HTA
Human Tissue Authority

Board Meeting Conducted in Public 29 June 2023

Human Tissue Authority
Board Meeting Conducted in Public

Date: 29 June 2023

Time: 09.30 – 10.00 Tea/coffee available, registration and networking

10.00 – 12.30 Main meeting (held in public)

13.30 – 15.30 Afternoon Board Session (HTA Board Members and staff only)

Venue: 2 Redman Place, London, E20 1JQ – Thames Meeting Room

Meeting Number: 104

Agenda

Meeting administration

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

Regular reporting

3. Chairs Report (Oral)
4. Chief Executive's Report (HTA 11/23)
5. HTA Performance Report (HTA 12/23)
6. Update from DHSC Sponsor Team (Verbal)

Items for decision

7. Living Organ Donation Update (HTA 13/23)

   Annex A, DRAFT HTA-POL-102 Policy for the assessment of living organ donation cases (HTA 13a/23)

Item for discussion

8. Governance around HTA's Insight Network (HTA 14/23)

Reports from Committees

9. Audit and Risk Assurance Committee Update (HTA 15/23)

10. Remuneration Committee Update (HTA 16/23)

Items for information only

11. Minutes of 9 March 2023 (HTA 17/23)

12. Matters arising from 9 March 2023 (HTA 18/23)

13. Stakeholder Engagement Update (HTA 19/23)

Questions from observers

14. This is an opportunity for the HTA to respond to any pre-submitted questions from observers (oral)

Any other business

15. Any other business (Verbal)

HTA
Human Tissue Authority

Chief Executive's Report

Human Tissue Authority
Board Meeting Conducted in Public

Date: 29 June 2023

Paper reference: HTA 11/23

Agenda item: 4

Author: Dr Colin Sullivan

Chief Executive's Report

Purpose of paper

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

Action required

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

Update on Quarter 4

3. During Quarter 4, we 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.

   One of the most noteworthy changes from previous years was the increase in the target number of inspections in the 22/23 business plan. Whilst recognising this was a stretch target, the number for completion per year increased from 140 in 21/22 to 210 in 22/23. I am pleased to report we achieved the target by year end, 31st March. In addition to completing an increased number of inspections, we also undertook a further 43 inspections linked to license applications assessments (LAAs). This category was previously counted within the overall inspection figure. My thanks to all staff involved, not least, those across the Regulation Directorate for achieving this notable stretch target and showing what is possible. It is a significant achievement.

4. The purpose of the target was: -

   - To stimulate rapid innovation in-year to make inspections more risk-targeted and proportionate, without the need for a change programme to achieve this aim;

   - To drive increased management focus on differentiation in the targeting of inspections; and

   - To give greater sector coverage (whilst being more proportionate and targeted) to provide greater overall assurance.

5. In response, in-year and without a dedicated project team, colleagues developed several innovative approaches which helped to achieve the revised target, with minimal additional expenditure. These innovations included: -

   - Identifying more inspections suitable for a solo inspector.

   - Trialling the use of video tours for certain parts of the visual inspection of human application premises.

   - Changing the approach to what we look at onsite.

   - Increasing the number of geographically linked inspections to reduce time spent travelling.

   - Where possible, removing the need for large, multidisciplinary roundtable discussions – which reduces the footprint of an onsite audit by several hours for hospitals that undertake living and deceased donor transplants.

   - In the HA sector, the two inspection report templates being used for HA-only and HA/Act combined inspections have been consolidated and made easier to complete - reducing the amount of time spent on the quality assurance step of the report sign-off process.

6. The recently commenced Review of Inspections project seeks to further develop innovative approaches whilst reviewing our own homegrown developments. This work is consistent with the DHSC Reform and Efficiency initiative which we are supporting. In addition, to reforming how we undertake our regulation responsibilities we have also focused on reducing costs and developing greater resilience in our support services. In March, the CQC Board agreed in principle to a shared services arrangement with HTA. We have subsequently been refining a cutover plan for shared services in Human Resources which commences roll-out from 1st July 2023.

7. During Quarter 4, the HTA continued to give full support to the Independent Inquiry led by Sir Jonathan Michael into the issues raised by the David Fuller case. We are responding as promptly as we can to regular requests for information and will provide any further advice, as requested, to the DHSC SoS on related matters.

8. I have previously drawn attention to the levels of staff turnover in 2022/2023, not least in Quarter 2. I am pleased to highlight that in Quarter 4 it was down to 8.6%, down from a high of 20% in the summer of last year.

9. In Quarter 4, my external engagements included the first meetings of our new stakeholders' forums. These covered four of our six sectors, namely, Post-Mortem, Human Application, Research, and Organ Donation and Transplantation (ODT). I also attended the BTS / NHSBT Congress in Edinburgh during March. This was an important opportunity to meet with many of the key players in the ODT sector.

Current Issues

10. On 1 June, the introduction of deemed consent for deceased organ and tissue donation for transplantation in Northern Ireland (NI) came into effect. To mark the occasion, the NI Department of Health hosted an event in the Long Gallery, Parliament Buildings, Stormont for organ donation champions. I attended on behalf of the HTA. The HTA has supported this work by revising Code of Practice F (Part 2 for deceased organ and tissue donation). Those excluded from deemed consent legislation are children under 18, people who lack the mental capacity to understand the change in law and visitors to NI and temporary residents. This brings NI in line with the other UK countries, whilst noting the different legislative framework for Scotland.

11. In parallel to the notable revision of Code F for deemed consent in NI, the HTA has also been updating its other Codes of Practice for several very minor changes (which reflect updates to corresponding guidance or legislation) as opposed to any substantive changes. We have been working with DHSC on this and it is anticipated that these can be published over the summer.

12. I attended the Welsh Transplant Advisory Group (WTAG) on 14 June. This brings together the key health sector stakeholders in ODT in Wales and serving Wales.

13. At recent Board meetings, I have mentioned the new Portfolio Management approach which monitors progress against our approved business plan. The same team are also responsible for development of the new business plan with input from colleagues all across the organisation.

You will recall that the draft Business Plan for 23/24 was presented to the Board for approval at the March meeting. We then submitted it for consideration by DHSC. I am pleased to report that during May, the department confirmed approval of the 23/24 HTA Business Plan.

14. DSPT (Data Protection and Security Toolkit) - over the last 6 months the HTA has been preparing for its annual assessment against the Data Protection and Security Toolkit (DSPT). During 22/23, considerable time has been spent on producing evidence of greater compliance and we have engaged the services of an Information Governance Lead and a Project Manager. Activity has included an interim assessment that was completed at the end of February and the collation of evidence in preparation for the internal audit fieldwork during May. This work has been monitored at ARAC meetings. Whilst field work is ongoing and the report is not due until the end of June, the early indications are that HTA has made good progress with a notable improvement in the number of standards being met or partially met compared to last year.

15. We launched a data collection exercise in June to improve and update the data we hold for establishments. We have asked establishments in the Anatomy, Post-Mortem, Research, Public Display and Organ Donation & Transplantation sectors to complete a short questionnaire with simplified answer options. The responses received will inform our assessment allocation and prioritisation and will also inform our understanding of risks and activities within establishments and sectors. The closing date for returns is set for early July, when we will be analysing the data and information provided.

16. The HTA supported the police investigation of the Ekweremadu case that resulted in a trial at the Old Bailey and subsequent convictions under the Modern Slavery Act (2015) for people trafficking for organ donation. The HTA's Head of ODT gave evidence at the trial as an expert witness. In light of these developments, we have responded to several press enquiries including providing material for a BBC Radio 4 File on Four programme. I believe we have robust systems in place, as verified by our auditors, whilst also being open to further refinements to our approach, as exemplified by the paper on today's agenda.

17. As Board members will be aware, a member of the Senior Management Team the HTA's Director of Finance and Resources, Richard Sydee, has recently moved on after six and a half years in post. I am grateful for the considerable contribution that Richard made to the HTA over a sustained period including during the Covid pandemic. We wish him well in his new role with the National Lottery Heritage Fund.

Recommendation

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

HTA Performance Report

Human Tissue Authority
Board Meeting Conducted in Public

Paper reference: HTA 12/23

Agenda item: 5

Author: CEO and Senior Management Team

HTA Performance Report

Purpose of paper

1. This paper informs the Board of the HTA's performance in Quarter 4 (Q4) against our objectives and operational delivery targets and also provides cumulative overall performance against targets for the year, 2022/23.

2. In addition, it provides an early indication of the initial performance against the new performance indicators for 2023/24.

Action required

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

Regulation

4. **Annex A** provides a summary of the Key Performance Indicators (KPIs) and two Performance Indicators (PIs) for Quarter 4 of 2022/23, including the year-end totals. Most of these relate to the Regulation Directorate but Enquiries and Freedom of Information Act (FoI) requests can arise in any area of the business.

5. The headline KPI for 2022/23 of the significantly increased target of 210 inspections was met.

6. The measure of inspections changed from 2022/23 to exclude inspections on new licence applications. Delivering 253 inspections in total (210 inspections on

existing licences plus 42 on new licence assessments) was a significant operational achievement, facilitated by the wider adoption of more proportionate, innovative and efficient approaches, which will be expanded on during 2023/24.

7. Unannounced inspections, in response to specific regulatory concerns, have continued to play a part in our inspection programme, with one unannounced inspection having been carried out in the Human Application sector.

8. Other performance indicators for Quarter 4 of 2022/23 and year-end show a mixed picture. Whilst, most of the year-end performance is close to target, the KPI data on the processing at least 90% of complete new licence applications shows this measure as notably missed. The Quarter 4 performance shows this at 50% (4 out of 8) and the year-end outturn was 60% (19 out of 32 cases). The main issue is that applications are marked as 'complete' when all relevant sections of the application form have been completed. This does not necessarily mean that a licence can be issued as compliance with standards still needs to be assessed. Therefore, even 'complete' applications may not be in a position to be offered a licence for some time.

9. The same issue arises with the licence variation request KPI. We have explored options to change the point at which we 'start the clock' and / or 'stop the clock', to allow time for relevant regulatory activity to ensure suitable compliance with standards before issuing a licence or licence variation. A system change to facilitate this is unlikely to be implemented before the next reporting year.

10. The HTA reviewed and updated its published guidance to the Anatomy sector licensing standards in Quarter 4. This entailed external engagement and feedback from stakeholders.

11. The HTA assessed several complex Living Organ Donation cases during Quarter 4. Decisions were made in all cases, with one case declined.

12. The HTA has actively engaged with the living organ donation sector, including NHS Blood and Transplant, to discuss recommendations to support the development and sustainability of living donor liver transplantation in the UK.

13. The Head of Regulation for ODT gave evidence on the HTA's living organ donation approval process at the recent trial for people trafficking for the purpose of organ donation. (Under the Modern Slavery Act 2015, people trafficking for the purpose of organ donation is one definition of exploitation amounting to modern

slavery). The defendants were convicted under the Modern Slavery Act; the first convictions of this kind in the UK.

14. On 1 July 2022, amendments to the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2004 came into force, inserting a new section 32A and 20A into each Act respectively. This extends the offences relating to commercial dealings in organ transplantation so that they now apply outside of the United Kingdom in certain circumstances. The HTA has been leading on developing and refining the process for referring suspected cases and this work continues.

15. During Quarter 4, the HTA referred 2 cases of potential Human Tissue Act offences relating to living organ donation to the police for further investigation.

16. During Quarter 4 a living organ donation that had been referred to the HTA for consideration took place before HTA approval had been given. Whilst the HTA approved the transplant retrospectively, the facts and circumstances that led to the hospital undertaking the transplant prior to obtaining HTA approval is being investigated by the HTA and the hospital concerned.

17. The HTA was involved throughout Quarter 4 in work to support a wider regulatory response to contamination issues with certain perfusion fluids. This required complex multi-agency activity, involving the Medicines & Healthcare products Regulatory Agency (MHRA) and others. The HTA issued a Regulatory Alert and a Regulatory Update and continues to maintain a watching brief.

18. Pressures on mortuary capacity last winter led to an increase in enquiries and in incidents reported to the HTA. One emergency mortuary licence was issued at short notice and several short-notice and urgent responsive regulatory actions were undertaken. A Regulatory Alert was issued on 10 January 2023 to provide advice and guidance on managing mortuary capacity issues. This topic was also discussed at the Post-Mortem Sector stakeholder engagement forum on 6 February 2023.

19. Finance

The table below is the summary position as at the 31 March 2023 (our financial year end). We have ended the year with a surplus over budget of £438k, below is the breakdown by exception of each component of this surplus.

Table 1: Summary income and Expenditure

	Actuals	Budget	Variance £	Variance %
Income				
Grant-in-aid	**814**	**966**	**(152)**	**(15.73%)**
Non-cash	78	78	-	-
Licence Fees	4,285	4,146	139	3.35%
Other Income	203	191	12	6.28%
Total Income	**5,380**	**5,381**	**(1)**	**(0.02%)**
Expenditure				
Salaries and Wages	3,739	3,882	(143)	(3.7%)
Other staff costs	202	282	(80)	(28.4%)
Other operating costs	137	180	(43)	(23.9%)
IT & Telecoms	344	370	(26)	(6.9%)
Legal / Professional	151	109	42	38.5%
Consultancy	74	10	64	644.3%
Accommodation	173	270	(97)	35.9%
Non-cash	122	78	44	55.1%
Contingency	0	200	(200)	-
Total costs	**4,942**	**5,381**	**(439)**	**(8.15%)**
Net income	**438**	**0**	**438**	

Income

20. Our income has ended the year on budget, despite the reduction in our grant in aid which was returned to the Department of Health and Social Care as part of the reform and efficiencies activity. The short-fall being made up from an increase in income from licence fees across all sectors except for the Public Display and Research sectors where there was a very small drop of less than £2k in each case.

Expenditure

21. We have underspent by £439k against budget. Areas of significant underspend are detailed below:

    - Salaries and wages - £143k, in particular staff salaries were underspent by £169k due to turnover which is offset by an overspend on contingent labour of £64k. The use of temporary staff to cover key roles that have taken time to fill in a volatile market. The balance of £38k relates to Board Members where we are carrying at least 4 vacancies which we expect to fill in the coming months.

    - Other staff costs - £80k underspent is in part due to reduced spend against training (£51k) correlates to the increased workload across the business. The second element is our travel and subsistence costs which are also down against budget by £23k.

    - Legal and Professional costs are over budget by £42k. This is represented by a significant increase in legal advice sought across several areas of work being conducted. Professional fees are on budget.

    - Consultancy costs ended the year overspent by £64k. The majority of the spend relates to the Fuller Inquiry which was previously funded but these funds were returned via our grant in aid. Additional consultancy spend not budgeted for related to changes required to the finance system which totalled £5k.

    - Accommodation costs are £97k below budget. This is a notional variance that has arisen due to changes in how we account for our rent/lease of 2 Redman Place. From 1 April 2022, the HTA has an asset on its balance sheet which represents the lease of space with 2RP. At the end of the year, our rent payments are removed from the Income and Expenditure

Account and transferred to the Balance Sheet thus creating an underspend. It may be that going forward, we reflect this in future budget setting.

- Non-cash cost overspend, relates to the inclusion of the lease and its subsequent depreciation and finance cost (interest).

- The budgeted contingency of £200k was set aside for other pieces of work which were delayed some in part due to the requirement for business cases in adherence to Cabinet Office controls and enhanced DHSC controls.

Outturn

22. Subject to the finalisation of our year end audit, the current underspend is not expected to change significantly.

Other key performance indicators

Debtors

23. Outstanding debt from licensing activities is provided below.

Sector	Number of establishments	Value of debt £	%
NHS	7	£33,779	30%
Government Bodies[1]	1	£4,141	3%
Non-Government Bodies[2]	16	£75,756	67%
Total	**24**	**£113,676**	**100**

24. Of the 7 NHS establishments, 3 (£19k) relate to the 2020/21 financial year, this is a significant reduction; of the 16 Non-Government Bodies, 1 (£7k) relates to 2020/21 financial year, 3 (£26k) to 2021/22 and 12 (£42k) to the year just ended – 2022/23.

[1] Is one ALB, and the account was cleared in June 2023.
[2] Includes Universities and private organisations

25. There has been a significant push in debt collection this year and the end position is a positive one. We continue to chase those that have been outstanding since 2021/22.

Financial Risks and Mitigations

26. As at 31 March 2023, our strategic finance risk was rated 'low' but above tolerance. This was an accepted risk with a review of this tolerance level undertaken in Q1 of 2023/24 and a request for the Audit, Risk & Assurance Committee (ARAC) to recommend to the Board that the level to be increased from 3 to 4. This was accepted by ARAC on 8 June.

Human Resources

27. Due diligence with CQC has continued over the past quarter in a positive manner. A paper has been submitted to SMT with the detail of the proposal. Subject to final approval in early July from the Board of CQC, the plan is to transition services from July starting with the recruitment process. CQC are developing a pack for HTA that will inform HTA Managers and employees of the new process going forward. A communications plan will be developed for HTA staff to ensure clarity. The current HR team will support this transition with further due diligence needed with their Learning and Development and Academy teams in Q2. There is a high-level plan that both organisations are working towards.

28. There are currently 6 vacancies and it should be noted that the volume of applications has increased significantly. The level of interest is encouraging, for example, the Corporate Services Officer role has received more than 100 applications.

29. The last all staff away day continued our organisational development (OD) work with leadership values now added to the framework. This will be agreed at SMT and fed back to the employees at the next all staff away day. Moving forward, our OD work is now focusing on Team Effectiveness and Team Based Working, with some individual team work to further embed the SDI (Strength Deployment Inventory) tool within the organisation.

30. The pay proposal has been agreed in principle and is now with the Department for consideration. This proposal addresses several historical issues that the HTA has faced. This proposal should be welcome news to HTA employees. The cost-of-living payment announced by the Government in early June is being

progressed with a collective submission for all DHSC ALBs to be submitted to the Minister.

31. A pulse survey has been conducted, the results of which are broadly very positive with a few factors to drill down into. These findings were shared with colleagues at the all staff day on 15 June.

Digital, Data and Technology

32. The Data Security and Protection Toolkit (DSPT) is an online self-assessment tool maintained by the NHS that allows organisations to measure their performance against the national data guardian's 10 data security standards. These standards are broken down into 120 assertions that focus on the area where compliance needs to be demonstrated.

33. The HTA is required to complete the DSPT assessment because we have access to NHS patient data and systems. We are required to provide assurance that we are practising good data security and that personal information is handled correctly.

34. The DSPT is an annual assessment which has two distinct stages, the baseline assessment and the final assessment. The baseline assessment was completed on 28 February 2023 and the deadline for the final assessment deadline is 30 June 23. The Government Internal Audit Agency (GIAA) has conducted an independent audit to assess the HTA's compliance against the DSPT and has selected 44 assertions at random which span across all 10 standards.

35. The fieldwork exercise stage was completed on 9 June and the auditors have provided indicative ratings based on the evidence provided and interviews with key policy and process owners. The final report will be published on 30 June.

36. The HTA heavily relies on IT equipment to complete its day-to-day tasks in all areas of the business. The HTA commits to refreshing our desktop IT equipment every 3 years. We commenced the latest refresh in April with further devices procured in June. All our latest devices are now covered under a 3-year warranty providing a cost saving on repairs.

37. We also set our standards in security within our Microsoft estate. A Microsoft secure score is a representation of the organisation's security posture. Similar organisations like HTA could typically score between the 40-55%. The HTA is

and has maintained high scores of over 90% for the past year. We are currently at 93.39% and looking at ways to improve it further.

Communications and Engagement

35. In Q4 we held four sector-focused forums covering Post Mortem, Anatomy, Human Application and Organ Donation and Transplantation. The forums came together virtually, and feedback from attendees was positive overall. A common thread was the importance of collaboration and engagement with the sectors we regulate. A summary of the forums was published as a blog on the HTA website. The team are planning forums across all sectors for Q3 of 23/24.

38. In March 2023, several colleagues attended the NHSBT/BTS congress in Edinburgh and for the first time HTA had a modest stand. Footfall and engagement with colleagues on the stand was “steady” and provided an opportunity to engage with a range of stakeholders.

39. In Q4 the website was independently audited by GDS for accessibility. The report highlighted template issues, which impact all pages of the website and issues with PDFs on the site. The template issues have been addressed and the team is working with colleagues to look at how to make more PDFs accessible. Within the collection of PDF documents, the initial focus is on inspection reports which are documents that command the interest of both licence-holders and the wider public.

40. Communications have supported the delivery of core business, issuing one Regulatory Alert and five Regulatory Updates in 2023 so far. In addition, we have published the HTA business plan for 2023/24 and the revised Code F part one, following the introduction of deemed consent in Northern Ireland.

Governance

41. The Risk Summary document can be found at **Annex C** to this paper. This was reviewed by SMT on 23 May 2023 and Audit and Risk Committee on 9 June 2023.

42. During Q4, the HTA received 7 Freedom of Information (FOI) requests. All except 1 of the FOI requests received were dealt with in line with the statutory timeframe. In Q4, 1 complaint was received by the HTA.

43. The Portfolio SMT process and monthly review meeting has continued, with detailed scrutiny of our performance and reprioritisation of our activities within our available resources. As this process matures, we are continually refining our approach and are now particularly looking to increase our maturity in project management through a standardised lifecycle, best practice tools and dedicated subject-specific training sessions.

44. As previously indicated, the format of **Annex A and B** to this paper have been revised to provide the Board with a wider subset of the data that informs the monthly Portfolio SMT process. The format for 23/24 includes analysis of all KPIs across our various business areas and covers progress updates against each of our agreed projects for the year. **Annex A** to this report covers the 22/23 year-end position and **Annex B** covers the latest, early 23/24 datasets.

Current performance position for 2023/24

45. **Annex B** reports data from month 1 (April) of 2023/24, whilst acknowledging it is still early in the year. The Board will note that there are changes in both the content and style of presentation of KPIs, which now cover all areas of the business.

Regulation

46. For month 1 of 2023/24, one out of the four KPIs for Regulatory Delivery is off track, with the median age of open Corrective and Preventive Action (CAPA) Plans relating to major shortfalls being at 98 days, against a target of 90 days. We know which cases are leading to this excess and are satisfied that effective action is being taken on some of our most complex, and at times, multi-faceted shortfalls. (For example, some of these are cumulative major shortfalls.) These actions should enable us to bring the KPI back on track.

47. We have identified those establishments that will require an inspection in 2023/24 to fulfil our statutory obligation to inspect HA licensed premises at a frequency of no less than once every two years. Whilst only one month into the business year at the time of reporting, we are on track to undertake 72 inspections by year end.

48. Through the Portfolio Management Process and our usual business delivery management, we continue to actively monitor amber and red KPIs to identify and address underlying issues.

Other areas of note

49. The KPI around our surplus against budget is a little misleading as it is the first month of the year and licence fee invoices for the HA sector have just been issued for c£1.4m against our costs for a single month, therefore showing a significant surplus. By Quarter 2, the position will begin to balance out as more cost is incurred.

50. Early project progress across our range of different projects has been acceptable to date, albeit that several indicative start dates have been adjusted to later in the year through our change control process to give a more realistic delivery programme.

Recommendation

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

Annex A – Quarterly Board Data Overview, 22/23 Year End Position

Core Operations

Business Plan KPIs & PIs

		3 On track	7 Amber	1 Off track		
		Q1 22/23	Q2 22/23	Q3 22/23	Q4 22/23	2022/23 Total
KPI	210 Inspections covering all sectors					210 ↑
KPI	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)	85% (50/59)	85% (52/61)	89% (198/222) ↓
KPI	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)	84% (43/51)	84% (42/50)	86% (185/214) ↓
KPI	At least 95% of enquiries are answered within ten working days of receipt	94%(320/340)	87%(261/301)	93%(287/308)	94%(340/362)	92% (1208/1311) ↑
KPI	All FOIs d/w in line with HTA procedures and meet statutory timetable	80% (4/5)	100% (6/6)	100% (4/4)	83% (10/12)	89% (24/27) ↓
KPI	At least 90% of licence variation request outcomes are communicated within 20 working days	90% (55/61)	70% (40/57)	78% (39/50)	97% (61/63)	84% (195/231) ↑
KPI	At least 90% of completed applications are processed within 90 working days of payment	75% (6/8)	80% (8/10)	17% (1/6)	50% (4/8)	60% (19/32) ↑
KPI	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)	100% (75/75)	100% (50/50)	99% (219/221) ↑
KPI	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%(194/194)	100%(188/188)	100% (754/755) ↑
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)	75% (40/53)	99% (73/74)	87% (176/202) ↑
PI	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)	93% (13/14)	83% (5/6)	90% (35/39) ↓

Change Activities

	Project	Sponsor	Oct 22	Nov 22	Dec 22	Jan 23	Feb 23	Mar 23	22/23 Year End Position
Activities	Values and Behaviours	Richard Sydee							Project **completed**
	Independent Inquiry (Fuller)	Nicolette Harrison							Project **continues** into 23/24
	Deemed Consent in NI	Louise Dineley							Project **completed**
	Compliance updates	Nicolette Harrison							Project **continues** into 23/24
	Communications Strategy	Louise Dineley							Project **completed**
	HTA Fees Review	Richard Sydee							Project **completed**
	Review of Inspections	Nicolette Harrison							Project **continues** into 23/24
	Refresh of IT Equipment	Louise Dineley							Project **completed**
	IT Shared Services	Louise Dineley							Project **continues** into 23/24
	HR Shared Services	Richard Sydee							Project **continues** into 23/24
	Factual Accuracy Update - Codes	Louise Dineley							Project **completed**
	Data & Security Protection Toolkit	Louise Dineley							Project **continues** into 23/24
	Explore RIMI	Louise Dineley							Project **continues** into 23/24
All	Portfolio	All SMT							Slippage largely due to capacity constraints

Annex B – Latest Board Data Overview, 23/24 Latest Position

Core Operations

Business Plan KPIs

9 On track	1 Amber	1 Off track

		Apr	May	Jun	Jul	Aug	23/24 YTD
	Operational Delivery						
Reg	222 inspections covering all sectors [measured quarterly against projection for the quarter]	19					19
Reg	100% of panel cases actioned within 10 working days	100% (15/15)					100% (15/15)
Reg	100% of required HA inspections are undertaken during the business year	N/A					N/A
Reg	Median age of open Corrective and Preventative Actions (CAPAs) for major shortfalls should not exceed 90 days	98					98
DT&D	90% media responses provided to deadlines	100% (6/6)					100% (6/6)
DT&D	Server downtime less than 3% (within working hours and excluding planned testing)	0%					0%
DT&D	100% of RTANCA (NHS cyber security alert) notifications actioned / replied to within 48 hours	100%					100%
P&CG	100% of FOIs responded to within 20 working days	100% (2/2)					100% (2/2)

		Apr	May	Jun	Jul	Aug	23/24 YTD
	People & Capability						
Resources	Surplus of income / expenditure no more than 5% of budget	8%					8%
	Debt no more than 3% of income at year end	2%					2%
	Unqualified external audit opinion received	N/A					N/A
	Attrition rate no more than 15%	0%					0%
	Staff sickness no more than 3%	0.01%					0.01%

Change Activities

	Project	Sponsor	Mar 23	Apr 23	May 23	Commentary
Activities	Create a new HTA strategy	Louise Dineley				Project put through Change Control Process, requesting start date amended from April 23' to July 23'
	Public Bodies review	Louise Dineley				Project not yet started – anticipated start date October 23'
	Assessment of our impact	Louise Dineley				The project has received necessary DHSC approvals and the successful consultancy firm will soon be notified that they have been offered the contract
	Establish an insight network	Louise Dineley				As part of the Business Plan, it has been agreed that a stakeholder group will be formed to advise the HTA on topics that arise via the horizon scanning process. As a result, this Project is highly dependant on the revision of the horizon scanning process that is being completed as part of BAU activity from April 2023
	Data collection exercise	Nicolette Harrison				A sector-focused data collection exercise to inform our assessment of risk. Questionnaires due to be issued and data returned during Q1
	Review of inspections	Nicolette Harrison				External consultants have been appointed following a competitive tendering exercise. Project due to start in Q1
	Independent Inquiry (Fuller)	Nicolette Harrison				Continuing activity to provide evidence and input into Sir Jonathan Michael's Independent Inquiry and take forward other activities as set out in the HTA's advice to the Secretary of State for Health and Social Care in December 2021
	Retained EU Law Bill	Louise Dineley				Work may not be required – Project put back to pipeline
	Windsor Framework	Louise Dineley				Work may not be required – Project put back to pipeline

	Project	Sponsor	Mar 23	Apr 23	May 23	Commentary
Activities	IT strategy requirements	Louise Dineley				Project not yet started – anticipated start date January 24'
	Records management review	Louise Dineley				Project not yet started – anticipated start date June 23'
	Finance system review	Richard Sydee				Project not yet started – anticipated start date July 23'
	People strategy development	Richard Sydee				Project not yet started – anticipated start date January 24'
	Performance management review	Richard Sydee				Project put through Change Control Process, requesting start date amended from April 23' to Sep 23'
	Data & Security Protection Toolkit	Louise Dineley				Check and Challenge sessions have been held with DSPT Leads to address residual actions and move towards increased compliance against DSPT standards. The focus during April is to ensure that colleagues have an opportunity to review policies and key documents prior to approval and that training plans are rolled out ahead of the DSPT Internal Audit on 25 Apr
	Develop RIMI (Regulatory Insight Model & Index)	Louise Dineley				Project put through Change Control Process, requesting start date amended from April 23' to July 23'
	Start the outsource of IT	Louise Dineley				Project put through Change Control Process, requesting start date amended from April 23' to July 23'
	Outsource HR	Richard Sydee				Project put through Change Control Process, requesting start date amended from April 23' to July 23'
All	Portfolio	All SMT				Overall RAG status for the Portfolio remains at Amber, however, work will need to be undertaken early in Q2 if more Projects are subject to Change Control and anticipated start dates pushed further back

Red	Amber	Green	White
• **Headline:** There is significant risk that the overall Activity will be delivered late or will fail to deliver everything within scope against the agreed baseline plan.	• **Headline:** There is a risk that one or more milestones may be late, or that the full scope will not be delivered. However, there is a good possibility of implementing mitigations to bring the plan back on track to meet the schedule and delivery as planned.	• **Headline:** Overall Activity is on track to be delivered against the baseline plan and there is no or minimal risk of milestones being delivered late.	• **Headline:** Activity not live

Annex C

Strategic risk register 2023/24
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	**9 - Medium**	Director of Regulation	Below tolerance	**10**	⇔⇩⇔⇔
R2: Failure to manage an incident	Delivery, Development and Deployment objectives	**6 - Medium**	Director of Regulation	At tolerance	**6**	⇔⇔⇔⇩
R3: Failure to manage expectations of regulation	Delivery (e) and Development (c)	**9 - Medium**	Director of Data, Technology & Development	At tolerance	**9**	⇔⇔⇔⇔
R4: Failure to utilise our staff capabilities effectively	Delivery, Development and Deployment (a, c, and d)	**9 - Medium**	Director of Resources	At tolerance	**9**	⇧⇔⇩⇔
R5: Insufficient or ineffective management of financial resources	Deployment (b) objective	**4 - Low**	Director of Resources	Above tolerance	**3**	⇔⇔⇔⇔
R6: Failure to take advantage of opportunities that allow the HTA to be an efficient regulator responsive to change and aware of the impact that it has on the sectors and activities that it	Development (a-d) objectives	**9 - Medium**	Director of Data, Technology and Development	At tolerance	**9**	⇔⇔⇔⇩

Risk area	Strategy link*	Residual risk	Risk owner	Status	Tolerance	Trend**
regulates to ensure public trust and confidence is maintained						
R7: Failure to optimise the safe use of existing and emerging 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**	⇔⇔⇧⇔
R8: Failure to deliver the agreed Business Plan	Delivery, Development and Deployment objectives	**9 - Medium**	Deputy Director of Performance and Corporate Governance	Above tolerance	**6**	⇔
R9: Failure to adhere to our corporate responsibilities	Delivery, Development and Deployment objectives	**9 - Medium**	Director of Resources	Above tolerance	**6**	⇔

* 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**	**3**	**9 - Medium**
Tolerance threshold:					**10 - Medium**

Commentary
Below tolerance. We believe we have a sound regulatory framework, which we continue to evolve in response to emerging risks and our own desire to continue to be risk-based, proportionate and data-driven. We have not identified any underlying or systemic failures or weaknesses in our approach to regulation that would contribute to a loss of public safety and confidence. We received an assessment of substantial assurance on the previous internal audit on key regulatory processes (final report issued 16 April 2019). We received an assessment of moderate assurance on the internal audit on the Effectiveness of the Inspection Process (final report issued 11 April 2022). Three out of the five recommendations have been accomplished on time, with two having an agreed deferred due date during the 2023/24 business year. Recent activity with the potential to raise public concern about the changing nature of risk in the Living Organ Donation sector has included information in the public domain concerning people trafficking for organ donation and changes to the offences in the Human Tissue Act to introduce an extra-territorial offence for organ tourism. The HTA continues to play a significant role in multi-agency efforts to address these issues as well as undertaking actions ourselves to address the changing nature of risk and to ensure clear, robust and proportionate messaging. The recent internal audit on the LOD approval process (final report issued 28 March 2023), including our internal review, gave moderate assurance overall, recognising that whilst our review and processes were robust, the risk profile of this activity was changing. We are in the process of making changes to our processes, including training for Independent Assessors and HTA staff and Board members involved in LOD approvals, to implement the recommendations of this audit. This will be covered in a paper to the Board in June 2023.

The HTA is continuing to evolve our approach to inspection, one of our core regulatory tools, introducing Evaluated Self-Assessments (EVAs) this year. We are further increasing our inspection coverage to 222 inspections on existing licences, plus full assessment of all new licence applications. The significant increase in inspection coverage over the last two years, plus the continuing publication of inspection reports and updates to the website to make these more visible, help provide public reassurance, as do the regular publication of data on incidents and our ongoing communications and engagement strategy.

The new suite of KPIs, reported quarterly to the Board and published in those Board Papers, provides public assurance on our delivery of core regulatory functions.

We prepare suitable public and media comment, at an appropriate time, on those cases we refer to the police for further investigation and which are taken forward for prosecution, ensuring alignment of messaging where appropriate with other relevant stakeholders.

We continue to support Sir Jonathan Michael's Independent Investigation into offending at a hospital mortuary and continue to pursue a programme of related activity, including with wider sector stakeholders, as set out in our published advice to the Secretary of State in December 2021.

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, adopting a wide range of approaches for dealing with issues of concern, including investigations and unannounced inspection where relevant.

SMT believes this risk is now reduced to just below tolerance.

R2: There is a risk that we will be unable to manage the lifecycle of a significant 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	**2**	**3**	**6 – Medium**
Tolerance threshold:					**6 – Medium**

Commentary
At tolerance. This risk concerns our ability to respond to and manage the whole lifecycle of incidents, irrespective of their nature or cause i.e. these are not necessarily incidents relating to our regulatory remit. Given this risk concerns our ability to respond to an incident whilst maintaining delivery of core business objectives, we believe it is within the HTA's control through the use of the Critical Incident and Business Continuity Plans (or based on those approaches). Hence we have set a low tolerance level. The HTA believes that our incident management response plans have been tested and found effective through their deployment in several different circumstances over the past few years. These have included managing the impact of the pandemic and related restrictions, in their adaptation for use in managing the potential impacts of EU Exit following the end of the Transition Period and in our mobilisation planning in preparation for the Fuller trial. We have rewritten our Critical Incident Response Plan and tested it during 22/23 with a specialist consultant and will complete a similar exercise for our Business Continuity Plan in Q1 23/24. Moving forward we will review both procedures annually and undertake a test with all staff each January to ensure that we are sufficiently prepared to manage incidents as they arise. 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. Sir Jonathan Michael's Independent Inquiry into the circumstances of Fuller's offending and any related wider concerns about settings in which the deceased are managed is still continuing and is expected to report on Phase 1 during 2023 and on Phase 2 in 2024. Given there are also other criminal proceedings concerning unrelated matters within our broader remit, we believe there is still the potential for significant impact of an incident, on our corporate objectives, either from those causes or others of which we may still be unaware. Hence the residual risk is now at the tolerance level, a reduction unchanged from the last review.

R3: There is a risk that we will fail to manage public and professional expectations of human tissue regulation stemming from limitations in current legislation, misperception of HTA regulatory reach and innovations in the use of human tissues and cells

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

Commentary– to be updated based on agreement of the risk
At tolerance. The HTA is approaching the end of the first year of delivering and embedding its Communications & Engagement Strategy. The strategy is underpinned by a commitment for more proactive and open in our communication and engagement with professionals and the public. In the last year this has been tested through day to day operational activity with improvements informed and impact evidenced through website analytics, feedback and a better understanding of how HTA communication and engagement channels are used. A similar approach has been adopted in our engagement with professionals with the establishment of sector based forums and roundtable events. These forums and events have been used to explore specific and emerging issues identified through horizon scanning and specific issues relating to the regulatory approach, sector based practice or the legislative framework. The combined impact of this work reflects an opportunity to clarify and confirm the vision and mission of the HTA and how we work to deliver the safe use of tissues and cells. The HTA acknowledges that to continue to regulate effectively it is important that it understand the impact of its activities whilst at the same time continuing to be responsive to innovation and growth across Life Sciences. The HTA has recently started a piece of work that seeks to assess the impact of the HTA as a regulator and its activities. This will culminate in a publication the aim of which will be to share insight and feedback on the regulated activities and sectors and promote public confidence in the safe use of tissues and cells. Looking ahead at 2023/24 the HTA will be reviewing its Strategy. This will set the direction of travel for the next 3 years and potentially beyond as well as showcasing the ongoing importance of regulating the use of human tissues and cells. SMT consider this risk to be at tolerance.

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	**3**	**3**	**9 - Medium**
Tolerance threshold:					**9 – Medium**

Commentary
At tolerance. We start of the 2023/34 business year with far fewer vacancies to fill that the same period last year. Churn and recruitment have returned to within expected tolerances, and with the exception of one IT post, we have been able to successfully fill most vacancies from the initial recruitment round. Retention of colleagues will remain an issue, our overall package of salary and benefits remains competitive across the public sector sphere in which we operate – although headline gross pay does not always seem competitive with the NHS. Our revised approach to advertising, and the work to review our salary bands, will manage internal and external expectations around salary – although the continued absence of real terms pay progression to band maximum will likely mean that churn will remain an issue and the lack of progression within the organisation a barrier to retaining necessary internally developed skills. We must continue to acknowledge that a number of our functions rely on single individuals and that unexpected departures in key roles will inevitably impact on delivery of some key outputs in the short term – this risk is further exacerbated by the difficulty current DHSC controls on the use of contingent labour. The transition to outsourced shared services should not impact significantly on key HR operations as we transition and in the medium term we feel this will provide a greater breadth of options and services available to our colleagues. There will need to be careful management of areas such as corporate training and organisational development to ensure that this is not lost sight of as internal HR colleagues are required to focus more on transition and handover to CQC.

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 2023/24 have been agreed and delegation letters to Directors issued. Our Grant in Aid (GIA) funding from the Department has initially been confirmed at previous levels and we have been provided with cover for asset purchases (Capital DEL - £30k) and depreciation and amortisation costs (Ring Fenced RDEL). Submissions have been made to Ministers regarding options to generate reductions in GIA delegations for 2023/24 and 2024/25 and we await the conclusion of that exercise. The position of the HTA is to make no reductions in the 2023/24 GIA. The budget for 2023/24 has absorbed a number of pressures, including additional costs related to the support of the Independent Inquiry, these were met by the DHSC last year. We have part funded a number of work programmes at the start of the year with the expectation that underspends will emerge though staff churn, and that licence fee income will again significantly overshoot our estimate. This will need to be carefully managed through the first and second quarters of the financial year and could require decisions to pause some programmes work before completion to ensure that the HTA does not exceed its spending controls. The departure of the incumbent Director of Finance & Resources will lead to additional workload pressures on the team for the remainder of the year – both in terms of the gap before the new Director starts and the onboarding process for the new incumbent.

R6: Failure to take advantage of opportunities that allow the HTA to be an efficient regulator responsive to change and aware of the impact that it has on the sectors and activities that it regulates to ensure public trust and confidence is maintained

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

Commentary
At tolerance. This risk has been updated and redefined for 2023/24 to reflect a central priority supporting efficiency and reform. As with risk 3 the HTA has progressed and delivered a number of projects in the post pandemic period reflecting changes in the way that it works and to ensure it remains responsive to opportunities for working differently. The 2023/24 Business Plan includes a number of projects that will impact this direction of travel. Activities under risk 3 and this risk 6 coalesce to support the HTA's vision and mission. It is anticipated that updates on the risk will reflect the progress of identified projects and align with updates and actions identified across other risks specifically risks 3, 4, 5 & 7. This alignment is critical as in previous years the availability of resources (people and financial) have been significant factors in setting the pace and appetite for change. A further consideration and alignment opportunity for the HTA will be with the myriad of central initiatives and programmes that see to take advantage of economies of scale and consolidation of improvement opportunities and skills.

R7: Failure to optimise the safe use of existing and emerging 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
Above tolerance. 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. Two projects were identified in 2022/23. These were (1) the adoption of an IT Shared Services model and (2) stage 2 development of the Regulatory Insight Model and Index. As identified under risk 6 progress has not been possible due to resource constraints. The HTA's IT function has been an area of consistent pressure and over commitment of internal resource for a number of years. As part of the 2023/24 business plan there has been confirmation of a substantive Head of IT position. The identified resource is positive however given the competitive IT recruitment market, successful recruitment is a risk. A revised recruitment plan and approach has been identified and will be shared with RemCo. As with risk 6 the HTA's ability to optimise the use of existing and emerging data, digital and technology opportunities is largely reliant on investment and resource. There is a clear vision and confidence in what could be delivered although the reliance on single roles in this area and wider ambitions means that substantive recruited resource is at capacity. At the start of 2023/24 this risk is above tolerance.

R8: Failure to deliver the agreed Business Plan

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	4	12 – High	**3**	**3**	**9 – Medium**
Tolerance threshold:					**6 – Medium**

Commentary
Above tolerance. The 23/24 Business Plan has been created through a codesign process involving Board and staff such that we are confident that it is both challenging but achievable. We operate a formal Portfolio Management approach to the management of our Business Plan delivery, with explicit processes and best practice outputs tracking progress and scrutiny at Business Delivery Team (middle management) fortnightly, Portfolio SMT (senior management) monthly and Board quarterly. Portfolio Management allows us to be flexible in-year so that as we are reviewing our performance, we can also consider additional requests and pressures as they arise, refining our Business Plan through change control and redeploying resources as needed. To date, progress to deliver the 23/24 Business Plan has been noted as acceptable, albeit that a number of indicative project start dates have been adjusted through change control to later in the year. This risk is currently considered slightly above tolerance on the basis that we have an ambitious Business Plan and anticipate that any repetition of staffing issues from 22/23 or the wider financial pressures and the drive for efficiencies from government may mean that we have to scale back our ambitions in-year. It is hoped that we will be able to bring this risk back to tolerance as we progress through the business year and start delivering outputs.

Reviews and revisions

(25/04/23) SMT review April/May 2023

At its meeting in April, the SMT reviewed each of its Strategic risks. There was discussion around whether we have sufficient breadth of risk and whether a risk that focused on data and digital was needed in addition to the risk around delivery of the Development programme. It was agreed that each risk owner should review their risk descriptions and in addition create 2 new risks around business plan delivery and strategy – strategic direction. A risk focussing on compliance is to be discussed at the next meeting.

(23/05/23) SMT review May/June 2023

At its May meeting, the SMT agreed the re-wording of risk 2 and a reduction in the likelihood. Risk 4 has been amended to reflect not just recruitment and vacancies but to reflect risks around the workforce.

Risk 5 has been re-cast, however, SMT felt that the tolerance level was too low and that this will be brought to ARAC in June to discuss a recommendation to the Board to increase it to 4.

Risks 6 has been split into two (risk 6 and risk 8) to reflect risks around our strategy and our business planning.

There is a final risk which requires further discussion. The risk update paper presented to ARAC in June will refer to this risk and the need for discussion.

HTA
Human Tissue Authority

Living Organ Donation Update

Human Tissue Authority
Board Meeting Conducted in Public

Date: 29 June 2023

Paper reference: HTA 13/23

Agenda item: 7

Author: Jessica Porter, Head of Regulation
Sumrah Chohan, Transplant Manager

Living Organ Donation (LOD) update

Purpose of paper

1. To update the Board on important issues and developments in the area of LOD, and the work undertaken so far to refine and strengthen systems and processes.
2. To ask the Board to approve the updated Policy for the assessment of living organ donation cases.

Decision making to date

3. There have been several conversations with SMT during the past 12 months which touch on a number of these issues.

Action required

4. The Board are asked to approve the revised Policy for the assessment of living organ donation cases (HTA-POL-102), available at Annex A.
5. The Board are asked to agree the proposed changes, which have been made in response to lessons learnt from recent experiences and in recognition of the increased risk posed by the growing threat of human trafficking for the purpose of organ removal.

Background on new and emerging risks

UK citizens travelling overseas for transplantation

6. On 1 July 2022, amendments to the Human Tissue Act 2004 (HT Act) and the Human Tissue (Scotland) Act 2006 came into force, inserting a new section 32A and 20A into each Act respectively.

7. These amendments extended the offences set out in Section 32 of the HT Act and Section 20 of the HT (Scotland) Act (HT (S) Act to acts done by defined classes of persons outside of the United Kingdom.

8. These offences relate to financial or commercial dealings in human material for transplant, such as buying or selling human organs. The amendment only applies to human organs, it does not apply to tissues and cells.

9. In practice, this means that a person habitually resident in England, Wales or Scotland, or a UK national not habitually resident in Northern Ireland, will be committing an offence if they:

    a) Give, receive, seek or offer payment or reward for donating organs for transplantation;

    b) Initiate or negotiate an arrangement involving the giving of a reward for the supply of or offer to supply any part of a human body for transplantation, or take part in the management or control of an organisation whose activities include the initiation or negotiation of such arrangements; or

    c) Publish or distribute an advert inviting people to supply or offer to supply part of a human body for transplantation or reward or indicating that the advertiser is willing to initiate or negotiate such an arrangement.

10. Whilst fewer than ten cases have been referred to the HTA so far since July 2022, the numbers of cases are higher than anticipated.

11. The HTA is actively engaged in further work with the Department of Health and Social Care (DHSC) and NHS Blood and Transplant (NHSBT) to raise awareness of this issue across the transplant community and the public.

12. This change in the statute has led to a notable increase in activity and hence in resource pressures on the LOD team.

Addressing the risk of people trafficking into the UK for the purpose of organ donation

13. During 2022/23, the HTA LOD team undertook a targeted and structured review of LOD cases with certain features that had been submitted for HTA approval over the previous five years.

14. That internal process aimed to identify if there were any indications of systemic weakness in HTA processes, for example, if cases that should have been referred to a panel of Board Members for decision had not been, or to identify if there were indications of any other major concerns with the internal processes. No systemic issues were identified although areas with scope for improvement were identified. All cases that had, by law, to be referred to a panel for decision had been referred.

15. Alongside this piece of work, other immediate actions were also put in place. These included holding Regulatory Decision Meetings (RDM) for all living donation cases where the donor was travelling from overseas, all cases from the private sector and all cases submitted from a particular NHS Trust. RDMs are a standard part of the HTA's regulatory decision making and escalation processes across all sectors we regulate. These meetings are attended by the Director of Regulation and/or Head of Regulation in addition to the LOD team.

16. Later in 2022/23, these criteria were amended, with RDMs continuing to be held for cases with an overseas donor and cases from the private sector.

17. Additionally, the HTA has seen a very significant increase in the number and complexity of enquiries in the LOD sphere, particularly in relation to complex overseas cases. These encompass all stages of the LOD pathway, including dealing with enquiries and issues from before the potential donor arrives in the UK, as well as after their arrival.

18. The Board should also note that the HTA is working closely and actively with other agencies to continue to strengthen LOD-related processes, including UK Visas and Immigration, the National Crime Agency, NHSBT and DHSC.

19. This significant increase in level and complexity of demand-led and proactive activity has further increased the resource pressure on the LOD team.

Review of Policies, procedures and guidance

20. The HTA Board is responsible for the Policy for the assessment of living organ donation cases (policy HTA-POL-102).

21. The Executive has undertaken a comprehensive review of this policy in response to the activities noted above and to implement recent learning. The revised policy has undergone legal review.

22. The Executive believes that the changes proposed make this policy more robust, with the additional detail helping to reduce the risk of approval of cases that may not meet the statutory tests or may involve people trafficking for the purpose of organ donation.

23. Three main changes have been to:

    i) provide additional clarity on which cases should, as a matter of HTA policy, be referred to panel (the so-called 'retained cases') by adding more detail to the section on retained panel cases.

    ii) provide clarity around what we mean by, and how to interpret, certain terms, such as 'economic dependence'.

    iii) provide for the Executive to make decisions to refuse a case, undertaken through a RDM process, for cases that would otherwise not need to be referred to panel.

24. We do not anticipate that these changes will of themselves increase the number of cases referred to panel for decision. However, the Board should note that this is an area of significant emerging risk and so we cannot be certain that number or complexity of cases requiring panel consideration will not increase.

Training

25. The LOD Team has planned and is delivering a significant amount of training and awareness-raising sessions across the sector.

26. Further training and awareness-raising for the Board will be covered in separate training organised by the LOD Team.

27. Two Independent Assessor (IA) training days were held in May and June, which has resulted in 19 new IAs being trained. There was a renewed emphasis on the purpose of the role, as well how to look for signs of trafficking through suitable challenge and probing.

28. Targeted, mandatory refresher training will be delivered to all existing IAs during this business year, to remind IAs of their role, namely to explore the risk factors on which the HTA needs to make a decision. This training will reinforce the importance of the role in identifying potential instances of people trafficking for organ donation as well as raising awareness of risk signs and indicators of other potential unlawful acts in connection with living organ donation.

29. The Head of Regulation attended, and presented at, a four-day course in June, organised by the Metropolitan Police, covering the investigation of Modern Slavery Offences.

30. The Head of Regulation has assisted in delivering four training and awareness sessions, in conjunction with the Metropolitan Police, on the risks of offences relating to LOD to NHS staff at one NHS Trust. A session was also delivered to staff at another NHS Trust.

31. In May, the Head of Regulation gave a presentation at the UK Living Kidney Donor Network Meeting, providing a number of current, anonymised scenarios for the clinical audience to engage with. This reinforced the importance of early contact with the HTA in complex overseas donor cases or any other challenging issues clinical teams may be facing that fall within the HTA's remit.

Additional checks

32. Some changes have been made to the HTA's internal processes to allow for the capture of risk factors in our case management (CRM) system and to provide a proportionate amount of additional scrutiny of cases prior to decision.

33. Two changes have been made to the CRM system.

    i) The first allows the LOD team to flag cases that meet certain criteria as high-risk to help identify and track these applications and increase visibility.

    ii) This functionality enables such higher risk cases which are also panel cases to be readily identified as such by the referring Officer and the panel themselves. This enables the panel to the importance of reviewing all relevant paperwork pertinent to decision making, including the Independent Assessor report, referral letter and donor declaration, when assessing these cases.

34. We have introduced a weekly quality assurance sample check by the Transplant Manager prior to a formal decision being made by the Living Donation Assessment Team.

Next steps

35. A review of both HTA Guidance documents for transplant teams and Independent Assessors (one for England, Wales and Northern Ireland and the other for Scotland) has begun. This will include a fundamental revision of content and layout. This will be a significant piece of work.

36. Changes will include strengthening the guidance in several areas, for example making clear that affidavits in isolation will not be accepted as proof of a claimed relationship and that translators must be professional translators who are independent of both the donor and recipient and of the clinical team.

37. We will publish these by the end of the calendar year once we have consulted with relevant colleagues in the sector.

38. A communications plan is being developed with the HTA Communications team to provide regular updates throughout the year to the sector.

Recommendation

39. The Board are asked to note the content of this paper and approve the revised Policy at Annex A.

Annex A

Draft HTA Policy for the assessment of living organ donation cases

HTA Policy 102

HTA Policy for the assessment of living organ donation cases

Please note: The yellow highlight indicates areas that are either new or have undergone extensive revision. Where minor changes have been made for clarity these have not been highlighted.

Purpose

1. This policy sets out the Human Tissue Authority's (HTA's) interpretation of the legal requirements for the assessment of living organ donation cases and its policy requirements in discharging these responsibilities. This policy is informed by independent legal advice.

2. More detailed guidance on how this policy translates into practice is provided in HTA Standard Operating Procedures (SOPs) and associated guidance. For external stakeholders, the documents 'Guidance for Transplant Teams and Independent Assessors' and 'Guidance for Transplant Teams, Independent Assessors and Accredited Assessors in Scotland' provide clarity on how they should apply the policy in practice.

3. The purpose of this document is to set out the HTA policy on the assessment of living organ donation cases. The policy describes the approach that applies to all cases and the additional requirements for certain categories of panel cases.

The Human Tissue Act 2004

4. The Human Tissue Act 2004 (the Act) sets out the legal framework for the storage and use of human organs and tissue from the living and for the removal, storage and use of human organs and tissue from the deceased. The Act covers England, Wales and Northern Ireland. There is separate legislation in Scotland – the Human Tissue (Scotland) Act 2006 and associated Regulations and Orders.

5. Under section 33 of the Act, a person commits an offence if they remove an organ from a living person for the purpose of transplantation. The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations) is the secondary legislation that sets out the requirements that must be met in order for the legal restriction on living organ donation to be disapplied. The relevant extract from the Regulations is attached at **Annex A**.

6. Scottish law covering living organ donation is similar to the law in the rest of the UK, although there are some significant differences, particularly with respect to adults lacking capacity and children, who are only able to donate organs removed from their body out of clinical necessity, known as domino donation. The HTA assesses living organ donation cases on behalf of Scottish Ministers. The Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 is the secondary legislation that sets out the requirements that must be met in order for the legal restriction on living organ donation to be disapplied.

7. The HTA's role is to disapply the legal restriction on transplants of organs involving a live donor where it is satisfied that the conditions set out in the Regulations have been met.

8. Specifically, Regulation 11 requires that:

   a) A registered medical practitioner who has clinical responsibility for the donor must have caused the proposed donation to be referred to the HTA.

   b) The HTA is satisfied that:
      i. No reward has been given or is to be given; and
      ii. that where transplantable material is removed.
         i. Consent for its removal for the purpose of transplantation has been given; or
         ii. its removal for that purpose is otherwise lawful.

   c) When making its decision, the HTA must take into account a report from a qualified person. The HTA uses the term Independent Assessor (IA) to designate a qualified person in connection with assessing living organ donation cases. The IA must have interviewed the donor (or person giving consent, if different from the donor) and the recipient. The Regulations set out that the IA report must cover certain specified matters, including information about any evidence of duress or coercion, information affecting the decision to give consent and any evidence of an offer of a reward.

d) The HTA must give notice of its decision to both the donor and proposed recipient (or any person acting on their behalf) and to the registered medical practitioner who referred the proposed donation to the HTA.

9. Similar provision exists in Regulation 2 of the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006.

10. The HTA must be satisfied that all living organ donors have given valid consent for the removal of their organ for transplantation. For consent to be valid, it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. [Regulation 11(3)(b)(i) and Code of Practice A: Guiding Principles and the Fundamental Principle of Consent.]

11. While the report from the IA is a key component in the HTA's assessment of living donation cases, the HTA is free to seek appropriate additional information direct from the donor and/or the recipient before reaching a decision, although this is not usual. Further information is usually sought from the IA or the Living Donor Coordinator. This document (HTA-POL-102) describes the circumstances in which additional information may be sought. In all cases, the HTA will discharge its duties in line with the principles of best regulatory practice; which the Act defines as including the principles that regulatory activities be transparent, accountable, proportionate, consistent and targeted only at cases where action is needed. [Human Tissue Act s38(2)].

12. In reaching a decision about whether it is satisfied in relation to the tests described, the HTA interprets satisfied to mean satisfied on the balance of probabilities when considering the tests in their entirety. For each individual test, the HTA will consider whether it has sufficient evidence to be satisfied. In situations where it is not satisfied, the HTA will provide its reasoning as part of its notice of decision set out in Regulation 11(5).

13. Regarding duress and coercion, the HTA is required to make a judgement about whether the donor has exercised his or her own free will in making the decision to consent to organ donation, or whether external influences exist which are acting on the donor strongly enough to say that this is not the case. *There does not need to be evidence that there is no duress or coercion.* Instead, the HTA must consider whether there are any circumstances that cause the decision maker to have concerns, such that it cannot be satisfied there is no duress or coercion.

14. The need for the HTA to be satisfied on these points necessitates an exploration of the donor's motivation to donate and any external pressures they may face. There is no directly relevant case law regarding duress and coercion in relation to consent to living organ donation. In line with the HTA's regulatory decision procedures, the HTA will seek independent legal advice on the adequacy of its evidence in every instance where it is minded to turn down an application because it is not satisfied the donor's consent has been freely given.

15. Section 32 of the Act creates offences relating to financial or commercial dealings in organs for transplantation, for example payment or reward for organs intended for transplantation. Reward is defined as 'any financial or other material advantage' [Section 32 (11) Human Tissue Act]. A payment of money will constitute reward even if it is a trivial sum because the word material only refers to the word advantage. Any non-monetary benefit has the potential to be properly described as a reward for the purposes of Section 32 if it could amount to a material advantage. A like offence is created at section 20 of the Human Tissue (Scotland) Act 2006.

16. This means a person will commit an offence if they:

    a. give or receive a reward for supplying, or offering to supply, organs for transplantation;

    b. seek to find a person willing to supply organs for transplantation for reward;

    c. offer to supply organs for transplantation for reward;

    d. initiate or negotiate an arrangement involving the giving of a reward for the supply or offer to supply any part of a human body for transplantation, or take part in the management or control of an organisation whose activities include the initiation or negotiation of such arrangements; or

    e. publish or distribute an advert inviting people to supply or offer to supply part of a human body for transplantation or reward, or indicate that the advertiser is willing to initiate or negotiate such an arrangement.

17. On 1 July 2022, amendments to the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 came into force, inserting a new section 32A and 20A into each Act respectively. These amendments extended the offences set out in Section 32 and Section 20 to acts done outside of the United Kingdom in certain circumstances. This means a person habitually resident in England,

Wales or Scotland who is a UK national and not habitually resident in Northern Ireland, will be committing an offence if they do any of the matters outlined in paragraph 16 above, outside of the United Kingdom.

18. The Act does permit donors to receive reimbursement for expenses, such as travel costs and loss of earnings, which are incurred in connection with the donation. While the Act does not restrict who may reimburse expenses, NHS England, and relevant agencies in the other nations of the UK, have policies and procedures in place to reimburse living donor expenses. For NHS cases, this should make reimbursement by other means unnecessary. However, if expenses are reimbursed by other means, such as fundraising or from the recipient or their family, the HTA may request evidence to prove that the donor has not financially or materially benefitted from the donation.

19. In assessing whether removal for transplantation is 'otherwise lawful' the HTA will consider whether there appears to be any other basis, other than consent, which would make the donation lawful.

20. In England and Wales, in line with the Mental Capacity Act 2005 (MCA) and the Code of Practice [see paragraphs 6.18, 8.18, 8.20], an application should be made to the Court of Protection to establish whether the removal of an organ from an adult lacking capacity for the purposes of transplantation is lawful.

21. In Scotland, adults with incapacity cannot be considered as living organ donors unless the removal of the organ is for the patient's own medical treatment [Part 3, The Human Organ and Tissue Live Transplants (Scotland) Regulations 2006].

22. The MCA does not apply in Northern Ireland. The Mental Capacity Act (Northern Ireland) was passed in 2016 and has partially been implemented at the time of publication of this policy. Once fully in force, it will provide a single legal framework for mental health and capacity issues. Until then, a dual system exists with the Mental Health (Northern Ireland) Order 1986 covering the assessment, treatment and rights of children and adults with a mental health condition who may need to be admitted to hospital for assessment in treatment. Decisions about capacity and treatment are considered by reference to the common law.

Broader legal framework

23. The HTA does not only consider the legislation that provides for its statutory function in living organ donation. The MCA, the Adults with Incapacity

(Scotland) Act 2000 and the Human Rights Act 1998, in particular, have bearing on the way the HTA interprets its role.

24. The HTA has a statutory role to ensure that individuals only make donations if they have capacity to make that decision, that they have made an informed decision, free from duress and coercion, after receiving proper medical advice and that there is no reward offered or given for the organ(s).

25. The HTA recognises that its role must be balanced with other rights of the individual, including those set out in other legislation. In particular, there should be a presumption that a potential donor has capacity to consent 'unless it is established that he lacks capacity' (s1(2) MCA) and that every person with capacity has a right to make decisions concerning their own body.

26. The HTA must also act in accordance with public law principles. These oblige the HTA to act within its lawful powers, to act reasonably and to follow fair procedures.

27. Personal data processed by the HTA through the implementation of this policy will be done so in accordance with the HTA's Privacy Notice and data protection law, including the UK General Data Protection Regulation and the Data Protection Act 2018.

Decision making in living donation case assessment

28. The HTA has a legal obligation to assess all cases that are referred to it. While decision making on some cases can be delegated to the HTA Executive (known as the Living Organ Donation (LOD) Team), others must be assessed by a panel of three Board Members ('panel cases').

29. The HTA currently distinguishes two types of panel cases:

    a) Those which by law (as prescribed in Regulation 12) must be dealt with by a panel of three Board members; and
    b) Those where the Board has made a policy decision to retain decision making and not delegate decision making to the LOD team (known as 'Retained panel cases').

30. Whether a case is categorised as retained is determined by characteristics of the case, including risk profile.

31. The HTA has identified some illustrative examples of circumstances the HTA would consider 'high risk'. These include:

    a. concern about potential reward (defined as material advantage);
    b. concern about potential duress and/or coercion;
    c. the donor is travelling from overseas and there is concern about the claimed relationship;
    d. concern about the independence of a translator, or any other concern in relation to the translator;
    e. apparent significant disparity between the donor and recipient (for example, age, wealth or education) that may be indicators of heightened risk of duress, coercion or reward.

32. For cases where the decision making is within the scope of the LOD team, the decision to reject a directed donation case can be made by the LOD team with the Director of Regulation in a formal Regulatory Decision Making Meeting (RDM).

Panel cases by law

33. Panel cases by law comprise situations where:

    a. The donor is a child,
    b. The donor is an adult lacking capacity to consent,
    c. Paired donations,
    d. Pooled donations, and
    e. Non-directed altruistic donations.

Retained panel cases

34. In all retained panel cases, the HTA considers that the nature of the relationship and / or the motivation for donation requires further exploration. The HTA considers these cases may present a higher risk of there being issues with the quality of the consent and / or of meeting the statutory criteria. Having such cases assessed by a Panel of three Board members enables the HTA to ensure there is robust assessment of these factors in cases considered to be potentially of higher risk.

35. The four categories of retained panel cases are set out below.

    a. **Certain overseas donor cases:** These are directed altruistic donation cases where the donor is travelling from overseas, and which fulfil the following two conditions:

i. The donation is being directed to a specific individual; and
ii. there is no evidence of a genetic or pre-existing emotional relationship between the donor and recipient.

(These cases can often involve a third party or mechanism bringing the donor and recipient together for the purpose of organ donation and transplantation).

b. **Economic dependence cases:** These are cases where the donor has, or appears to have, some form of economic dependence on the recipient, for example, the donor is an employee of the recipient, or the donor is a tenant of the recipient and the donor has no genetic or pre-existing emotional relationship with the recipient. In cases where the donor and recipient have a genetic or pre-existing emotional relationship, the decision can be made by the LOD team.

c. **Some cases which enter the HTA's RDM process:** Any case that is otherwise delegated to the LOD team, but which the LOD team feels needs to be referred to panel. This is likely to include cases identified as 'high risk' and with significant elements of complexity or uncertainty for which panel consideration would be beneficial (these are likely to be the exception).

d. **Novel living organ donation cases:** These are organ donations that the HTA does not consider to be routine. The HTA defines routine living organ donation cases as follows:
   - Kidney
   - Liver Lobe.

Once the HTA has approved at least 8 novel donation cases (for any specific novel organ), the Board can consider redefining this organ as routine. More detailed information on novel organ donations is set out in Annex C.

36. For all cases referred to panel, the LOD team provide a summary document detailing relevant necessary information about the case to support the panel in its decision making. The CRM record for each case contains all relevant information and documentation pertaining to HTA decision-making for that case.

37. Where the LOD team identify that a case referred to panel is high risk, panel members are directed to review all the relevant primary documents relating to the case as well as the case summary. This is to enable the panel to make their decision based on an assessment of all pertinent factors, including the IA report, the hospital referral letter and donor declaration.

HTA requirements in all living donation cases

38. The remainder of this document should be read with reference to Code of Practice F part one: Living organ donation and Annex A.

39. In addition to the statutory requirements, HTA experience in the assessment of living donation cases has led to the introduction of a number of other policy requirements (must) and recommendations (may) which need to be met as part of the referral process.

Clinicians and transplant teams

40. As a matter of either legislation or policy, certain activities need to be completed prior to the case being referred to an IA.

41. Regulation 11(2) requires that a medical practitioner must have referred the proposed donation to the HTA. Specifically, the referral must state that the medical practitioner, or person acting on their behalf:

    a) is satisfied that the donor's health and medical history are suitable for the purposes of transplantation;
    b) has provided the donor with the information the donor requires to understand the consequences of donation; and
    c) has endeavoured to obtain information from the donor that is relevant to the transplantation.

42. As a matter of HTA policy, the referral must also state that the medical practitioner, or person acting on their behalf, is satisfied that the donor has capacity to consent to the donation.

43. The HTA must ensure that safeguards are in place to be satisfied that no reward has been, or is to be, given in contravention of Section 32 of the Act. As a matter of policy, all donors are asked to sign a declaration confirming that they have read the Guidance for living organ donors on the HTA's Independent Assessment process and no payment or reward is associated with the organ donation and transplantation.

44. All donors may be asked during work up what they wish to happen in the event that their organ or part organ cannot be transplanted into the intended recipient. This is a precaution to avoid the possible worst-case scenario of an organ being disposed of when the donor's wishes are not known. The HTA identified four potential options:

    - organ or part organ can be transplanted into an alternative recipient;
    - organ can be re-implanted into the donor (not appropriate for liver lobes);
    - organ or part organ can be used for research; or
    - organ or part organ can be disposed of.

45. The HTA must give separate approval where the donor has consented prior to surgery for the organ or part organ to be transplanted into an alternative recipient on the national deceased wating list. The HTA does not need to be

informed of the donor's decision where they have chosen for the organ to be re-implanted, used for research or disposed of. However, the HTA must have assurance that where the donor has selected re-implantation, the donor understands the additional surgical risks attached to re-implantation.

46. The medical team must ensure that where there are risks specific to a donor, these have been addressed by the clinical team and have been understood by the donor. As a matter of HTA policy these risks and confirmation of the donor's understanding must be included in the referral letter and the IA report.

Cases in which a presumed genetic relationship is not substantiated by test results.

47. Donors may be asked to consider whether they wish to be informed if a presumed genetic relationship is revealed to be absent during the work up. The HTA will assess all cases regardless of whether this has been discussed with the donor, although evidence that the donor's wishes were sought may be requested.

Administrative requirements

48. Written referrals must include confirmation of the evidence of identity and relationship seen by the transplant team for both the donor and recipient. Proof of identity and relationship must be confirmed at the IA interview.

49. Where satisfactory documentary evidence of the relationship cannot be provided, or does not exist, the case will be treated as a directed altruistic case.

Independent assessment

Legislative and policy requirements

50. Regulation 11(6) sets out the requirement that the IA must have conducted separate interviews with the donor (or person giving consent if different from the donor) and the recipient. In addition, it is HTA policy that an interview must be undertaken with the donor and recipient together. The purpose of this is to allow the IA to observe the interaction between the donor and recipient to aid understanding of whether duress or coercion are likely to be factors in the donor's decision to donate. It also allows the IA to explore the issue of reward jointly with the donor and

recipient. The need for an IA interview with the donor is dispensed with in situations where the removal of an organ for transplantation is authorised by a court order. A recipient interview cannot be undertaken for non-directed altruistic donations as no recipient is identified until after HTA approval is given. Requests for the joint donor and recipient interview to be waived will be considered on a case-by-case basis by the Director of Regulation and the rationale for the decision will be documented with the case application.

51. Regulations 11(7) and (8) detail the content of the reports on the interviews to be submitted by IAs. As a matter of policy, the report may also contain an account of any relevant concerns the IA has that may contribute to the HTA's assessment of whether or not it is satisfied in relation to the three statutory tests.

52. ***Recipient interviews***. Regulation 11(8)(a) requires that the report on the interview with the recipient should cover any evidence of duress and/or coercion affecting the decision to give consent. As the recipient's consent to undergo surgery to receive transplantable material is a clinical matter, the HTA interprets this to mean any evidence of duress or coercion (which the recipient is aware of or has brought to bear) affecting the donor's decision to give consent to the removal of their organ for the purposes of transplantation.

53. ***Interviews with recipients lacking capacity to consent***. While the Regulations make provision for interviews where the donor lacks capacity to consent, they are silent on recipients lacking capacity to consent. HTA policy is that the referral letter from the clinician should highlight any issues relating to the recipient's capacity to undergo the interview. The IA must undertake, or attempt to undertake, an interview with the recipient except in circumstances where either the recipient lacks capacity or where an interview is not considered to be in the best interests of the recipient. In all circumstances, whether or not an interview was attempted, the IA should include this information in their report, commenting on any capacity issues under the provision of Regulation 11(8)(c) relating to communication difficulties and how (where possible) these were overcome. Where the recipient lacks capacity, there is no legal provision for someone to be interviewed on their behalf.

54. In cases where the proposed donor indicates during an IA interview that they do not wish to proceed with the donation, the HTA should take this as evidence that the donor has withdrawn his or her consent. The IA must inform the HTA and the relevant Living Donor Coordinator. The referring

clinician may withdraw his or her referral to the HTA and the case should be submitted as a record of the interview, but the HTA is not obliged to make a decision. Transplant Units may benefit from developing local policies to halt the preparation for the transplantation in these circumstances in a way that ensures adequate protection for the donor.

Case assessment

55. Once the HTA receives a case it will assess this in line with the Standard Operating Procedure(s) and the service standards relevant at the time.

Regulatory decision making

56. For applications where, having considered the IA report, the HTA is not fully satisfied in line with Regulation 11(3), rejecting the application becomes a possibility. In these instances, the HTA will make its decision in line with the Standard Operating Procedure(s) and service standards relevant at the time.

57. Where there is insufficient evidence for the HTA to be satisfied that the donor has capacity to consent in line with the requirements of the MCA (or other relevant legislation), the HTA may refer the case back to the medical practitioner, who will be asked to provide the evidence underpinning their assessment of capacity to consent.

58. Where there is insufficient evidence for the HTA to be satisfied that the donor's consent is being given free from duress or coercion, or insufficient evidence for the HTA to be satisfied that reward is absent, the LOD team will undertake further investigation or request other information as appropriate in order to fulfil its statutory obligation.

59. In situations where a panel of three Board Members cannot reach a unanimous decision, the panel may reach a majority decision. The Chair of the panel records the decision on CRM but all panel members including the Chair, have equal status.

Reconsiderations

60. Once the HTA has given approval for a donation to proceed it will have done so on the basis of being satisfied that the statutory tests have been met, as well as being satisfied that there is no other legal reason that would make the surgery unlawful. If the HTA receives evidence, between giving approval and the surgery proceeding, that could affect the test of being satisfied, then it has power under Regulation 13 to reconsider the case as a fresh decision.

61. In deciding to reconsider a decision, the HTA must be satisfied that any information given for the purpose of the decision was in any material respect false or misleading or there has been a material change of circumstances since the decision was made. Regulation 14 requires that reconsideration is made as a fresh decision and that any members involved in the original approval are disqualified from participating in the fresh decision. Depending on the facts of the case, further information may be required from the donor and/or recipient in order to reach a decision.

62. For reconsiderations initiated by specified persons [Regulations 13(2) and (3)] the reconsideration will be managed in line with the appropriate Standard Operating Procedure(s) and service standards.

Annexes:

Annex A: Relevant extract from The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006
Annex B: Sets out the cases where the Board delegates decision making to the LOD team.
Annex C: Novel organ donations
Annex D: Halted and paused cases
Annex E: Cases involving cross-border donations

Revision history

Reference: HTA-POL-102

Author(s): Allan Marriott-Smith

Reviewed by: Jessica Porter

Approved by: The HTA Board

Owner: Jessica Porter

Distribution: HTA Executive staff
HTA Board Members

Protective Marking: OFFICIAL

- (29.11.2011 / 0.1: Drafted by AMS)
- (07.12.2011 / 0.2: Redraft with team comments and taking into account HH)
- (09.01.2012 / 0.3: Redraft based on QC advice, discussion with NHSBT and further views from HH)
- (28.01.2012 / 0.4: Redraft based on QC advice dated 15.01.12)
- (09.02.2012 / 0.5: Redraft based on SMT discussion 07.02.12)
- (17.02.2012 / 0.6: Redraft based DW comments 15.02.12)
- (06.03.12 / 0.7: Redraft based on Authority comments 28.02.12)
- (23.05.12 / 1.0: Approved by Director)
- (31.07.2013 / 2.0: Policy transferred from Authority Meeting folder. SOP reference added by SP. Approved by Director)
- (15.08.2014 / 2.1: Revisions based on legal advice and policy decisions made by Authority)
- (02.10.2014 / 2.2: Revisions based on Authority comments)
- (10.10.2014 /14.0: Approved by AMS)
- (23.03.2015 /15.0: Revised to reflect Authority decision on retaining cases which enter the regulatory decision-making process. Approved by Director)
- (August 2016 / 16.0: Revised as part of regular review process. Approved by Head of Regulation for the sector)
- (March 2019 / 16.1: Reviewed and updated for GDPR compliance)
- (November 2019 / 19.0: Revised as part of quality forum review process. Approved by JP, Head of Regulation)
- (June 2020 / 20.0: Added policy detail on consideration of novel cases. Approved by JP, Head of Regulation)
- (23.12.2020 /21.0: Updated policy to include section on domino donation. Approved by JP, Head of Regulation)
- (May 2021 / 22.0: Updated policy to include section cross-border donation. Approved by JP, Head of Regulation)
- (January 2022 / 22.1: Document transferred to new policy document template and HTA website links updated. Approved by SC as no content change)
- May 2023, Comprehensive revision, updated to clarify how higher risk cases should be handled. Legal review undertaken.

This policy will be reviewed every three years or as necessary.

Annex A - The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 - extract

Meaning of transplantable material for the purposes of section 34 of the Act

9. For the purposes of section 34 of the Act (information about transplant operations) “transplantable material” means—
(a) the whole or part of any of the following organs if it is to be used for the same purpose as the entire organ in the human body—
(i) kidney,
(ii) heart,
(iii) lung or a lung lobe,
(iv) pancreas,
(v) liver,
(vi) bowel,
(vii) larynx;
(b) face; or
(c) limb.

Meaning of transplantable material for the purposes of section 33 of the Act

10. (1) Subject to paragraphs (2) and (3), for the purposes of section 33 of the Act (restriction on transplants involving a live donor), “transplantable material” means—
(a) an organ, or part of an organ if it is to be used for the same purpose as the entire organ in the human body,
(b) bone marrow, and
(c) peripheral blood stem cells, where that material is removed from the body of a living person with the intention that it be transplanted into another person.

(2) The material referred to in paragraph (1)(a) is not transplantable material for the purposes of section 33 of the Act in a case where the primary purpose of removal of the material is the medical treatment of the person from whose body the material is removed.

(3) The material referred to in paragraph (1)(b) and (c) is transplantable material for the purposes of section 33 of the Act only in a case where the person from whose body the material is removed is:
(a) an adult who lacks the capacity, or
(b) a child who is not competent,
to consent to removal of the transplantable material.

Cases in which restriction on transplants involving a live donor is disapplied

11.—(1) Section 33(1) and (2) of the Act (offences relating to transplants involving a live donor) shall not apply in any case involving transplantable material from the body of a living person (“the donor”) if the requirements of paragraphs (2) to (6) are met.

(2) A registered medical practitioner who has clinical responsibility for the donor must have caused the matter to be referred to the Authority.

(3) The Authority must be satisfied that:
(a) no reward has been or is to be given in contravention of section 32 of the Act (prohibition of commercial dealings in human material for transplantation), and
(b) when the transplantable material is removed;
(i) consent for its removal for the purpose of transplantation has been given, or
(ii) its removal for that purpose is otherwise lawful.

(4) The Authority must take the report referred to in paragraph (6) into account in making its decision under paragraph (3).

(5) The Authority shall give notice of its decision under paragraph (3) to:
(a) the donor of the transplantable material or any person acting on his behalf,
(b) the person to whom it is proposed to transplant the transplantable material (“the recipient”) or any person acting on his behalf, and
(c) the registered medical practitioner who caused the matter to be referred to the Authority under paragraph (2).

(6) Subject to paragraph (7), one or more qualified persons must have conducted separate interviews with each of the following:
(a) the donor,
(b) if different from the donor, the person giving consent, and
(c) the recipient,
and reported to the Authority on the matters specified in paragraphs (8) and (9).

(7) Paragraph (6) does not apply in any case where the removal of the transplantable material for the purpose of transplantation is authorised by an order made in any legal proceedings before a court.

(8) The matters that must be covered in the report of each interview under paragraph (6) are:
(a) any evidence of duress or coercion affecting the decision to give consent,
(b) any evidence of an offer of a reward, and
(c) any difficulties of communication with the person interviewed and an explanation of how those difficulties were overcome.

(9) The following matters must be covered in the report of the interview with the donor and, where relevant, the other person giving consent:-
(a) the information given to the person interviewed as to the nature of the medical procedure for, and the risk involved in, the removal of the transplantable material,

(b) the full name of the person who gave that information and his qualification to give it,; and
(c) the capacity of the person interviewed to understand;
(i) the nature of the medical procedure and the risk involved; and
(ii) that the consent may be withdrawn at any time before the removal of the transplantable material.

(10) A person shall be taken to be qualified to conduct an interview under paragraph (6) if:
(a) he appears to the Authority to be suitably qualified to conduct the interview,
(b) he does not have any connection with any of the persons to be interviewed, or with a person who stands in a qualifying relationship to any of those persons, which the
Authority considers to be of a kind that might raise doubts about his ability to act impartially, and
(c) in the case of an interview with the donor or other person giving consent, he is not the person who gave the information referred to in paragraph (9)(a).

Decisions of the Authority: procedure for certain cases
12. (1) In any case to which paragraph (2), (3) or (4) applies, the Authority's decision as to the matters specified in regulation 11(3) shall be made by a panel of no fewer than 3 members of the Authority.

(2) A case falls within this paragraph if:
(a) the donor of the transplantable material is a child, and
(b) the material is an organ or part of an organ if it is to be used for the same purpose as an entire organ in the human body.

(3) A case falls within this paragraph if:
(a) the donor of the transplantable material is an adult who lacks capacity to consent to removal of the material, and
(b) the material is an organ or part of an organ if it is to be used for the same purpose as an entire organ in the human body.

(4) A case falls within this paragraph if:
(a) the donor of the transplantable material is an adult who has capacity to consent to removal of the material, and
(b) the case involves:
(i) paired donations,
(ii) pooled donations, or
(iii) a non-directed altruistic donation.

(5) In this regulation:
“non-directed altruistic donation” means the removal (in circumstances not amounting to a paired or pooled donation) of transplantable material from a donor for transplant to a person who is not genetically related to the donor or known to him;
“paired donations” means an arrangement under which:
(a) transplantable material is removed from a donor (“D”) for transplant to a person who is not genetically related or known to D, and
(b) transplantable material is removed from another person for transplant to a person who is genetically related or known to D; and
“pooled donations” means a series of paired donations of transplantable material, each of which is linked to another in the same series (for example, transplantable material from D is transplanted to the wife of another person (“E”), transplantable material from E is transplanted to the partner of a third person (“F”) and transplantable material from F is transplanted to D’s son).

Right to reconsideration of Authority’s decision
13. (1) The Authority may reconsider any decision made by it under regulation 11(3) if it is satisfied that:
(a) any information given for the purpose of the decision was in any material respect false or misleading, or
(b) there has been any material change of circumstances since the decision was made.

(2) A specified person may in any case require the Authority to reconsider any decision made by it under regulation 11(3).

(3) “Specified persons”, in relation to such a decision, are:
(a) the donor of the transplantable material or any person acting on his behalf,
(b) the recipient of the material or any person acting on his behalf, and
(c) the registered medical practitioner who caused the matter to be referred to the Authority under regulation 11(2).

(4) The right under paragraph (2) is exercisable by giving to the Authority, in such manner as it may direct, notice of exercise of the right.

(5) A notice under paragraph (4) shall contain or be accompanied by such other information as the Authority may reasonably require.

(6) On receipt of the information required by paragraph (5), the Authority shall provide to the person requiring the reconsideration—
(a) a copy of each report made under regulation 11(6) of the interviews that were conducted in the case, and
(b) a statement of the Authority’s reasons for its decision.

(7) Paragraphs (1) to (6) do not apply to a decision made by the Authority on reconsideration in pursuance of a notice under this regulation.

Procedure on reconsideration

14. (1) Reconsideration shall be by way of fresh decision made at a meeting of the Authority.

(2) The meeting shall take place as soon as reasonably practicable after the provision of the reports and statement required by regulation 13(6), having regard to the need to allow time for the information contained in that material to be taken into account.

(3) Where a member of the Authority has taken part in the making of a decision subject to reconsideration (whether under regulation 12 or otherwise), he is disqualified from participating in the Authority's reconsideration of it.

(4) On reconsideration under regulation 13(2)—
(a) the person ("A") by whom the reconsideration is required under regulation 13(2) shall be entitled to require that he or his representative be given an opportunity to appear before and be heard at the meeting of the Authority at which the decision is reconsidered, and
(b) the members of the Authority in attendance at the meeting at which the decision is reconsidered shall consider any such written representations and comments.

(5) The Authority shall give a notice of its decision to A.

(6) If on reconsideration the Authority upholds the previous decision, the notice under paragraph
(5) shall include a statement of the reasons for the Authority's decision.

(7) "Reconsideration" means reconsideration in pursuance of a notice under regulation 13.

Annex B - Retained panel cases and delegated cases

Retained panel cases

In addition to the cases which Board Members must consider as a matter of law, it has also decided to retain decision making in a number of other situations. These are referred to as retained panel cases.

Type of case	Description
Economic dependence cases: These are cases where the donor has, or appears to have, some form of economic dependence on the recipient.	Examples: • The recipient appears to have significant financial strength and independence, such as private income, business interests, or a secure and well-paid professional role, whereas the donor appears to be insecure financially with a low paid and insecure job • The donor has a low social status and the recipient has high social status and a significant and / or powerful public position • The donor is an employee of the recipient • The donor is a tenant of the recipient (In cases where the donor and recipient have a genetic or pre-existing emotional relationship, the decision can be made by the LOD team).

Some cases which enter the HTA's Regulatory RDM process: Any case that is not a directed donation case, and the following two criteria apply: • the case has been identified as 'high risk' (see illustrative explanations of 'high risk') • the LOD team consider that rejecting the case is a possibility.	Examples: • The IA report for a directed altruistic case indicates that the translator may not have been independent • The IA report for a directed altruistic case suggests reward may be a factor.
Novel living organ donation cases: These are organ donations that the HTA does not consider to be routine. The HTA defines routine living organ donation cases as follows: • Kidney • Liver Lobe.	All novel living organ cases will be referred to a panel of Board Members for decision. Once the HTA has approved at least 8 novel donation cases (for any specific novel organ), the Board can consider redefining this organ as routine.

Cases delegated to the LOD team – subject to evidence of stated relationship

Type of case	**Description**
Directed donation (subject to evidence of claimed relationship being provided)	*Examples:* • *Spouse or partner* • *Parent or child* • *Brother or sister* • *Grandparent or grandchild* • *Niece or nephew* • *Uncle or aunt* • *Stepfather or stepmother* • *Cousin* • *Half-brother or half-sister* • *Step brother or step sister* • *Mother-in-law or father-in-law* • *Brother-in-law or sister-in-law* • *Friend of long standing* • *Work colleague*
Directed altruistic cases where the donor is **not** travelling from overseas • Genetic relationship and no established emotional relationship • No pre-existing relationship.	*Examples:* • *UK resident: Cousin who has come forward as a donor but has not had an active relationship with the recipient e.g. due to geographical location and they cannot evidence the genetic or emotional relationship* • *UK resident: Relative with whom there has been no contact which may be due to a relationship breakdown or adoption (sibling, parent, child etc.)* • *UK resident: Friend of a friend (have an awareness of each other e.g. through a mutual person, but no relationship has been formed and there has been no contact / interaction)* • *An organisation has campaigned for a donor (have an awareness of each other e.g. through a mutual organisation, but no relationship has been formed and there has been no contact / interaction)* • *UK donor comes forward after a media campaign (but no relationship has been formed and there has been no contact / interaction).*

Domino donation in Scotland where the donor is an adult with incapacity or a child.	Adults with incapacity can only be considered as living organ donors in Scotland if the removal of the organ is for the patient's own medical treatment, known as domino donation. The same applies to children, who are defined in the HT Scotland Act as those aged under 16 years of age. *Example:* • *It is necessary for a person's treatment to have their kidney removed, which is then offered as a domino donation to be transplanted to someone else.*

Annex C - allocation and assessment of novel living organ donation cases

Background

The HTA has received a small number of novel living organ donation cases, such as small bowel and uterus. These cases are referred to a panel of Board Members to assess and provide a decision. The HTA adopted this approach to provide additional scrutiny to applications for donations which are not yet established or routine.

However, there is no statutory requirement in the Regulations or the Human Tissue Act for novel cases to be considered by a panel of Board Members. The only exceptions are set out in reg 12 which provide for cases of 'greater complexity' to be considered by a panel.

Decision Making

Independent legal advice supported our view that novel organ donation cases should be referred to a panel of Board Members. Legal advice confirmed this approach is in line with the statutory intention of regulation 12 and is a responsible way of exercising powers of delegation which would otherwise allow delegation to the LOD team for these decisions.

Routine donations

At the beginning of each financial year the HTA should review the list of routine living organ donation categories to take account of developments. Any organ donation categories not on this list should be considered as a novel organ donation and referred to a panel.

In order to decide whether to add a donation category to the list of routine living organ donations, the HTA must consider the following:

- How many cases have been submitted to the HTA, if more than **eight** this could be considered a routine donation;
- How often is, or has, the procedure been undertaken in the UK;
- The relative risk to life for both the donor and the recipient in this procedure;
- The relative risk of other serious complications to both the donor and the recipient; and
- Any unusual ethical considerations that might arise from donation.

Annex D - Halting and pausing living organ donation cases

Background

There have been a number of living organ donation cases referred to the HTA where it becomes apparent that a decision is either no longer required due to a change in circumstances, or the HTA is unable to make a decision until further clarifications have been sought. These cases should be halted or paused on the CRM system. The difference between halted and paused is outlined below.

Halting cases

Where a decision is no longer required on a living organ donation case, the HTA should resolve the case with the status of ‘halted’. An example of this may be if the donor and/or the recipient no longer wish to proceed, or the donation is unable to proceed for medical reasons. Therefore, the case is halted as the HTA is not required to make a decision.

Where a case is halted on the system, there is no need to provide a decision to external stakeholders, such as Independent Assessors, Living Donor Coordinators and Clinicians.

It is important for the LOD team to clearly document the reasons why the case has been halted in the case notes section.

Pausing cases

A case should be paused where there is further information or clarification required before the HTA is able to make a decision.

Pausing cases is more common than the need to halt cases. This is due to the number of clarifications that will often need to be sought on a case and how long it takes to provide the information requested. Paused cases remain open and active in the CRM case queue until further information or clarification is received and reviewed.

An example of when a case would be paused would be where the donation category is subject to change. This could be due to the case being submitted as a directed donation, and then being re-categorised because a decision has been made to enter the National Kidney Sharing Scheme matching run to see whether a better HLA tissue match can be identified and therefore proceed with paired/pooled donation instead. At present, the HTA can only provide a decision on one category of donation.

It is important to clearly document what information is outstanding in the case notes section, any updates and a record of all contact with the Independent Assessor or Transplant unit.

Annex E - Cases involving cross-border donation

Background

The HTA received two living organ donation cases for approval where the retrieval and subsequent transplant were to take place in two different UK nations, namely Scotland and England.

As the legislation is different for both countries, it is important that the approach to assessing cases involving cross-border donation is both reasonable and lawful. The decision as to which legislation these types of cases are to be assessed under also impacts whether the IA must cover two additional requirements under the HT (Scotland) Act 2006. These requirements concern the donor’s consideration of the wider implications of donation and also confirmation that the recipient has not been subject to duress/coercion in their decision to accept the organ.

Decision making

Independent legal advice supported our approach and presented three options, one of which was to assess the case under the legislation of the location where the

organ was removed. The independent legal advice confirmed this as being ‘a reasonable and lawful approach, and the risks of legal challenge are low’.

After approval from the Director of Regulation, a decision was made that all cases involving cross-border donation are to be assessed under the legislation of the location where the organ is removed.

Cases involving cross-border donation are to be monitored by the Transplant Manager, in case of any changes needed to the current approach in decision making.

Governance around HTA's Insight Network

Human Tissue Authority
Board Meeting Conducted in Public

Date: 29 June 2023

Paper reference: HTA 14/23

Agenda item: 8

Author: Tom Billins

Establishing the HTA Insight Network

Purpose of paper

1. To inform the Board of the Executive's plans to establish an Insight Network to support and strengthen the HTA's Horizon Scanning capability.

Action required

2. The Board is invited to comment on the Executive's plans to establish an Insight Network.

Background

3. In recent years the Life Sciences sector has grown, with innovation and the pace of change identifying emerging technologies and generating new products.
4. In May 2023, the Government Chief Scientific Advisor published the 'Pro-innovation Regulation of Technologies Review'. The review seeks to further support the growth and innovation of new technologies and ensure that regulation in this area is seen as an enabler of research and innovation.
5. To be an efficient and effective regulator the HTA needs to keep pace with change. It must also proactively anticipate and prepare for future changes. To do this, the HTA needs to further develop its Horizon Scanning activities and capabilities. The Horizon Scanning function is currently being revised and strengthened to ensure it is sufficiently forward looking to identify and respond to innovation and the pace of product development.

6. To ensure the Horizon Scanning function is proactively considering and responding to all relevant issues and future breakthroughs affecting HTA-regulated sectors, the Executive plans to form an Insight Network.

7. The Insight Network aims to bring together industry experts, professionals in life sciences and leaders in other relevant sectors, to capture and debate:

    - their vision for the future
    - the technologies and practices being developed, and
    - the changes that may be realistically delivered.

    It is envisaged that the Insight Network will support the Executive to consider scientific, clinical, ethical and / or legal implications associated with issues and breakthroughs identified via Horizon Scanning. This will equip the Executive with the necessary information to decide where further exploration or joint working is required.

8. This paper sets out how the Insight Network will work to strengthen the HTA's Horizon Scanning capability. It has been informed by the practices of similar activities in other settings and by incorporating learning from other organisations in the health and care regulatory environment – including those that use similar networks to varying degrees to support and enhance their Horizon Scanning function.

The purpose and governance of the Insight Network

Purpose

9. The purpose of the Insight Network is to provide the HTA with a unique perspective on the future of life sciences by helping to identify research, changes in practice and emerging technologies, which may alter how HTA-regulated activities are delivered in the future. The group will also play a vital role in proactively identifying potential opportunities that may be explored further or used to inform future strategy and policy.

10. The establishment of the Insight Network aims to bring together a small number of different specialists who cover areas within the scope of the HTA's regulation, are advocates of growth and innovation in life sciences, and who can act as professional connections with industry innovators. The network will help with identifying new and emerging priorities, scientific and clinical breakthroughs, and future technologies and products. It will also help to identify how the regulation of these areas may need to change to maintain quality standards, and continue to be responsive and relevant to the needs of the sectors.

11. The value of the Insight Network will be in the diversity of its membership and the sharing of professional and technical views. The network will provide virtual and in person forums to:

    - identify any additional areas of consideration for the Executive (through a bi-annual summary report produced after network meetings)
    - assist in the prioritisation of issues raised through the Horizon Scanning process, based on timelines for impact, the level of risk, and the likely impact on the research or commercial market (drawing on their own experiences to make these judgements)
    - provide a view on items raised – from a regulatory and industry perspective – based on their expertise and knowledge, and
    - highlight any issues that may impact or have implications for other regulators or organisations (such as the potential for regulatory overlap and information sharing to minimise duplication in data submissions).

12. It is anticipated that the scope and purpose of the Insight Network will help to strengthen the HTA's Horizon Scanning capabilities and strategic planning. The Policy and Development team will be able to draw on conversations with network members and the network's bi-annual summary reports to strengthen the insights gained from the Horizon Scanning process. This will also enable better informed prioritisation and greater clarity on areas to explore and act upon. Ultimately, the network will allow the HTA better to support and promote innovation, new technologies and new products in its sectors and life sciences overall.

13. Given its role is to provide insights to help navigate and support Horizon Scanning at the HTA, the Insight Network will not have any decision-making powers.

Governance

14. The Insight Network will come together no more than twice a year; timed to coincide with strategic and business planning for the coming year(s). There will also be ongoing opportunity for the sharing of information with the Executive by individual members, as necessary. This will help the HTA to assure itself on its strategic direction of travel, its maintained credibility as a responsive regulator and to inform HTA strategy and annual business planning. Network members will also support the HTA in ensuring it is responsive to emerging practice and technologies through its regulatory model, engagement with stakeholders and management of potential risks. This frequency is seen in other organisations who generally meet 1-2 times a year with their designated network.

15. Members of the Insight Network will report their insights to the Executive. Meetings will be co-ordinated and supported by the Policy and Development team and chaired by the Director of Data, Technology and Development. This will ensure that those leading on Horizon Scanning among the Executive are able to inform and advise the Senior Management Team (SMT). In turn, SMT will consider how the HTA strategically approaches regulatory change and adapts to support innovation and the adoption of new technologies. Updates will also be provided to the Board by the Executive on an annual basis as part of an annual report on Horizon Scanning.

16. While the Insight Network is an informal group without decision-making powers, members of the network will need to abide by terms set by the HTA. Members will receive reimbursement for travel and subsistence. Further remuneration may be limited although this is being explored further.

Membership

17. The network will be a diverse group that brings different perspectives together, allowing for rounded views on different subjects. The value of membership will be in the contribution made to ensuring that the HTA can meet the challenges presented by changes in technology, science and clinical practice.

18. To sufficiently support the Executive, the Insight Network should have a core set of members that span HTA-regulated sectors and a sample of the various professions within them (e.g., scientists, clinicians, ethicists, etc.). The membership may also seek to reflect representation of other professional and non-professional groups. The HTA seeks to demonstrate equality, diversity, and inclusion in how it operates, and this will be the ambition in composing the Insight Network.

19. Given the breadth of expertise required, it is envisaged that the Insight Network will comprise of around 12 members. Its size ensures that all members will be able to partake in discussions. This size is also consistent with similar groups and networks that support Horizon Scanning in other organisations.

20. As Horizon Scanning will identify new technologies and innovations in clinical practice, the Insight Network should allow for new members with the relevant expertise to be called upon (and subgroups established, where necessary). It is envisaged that core members of the Insight Network will be able to draw on their own networks to help identify these additional ‘co-opted’ members.

21. To ensure it is fit for function, the Policy and Development team will review the effectiveness of the Insight Network as part of the Horizon Scanning function once it has been in place for a year.

Next steps

22. The Executive, taking into account comments from the Board, will continue to incorporate the Insight Network into the updated Horizon Scanning function and recruit members.

23. A paper will be presented to the Board on the revised Horizon Scanning function later in the year.

Audit and Risk Assurance Committee Update

Human Tissue Authority
Board Meeting Conducted in Public

Date: 29 June 2023

Paper reference: HTA 15/23

Agenda item: 9

Author: Gary Crowe

Audit and Risk 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 8 June 2023.

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 noted four reports since their last meeting that concluded the 2022/23 internal audit plan, these included three moderate assurance reports for Living Organ Donation; Record to Report Financial Processes and Performance Measurement. The fourth, a review of HTA's Records Management Processes provided limited assurance, but this was anticipated

and the report provides helpful recommendations for revised process currently being developed within the organisation.

5. The Committee then received the internal audit opinion for 2022/23 from the Head of Internal Audit, which concluded that an overall rating of moderate assurance could be provided. This was in keeping with previous years, although the committee noted that the report indicated a slight downward trajectory from previous years and that this would need to be addressed during 2023/24 if moderate assurance levels were to be maintained.

Annual Report and Accounts 2022/23

6. The Director of Resources presented the Annual Report and Accounts for the 2021/22 financial year to the Committee. The committee noted and discussed material movements in the accounts from the previous financial year and the new disclosures for this reporting year.

7. The Committee then received the draft External Audit Completion Report from Dean Gibbs of KPMG on behalf of the National Audit Office. The committee noted that there were no material errors found or audit adjustments recommended, and that the opinion was for the accounts to be unqualified.

8. Subject to the conclusion of the audit process with no further material findings, the Committee endorsed the recommendation that the Annual Report and Accounts be signed by the Accounting Officer.

Strategic Risk Register

9. The revised Strategic Risk Register (SRR) was considered by the Committee, this had been updated to reflect the 2023/24 Business Plan and included updates to several risk areas and the Executive's proposal to create new risks for failure to deliver the Business Plan and failure to adhere to corporate responsibilities. The Committee were not minded to agree with the Executive regarding the new risks and felt that the areas identified did not necessarily require explicit separation but could be conveyed within the existing 7 strategic risks.

Other items

10. The Committee received an update on Cyber Security from Louise Dineley, Director of Data, Technology & Development, and noted the annual report from the Senior Information Risk Owner.

11. The Committee noted that the HTA was in the process of finalising its annual Data Security Protection Toolkit submission to NHS Digital, which is due on 30 June 2023.

12. The Committee also received an update on the HTA's assessment against Government Function Standards. The Committee noted the work to assess the current adherence and asked for more explicit indication of the further work that would be undertaken to move towards compliance or recommendations to risk accept partially met against areas where full compliance would be both resource intensive with limited additional risk mitigation.

Recommendation

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

Renumeration Committee Update

Human Tissue Authority
Board Meeting Conducted in Public

Date: 29 June 2023

Paper reference: HTA 16/23

Agenda item: 10

Author: Ellen Donovan

Remuneration Committee Update

Purpose of paper

1. This paper provides an overview of the business of the Remuneration Committee meeting held on 22nd May 2023.

Proposed Pay Award and Grading Structure

2. An update was provided to RemCo by the CEO on the proposed pay award for 2023. The guidance given by DHSC was a 4.5% uplift. There was an additional 0.5% that could be used to target lower paid employees

3. A detailed paper on the proposed pay increase was discussed. HTA took a creative approach to meeting the needs of the organisation within the envelope of the guidance given. The approach taken was to offer either a lump sum payment or 4.5% whichever was the greater. There was also an opportunity to correct some historical internal pay anomalies, particularly in Regulation. This meant that certain individuals would attract a further payment to bring them in line with their colleagues.

4. This paper also presented an opportunity to review the current banding within HTA. Historically the banding was wide and presented difficulties in managing candidate expectations when recruiting. Given that HTA doesn't currently offer progression within bands, it was proposed to narrow some of the bandings in

order to address this issue. RemCo requested additional data in relation to Gender Pay, on review it was noted that the gender pay gap, with this proposal was narrowed. Following a detailed discussed RemCo approved the proposal. This is now with the department for final sign off. Once signed off HTA will be able to communicate the new structure internally and externally. The intention would be to implement the pay award in line with Department guidance of 1st August 2023.

5. There was an additional paper presented that discussed difficult to fill positions, in particular within the IT Function. It was agreed that, in particular at senior levels, these roles were hard to attract quality candidates at the level of remuneration on offer. The committee agreed that HTA on this occasion could recruit slightly outside of the current senior banding to secure the right candidate. The recruitment for this position is currently ongoing.

Organisational Development

6. A further verbal update on the OD work was given. Good progress had been made on Values and Behaviours through away day work and staff engagement activities. The organisation has signed up to the framework pending board approval. Once agreed the framework will be incorporated into HR processes going forward, in particular Recruitment and Onboarding. The committee agreed with this approach going forward. It was noted that this work was having a positive impact on the organisation.

7. RemCo will be updated on the implementation of the pay award and the updated banding at the next meeting. They will also receive a further update on the OD implementation.

Action required

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

Minutes of 9 March 2023
Matters Arising

Minutes of the meeting of the Human Tissue Authority (HTA) Board

Date: 9 March 2023

Time: 10.00 – 12.00 hrs

Venue: 2RP

Meeting Number: 103

Attendees:

Board Members
Lynne Berry, HTA Chair
Tom Chakraborti
Professor Gary Crowe
Helen Dodds
Ellen Donovan
Andy Greenfield
Dave Lewis

Apologies
Professor Deborah Bowman
Maria Nyberg, Deputy Director Health Ethics, DHSC
Jacky Cooper, Team Leader Human Tissue Policy and Ethics of Consent, DHSC

HTA attendees
Dr Colin Sullivan, Chief Executive
Louise Dineley, Director of Data, Technology and Development
Nicolette Harrison, Director of Regulation
John McDermott, Deputy Director for Performance & Corporate Governance
Richard Sydee, Director of Resources
Debra Smith, Lead of the Private Office
TJ O'Connor, Executive Assistant
Alison Margrave, Board Support (minutes)

HTA Staff Observers
Paul Lawrence, Business Portfolio Manager
Dee Noonan, Project Manager

Item 1 – Welcome and apologies

1. The Chair welcomed Board Members, HTA Staff and HTA Staff observers to the meeting.

2. Apologies were received from colleagues in the Department of Health and Social Care and Professor Deborah Bowman.

Item 2 – Declarations of interest

3. The Chair asked Members if there were any declarations of interest of relevance to the agenda; none were declared.

4. The Board noted new declarations of interest for a Board Member (though no conflicts were thought to arise), and that the Private Office will update the HTA records accordingly.

Item 3 – Chair's Report

5. The Chair provided an oral update on the following items:
    - Attendance at the Fuller Independent Inquiry.
    - Attendance at the Chair and CEO Meeting of ALBs with DHSC.
    - Meeting with William Vineall, the HTA's senior sponsor in DHSC.
    - Participating in the staff Weekly Exchange Call.
    - One-to-one meetings with all Board Members.
    - Reviewing the results of the recent Board Effectiveness Review.

Item 4 – Chief Executive's Report (HTA 01/23)

6. Dr Colin Sullivan on World Kidney Day took the opportunity to recognise the role of HTA Board Members in approving living organ donations and the positive impact this has on the lives of many patients.

7. Dr Colin Sullivan introduced the report and highlighted several key issues in Quarter 3 and the beginning of Quarter 4. He noted that the HTA's work has been impacted by the number of vacancies it carried previously in the year during Q2 which has affected several of the KPI's. He spoke about the additional restrictions applied by DHSC on public spending to ensure greater Value For Money and the need for business cases to receive Ministerial approval.

8. He provided further information on the Fuller Independent Inquiry and informed the Board that the phase 1 report is currently expected in the summer. HTA's revised guidelines for both the Post-Mortem and the Anatomy sectors have been published. He informed Board Members that Northern Ireland will introduce Deemed Consent for deceased organ and tissue donation from 1

June and this means all parts of the United Kingdom will then have Deemed Consent in place. He also highlighted HTA's work with other ALB's; work around the creation of HTA's redefined vision, mission and values and the approach to portfolio management work.

9. In response to a Board member's question, he confirmed that HTA does have a working list of areas for discussion with the Department about possible changes / refinements to legislation and the Director of Data, Technology and Development undertook to share this with the Board, for information.

10. In response to a question, the Chief Executive provided the Board with further information about the outcomes and learning flowing from the Critical Incident Response Plan testing.

11. The Board discussed staff engagement, especially regarding articulating our public service values and the importance of these. Concern was expressed regarding the IT vacancies and the impact this has on being able to deliver several projects. The Executive were urged to think creatively to fill these roles so that HTA's ability to deliver on projects is not further affected.

12. The Board noted the report.

Item 5 – HTA Performance Report (HTA 02/23)

13. 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 and on staffing/personnel matters.

14. In response to a question, he provided further information on the 3 KPIs which are currently showing red (more than 10% below target) out of a total of 9 key targets. He noted the KPIs were stretch targets and, overall, performance was holding.

15. In response to a question, the Director of Regulation provided further information about the process for licence applications and how this KPI is affected by delays in receiving responses from prospective applicants. This raised questions about how realistic some of this year's KPIs might be so that the HTA is only judged on what it can be held accountable for. The Board

acknowledged that KPIs cannot be amended mid-year but questioned whether the presentation of this material could be amended to highlight the difference.

16. The Board discussed the financial underspend, noting the impact that staff vacancies has had on the ability to deliver on key projects. The shortage of IT expertise was again acknowledged, and the possibility of secondments from other parts of the public sector was discussed.

17. The Board welcomed how the HTA is engaging better and more frequently with its stakeholders and how this can help drive forward HTA's work.

18. The Board noted the report.

Item 6 – Update from DHSC Sponsor Team

19. This item was deferred to the next meeting.

Item 7 – HTA's differentiated, risk-based approach to developing the inspection programme 2023/24 (HTA 03/23)

20. Nicolette Harrison, Director of Regulation, introduced the paper and provided further information about how HTA is using data to map out the profile of inspections for the coming year. She provided further details about the different inspections undertaken and the drivers for change. She referred to the paper which was presented to the Audit, Risk and Assurance Committee in January of this year, in relation to relative risks across the different sectors regulated by the HTA.

21. The Board discussed the paper in-depth, noting the importance of the proposed Regulatory Insight Model and Index work.

22. The Board endorsed this direction of travel and asked whether lessons could be learnt from the approaches taken by other regulatory bodies. This will be one aspect of the Review of Inspections project. The Board expressed thanks to the regulation team for the paper.

23. **Action 1** The Board noted HTA's developing approach to using data to inform sectoral risk assessment through the implementation of a segmented approach

to its inspection work. The Board noted this approach has been used to inform the inspection programme for 2023/24.

Item 8 – Review of HTA's Risk Tolerance (HTA 04/23)

24. Richard Sydee, Director of Resources, introduced the report and explained the proposed changes and the discussions which the Audit and Risk Assurance Committee had during their meeting in January.

25. The Board discussed the proposals and proposed that risk 2 should be further amended to read "consent, if required".

26. **Action 2** The Board approved the revised risk tolerance statements for the HTA's strategic risks 2, 3 and 7.

Item 9 – Business Plan 2023/24 (HTA 05/23)

27. John McDermott, Deputy Director for Performance & Corporate Governance, introduced the draft business plan for 2023/24 and stated that this plan assumed the same level of funding as previously secured. A departmental settlement had not yet been confirmed. He spoke about the proposed changes to the KPIs and how to best record the HTA's performance.

28. He informed the Board of some further proposed changes including rewording of IT and HR core operations. He stated that a revised business plan would be circulated to the Board via email by 17 March and the Board would be asked to provide any further feedback no later than 24 March. This would ensure that the final business plan could be submitted to DHSC before the end of March.

29. The Board discussed the areas for rephrasing some of the wording to make it stronger and provide greater clarity.

30. The Board discussed the role of social media within HTA's communication strategy and whether HTA was measuring the right parameter in this regard.

31. The Board discussed the setting of targets, providing appropriate stretch for the organisation, but that such targets should be realistic and achievable.

32. In response to a question, further information was provided on the proposed Horizon Scanning expert group and the likely expertise that might be included.

33. **Action 3** The Board approved, in principle, the HTA Business Plan for 2023/24 subject to the final draft being distributed via correspondence, and taking into account the proposed changes agreed at the Board Meeting.

Item 10 – Audit, Risk and Assurance Committee Update (HTA 06/23)

34. Professor Gary Crowe, Chair of the Audit, Risk and Assurance Committee, presented the report to the Board. He provided several highlights to the Board on the Committee's discussions.

35. He stated that the Committee had received updates on the Data Security and Protection Toolkit, noting that HTA has more to do to attain full compliance. He stated that preparations for the external audit are progressing well, and several issues have been addressed for the internal audits.

36. The Board noted the report**.**

Audit, Risk and Assurance Committee Terms of Reference

37. Richard Sydee, Director of Resources, presented the revised ARAC Terms of Reference to the Board and explained the two minor amendments recommended by the Committee.

38. **Action 4** The Board agreed the amended Terms of Reference for the Audit, Risk and Assurance Committee.

Item 11 – Remuneration Committee Update (HTA 07/23)

39. Ellen Donovan, Chair of the Remuneration Committee, presented the report to the Board. She provided several highlights on the Committee's discussion regarding staff remuneration, organisational development and communication.

40. She spoke about the Committee's role in supporting the organisation in personnel matters and was keen that RemCo governance and meetings (virtual

as needed) could be arranged quickly when that was needed so that decision making could be timely.

41. The Board noted the report.

Item 12 – Shared Services Update (HTA 08/23)

42. The Board noted the information report presented to the meeting on Shared Services.

Item 13 – Minutes of 3 November 2022 (HTA 09/23)

43. The Board agreed the draft minutes as an accurate record of the meeting on 3 November 2022.

Item 14 – Matters arising from 14 July 2022 (HTA 36/22)

44. The Board noted the matters arising report.

Item 15 – Any other business

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

Date of Next Meeting

29 June 2023 at 2 Redman Place.

Meeting actions

Action 1

The Board noted HTA's developing approach to using data to inform sectoral risk assessment through the implementation of a segmented approach to its inspection work. The Board noted this approach has been used to inform the inspection programme for 2023/24.

Action 2
The Board approved the revised risk tolerance statements for the HTA's strategic risks 2, 3 and 7.

Action 3 The Board approved, in principle, to the HTA Business Plan for 2023/24 subject to the final draft being distributed via correspondence, and taking into account the proposed changes agreed by the Board Meeting.

Action 4
The Board agreed the amended Terms of Reference for the Audit, Risk and Assurance Committee.

Human Tissue Authority
Board Meeting Conducted in Public

Date:	29 June 2023
Paper reference:	HTA 18/23
Agenda item:	12
Author:	Heather Troy

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 31st May 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_10	July 22	**Development Programme** 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	**Review in July**	An initial PID has been drafted that sets out the approach to be adopted. Further detail including timescales and updates to risks will be included following the outcome of a high-level discovery phase that is focused on affordability which is due to report in early July. **Completed.**
B_2023_01	March 23	**HTA's differentiated, risk-based approach to developing the inspection programme 2023/24** The Board noted HTA's developing approach to using data to inform sectoral risk assessment through the implementation of a segmented approach to its inspection work. The Board noted this approach has been used to inform the inspection programme for 2023/24.	Director of Regulation			**Completed** No further action required.
B_2023_02	March 23	**Review of HTA's Risk Tolerance** The Board approved the revised risk tolerance statements for the HTA's strategic risks 2, 3 and 7.	Director of Resources			**Completed** No further action required.

Number	Date added	Action	Assigned to	Target date	Revised date	Status
B_2023_03	March 23	**Business Plan** The Board approved, in principle, to the HTA Business Plan for 2023/24 subject to the final draft being distributed via correspondence, and taking into account the proposed changes agreed by the Board Meeting.	Deputy Director for Performance & Corporate Governance			**Completed** No further action required.
B_2023_04	March 23	**Audit, Risk and Assurance Committee Terms of Reference** The Board agreed the amended Terms of Reference for the Audit, Risk and Assurance Committee.	Head of Finance			**Completed** No further action required.

Stakeholder Engagement Update

Human Tissue Authority
Board Meeting Conducted in Public

Date: 29 June 2023

Paper reference: HTA 19/23

Agenda item: 13

Author: Jonathan Spencer

Update on the Communication and Engagement Strategy

Purpose of paper

1. To provide an update on the Communication and Engagement Strategy.

Decision making to date

2. The board approved the HTA Communications and Engagement Strategy in May 2023. SMT made additional decisions on the stakeholder approach, internal comms activity and regulatory updates in Q2 & Q3 of 2022 to 2023

Action required

3. To note what has been delivered since the strategy was agreed in May 2022 and the plans for 2023/24.

Background

4. On 5 May 2022 the Board approved the Communication and Engagement Strategy. The strategy outlined four strategic principles: be present, be relevant, be proactive, be clear and consistent. These principles have shaped the approach taken over the last year.

5. It should be noted that delivery of the strategy has been against a background of staff turnover, with two existing team members leaving in Q1 and Q2 and new members joining in Q1 and Q3. The team now consists of Head of Communications and Engagement, Stakeholder Manager, Communications Officer and Content Designer.

Media

6. Engagement with the media has gradually increased throughout the year. There has been work in the background to review and improve our contact lists, drive up our responsiveness to enquiries and shift the internal culture to be more open to engaging with the media. Whenever possible, we provided a spokesperson response and we have put forward Heads of Regulation and a Regulation Manager to provide journalists with background briefings. This shift has also seen an increase in enquires we receive.

Moving forward

7. We aim to deliver two proactive stories a quarter, covering the work of the HTA, this will include updates to guidance, new or innovative licence approvals and HTA business such as the annual report and business plan. To supplement this, we have increased the use of blogs and use of HTA data to highlight activity on the website and social media. For example, every month we now publish the live donation approvals data and are working with colleagues to agree a plan to increase proactive messages around our data releases and inspection reports. A forward look of activity can be found at Annex A.

Stakeholder relations

8. The Communications and Engagement Strategy included re-establishing stakeholder groups. Internal feedback had been to change the governance and structure to ensure they were reflective of all sectors and could work as a useful tool to listen and engage with representative organisations across the sectors we regulate.

Events

9. The approach outlined (summer 2022) was for a series of sector focused engagements in Q4 and roundtables in-between. Following executive review a revised approach was rolled out in Q4, with more structured sector engagement forums twice a year, with the option for roundtables between.

10. To align with a more modern approach, the forums and roundtables are reported via blogs externally and supported by internal meeting notes.

In Q3 there was a roundtable with the Devolved Administrations and in Q4 sector-focused forums covered Post Mortem, Anatomy, Human Application and Organ Donation and Transplantation.

11. The forums came together virtually, and feedback from attendees was positive overall. A common thread was the importance of collaboration and engagement with the sectors we regulate.

12. Blog posts about HTA stakeholder engagement activity are below.

    - HTA and devolved administrations - working together | Blog | Human Tissue Authority
    - Introducing our sector-focused stakeholder forums | Blog | Human Tissue Authority (hta.gov.uk)
    - An update on our stakeholder forums for Anatomy, Human Application and ODT | Blog | Human Tissue Authority (hta.gov.uk)

13. In March 2023 we attended the NHSBT/BTS congress in Edinburgh and for the first time had a modest stand. Footfall and engagement with colleagues on the stand was steady and provided an opportunity to engage with a range of stakeholders. We have supported regulation colleagues providing training presentations at events in the PM sector.

Newsletters and Alerts

14. We have shifted the stakeholder newsletter from every two months to quarterly. This change followed an assessment of the newsletter performance and in recognition of the quality and quantity of updates regulations teams were able to provide. With a lower frequency, the newsletters contain more information and there has been a slight increase in engagement with them.

15. In Q3, we introduced regulatory updates to build flexibility to how we message establishments. These sit at a level below alerts. **Alerts** are now issued when immediate action might be needed to protect patient safety. **Updates** are used when the standards or guidance are changed or updated, and other important but non-urgent information needs to be relayed. In Annex B you can see data on the performance of the stakeholder newsletters and regulatory alerts and updates.

Moving forward

16. Summer roundtables are being scoped. We are exploring opportunities to work with the National Crime Agency to focus on trafficking for organ donation and transplantation and are developing a roundtable on the management of the deceased for July.

17. The plan is for the sector-focused forums to be held twice yearly in Q1 and Q3. With the next set planned for autumn 2023. The autumn series will also include engagement with public display and research.

18. We are currently scoping options for face-to-face activity either later in 2023 and/or 2024. We will update the Board on their involvement with these as the plans become firmer.

Website

19. At the end of March 2022 the HTA website passed the final assessment of NHSX's quality assurance scheme which allowed the site to move from public beta, into the live. Since then, the focus has been on incremental content improvements and driving more traffic. We have built a section where users can find the most recent inspection reports and increased the number of news items published on the site.

20. In Q4 the website was independently audited by GDS for accessibility. UK law required all public sector websites to be fully compliant with the Web Content Accessibility Guidance (WCAG 2.1) AA accessibility standards by 28 September 2020, or be demonstratively working towards this standard. The global standards define how to make web content more accessible to people with disabilities.

21. GDS assessed the HTA site and published a report on 9 March. Accessibility report for www.hta.gov.uk (accessibility-monitoring.service.gov.uk). The report highlighted template issues, which impact all pages of the website. The four issues were:

    - the close button within the search banner is not accessible using the keyboard
    - at 400% zoom, once opened the menu does not reflow correctly
    - at 400% zoom and in mobile view, the privacy setting button covers content at the bottom of the webpage
    - there is poor colour contrast when the keyboard tabs onto buttons in the cookie banner, this refers to the green privacy button in the bottom of the webpage.

22. The website templates were updated in spring 2023 to address the website design issues raised in the GDS audit. The remaining areas that need to be addressed are publications on the website.

Moving forward

23. As part of our content improvement work, we are looking at converting more of our content into HTML. This will make the content accessible and improve how the content performs in search. Search engines cannot search inside pdf documents. These pages include a downloadable pdf. There are between 40-50 pdfs that we plan to convert. A couple of examples where we have done this are:

    - https://www.hta.gov.uk/guidance-professionals/guidance-sector/human-application/human-application-sector-hta-standards

    - https://www.hta.gov.uk/guidance-professionals/guidance-sector/post-mortem/post-mortem-examination-licensing-standards-and.

24. GDS reported that HTA inspection reports are not accessible. The main issue is the use of text-based tables, where the headers and content do not match and are not labelled. To make the reports accessible, we are working with Regulations Directorate to consider the overall design of the reports to see if the tables can be designed out. We will also take the opportunity to remove any non-essential information that can be found elsewhere on the website.

25. Working with the organ donation and transplantation and post-mortem regulation teams we are trialling different approaches to make it easier and clearer to understand guidance, find content on the website, develop content in other formats such as video and improve content related to our most common enquires to try and reduce email enquiries.

Social Media

26. Social media activity and engagement has increased, seeing a modest uplift in engagement and followers. The team are going to focus in on Twitter and LinkedIn as the primary social media channels for HTA.

27. We have been trialling a range of approaches, building on national and international themed weeks and causes, capitalising on high profile activity like the documentary on body donation in December 2022 and tyring to generate more content through blogs, data and case studies.

28. Each month we use social media to report on the live donation approvals that have been made by HTA. We have also responded to questions we get asked on social media channels. With a commitment to regularly post and to engage more, our social channels continue to grow. Virtually all of our social content drives through to published material on our website. The website has also seen an increase in traffic. Data on the website and Twitter account are available at Annex C.

Moving forward

29. We will continue to test and learn different approaches across social channels, increasing the range of content we produce and engagement with other stakeholders on social media. In the autumn, we plan to support body donation week, which continues to perform well on social and is one of our most viewed pieces of content on the website. We will link social media activity to areas of the website where we have made improvements.

Internal Communications

30. Following a pilot in the summer, which showed an increase in engagement with reduced frequency, we have moved the internal newsletter to every fortnight.

31. In Q2 following feedback at an all-staff event, we introduced an “Ask the CEO” teams call. This call is every other month and provides a dedicated opportunity to ask Colin any questions. Engagement with these remains stable, the main focus of questions has been about pay and terms and other conditions. It has shown that Colin and SMT are listening and responding, with the January Ask the CEO event leading to a blog by Richard to clarify the pay position.

32. In Q4, we restructured the weekly exchange call to provide a wider range of voices on the call, and developed a plan for a different area of HTA to share how their work is supporting the vision and mission. Staff have shared informally that they like hearing about the work of teams across HTA.

33. In Q4, we have supported the development of the HTA values, consulting with colleagues on design options and bringing in line with brand guidelines. Following changes in the HR team, the communication team picked up the Superbowl call, which provides an informal way for colleagues to get to know each other through a Q&A session. We aim to deliver at least one a quarter.

Moving forward

34. The team supported the development of the HTA business plan, providing an engagement plan and visual timeline to help enable a more collaborative approach to its development. The team will provide similar support this year for the business plan and the HTA strategy.

35. We have developed a narrative for the HTA, which builds out from the vision and mission to provide top level descriptions about the work of the HTA. It also enables us to share case studies and short descriptions of each team. The narrative will be shared across the organisation in Q2 of 2023/24.

Recommendation

36. To note what has been delivered since the strategy was agreed in May 2022 and the plans for 2023/24.

Annex A

	April – June (Q1)	July – Sept (Q2)	Oct – Dec (Q3)	Jan-March (Q4)
Media/ Stakeholder	ODT roundtable tbc HTA business plan Code F update (NI) Stakeholder newsletter Quarterly closed incidents stats ODT comms plan Trafficking sentencing Media monitoring renewal PM guidance videos	PM roundtable 5 July HTA Annual Report tbc Stakeholder newsletter Quarterly closed incidents stats Annual report of accounts PM guidance videos	**Forums** Post Mortem – Wednesday 13 September Public Display – Monday 2 October Human Application – Friday 13 October ODT - Wednesday 8 November Anatomy - Wednesday 22 November Research - Monday 4 December Stakeholder newsletter Quarterly closed incidents stats Sectors annual review	Stakeholder newsletter BTS congress Quarterly closed incidents stats
Social Media and Website	Accessibility web design fixes, accessible inspection reports, Accessibility audit Stakeholder forum blogs Monthly living donation stats (Accessibility fixes)	Retender website contract Content improvement plan World Transplant Games AAPT consent training Monthly living donation stats Quarterly spend data	Content Improvement Plan Monthly living donation stats Quarterly spend data HR transparency data	Content Improvement Plan Monthly living donation stats Quarterly spend data HR spend data
Internal	Staff newsletter Daily news round-up Ask CEO HTA Superbowl Values design	Staff newsletter Daily news round-up Ask CEO HTA Superbowl Publish the narrative	Staff newsletter Daily news round-up Ask CEO HTA Superbowl	Staff newsletter Daily news round-up Ask CEO HTA Superbowl

Annex *B* Stakeholder Activity

Newsletters

37. There were three newsletters issued in 2022 to 2023, we are able to monitor and track performance and check against similar campaigns: average open rate 31.7%, average click rate 4.2%, average unsubscribe rate 0.1%. The first two newsletters had lower than average open rates, but higher click throughs. The March newsletter outperformed the benchmark.

Newsletter	Recipients	Opened	Clicks	Unsubscribed
July	4842	1196 (26.3%)	270 (5.9%)	6 (0.1%)
November	4875	1216 (27.5%)	230 (5.2%)	10 (0.1%)
March	4669	2138 (48.7%)	187 (9.7%)	11 (0.1%)

Regulatory Alerts and Updates

38. In 2022 we issued two alerts and two updates. In 2023 there have been one alert and four updates issued so far. We are monitoring performance, but the increase frequency of updates has not impacted performance against industry standards of 32.7% open rate, 7.7% link click and 0.1% unsubscribe.

Alert/Update	Recipients	Opened	Clicks	Unsubscribed
Alert 001/2022 West Nile Virus (NI only)	14	3 (25%)	19 (8.3%)	0
Alert 002/2022 Dengue cases in France	411	229 (58.15%)	133 (37.3%)	1 (0.3%)

Update 001/2022 PM sector guidance	167	110 (66.7%)	87 (52.7%)	0
Update 002/2022 ODT sector guidance	166	63 (41.1%)	43 (28.3%)	0

Alert/Update	**Recipients**	**Opened**	**Clicks**	**Unsubscribed**
Alert 001/2023 HA and ODT product defects	304	116 (40.1%)	23 (8%)	0
Update 001/2023	1066	455 (47.7%)	329 (34.5%)	2 (0.1%)
Update 002/2023	88	52 (59%)	25 (28.4%)	0
Update 003/2023 HA and ODT update on product defects	301	92 (32.2%)	30 (36.2%)	0

Alert/Update	Recipients	Opened	Clicks	Unsubscribed
Update 004/2023 Data collection exercise	3376	1001 (32%)	240 (7.7%)	4 (0.1%)
Update 005/2023 Code of Practice F, Part two update	128	47 (40.2%)	25 (21.4%)	0

Annex C Social media and website

39. To provide supporting data from across communication activity, how we are bench marking and measuring through our KPIs and PIs and comparing to other similar organisations. Comparing Twitter activity in April 2022 and April 2023 you can see there has been an increase in followers by 193, or around 16 a month. Impressions have increased. We are aiming to achieve a good engagement rate of 3.7% which across most months we are meeting.

Month	Followers	Engagement Rate	Impressions
April	2,666	4.3	4,000
May	2,688	2.2	10,000
June	2,694	3.6	6,987
July	2,711	3.9	5,772
August	2,714	4.1	8,294
September	2,718	3.9	6,972
October	2,723	5.0	11,300
November	2,739	6.5	5,581
December	2,783	4.8	14,300
January	2,788	3.3	9,701
February	2,840	4.6	15,600
March	2,859	4.3	12,200

Website performance April 2022 to March 2023

40. From April 2022 to April 2023, there was a significant increase in activity across all categories on the website. The total site activity measured as page views grew from 29,337 to 44,339. Overall, the website experienced a substantial uptick in engagement and growth across all areas. The bounce rate remain fairly static during this period of growth and is comparable with an average bounce rate. With improved content and navigation, this rate may improve.

Month	Users	Sessions	Page views	Average time on site	Bounce rate
April	11,554	16,382	29,337	2.03	49%
May	11,887	16,876	29,701	1.59	50%
June	10977	15,287	26,841	1.59	50%
July	13,393	17,939	29,195	1.39	55%
Aug	14,153	18,882	30,585	1.62	54%
Sept	14,757	19,659	32,405	1.45	53%
Oct	16,468	22,534	37,127	1.53	53%
Nov	16,794	25,584	40,143	1.53	53%
Dec	16,958	22,159	35,832	1.47	50%
Jan	19,142	26,360	44,399	2.12	50%
Feb	17,873	24,249	41,135	2.17	52%
March	18,992	26,300	44,835	2.19	53%