerance

Risk appetite and tolerance are two different but related terms. We define risk appetite as the willingness of the HTA to take risk. As a regulator, our risk appetite will be naturally conservative and for most of our history this has been low. Risk appetite is a general statement of the organisation's overall attitude to risk and is unlikely to change unless the organisation's role or environment changes dramatically.

Risk tolerances are the boundaries for risk taking. The risk appetite statement informs the development of risk tolerances for the HTA and provides guidance on how the risk appetite statement is to be applied in everyday business activities and decisions.

Assessing inherent risk

Inherent risk is usually defined as ‘the exposure arising from a specific risk before any action has been taken to manage it.’ This can be taken to mean ‘if no controls at all are in place.’ However, in reality the very existence of an organisational infrastructure and associated general functions, systems and processes introduces some element of control, even if no other mitigating action were ever taken, and even with no risks in mind. Therefore, for our estimation of inherent risk to be meaningful, we define inherent risk as:

‘the exposure arising from a specific risk before any additional action has been taken to manage it, over and above pre-existing ongoing organisational systems and processes.’

Contingency actions

When putting mitigations in place to ensure that the risk stays within the established tolerance threshold, the organisation must achieve balance between the costs and resources involved in limiting the risk, compared to the cost of the risk translating into an issue. In some circumstances it may be possible to have contingency plans in case mitigations fail, or, if a risk goes over tolerance, it may be necessary to consider additional controls.

When a risk exceeds its tolerance threshold, or when the risk translates into a live issue, we will discuss and agree further mitigations to be taken in the form of an action plan. This should be done at the relevant managerial level and may be escalated if appropriate.

The Fees Paper - Confidential

Human Tissue Authority Board meeting

Date: 3 November 2022

Paper reference: HTA 33/22

Agenda item: 8

Approved by: Professor Gary Crowe

OFFICIAL

Audit, Risk and Assurance Committee update

Purpose of paper

1. This paper provides an overview of the business of the Audit, Risk and Assurance Committee (ARAC) meeting held on 6 October 2022.

Action required

2. The Board is asked to note the content of this report.

Background

3. The Committee discussed the following items as material elements of the meeting.

Internal Audit

4. The Committee received a report from GIAA on the progress of the planned Internal Audits and agreed the proposed change of audit schedule. The proposed

change, to undertake an audit relating to processes relating to living organ donation approval was agreed by the Committee.

External Audit

5. KPMG provided an update on planning for the 2022/23 financial audit and drew the Committees attention to changes to their audit approach this year, in particular the additional requirement to make more active risk-based assessments of areas for substantive testing and the need to include all IT systems that may provide information and data that support the financial statements.

Data Security and Protection Toolkit (DSPT)

6. The Committee received a detailed report from the Executive on HTA's assessment and response 2021/22 and 2022/23 including a detailed improvement and action plan following a "limited" assurance review from Internal Auditors.
7. The Committee discussed the reports in detail and the requirement for HTA to meet these targets.

Strategic Risk Register

8. The revised Strategic Risk Register (SRR) was considered by the Committee.
9. The Committee noted that the Executive review this register each month and amend the risk ratings as required.
10. The Committee noted the actions taken by the Executive to mitigate the potential risks. The Committee asked that future updates provide more clarity on actions to reduce risks currently above agreed tolerance levels, this was felt to be of increased significance given 6 of 7 risks were currently above tolerance.

Other items

11. The Committee received an update on Cyber Security, the Committee noted that the format of the report would be revised and as appropriate aligned with NHS Digital reporting and to meet the requirements of DSPT.

12. The Committee considered a number of policies and procedures including approval of the counter fraud, bribery and corruption strategy and reserves policy and reviewing the gifts and hospitality register.
13. The Committee received a report on the new Governmental Functional Standards (GFS) and how these relate to the work of the HTA.
14. The Committee held a deep dive discussion which primarily focussed on strategic risk 5, financial risk.

Recommendation

15. The Board is asked to note the content of this report.

Human Tissue Authority Board meeting

Date: 3 November 2022

Paper reference: HTA 34/22

Agenda item: 9

Approved by: Ellen Donovan

OFFICIAL

Remuneration Committee Update

Purpose of paper

1. This paper provides an overview of the business of the Remuneration Committee meeting held on 22 September 2022.

Action required

2. The Board is asked to note the content of this report.

Minutes and Action Points of Previous Meeting

3. The Committee agreed the minutes of the previous meeting held on 4 July 2022.

Pay Award for General Grades

4. The Chief Executive provided a verbal update to the Committee on the pay award for general staff. This was paid to all staff, except the Executive, in September's pay.

Organisational Development /Culture Programme

5. The Committee received a report which provided background and insights into the drivers behind the Organisational Development (OD) programme, why the work was commissioned and how it underpins delivery of the mission and values of HTA.
6. The Committee noted the report and welcomed the programme of work outlined across the organisation over the remainder of the business year. RemCo members were keen to see the renewed focus on values and behaviours and stressed the need to ensure that accountability and performance were a key consideration in developing this area further.
7. The Committee were pleased to see a renewed focus on communication, recognising the intention to shift from broadcast to more inclusive and interactive methods that brought the organisation together. This was felt to be especially important as the HTA looks to move forward with its hybrid working approach, acknowledging that the natural opportunities for colleagues to meet and develop professional working relationships are more limited with increased home-working.
8. As the OD work is advanced, RemCo members will be updated on progress at their next meeting, timed for January.

Recommendation

9. The Board is asked to note the content of this report.

Minutes of the meeting of the Human Tissue Authority Board

Date: 14 July 2022

Time: 09.30-11.30

Venue: Virtual via Zoom

Meeting Number: 101

Protective Marking: OFFICIAL

Attendees:

Board Members

Lynne Berry, HTA Chair
Tom Chakraborti
Professor Gary Crowe
Helen Dodds
Ellen Donovan
Dr Charmaine Griffiths
Andy Greenfield
Dave Lewis

Apologies

Professor Deborah Bowman

Observers

Jacky Cooper, Team Leader Human
Tissue Policy and Ethics of Consent,
DHSC
Dylan Parrin, Senior Policy Manager
DHSC

HTA attendees

Dr Colin Sullivan, Chief Executive
Louise Dineley, Director of Data,
Technology and Development
Nicolette Harrison, Director of
Regulation, HTA
Richard Sydee, Director of Resources
TJ O'Connor, Executive Assistant
Alison Margrave, Board Support
(minutes)
Audrey Jessiman, Head of Policy and
Development (items 7 and 9)
Jessica Porter, Head of Regulation
(item 7)
Dr Julie Edgeworth, Policy Manager
(item 7)

HTA Staff Observers

Michelle Lancaster, Regulation
Manager
Rebecca Proud, Regulation Officer

Item 1 – Welcome and apologies

1. The Chair welcomed Board Members, HTA Staff and observers from the Department of Health and Social Care to the meeting.

Item 2 – Declarations of interest

2. The Chair asked Members if there were any declarations of interest of relevance to the agenda; none was declared.
3. In addition, the Board noted new declarations of interest for two Board Members and that HTA records would be updated accordingly.

Item 3 – Chair's Report

4. The Chair provided an oral update on the following items:
 - Chair's forum, gathering all the Chairs of ALB together with a number of interesting presentations from the Cabinet Office.
 - Attending the Audit and Risk Committee meeting and the Remuneration Committee meeting.
 - Development of the shopfloor programme for Board Members so that they can gain a greater knowledge and understanding of HTA's work.

Item 4 – Chief Executive's Report (HTA 20/22 and HTA 20a/22)

5. Dr Colin Sullivan introduced the report and highlighted progress with several workstreams during Q1. He emphasised the work of preparing for the Fuller Independent Inquiry and the Covid Inquiry; completion of the governance Framework document between DHSC and HTA and ongoing EDI collaboration work with colleagues at 2 Redman Place.
6. In response to a question, he provided further information about the preparation work for the Fuller Inquiry and how this additional work is being resourced and managed.
7. In response to a question regarding the HTA's vision and mission he reported that there was broad acceptance of these at the staff day in late June. He reminded the Board that staff had been involved in the preparation of these statements and had been kept informed throughout the process.
8. In response to further questions, he provided additional information and clarity about the potential of for creating shared services partnerships for he HTA's

support functions and the potential of additional requests for advice and guidance such as that which had been received from the Isle of Man.

9. The Board noted the report.

Item 5 – HTA Performance Report (HTA 21/22, HTA 21a/22, HTA 21b/22 and HTA 21c/22)

10. Dr Colin Sullivan introduced the report and provided highlights to Board Members regarding operational performance, the financial position; the review of the Strategic Risk Register; KPI reporting in the data annex; people matters and EDI.
11. In response to a question, he provided further information about staff turnover. This was up a little on previous years and was being monitored, A variety of different reasons were cited at exit interview, and he noted that as a small organisation there were limited opportunities for promotion. He spoke about the cultural and organisational review which was started in late June.
12. In response to a question, he provided further information about certain projects that could be implemented if funds were available.
13. The Board noted the report.

Item 6 – Update from DHSC Sponsor Team

14. Jacky Cooper, Team Leader Human Tissue Policy and Ethics on Consent DHSC, provided an update to the HTA Board regarding the changes in the Ministerial Team. She spoke about the Secretary of State's keen interest in the areas of data, transparency, and digital solutions. She spoke about the review of the civil service, which has been previously announced, and how this could affect the department.

Item 7 – Deemed Consent NI (HTA 22/22 and HTA 22a/22)

15. Jessica Porter, Head of Regulation, introduced the report and highlighted the consultation process undertaken from direct communications to roundtable events. She spoke to the comments received during this process and the

proposed changes to Code F. She corrected one spelling mistake in the proposed revised Code.

16. Audrey Jessiman, Head of Policy and Development, spoke of the next steps including laying of the document in Parliament, proposed communications and the training being offered by NHSBT. She thanked the team responsible for this piece of work.
17. The Board expressed their thanks to the staff for progressing this piece of work so efficiently and effectively.

Action 1

18. The Board approved the revised Code F (Deemed Consent) and the proposed next steps including submitting it to Department of Health & Social Care (DHSC) for it to be laid before Parliament and delivered to the offices of the NI Assembly in September.

Item 8 – Development Programme (HTA 23/22)

19. Louise Dineley, Director of Data, Technology and Development, introduced the report. She stated that the previously reported case for change is still valid, but that HTA needs stronger foundations on which to build future developments. Having robust IT provision and systems is a cornerstone in strengthening the HTA's capability generally and in respect of digital and data development.
20. She spoke to the projects proposed in the report and how the Programme Initiation Document (operational document for delivery) will be worked up and once finalised by the SMT can be shared with the Board via email. She spoke of the proposed timelines and the additional projects which could be implemented if resources were allocated.
21. In response to questions, she provided further detail about possible timelines and the affordability of different elements of the proposed scope of works. The Board spoke of the strategic importance of the proposed programme and the importance of seizing opportunities to improve data and digital intelligence.

Action 2

22. The Board noted the review of the former Development Programme and the reframed work and endorsed the revised scope of work. The Board also

agreed that a Programme Initiation Document (PID), be shared with the Board following agreement by SMT in Q2.

Item 9 – Horizon Scanning (HTA 24/22)

23. Louise Dineley, Director of Data, Technology and Development, introduced the report and spoke of the proposed process for engaging the Board at a strategic level to support HTA's horizon scanning activities. She highlighted the importance of engaging Board Members in the process much earlier than is current practice.
24. The Board members spoke about the importance of utilising their areas of special interest and were supportive of the approach proposed in the report.

Action 3

25. The Board agreed the proposed process for engagement of Board Members on horizon scanning and agreed the proposed next steps contained within the report.

Item 10 – Risk Appetite (HTA 25/22)

26. Richard Sydee, Director of Resources, introduced the report and highlighted the changes to the current risk appetite document to reflect the redefined strategic risks for the business year 2022/23.
27. The Board asked several questions regarding risks 2, 3 and 7 and whether their tolerance level was correct and whether data protection should be captured within one of the risks.

Action 4

28. The Board agreed in principle to the redefined strategic risks for the 2022/23 business year as shown at annex A of HTA 25/22 and asked the Audit & Risk Assurance Committee to consider the questions raised in relation to risks 2, 3 and 7.

Item 11 – Audit and Risk Assurance Committee Update (HTA 26/22)

29. Professor Gary Crowe, Chair of the Audit and Risk Assurance Committee, presented the report to the Board. He provided several highlights to the Board on the Committee's discussion on DSPT (Data Security & Protection Toolkit), internal and external audits, Strategic Risk Register and risk appetite.
30. He referred to the annex appended to the Committee's report which had been provided by the Executive on DSPT. The Chief Executive covered the annex to the report and explained the reasons why HTA had not met the initial submission target date and the remedial work which was being undertaken to address this.
31. The Board noted the report.

Item 12 – Remuneration Committee Update (HTA 27/22)

32. Ellen Donovan, Chair of the Remuneration Committee, presented the report to the Board. She provided several highlights on the Committee's discussion regarding staff matters and the proposed pay award.
33. The Board noted the report.

Item 13 – Minutes of 5 May 2022 (HTA 28/22)

34. The Board agreed the draft minutes as an accurate record of the meeting of 5 May 2022.

Item 14 – Matters arising from 5 May 2022 (HTA 29/22)

35. The Board noted the matters arising report and that all the actions had been completed.

Item 15 – Any other business

36. There being no further business the Chair thanked members for their contributions and closed the meeting. She also thanked all who had prepared papers and attended the meeting.

Date of Next Meeting

3 November 2022 – in person meeting at 2 Redman Place.

Meeting actions

Action 1

The Board approved the revised Code F (Deemed Consent) and the proposed next steps including submitting it to Department of Health & Social Care (DHSC) for it to be laid before Parliament and delivered to the offices of the NI Assembly in September.

Action 2

The Board noted the review of the former Development Programme and the reframed work and endorsed the revised scope of work. The Board also agreed that a Programme Initiation Document (PID), be shared with the Board following agreement by SMT in Q2

Action 3

The Board agreed the proposed process for engagement of Board Members on horizon scanning and agreed the proposed next steps contained within the report.

Action 4

The Board agreed in principle to the redefined strategic risks for the 2022/23 business year as shown at annex A of HTA 25/22 and asked the Audit & Risk Assurance Committee to consider the questions raised in relation to risks 2, 3 and 7.

Human Tissue Authority Board meeting

Date: 3 November 2022
Paper reference: HTA 36/22
Agenda item: 11
Author: Alison Margrave, Board Support

OFFICIAL

Matters Arising from previous HTA Board meetings

Purpose of paper

1. To provide an update to the Board on the actions arising from previous Board Meetings. Colour coding used is blue = completed, green = on target and amber = at risk of not meeting target date.

Decision making to date

2. The SMT agreed this paper on 14 October 2022 for submission to the Board.

Action required

3. The Board is to note the report.

Number	Date Added	Action	Assigned to	Target date	Revised date	Status
B_2022_09	July 22	The Board approved the revised Code F (Deemed Consent) and the proposed next steps including submitting it to Department of Health & Social Care (DHSC) for it to be laid before Parliament.	Director of Data, Technology and Development	Sept 22		Completed. Laid before Parliament on 5 September.
B_2022_10	July 22	The Board noted the review of the former Development Programme and the reframed work and endorsed the revised scope of work. The Board also agreed that a Programme Initiation Document (PID), be shared with the Board following agreement by SMT in Q2.	Director of Data, Technology and Development	Sept 22	December 2022 – subject to recruitment	Recruitment is in progress following unsuccessful attempts earlier in the Summer. The absence of the Project Manager resource and skill is limiting progress of the projects and the development of the PID.
B_2022_11	July 22	The Board agreed the proposed process for engagement of Board Members on horizon scanning and agreed the proposed next steps contained within the report.	Director of Data, Technology and Development			Completed.

HTA meeting papers are not policy documents.
Draft policies may be subject to revision following the HTA Board meeting

Number	Date Added	Action	Assigned to	Target date	Revised date	Status
B_2022_12	July 22	The Board agreed in principle to the redefined strategic risks for the 2022/23 business year as shown at annex A of HTA 25/22 and asked the Audit & Risk Assurance Committee to consider the questions raised in relation to risks 2, 3 and 7.	Director of Resources	Oct 22	Jan 23	Whilst the October ARAC discussed the Strategic Risk Register, they did not specifically discuss these questions in detail. This action will be carried over to the next ARAC Meeting.

HTA meeting papers are not policy documents.
Draft policies may be subject to revision following the HTA Board meeting