One-hundredth meeting of the Human Tissue Authority Board

Date: 5 May 2022

Time: 10.00-12.30

Venue: 2 Redman Place, London

Protective Marking: OFFICIAL

Agenda

Meeting Administration

1. Welcome and apologies (LB)

2. Declarations of interest (LB)

Regular Reporting

3. Chairs Report (Oral) (LB)

4. Chief Executive's Report (HTA 12/22) (CS)

5. HTA Performance Report (HTA 13/22) (CS)
   Annex A Board Data Overview (HTA 13a/22)
   Annex B Summary of Strategic Risk Register (HTA 13b/22)
   Annex C Strategic Risk Register (HTA 13c/22)

Items for discussion

6. Communication and Stakeholder Engagement Strategy (HTA 14/22) (LD)
   Annex A HTA draft Communication and Stakeholder Engagement Strategy (HTA14a/22)
   Annex B Summary of stakeholder research findings (HTA14b/22)

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7. Development Programme Annual Report (HTA 15/22) (LD)

8. Remuneration Committee Terms of Reference (HTA 16/22) (CS)

Items for information only

9. Minutes of 10 February 2022 (HTA 17/22)

10. Matters arising from 10 February 2022 (HTA 18/22)

11. Deemed Consent NI (HTA 19/22)

Questions from observers

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

Any Other Business

13. Any other business (oral)

This version 27 April 2022

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Human Tissue Authority
Board Meeting

Date: 5 May 2022

Paper reference: HTA 12/22

Agenda item: 4

Author: Dr Colin Sullivan

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Chief Executive's Report

Purpose of paper

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

Action required

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

Update on Q4

3.   At the outset of Quarter 4 of 2021/22, it was important for me to quickly get up to speed so that pending decisions could be taken, not least, on how best to deploy in-year underspent resources within the remainder of the financial year to maximise the benefits available. This included support for the development of our Communication and Engagement strategy, additional resources for the Development Programme, creation of several HR recruitment and performance management packs and additional investment in IT hardware.

4.   Q4 was also a busy period for recruitment activity. There were campaigns for an Interim Chief Information and Technology Officer (a six-month fixed term contract starting in February) and an interim Head of Policy and Development (who started with us in March). Additionally, we have secured a long-term secondment for the Head of Communications and Engagement role, a

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permanent Stakeholder Engagement Manager, and a permanent Transplant Officer all of whom have or will start during Q1. The recruitment process for a Deputy Director, Performance and Corporate Governance commenced in March and continues at present.

5.   An important feature of Q4 was the conclusion of the Business Plan for 2022/23. Again, some aspects of business planning had been left pending my arrival and this meant there was less time than would normally be the case to consult with staff and to develop a set of draft proposals which were consistent with the 3 year (2021/24) Corporate Strategy. My thanks to Richard Sydee and Jas Badhan for the way they have progressed business planning at pace this year. I was pleased that we had a draft plan with the HTA Board by the third week in March and were able to share the Board approved plan with our DHSC sponsor team colleagues before the end of March. This is a notable improvement on last year and allowed us to start the financial year at the beginning Q1 of 22/23 with a clear focus on implementation.

6.   In Q4, the HTA continued to support the work of the Fuller Independent Inquiry led by Sir Jonathan Michael. We provided comments on the Inquiry's draft terms of reference on 3 February 2022, with the final version published by the Inquiry on 23 February 2022. We have subsequently responded to the Inquiry with the provision of two sets of relevant information.

7.   My first 100 days as CEO paralleled with the whole period of Q4 and I reached that milestone on 10 April. During this time, I met with staff and stakeholders to learn and listen, and to then formulate ways forward. We held an "All Staff Workshop" in March which was an opportunity to meet in-person with staff and it was pleasing to have a very high level of attendance with good levels of engagement. This event was a chance to both build stronger bonds amongst colleagues (some of whom were new within the last 2 years and hadn't met with many colleagues), and also an opportunity to progress several important issues, namely, a new Vision and Mission and to consult with staff on what was at that stage, the draft Business Plan.

8.   During Q4, meetings with external stakeholders included meetings with the CMO for Wales (Sir Frank Atherton), the CEOs of CQC, NICE and MHRA (Ian Trenholm, Sam Roberts, and Dame June Raine). I attended the Secretary of State's Speech on the "Road to Recovery" at The Royal College of Physicians

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and the Launch of the NHSBT Strategy (NHS Blood & Transplant). I also met with DHSC sponsor team colleagues (led by William Vineall). As regards Deemed Consent for Northern Ireland; I met with NI Department of Health (DoH) Officials and attended a meeting of that department's Clinical Advisory Group for Organ Donation; and attended a function hosted by Minister Swann at the NI Assembly, Stormont, to mark the completion of the legislative passage of the Organ and Tissue Donation (Deemed Consent) Act 2022.

9.   Following a gap due to the priorities around dealing with the Covid-19 pandemic, DHSC has re-introduced accountability review meetings on a quarterly basis. We met on 3 March 2022 to discuss progress during Q3 of 2021/22 and the Q4 review meeting will be later in May. I very much welcome the re-introduction of these meetings, recognising that all of us in the HTA are accountable public servants.

Current issues

10.   The draft Business Plan for 22/23 (which the Board saw at the end of March) is with DHSC for scrutiny and comment. It sets out the core business and projects that we are planning to deliver throughout the year. These are aligned to our key themes and strategic objectives. In 22/23 we are aiming to significantly increase the number of inspections (from 140 in 2021/22 to 210 in 2022/23) by adopting a greater variety of regulatory approaches, such as more focused thematic inspections, in line with our assessment of risk. This will also link in with the work we are planning to do on reviewing our approach to inspection and reintroducing regular data collection from our licensed establishments, to inform our picture of risk and ensure that inspections can be suitably targeted to the level of risk.

11.   After the impact of the pandemic, I am pleased that we have re-introduced Key Performance Indicators. This is important to demonstrate how we are progressing against our ambitions and is a key element of accountability. We will also be developing key strategies for Communications and Stakeholder Engagement, People, and Information Technology. Once approved, work will begin on implementing these strategies which form part of our portfolio of projects for the year ahead.

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12. The departmental / arm's length body Framework Agreement is currently being revised in concert with the DHSC sponsor team. Members of the HTA Senior Management Team have reviewed and passed the agreement back to the department. We expect to have the document confirmed by the department and HMT by early June 2022.

13. The HTA has been invited to give evidence to the House of Commons Science and Technology Committee Inquiry, *"Right to privacy: digital data"* the likely date of HTA's (CEO) attendance is 8 June. The committee has a specific focus on health data.

14. Previously, I have highlighted that I am keen to review and, if necessary, refine our strategic goals and approach and this work has commenced with development of draft vision and mission statements.

15. We are seeking to discuss with the board the draft statements that have been developed through staff engagement, as mentioned above. At present, these are currently drafted as follows:

    Vision: **"Safe and ethical use of human tissue and organs**"

    Mission: **"To be an excellent, modern, accountable regulator which is transparent, proportionate, agile, collaborative and innovative to ensure that the removal, use and storage of human tissue and organs commands public confidence, through patient safety and appropriate consent"**

16. Once these are confirmed, we will move to look at how we can best achieve these strategic gaols by looking at the values and behaviours that underpin our approach.

17. The executive welcomes the 4 new Board Members for England (Helen Dodds, Tom Chakraborti, Dave Lewis, and Andy Greenfield) who joined the Board from 1 April 2022. The new Board Members have all received training in Living Donation, as well as other areas of induction.

18. We are very grateful to Lorna Williamson, Penney Lewis, Jan Williams, and Stuart Dollow who have recently stood down. In addition, a new Board Member

for Northern Ireland is also due to join us later in the year to replace Glenn Houston who completed his term of office on 30 April after 7 years of board membership. Our thanks to all for their dedicated service.

19. With these recent changes to board membership, we have reviewed and revised our induction and orientation training for Board Members. HTA Board Members also completed a board effectiveness questionnaire for 21/22 during March and the findings and any follow up actions will be discussed by members of the HTA Board.

Recommendation

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

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Human Tissue Authority Board meeting

Date:	5 May 2022
Paper reference:	HTA 13/22
Agenda item:	5
Author:	Senior Management Team

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HTA Performance Report

Purpose of paper

1. To inform the Board of HTA's performance in Q4 against our objectives and operational delivery targets.

Decision making to date

2. The SMT agreed this paper on 12 April for submission to the HTA Board.

Action required

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

Operational Delivery

(a) Regulation

4. The target of 140 inspections (on site, virtual and hybrid) was accomplished, with a total of 157 achieved, 40 of which were Licence Application Assessments. All other regulatory milestones from our 2021/22 business plan were met.

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5. Following feedback on the former Regulation Data Annex, we have developed a revised approach (Annex A HTA 13a/22) to present high-level regulatory data in a dashboard style display.

6. Slide 2 in the Board Data Overview shows the return of inspection numbers to a scale comparable with pre-Covid years, now comprising a combination of Virtual Regulatory Assessment and site visits, with routine site visits having resumed from Quarter 3.

7. Aside from the HA Sector, there is no legal requirement for the HTA to carry out inspections. The HTA does not operate an inspection cycle, with inspection being driven by our risk profiling process, which varies between sectors. The reinstatement of a full programme of inspections by the final quarter of 2021/22 has enabled the HTA to make good progress in recovering its position on meeting the legislative obligation to undertake site visits at least two-yearly in the HA sector. We expect to be back on track with this obligation by the end of October [1] We also expect to have assessed all Post Mortem sector establishments under the 2017 licensing Standards by the end of Quarter 1, 2022/23.

8. Slide 3 in the Board Data Overview gives some more information about incidents and Corrective and Preventative Action (CAPA) plans. Total numbers of incidents by category, during 2021/22 and the four preceding years, are summarised. The profile of incidents reported to us has continued to follow a pattern of slight seasonal variation. For the previous Board Data Annex, we analysed data on incidents reported to us over a 5-year period using Statistical Process Control techniques. This did not highlight any variations outside of expected random variation.

9. CAPA plans are developed by licensed establishments with HTA oversight and are used to address shortfalls identified on inspection or to address other issues that might arise, such as following an incident or in connection with a licence application. The majority of these are resolved by establishments taking action to the HTA's satisfaction within six months of being opened, with escalation processes for those not resolved within that period. The summary on Slide 3 shows that most (52 out of 65) open CAPA plans are less than 6 months old, with

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[1] Note: The one establishment that has never been inspected has never been operational and this licence is under review.

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9 being between 6-12 months. 3 CAPA plans have been open for more than two years, each of which is being actively managed with oversight from the relevant Head of Regulation and the Director of Regulation. The final chart on Slide 5 shows numbers of CAPA Plans opened each year over the past five years.

10. Slide 4 of the Board Data Overview provides 5-year overviews of enquiries received by the HTA, Licence applications and variations, and incidents reported to the HTA. As noted above, the 5-year data on incidents was analysed using Statistical Process Control techniques for the previous Board Report. Licence variations and new licence applications have mostly increased over the past five years, with some of this reflecting actual sector growth (such as in the Research sector) and some reflecting other changes to licences (particularly during the period of Covid restrictions) and some re-configuration and consolidation of licences reflecting changes in the organisations licensed (such as NHS Hospital Trusts). Following the increase in Enquiries broadly linked to Covid, numbers have returned to a pre-Covid level. The most significant trend has been the reduction in Body Donation Enquiries, which are enquiries from members of the public seeking information about body donation. Whilst the HTA has no direct role in the body donation process, we have made helpful information available to the public and used to issue paper packs. That information is now readily available on our website, which may explain the reduction in enquiries as well reflecting a Covid-related reduction in activity in the anatomy sector.

11. Slide 5 gives summary activity data over 2021/22 and the previous 4 years in the HTA's statutory role in approving living organ donation and some bone marrow and peripheral blood stem cell (PBSC) donations. As noted previously, the 5-yearly statistical process control analysis undertaken for the last Board report did not show any significant variation outside of expected random variation, whilst also showing the notable dip in activity during the period of Covid restrictions, reflecting the reduction in transplant activity. A similar pattern is obvious in the final chart showing CAPA plans opened each year over the past 5 years, with a marked reduction as HTA inspections were suspended and gradually reintroduced during Covid.

12. In future, a combination of reporting on Key Performance Indicators and exception-based reporting, using tools such as multi-year trend analysis and statistical process control, will be used to provide the in-year quarterly and end-of-year annual review of regulatory activity.

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13. The HTA has contributed to the Department of Health and Social Care (DHSC) led statutory Post Implementation Review of The Quality and Safety of Organs Intended for Transplantation Regulations 2012. This review is appraising how well the policy objectives of the original legislation have been met and whether the legislation remains appropriate.

14. In January, the closure of the Virtual Regulatory Assessment (VRA) development project was formally approved by SMT and a lessons learned exercise completed. The project has delivered a standardised, cross-sector process for undertaking VRAs that has been successfully incorporated into business-as-usual activities.

15. The closure of the Safe Site Visits project, which had enabled the HTA to establish new policies and processes in order to undertake site visits safely in the context of Covid restrictions, was also formally approved by SMT and a lessons learned exercise completed.

16. During Q4, critical shortfalls were found at two establishments in the Post-Mortem sector, one of which related to an unannounced inspection, the other was a routine inspection. The critical shortfalls related to findings concerning traceability and the condition of the premises. In both cases, immediate regulatory action was taken to issue notice of Directions requiring the establishment to take urgent action to address these shortfalls. We have received assurance that prompt action is being taken in both cases, including urgent full refurbishment programmes, with the accompanying action plans being monitored by the HTA.

17. The HTA has established an internal Working Group to progress actions in response to offending identified in the hospital mortuary at Maidstone and Tunbridge Wells Hospital Trust and in support of the Fuller Independent Inquiry. Following conclusion of the judicial process relating to Fuller, we provided advice to the Secretary of State for Health and Social Care in December 2021. The HTA intends to publish this advice in May, with a brief update on progress on the potential actions explored in that advice, including starting to review and revise guidance to certain licensing standards, supporting the wider system response and preparing to provide input to the Independent Inquiry.

(b) Finance

Table 1 Financial position for Q4 2021/22

Human Tissue Authority

Summary Management Accounts for the twelve months ended

31 March 2022

	Actual	Budget	Variance	
	£	£	£	%
INCOME				
Grant in Aid	911,000	771,000	140,000	18.16
Non-cash cover	78,123	78,123	0	0
Licence Fee income	4,078,605	3,951,321	127,284	3.22
Devolved Governments	133,572	133,572	0	0
Other Income	50,257	50,258	(1)	0
TOTAL INCOME	**5,251,556**	**4,984,274**	**267,283**	**5.36**
OPERATING COSTS				
Staff costs (salaries etc)	3,377,543	3,236,529	141,014	4.36
Other staff costs (excl inspections)	153,382	151,800	1,582	1.04
Board Costs	122,713	173,000	(50,287)	(29.07)
Inspection Costs	23,923	60,000	(36,077)	(60.13)
Living Organ Donation and Transplantation costs	624	9,000	(8,376)	(93.07)
Communication Costs	32,977	31,500	1,477	4,69
IT and Telecoms	370,966	360,000	10,966	18.20
Office and Administration Costs	21,100	123,290	(102,190)	(82.89)
Other costs	138,133	129,850	8,283	6.38
Legal and Professional	488,852	415,520	73,332	296.92
Bad Debts/Impairments	(32,858)	0	(32,858)	0
Accommodation costs	165,101	220,967	(55,866)	(25.28)
Non-cash costs	56,385	78,123	(21,738)	(27.58)
Total operating costs	**4,918,841**	**4,989,579**	**(70,738)**	**(1.42)**
Net Income/(expenditure)	**322,716**	**(5,305)**	**338,021**	**(63.72)**

18. Table 1 provides a summary of our financial position at the end of Q4 of the 2021/22 business year. The final position a surplus of **£322k** before any

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adjustments and a surplus against budget of £338k. Below, is a breakdown of the components that make up our net position.

Income

Table 2 Income summary

Human Tissue Authority
Income Summary
For the Twelve Months Ending 31 March 2022

	Actuals	Budget	Variance	
	£	£'	£	%
Grant in Aid	911,000	771,000	140,000	18.16
Non-cash	78,123	78,123	0	0
Sub-Total	**989,123**	**849,123**	**140,000**	**16.49**
Licence Fees				
Application Fees	102,125	0	102,125	0
Anatomy	112,430	109,880	2,550	2.32
Human Application	1,484,683	1,486,426	(1,743)	(0.12)
ODT	317,125	310,360	6,765	2.18
Post-mortem	1,280,215	1,285,180	(4,965)	(0.39)
Public Display	20,035	20,360	(325)	(1.60)
Research	761,991	739,115	22,876	3.10
Sub-Total	**4,078,604**	**3,951,321**	**127,283**	**3.22**
Other				
Secondees	50,257	50,258	(1)	0
Devolved Assemblies	133,572	133,572	0	0
Sub-Total	**183,829**	**183,829**	**(1)**	**0**
Total Income	**5,251,556**	**4,984,273**	**267,283**	**5.45**

19. Table 2 provides a breakdown of our income for the year. Key variances are as follows:

   a) Grant in aid – £140k higher than budgeted due to drawdown of ring-fenced funding of £140k.

b) Licence fees – including application fees are above budget by **£127k**, which is largely due to application fees which are not budgeted for and an increase in the size of the Research sector.

c) Other income – is on budget.

Expenditure

20. **Staff costs (salaries)** – these are over budget (£141k) due to the use of contract staff to fill permanent roles. These costs also include recruitment placement fees. We spent £85k on recruitment which is 2% of our pay bill. In addition, we have spent £393k on contingent labour which is 11% of our pay bill.

21. **Board (Authority) costs** – are under budget by £50k, including Member allowances, travel, and venue hire. The underspend relates to vacancies at Board level (£27k) and the balance relates to travel and venue costs where most meetings were held virtually, totalling £23k.

22. **Inspection costs** –under budget (£36k) and reflects the reduction in site visits and an increase in virtual assessments as a response to the COVID-19 restrictions. It is expected that costs will increase in 22/23 when site visit inspections will increase.

23. **Living Organ Donation and Transplantation cost** – is under budget (£8k). The move to providing online virtual training for Independent and Accredited Assessors, rather than costly face-to-face training, is the main cause of this variance. The balance represents unutilised funds for printing of ODT leaflets.

24. **IT and Telecom costs** – at the end of the year we are over budget by £11k. This is represented by overspends within IT Maintenance of £28k, IT Consultancy £23k. The overspend within IT Maintenance is partly due to accrued costs for 2 Redman Place of £8k with the balance relating to additional contracts relating to security of our networks and systems. Offsetting the above are underspends within Consumables of £14k, IT Support costs of £4k and Telephone costs £22k.

25. **Office & administration costs** – which is £102k under budget; this includes costs for office relocation, bad debts written off and other office administration costs. The most significant variances are for the office relocation (£92k) which covers additional travel costs for staff which due to restrictions have not materialised; bad

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debts written off totalling £16k[2] and reversal (credit) of a provision of £49k. Added to this are small underspends against printing, postage, stationery, and publication costs totalling £5k.

26. **Other costs** – are over budget by £8k and is due to an overspend against project costs where there was no budget. The cost relates to a new HR toolkit.

27. **Legal & professional costs** – are over budget by £73k. Legal fees are under budget by £6k. We are overspending on audit costs by £18k. In addition, we are overspending against our Consultancy costs by £61k. The Consultancy costs are those relating to portfolio business planning, technical support with communications, and work relating to the Development Programme.

28. **Accommodation costs** – are under budget by £56k. The underspend relates to expected charges for 2 Redman Place. The budget was based upon figures provided at the end of 2020/21, but the initial invoices received from DHSC have been lower than advised.

29. **Non-cash costs** – underspend of £22k represented by depreciation and amortisation costs of our tangible and intangible assets. This underspend materialised due to the original budget being set prior to the major write-off of obsolete assets at the end of last year. These costs are covered by the ring-fenced RDEL provided by the DHSC of £78k which is shown within income as non-cash cover.

Outturn

30. The year-end position of an underspend of £333k is before any adjustments that may arise from the financial audit which will commence late April. The underspend is significant; however, the slow-down of our Development Programme due to other priorities reduced planned expenditure, in addition the reduced site visits and in person meetings in 2021/22 against the planned activity also resulted in significant under expenditure.

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[2] These debts are for establishments that have revoked their licence or have been credited where they have a satellite site which was never used.

Other key performance indicators

Debtors

31. At the end of Q4, the total value of our debtors was **£308k** represented by **62** licensed establishments. This is an increase on the same period in 2020/21 where our debtors were £187k for 48 establishments. We expect to collect these monies over the coming months. The challenge remains making contact with the relevant staff at establishments to obtain payment; where establishments have accounts outstanding from prior years, we have added these to recent invoice runs and this had provided some success in the last quarter.

32. The table below gives a breakdown by sector of the outstanding amounts and the movement from Q3 to Q4 of the 2021/22 business year.

Table four Debtors by sector

Sector	No. of a/cs Mar-22	No. of a/cs Dec-21	Change	Value of debt Mar-22	Value of debt Dec-21	Change
NHS	33	42	21%	£197,512	£268,820	(27%)
Government Bodies[3]	3	5	40%	£5,543	£31,615	(83%)
Local Authorities	2	2	0%	£13,030	£13,030	0
Non-Government Bodies[4]	24	33	(27%)	£92,543	£129,306	(28%)
Total	**62**	**82**	**(24%)**	**£308,617**	**£442,771**	**(30%)**

33. Of the 33 outstanding NHS accounts, 21 (£155k) relate to the 21/22 business year, with the remainder from previous financial years.

34. Of the 24 Non-Government Bodies, 16 (38k) are old and are a mixture of universities and small private establishments. The remaining 8 are from the April and September 2021 billing runs.

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[3] Includes ALBs, museums

[4] Includes Universities and private organisations

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35. Within the Government Bodies there are two from September 2021 which are for local authorities (mortuaries); two organisations that have licences for research with the final account being a credit which will be used to offset their licence.

36. We are actively pursuing all outstanding debt in the above table but have limited options and levers available – there are controls around debt recovery through agents or courts between public sector bodies. We will be raising these issues with DHSC colleagues with the intention of raising concerns through NHS England and other Government Departments where relevant.

Financial risks and mitigations

37. Financial risks are monitored on an ongoing basis. Below, is a table of the current key risks identified and the mitigating actions and controls taken to minimise them. The financial risks in this summary are linked to one or more of the 6 high-level strategic risks that SMT has identified and is managing. The strategic risk 5 – insufficient, or ineffective management of financial resources – at year end is rated yellow (medium) as we have ended the year with a surplus.

Risk	Mitigating actions and controls
Risk that we cannot maintain continuity of payments and salaries	Regular review of cashflow and maintenance of agreed level of reserves.
An overspend or significant underspend may lead to a lack of stakeholder confidence in HTA's ability to manage resources effectively.	Monthly review of financial position and quarterly re-forecasting. Review of activities that can be deferred.
Unexpected increases in regulatory responsibilities	Prioritisation when work requirements change. DHSC funding if appropriate.
Management fails to set licence fees at a level that recovers sufficient income	Financial projections and cash flow forecasting and monitoring.

(c) Governance

38. The Risk Summary document is at **Annex B** (HTA 13b/22) and the Strategic Risk Register is at **Annex C** (HTA 13c/22) to this paper.

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39. At its March assessment of Strategic Risks, SMT concluded that all 6 risks were rated as medium (scoring between 6 and 10). In particular, risk one – failure to regulate appropriately - is below tolerance due to the full inspection schedule in quarter 4 which included VRAs.

40. Risk 4 – failure to utilise our capabilities effectively historically had been rated as high (scoring of 12 and above) but has been reduced to medium. The recruitment to several posts of fixed term contracts has seen pressures somewhat reduced. This effect can be seen in the finance report above. Risk 4 will continue to present an area of risk for the HTA until a full skills gap analysis can be conducted although, as above, this is currently manageable. This should follow the development of the operating model.

41. The remaining risks have not changed significantly.

People Issues
Diversity and Inclusion

42. A revised Equality, Diversity, and Inclusion (EDI) and Human Rights policy was relaunched and published in Q4. The delayed Internal Audit on EDI concluded in January with a generally positive outcome but 3 areas for improvement. Two areas were assessed as low-level risk with one as medium level risk. All three have now been addressed.

43. Through Q4 we engaged an interim Accessibility Lead to review and ensure our web-based documentation was within the Accessibility standards. Accessible templates were created and awareness workshops delivered across the HTA. The Staff Mandatory training programme included a 'Challenging Unconscious Bias module which received very positive feedback from staff.

COVID-19 response

44. Following the latest Government guidelines, and with the end of many of the pandemic related restrictions, the HTA is now looking forward to a new Business as Usual approach and renewed ways of working.

45. More staff are choosing to attend the office to work, and managers have started to schedule face-to-face meetings within 2 Redman Place. The HTA remains sensitive to staff concerns and will continue to consider these on an individual basis.

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Wellbeing

46. The focus on Wellbeing is now a Business As Usual programme of events. Through Q4, our monthly themes have focused on Renew and Assess. Staff were encouraged to be reflective about their own well-being and to consider self-development and mental fitness for 2022. In January, a Year Compass was launched encouraging staff to assess the accomplishments of 2021 and to plan for 2022.

47. In February, we launched the Wellbeing Charter, which was also LGBTQ+ history month. The HTA took part in the national Mental Health Conversation initiative and held a 'Time to Talk' session for staff to come together. This was a powerful session with several staff giving an honest account of their personal experiences.

48. All staff completed a home working risk assessment during Q4, with very few issues raised and all now resolved.

Social Committee

49. The Social Committee has continued to deliver various all staff events. We have also introduced a Friday Superbowl. This is an opportunity for a staff member to be 'quizzed' by others in a friendly, light-hearted manner. The first session was role modelled by the new CEO. All Social Committee activities are conducted both at lunch time and after work and appear to be having a positive impact on staff morale. In the recent Staff Engagement Survey, 82% of staff said they believe the HTA cares about their Health and Wellbeing.

Recruitment and Retention

50. During Q3 and into Q4 the external recruitment market has become much more volatile. Data and Technology roles have become particularly hard to fill with aggressive recruitment tactics being adopted by many organisations. Organisations can no longer assume an accepted offer of employment will lead to the candidate starting or that new starters will stay. Several published research papers highlight an expectation that one third of the UK workforce will look to change jobs before the end of Q2 2022/23 and this has become known as the 'Great Resignation'. Whilst it remains to be seen if this will materialise, we are seeking to respond to greater volatility. The HTA is adopting a more agile approach to recruitment with line managers moving the recruitment process at pace so as not to 'lose' the best candidates. We are also looking at where we advertise opportunities with a much greater UK-wide focus.

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Draft policies may be subject to revision following the HTA Board meeting

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51. Through 2021/22 it was clear the skill set needs of the HTA were changing particularly within the Data, Technology and Development Directorate. To facilitate immediate versus longer term needs and to adopt an agile approach to staffing, the Director decided to fill a number of roles with an interim or fixed term resource. Additionally, due to the Government Communications Service (GCS) placing a 'hold' on permanent recruitment across all Government and non-departmental public body (NDPB) within Communications, these roles were also filled with interim and fixed terms resources. All this activity has led to a higher turnover of staff than we might otherwise have expected.

52. Retention of staff in 2021/22 was lower than the previous year as we came out of the pandemic. The attrition rate for those on permanent contracts, stands at 15% (7), on an average headcount of 47.5 and this is a slight increase from 2020/21 when 13% (6) of those on permanent contracts left, based on an average headcount again of 47.5. The pandemic has influenced people decisions during this period which makes like for like comparisons for year-on-year analysis difficult. The total attrition for 2019/20 (excluding fixed term contractors) was 20% based on an average headcount of 49.
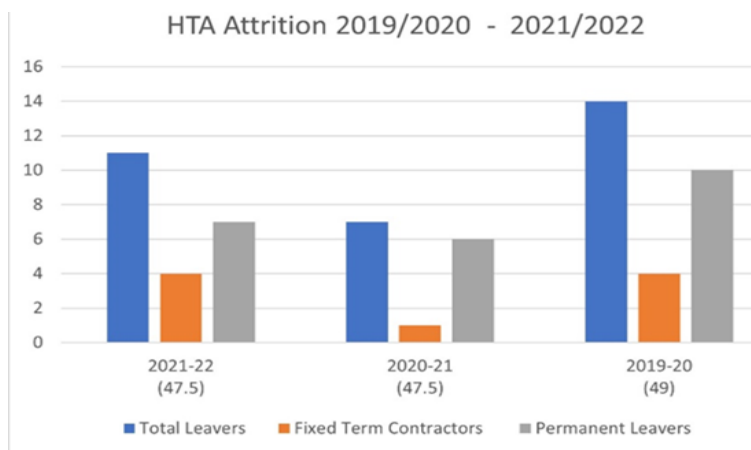
53. During Q4, two members of staff resigned. One additional member of staff left due to the end of a Fixed Term contract. Throughout Q4, SMT approved a programme of recruitment for 9 roles. Three permanent roles are now filled with new starters joining in the next few weeks. Two fixed term contractors are in place, and recruitment is ongoing for an additional permanent role and 2 permanent, and one Fixed Term Contract roles will go to market in Q1.

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54. SMT have agreed a new process for Recruitment across the HTA. Line Managers will now take the lead and manage their recruitment needs with more limited support from HR. To better support our recruitment campaigns and demonstrate the value the HTA places on securing the right future talent for our needs, an HTA Recruitment candidate information pack is in development and will be launched early in Q1.

Sickness absence

55. There were 142 days of sickness related absence in 2021/22, although significantly higher than the reported sickness in 2020/21 at 83 days, it is directly comparable to 2019/20 with 143 days reported sickness related absence. There has been considerable research published to suggest 'normal' sickness, colds, flu and respiratory transmitted bugs and virus were significantly reduced in 2020/21 due to social distancing and the wearing of masks over the course of the pandemic. It was also widely expected that these viruses would re-emerge during the winter months of 2021/22 with a heightened impact on the population. It appears the HTA reflects this national trend.

Engagement Survey

56. The biannual staff engagement survey due in Q3, was delayed allowing the new CEO to lead. This was conducted in February into March with a response rate of 81%. The survey was conducted on behalf of the HTA by a new provider, which is able to provide benchmarking with similar organisations. First analysis indicates the HTA has exceeded the benchmark score in all categories except two. The full analysis and next steps are being considered by SMT during Q1.

PDP Process

57. The process of 360-degree feedback was introduced for SMT and Heads of Function in Q4. A simple 'Stop, Start, Continue' form was developed and launched to facilitate the feedback. Recorded training and Drop-In sessions were developed and delivered to all HTA staff. An assessment of the process will be conducted in Q1 with a view to roll out further across the HTA during the calendar year.

58. To further support improved performance management, a professionalised PDP toolkit is in development and will be launched during Q1.

Training

59. An external provider delivered "Thinking on your Feet" training for a number of staff with very positive feedback. The Career Investment Scheme (CIS) has been revised with staff now required to make a (designated) personal financial contribution to approved courses. One member of staff had a course approved by SMT under the CIS programme in Q4.

60. Four new staff recruited into Regulation Directorate in Summer / Autumn 2021 have successfully completed their initial training and induction. A training event in January for all Regulation Directorate staff included learning from recent incidents reported to the HTA and an overview of the legal, procedural, and practical processes following death and their relevance to the Human Tissue Act and HTA regulation.

Digital, Data and Technology

61. There is a separate paper presented at this meeting of the Board which is the Annual Report for the Development Programme. The draft Communications and Stakeholder Engagement strategy is also presented as a separate paper for the Board's scrutiny.

62. In addition, there is a separate paper for the Board on our plans to revise Code of Practice F to reflect the introduction of Deemed Consent in Northern Ireland (HTA 19/22 refers). The Policy Team continues to work with the Regulation Directorate to identify any areas of the Codes of Practice that may require amendment and we will be considering these matters at SMT over the next few months.

63. The development of the external HTA website to ensure we meet our legal obligation for Accessibility standards, successfully passed the final NHSX assessment at the end of March 2022. With the closure of this project, we can now move out of the Beta stage and into a 'Live' status. This has been a much longer process than we would have liked, and it has required the input and support of many across the HTA, specifically the Digital Communications Manager, the DDT Project Manager, and the Chief Information and Technology Officer. It is pleasing that what has been a time-consuming activity for a small organisation is now completed.

64. During 2022/23, the Policy Team will advance work on reviewing requirements for policy change and reform, informed through Horizon Scanning and our legislative review work. We are seeking to identify the top policy issues facing the HTA and

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propose developed options to address these issues in light of operational constraints and strategic risks. The Policy and Communications teams will work closely to ensure the Policy priorities being advanced reflect feedback from stakeholder engagement activity. A detailed action plan for the policy team is in development and will reflect the HTA updated strategic priorities and the existing Business Plan.

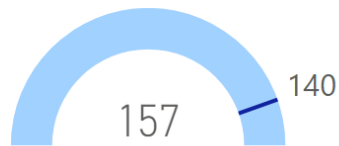# End of year overview 2021/22
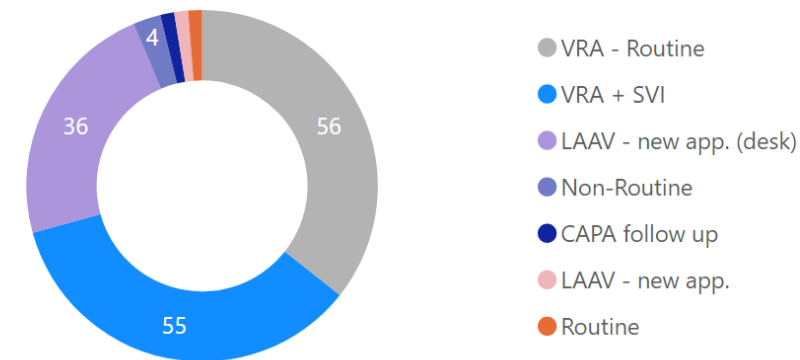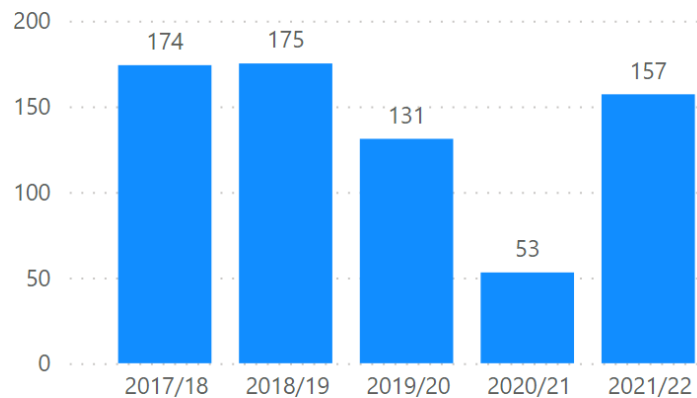
Inspections

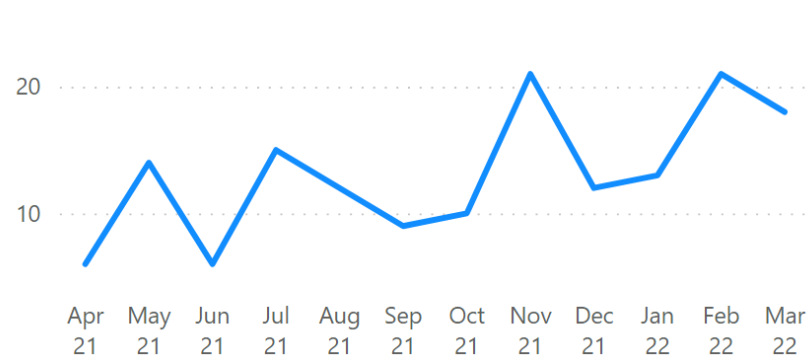**157** 2021/22 YTD

140 2021/22 Target

Inspections 2021/22
140
157

Inspection Type 2021/22

- VRA - Routine (56)
- VRA + SVI (55)
- LAAV - new app. (desk) (36)
- Non-Routine (4)
- CAPA follow up
- LAAV - new app.
- Routine

Inspections by Year

2017/18	2018/19	2019/20	2020/21	2021/22
174	175	131	53	157

Inspections by Month

Apr 21, May 21, Jun 21, Jul 21, Aug 21, Sep 21, Oct 21, Nov 21, Dec 21, Jan 22, Feb 22, Mar 22

Date of Last Inspection	No. of Est
0-12 months	145
12-24 months	36
24-36 months	104
36-60 months	194
+ 60 months	132
Never Inspected	1
Total	**612**

Licensing

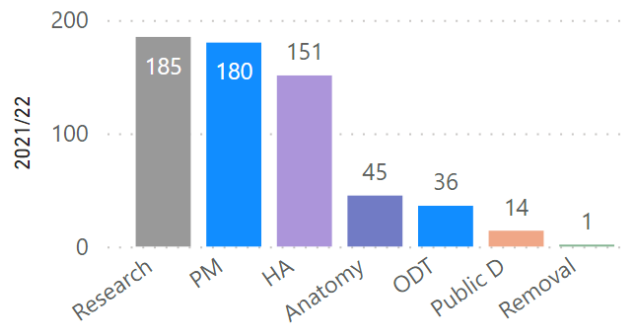**New Licence Apps**
46
2021/22 YTD

Revocations
18
2021/22 YTD

Licence Variations
811
2021/22 YTD

Main Licence by Sector

Research	PM	HA	Anatomy	ODT	Public D	Removal
185	180	151	45	36	14	1

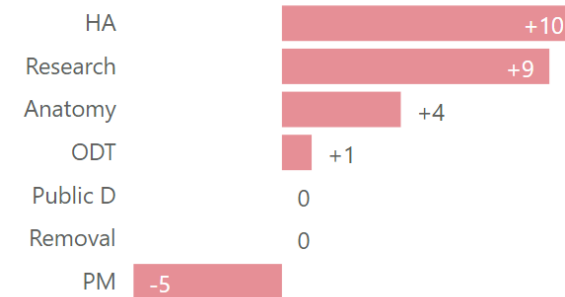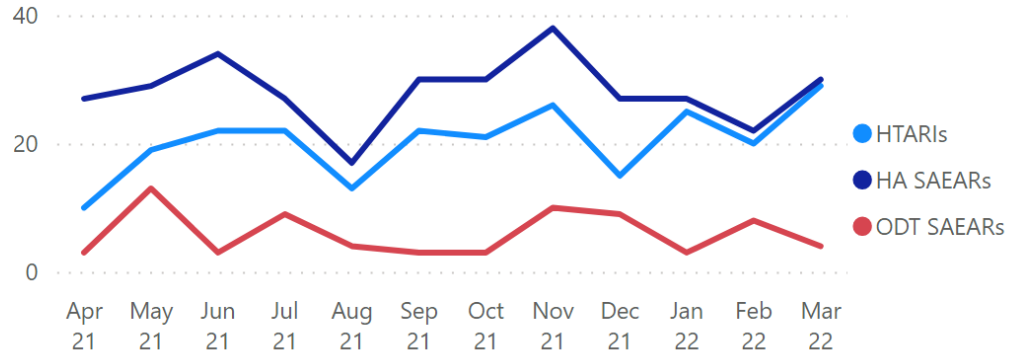| Year	New Licence Apps	Revocations	Variations
2017/18	16	18	521
2018/19	14	11	637
2019/20	22	10	710
2020/21	41	13	837
2021/22	46	18	811
Total	**139**	**70**	**3516**

612 Main Licences

330 Satellites

Changes in Sector (Main Licence Only)
*Apr 2022 compared to Apr 2021

HA	+10
Research	+9
Anatomy	+4
ODT	+1
Public D	0
Removal	0
PM	-5

Incidents

Incidents reported by Month

Year	HTARIs	HA SAEARs	ODT SAEARs
2017/18	224	184	37
2018/19	203	323	62
2019/20	217	320	105
2020/21	198	340	51
2021/22	244	338	72
Total	**1086**	**1505**	**327**

CAPAs

Open CAPA Plans
65

Open CAPA Plans by Sector
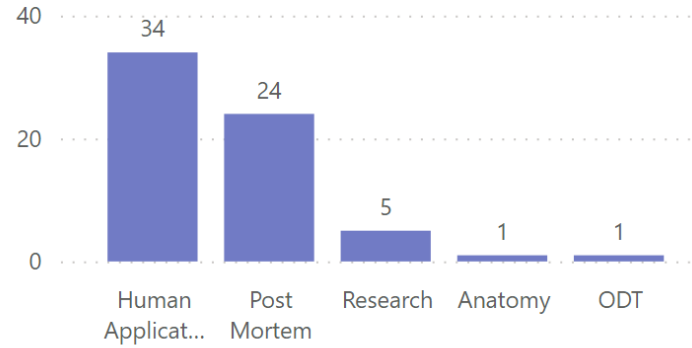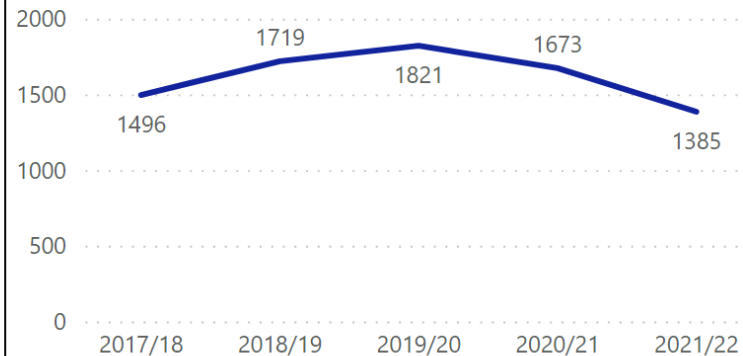

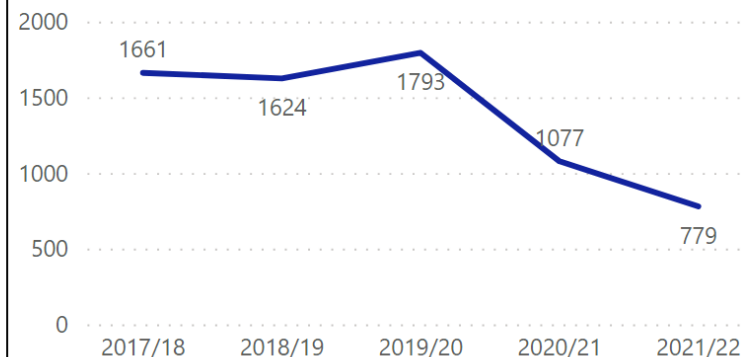| Age	CAPA Plans
0-6 Months	52
6-12 Months	9
18-24 Months	1
+24 Months	3
Total	**65**

HTA 5 Year Overview 2017 - 2022

Enquiries

General Enquiries Received by Year

Year	Value
2017/18	1496
2018/19	1719
2019/20	1821
2020/21	1673
2021/22	1385

Body Donation Enquiries Received by Year

Year	Value
2017/18	1661
2018/19	1624
2019/20	1793
2020/21	1077
2021/22	779

Licensing

New Licence Applications Received by Year

Year	Value
2017/18	16
2018/19	14
2019/20	22
2020/21	41
2021/22	46
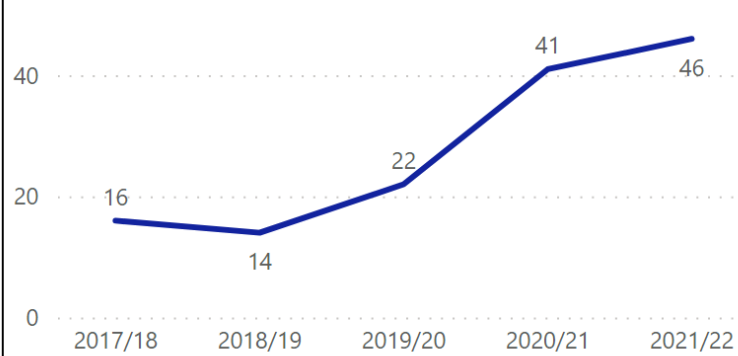
Licence Variations Received by Year

Year	Value
2017/18	521
2018/19	637
2019/20	710
2020/21	837
2021/22	811
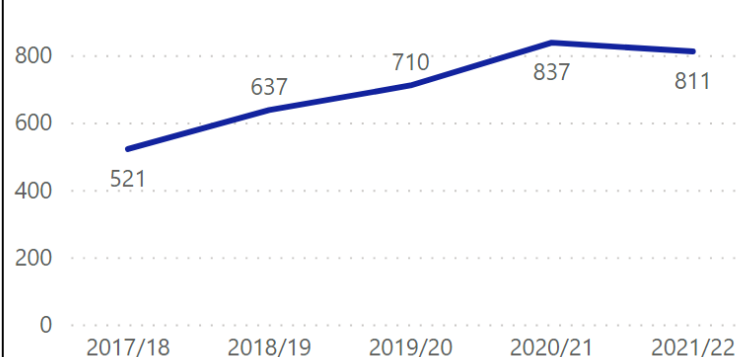
Incidents

HTARIs Opened by Year

Year	Value
2017/18	224
2018/19	203
2019/20	217
2020/21	198
2021/22	244

HA SAEARs Opened by Year

Year	Value
2017/18	184
2018/19	323
2019/20	320
2020/21	340
2021/22	338

ODT SAEARs Opened by Year

Year	Value
2017/18	37
2018/19	62
2019/20	105
2020/21	51
2021/22	72
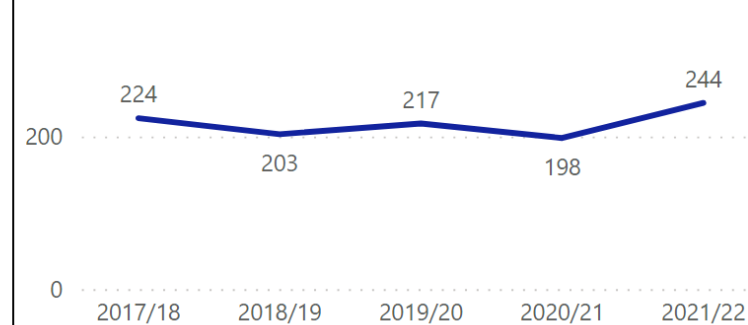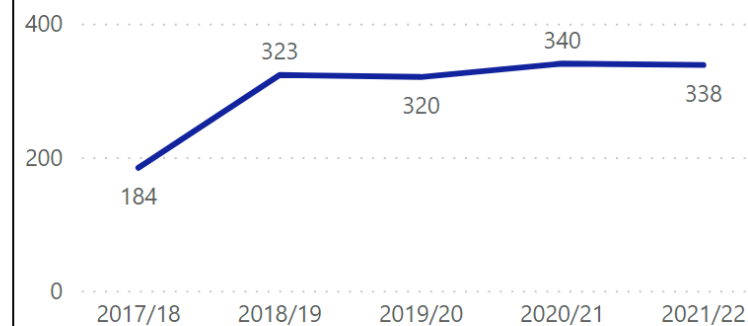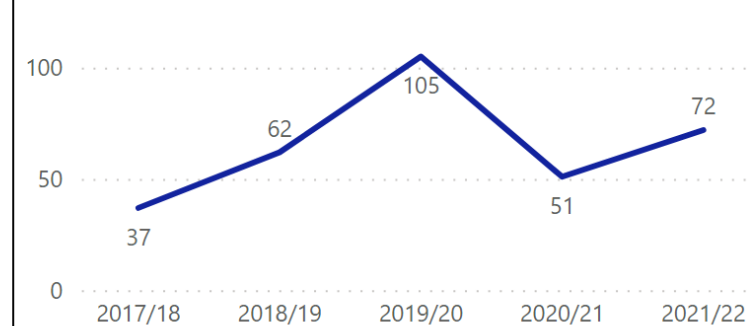
Living Organ Donation

LDAT Cases Approved by Year

Year	Cases
2017/18	886
2018/19	899
2019/20	907
2020/21	440
2021/22	736

Panel Cases Approved by Year

Year	Cases
2017/18	309
2018/19	322
2019/20	382
2020/21	121
2021/22	269
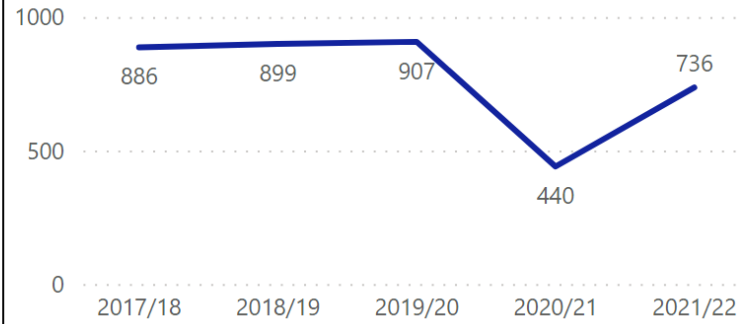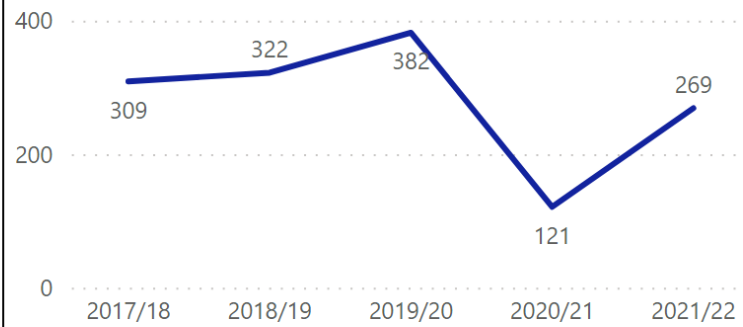
Bone Marrow and PBSC Cases Approved by Year

Year	Cases
2017/18	58
2018/19	71
2019/20	67
2020/21	62
2021/22	62
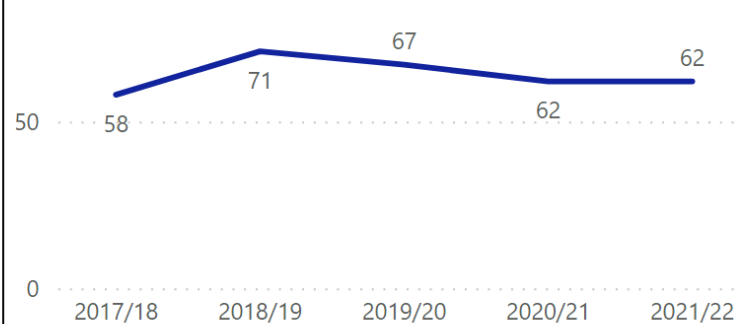
CAPA Plans

CAPA Plans Opened by Year

Year	Plans
2017/18	137
2018/19	169
2019/20	134
2020/21	40
2021/22	112
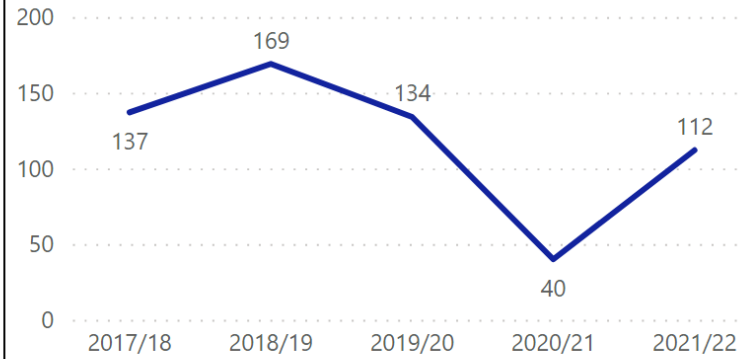
Latest review date – 23/03/22

Strategic risk register 2021/22
Risk summary: residual risks

Risk area	Strategy link*	Residual risk	Status	Trend**
R1: Failure to regulate appropriately	Delivery (a-d & f) and Development (a-d) objectives	**10 – Medium**	Below tolerance	⇔⇔⇔⇩
R2: Failure to manage an incident	Delivery, Development and Deployment objectives	**9 - Medium**	Above tolerance	⇧⇔⇔⇩
R3: Failure to manage expectations of regulation	Delivery e) and Development c)	**9 - Medium**	At tolerance	⇔⇔⇔⇔
R4: Failure to utilise our capabilities effectively	Delivery, Development and Deployment (a, c, and d)	**8 - Medium**	Below tolerance	⇔⇔⇔⇩
R5: Insufficient or ineffective management of financial resources	Deployment (b) objective	**6 - Medium**	Above tolerance	⇔⇔⇔⇔
R6: Failure to achieve the benefits of the organisational Development Programme	Development (a-d) objectives	**9 - Medium**	At tolerance	⇔⇔⇔⇔

* Strategic objectives 2019-2022:
** 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	**2**	**4**	**8 - Medium**
Tolerance threshold:					**10 - Medium**

Commentary
Below tolerance.   We have a good regulatory framework, with a strong assured position on our key regulatory processes from an Internal Audit review within the past two years. Activity in the PM sector is now stable with no current activity on emergency mortuary licensing. The pilot temporary licensing of a very small number of funeral directors' premises to support national public health post-mortem Covid surveillance sampling by the UK Health Security Agency has now ceased as the project has been wound-up.   Quarter 4 has seen a full schedule of inspections, including site visits as well as VRAs and hybrid inspections. Activity is now in line with pre-pandemic activity, enhanced by the successful completion of their initial induction period by three new Regulation Managers.   We continue to use all other regulatory tools and processes, such as managing and responding to incident reports (Serious Adverse Events and Reactions and HTA Reportable Incidents), whistleblowing / informant information and ongoing engagement with our regulated sectors, with investigations and active regulatory action having continued. We continue to actively manage a small number of more unusual regulatory matters with establishments.   SMT believes this risk has reduced and is below tolerance in March 2022.

R2: There is a risk that we will be unable to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident: relating to an activity, we regulate; caused by deficiency in the HTA's regulation or operation; where we need to regulate, such as with emergency mortuaries; that causes business continuity issues.

Inherent risk level:			Residual risk level:		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	5	20	**3**	**3**	**9 - Medium**
Tolerance threshold:					**6 - Medium**

Commentary
Above tolerance This risk concerns our ability to respond to incidents irrespective of their nature or cause, which could be from matters outside the HTA's remit or control as well as matters for which we are directly responsible. The Executive has therefore set a lower tolerance level on this risk as our ability to respond appropriately is within the HTA's control. The HTA believes that our incident management response plans have been well tested and found to be robust and effective through their deployment in managing the impact of the pandemic and related restrictions and in their adaptation for use in managing the potential impacts of EU Exit following the end of the Transition Period. We also found these arrangements useful and effective in preparing for and managing our response to the public revelation of sexual offending in a mortuary through the trial of David Fuller during Quarter 3. Whilst that incident placed significant demands on senior management and some teams within the HTA, our arrangements stood up well to the most critical phase of this incident during Quarter 2 and 3. Having increased the risk scoring in July we are now of the opinion that the likelihood of this risk materialising has subsided – we now score this risk as 9 – Medium and this is unchanged from the last review.

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

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

Commentary
At tolerance.   We continue to communicate our remit and advise where appropriate.   There is ongoing dialogue with DHSC (Department of Health and Social Care) and wider stakeholders regarding Sir Jonathan Michael's Independent Inquiry into offending by David Fuller and we provide clear lines to the media when necessary.   In 2020/21, the Development programme included a specific workstream to strengthen horizon scanning on emerging changes to policy and activities where the HTA may be required to act or offer an authoritative voice. This approach has been embedded in 2021/22 alongside the piloting of alternative and additional approaches to engagement.   We continue to support the wider Government agenda to encourage development and innovation across UK life sciences and contribute to work looking at better regulation across all sectors of UK business. In late quarter 2/ early quarter 3 the HTA convened round table discussions with key external stakeholders. These sessions represented the first of what we expect to develop into a series of roundtables aimed at supporting innovation and growth in the life sciences sector. The first two roundtables were focused on issues raised over retention of tissue blocks and slides from coronial post-mortems for research and on supporting innovation in the Human Application sector.   The HTA have submitted areas of potential legislative change to the Department in response to requests and this, should these be taken forward, we believe these would clarify and strengthen the HTA's remit going forward.   All these matters are being actively managed.   SMT agreed this risk remains unchanged, at tolerance.

R4: There is a risk that we will fail to utilise people, data, and business technology capabilities effectively.

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

Commentary
Below tolerance. From Quarter one of 2021/22, the HTA started implementing a partial organisational redesign to address capability gaps identified during the previous year and has started an ambitious recruitment campaign for several posts including that of a Deputy Director adding further support and resilience to the Senior Management Team. By August 2021, appointments had been made to seven and a half posts, with plans to progress the recruitment to the remaining 2.5 Wte in Q3 2021/22. Progress in the recruitment to the remaining posts has been consciously paused to facilitate input from the incoming CEO to both roles and future organisational design. The key vacancies remain relating to the planning and portfolio manager and Chief Information & Technology Officer. Interim appointments have been made to both posts and these individuals will continue in post through the first quarter of the 2022/23 business year. The combined pressures of the critical incident and vacancies led to the need to reprioritise activity across quarter 3, as captured on other risks this has had some implication for strategic delivery in relation to communications and the development programme. A renewed focus on the business plan for Quarter 4 recognises and prioritises key activities across Quarter 4 that are either in direct support of current business activity or are dependencies for ongoing project activity which will continue in the next business year. Recruitment and retention remain a key priority for the HTA. The HTA's new Chief Executive, Dr Colin Sullivan, began his new role on 1 January 2022 and this is clearly a key mitigator of some organisational risk. Although some key vacancies remain unfilled on a permanent basis progress continues to be made and key roles in Communications, Business Planning and IT have interim resource in place and activity is underway to conclude recruitment in quarter 4.   This risk was increased during Quarter 3, and although still above tolerance SMT believe this risk has reduced since the last review and will continue to do so over this quarter.

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 – High	**3**	**2**	**6- Medium**
Tolerance threshold:					**3 - Low**

Commentary
Above tolerance.   Our financial review at the end of quarter 3 provides assurance that expenditure for the full year will be in line with budgets. We forecast a balanced year end position, with risk more likely to see small underspends emerging if planned activity cannot progress as planned.   At this time, we still await formal confirmation of the GIA settlement from DHSC, although we are assured that this is likely to be in line with previous years with no direct savings applied. Our bids for additional funding for work associated with the Fuller inquiry and in relation to COVID 19 inquiry responses are less certain, not receiving this funding will require prioritisation of resources between emerging pressures from these tasks and planned operational delivery objectives.   Recommendations on 2022/23 fees were discussed and Board agreement reached on fee levels at the November Board meeting. Although CPI has increased significantly since this agreement any upward pressure on the HTA's expenditure for 2022/23 will be dependent on the availability and scale of any public sector pay award remit in 2022. Continued inflation and current levels could result in more significant pressures from 2023 onwards.   SMT have agreed that this risk is unchanged.

R6: There is a risk that we fail to achieve the full benefits of the organisational Development Programme

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

Commentary
At tolerance. The Development Programme has been adversely impacted this year by the availability and commitment of resources (people and financial). The project deliverables in late quarter 2 and quarter 3 have been reframed to support incremental progress. The continued uncertainty of available investment into early December 2021 has negatively impacted on the programme's progress. On 18 January, SMT agreed the resourcing and investment to a reprioritised set of commissions and deliverables for quarter 4. These commissions included targeted work to strengthen data and intelligence, support the development of the target operating model and development stakeholder engagement.   The agreement of this resource will support identified developments. The risk is at tolerance as plan for delivery are implemented.

Reviews and revisions

(11/03/21) SMT review March 2021

SMT reviewed all risks - generally our risk levels are stable and there have been no significant changes from the last review conducted in February. A detailed review of our risk summary is being conducted.

(30/03/21) SMT review March 2021

SMT reviewed the risk and set tolerance levels for each risk. It was agreed that further review will be undertaken in early April prior to sharing this summary with both the Board and ARAC (Audit and Risk Assurance Committee) in May and June, respectively. To note, is the relationship between risks one and two and their respective tolerance levels as they are interdependent.

(29/04/21) SMT review April 2021

Updates to the narrative, reflect the new arrangements for this financial year. This new format will allow SMT to review the strategic risks and their respective tolerance levels and implement the necessary activities to either reduce residual risks to tolerance or maintain them at an accepted level.

Risk six, SMT felt no longer reflects where we are now that key work pages within the Development Programme have been completed.

(27/05/21) SMT review May/June 2021

The above risk summary was reviewed by SMT, and it was agreed that the risk scorings have remained stable. Risk four was discussed in detail in light of the change in senior staff that will take place in quarter three and the revised structure that will be implemented over the coming months. To ensure the recruitment process continues, SMT have agreed to extend HR support to the end of the process.

(09/07/21) SMT review July 2021

SMT had a brief discussion of the overall risks with a view to a deeper dive at the end of July.

(06/08/21) SMT review August 2021

SMT have taken a detailed look at the underpinning assessment of each risk. In particular the following risks were flagged; R4 where the recruitment of key staff may have an impact on the both the likelihood and impact. It was agreed that this would be deferred till the new starters were in post and fully embedded. It was agreed that at least this risk will need to be reframed, possibly in line with the strategy update. R2 – Sandpiper may be driving up the residual risk score, and it was felt that this should also be reflected in the inherent risk as a new cause has materialised. R1,

HTA 13b/22

the re-introduction of site visits in conjunction with VRA's may reduce the scoring and will be looked at again in the autumn.

(09/09/21) SMT review September 2021

SMT deferred a final review of risks until the 6 October 2021. All risks remain unchanged from the August 2021 review, although narratives have changed significantly to provide more current updates on risk levels.

(18/11/21) SMT review November 2021

SMT discussed the risks and in particular the impact that the current incident that has become public is having on workloads. The current vacancies that exist are also adding pressure across the business. A more detailed discussion is to take place early December.

(13/01/22) SMT review January 2022

A detailed discussion took place with our new Chief Executive in attendance. The SMT downgraded risks 2 and 4.

(23/02/22) SMT review March 2022

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

Strategic Aims

Delivery: Deliver a right touch programme of licensing, inspection, and incident reporting, targeting our resources where there is most risk to public confidence and patient safety.
(a) Deliver effective regulation of living donation.
(b) Provide high quality advice and guidance in a timely way to support professionals, Government, and the public in matters within our remit.
(c) Be consistent and transparent in our decision-making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing firmly and fairly with those who   do not comply with our standards.
(d) Inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them and influence them in matters that are important to us.

Development: • Use data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target resources effectively.
(a) Make continuous improvements to systems and processes to minimise waste or duplicated effort, or address areas of risk.
(b) Provide an agile response to innovation and change in the sectors we regulate, making it clear how to comply with new and existing regulatory requirements.
(c) Begin work on implementing a future operating model, which builds our agility, resilience, and sustainability as an organisation.

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

Criteria for inclusion of risks

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

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

Rank

The risk summary is arranged in risk order.

Risk scoring system

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

Likelihood: 1=Rare   2=Unlikely   3=Possible   4=Likely   5=Almost certain

Impact: 1=Very low   2=Low   3=Medium   4=High   5=Very High

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

(IMPACT is the vertical axis label for the matrix rows.)

Risk appetite and tolerance

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

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

Assessing inherent risk

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

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

Contingency actions

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

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

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL I	RESIDUAL L	ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
1	**Failure to regulate in a manner that maintains public safety and confidence and is appropriate** *(Risk to Delivery objectives a-d & f Development objectives a-d)* Risk Owner: **Allan Marriott-Smith** **Dr Sullivan**	**Causes** • Failure to identify regulatory non-compliance • Regulation is not transparent, accountable, proportionate, consistent and targeted • Regulation is not sufficiently agile to respond to changes in sectors • Insufficient capacity and/or capability, including insufficient expertise, due to staff attrition, inadequate contingency planning, difficulty in recruiting (including Independent Assessors (IAs)). • Inadequate adherence to agreed policies and procedures in particular in relation to decision making • Poor quality or out of date policies and procedures • Failure to identify new and emerging issues within HTA remit • Failure to properly account for Better Regulation • Insufficient funding in regulated sectors • Failure to deal with regulatory consequences of the Transition Period and the period after 31 December 2020. • Failure to properly manage the business impact of the coronavirus pandemic. **Effects** • Loss of public confidence • Compromises to patient safety • Loss of respect from regulated sectors potentially leading to challenge to decisions and non-compliance • Reputational damage	5	3	Ongoing	**Regulatory model** Regulatory model comprising a mixture of proactive regulatory assessment (e.g. through site visit inspections and sector engagement) and reactive tools (such as responding to incidents reported to the HTA, investigations of concerns raised etc). Process for consideration of police referral maintained and used. Annual collection of activity data in HA sector; biennial collection of compliance updates data from other sectors.	4	2	Following the suspension of routine site visit inspections at the onset of Covid-19 pandemic restrictions, work was undertaken in 2020/21 to develop a risk assessment and a virtual regulatory assessment tool. VRAs are now incorporated into business alongside a decision making framework to inform decisions about whether to undertake a site visit, VRA or hybrid inspection. Development Programme-led activity from 2020/21 to develop a new Target Operating Model to re-state and clarify the key elements in our approach to regulation. A full inspection timetable has been implemented from quarter 3 of the 21/22 business year.	10	X			Preventative	Board developed and approved the current HTA Strategy and was aware of the risks and opportunities associated with the suspension of routine site visit inspections during Covid restrictions and how VRAs were being incorporated into BAU. Board were aware of the issue of failing to meet the legal obligation to carry out a site visit of HA establishments at least once every two years because of the suspension of routine site visits during Covid. SMT agreed late May 2021 to resumption of routine site visits in HA sector once restrictions are lifted, alongside continuing use of VRAs. Routine site visit elements are now being included in HA inspections, although some are VRA only, determined on a risk-based approach. Continuing use of all other regulatory tools during the pandemic restrictions, including managing HTARIs and SAEARs, investigations, advice to regulated sectors (such as seminars in Anatomy sector, Professional Newsletters). Development and use of emergency mortuary licensing regime during the pandemic, including use of virtual assessment techniques. Development and use of funeral director licensing regime to support PHE-sponsored pilot project of post-mortem public health surveillance for Covid-19.	In-depth evaluation of pilot programme of 10 x virtual regulatory assessments in the HA sector in quarter three 2020/21 carried out and reported to the HTA Board Meeting February 2021 and a further evaluation of the expansion into remaining sectors in summer 2021. VRAs incorporated into BAU in all sectors, as evidenced in Business Plan and inspection schedule. Internal Audit late Quarter 3 / early Quarter 4 2020/21 on 'Inspection Process during Covid-19' - report agreed late May 2021; Moderate assurance; considered by ARAC; all actions now complete (per ARAC Quarter 3 2021). Renewal of some emergency mortuary licences although most have now been revoked as no longer required. SMT consideration of request by UKHSA to extend the small number of Funeral Director removal licences (for post-mortem public health surveillance for Covid-19) agreed on basis of bringing them into a normal regulatory regime i.e. LAAV, open-ended licences funded by appropriate fees. (Head of Regulation written to UKHSA Project Lead 21 Dec. 2021.) Police referral made late 2019/20 has been investigated by the police, supporting Witness Statements provided by the HTA, decision pending with CPS.
						Regulatory decision making framework			Heads of Regulation using dashboards to track open cases and ensure there is effective follow-up, in accordance with the HTA's decision-making framework.		X			Preventative	Reports summarising numbers of Regulatory Decision Meetings included in monthly performance pack and recorded in CRM. Case Review Meetings all summarised in CRM.	Satisfactory Internal Audit Report (strong assurance) November 2020. Lessons learned from Regulatory Decision Meetings (RDMs) held January 2020 and used to inform update to Regulatory Decision Making SOP. Regulatory Decision Making SOP updated February 2020. Evidence of regulatory decision making framework being used in practice e.g. Case Review Meetings recorded in CRM, numbers of RDMs reported in monthly performance data pack.
						Annual scheduled review of Strategy					X	X		Preventative	Outputs from annual strategy review translate into revised annual Strategy	Annual Board Strategy session held 27 April 2021 informed annual strategy refresh. Latest update of HTA Strategy published November 2021.
						The HTA has produced a detailed business plan for the remainder of the year. These plans are approved by SMT and balance core regulatory functions, development priorities and resource deployment considerations.			In the continuing absence of a role with specific responsibility for the business plan, SMT and their respective Heads have ensured there is regular review and updating of the operational business plan and monthly performance pack. Consultancy-led review developed a portfolio management approach that SMT could adopt, including some initial tools. Interim Portfolio Planning Manager (contractor) appointed on short-term contract to develop and implement this new approach, between December 2021 and February 2022.		X	X		Preventative	Operational business plan for 2021/22 (using Excel spreadsheet template developed in 2020/21) in use and reviewed regularly by SMT. Contractors engaged Quarter 1 2021/22 to support development of business planning through adoption of a portfolio management approach. 2020/21 narrative Business Plan for 2021/22 published during Quarter 3 (Covid-related delay).	Progress on the Portfolio Management approach regularly discussed at SMT meetings. SMT receives monthly reports of Management Information for review and action. Interim Portfolio Planning Manager appointed December 2021.
						Well established processes support our core regulatory business.			Development and introduction of new regulatory process (VRA) managed as a project with Director of Regulation as SRO, Head of Regulation (for Research and Anatomy) as Deputy SRO, and a RM as Project Manager. Project now in process of closure with formal closure report to be discussed by SMT in January 2022. Post-closure actions are in hand. (December 2021.) Detailed evaluation carried out on two occasions, prior to adoption in HA sector and expansion into other sectors. Completion of further management actions identified by Internal Audit of effectiveness of the inspection process - by Quarter 3 2021. (Reviewed by ARAC.) (Principally ensuring other regulatory processes and documentation (SOPs) were updated to take account of VRAs.)				X	Detective	Internal audit conducted on Key Regulatory Processes late 2018/19, receiving substantial assurance and noting good areas of best practice. Internal audit on the Inspection Process during Covid-19 conducted late 2020/21 - see R4. Moderate assurance and management actions complete, as noted by ARAC Quarter 3 2021.	Internal Audit 2019: Final report received April 2019 and showed substantial assurance. The low priority recommendations were followed-up with management actions completed during 2019/20, namely review of SOPs for key regulatory processes (completed) and training on core legislative framework, HT Act which was delivered in March 2020. Internal Audit 2021: low priority actions all complete by Autumn 2021.
						Quality management systems The HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model			The HTA's Quality Manager left in 2019/20 and has not been replaced. This function has not been formally re-allocated. A Regulation Manager with experience in QMS continues to coordinate activities to ensure policies are reviewed and updated, with input and support from the Quality Forum as relevant.		X			Preventative/ Monitoring	Management oversight and reporting trough the monthly performance pack. This work had been expected to transfer to a newly created role during Quarter 2 2021/22 but this has not happened, hence the RM is still coordinating this work.	Limitations in QMS still remain. Scheduled reviews have now been re-instated by the RM who is covering this work following the departure of the quality manager in 2020/21. QMS and monthly performance reporting pack includes evidence of degree to which the documents are current.
						People Adherence to the HTA People Strategy which has been substantially amended and approved by the Board					X			Preventative	Management information and assessment presented to the Board quarterly.	Chief Executive's report to the Board now includes HR report - last presented to November 2021 meeting. Mid-year reviews completed during Quarter 3 2021.
						Training and development of professional competence					X			Preventative	Annual PDPs, which include Development Objectives, Corporate Training Programme (led by Head of HR), Career Investment Scheme proposals to SMT, induction programme for new entrants, with a bespoke programme for RMs.	Evidence of corporate training programme, including quarterly mandatory training. Quarterly Regulation-led Training sessions held virtually in July 2021, September 2021 and scheduled for January 2022. 'Lunch and Learn' programme.
						Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas			As vacancies arise, SMT take the opportunity to review business requirements and target building capability and filling skills gaps. An organisational redesign for aspects of the HTA's work was developed during late 2020/21 to enable key gaps and capability issues to be addressed and a large-scale recruitment programme for 10 posts, including the redesign, initiated in Quarter 1 of 2021/22.		X	X		Preventative/ Monitoring	SMT assessment of skills requirements and gaps as vacancies occur. Organisational design. Recruitment policy.	Staffing levels and risks reported quarterly to the Board most recently July 2021. Large recruitment programme for 10 vacancies started May 2021, incorporating the new roles created by the organisational redesign of key support functions and search for key additional capability identified as required in the RM cadre. Recruitment policy reviewed by SMT May 2021 to be completed by autumn 2021.
						EU Exit (End of Transition period and HTA Exit SIs 'grace period') Fortnightly Transition Period oversight meetings from February 2020 with+H4:Q16+H4:Q15 Close liaison with DHSC to ensure communications are in line with government policy and that appropriate arrangements are made to support DHSC during the transition period. HA Guide, ODT Framework and other external guidance being updated in line with new legislation to ensure we can regulate accordingly.			Weekly project meetings from Quarter 3 2020/21. Dedicated project manager (external contractor) and Regulation Directorate and comms team resource. Weekly Project Governance meetings from mid-January 2021 (after daily / thrice weekly stand-ups ceased). Continued close liaison with DHSC policy and communications teams and EU Exit and Trade teams, including participation in DHSC-led meetings with ALBs. Project maintaining active oversight of risks, issues, and resource requirements.		X	X		Preventive / Detective / Monitoring	Weekly reporting by ANH to SMT under standing item on SMT agenda. Internal Audit Quarter 3 of 2020/21 - moderate assurance. SMT lead for project - ANH (Director of Regulation). Formal project re-established from Quarter 3 2020/21. SMT papers for key decisions.	EU Exit - dedicated project manager (contractor) appointed Quarter 3 2020/21 until 31 July 2021. (Project due to be closed and handed over to business as usual by 31 July 2021.) EU Exit / UK Transition Project documentation and records in Teams Channel. Internal Audit on Risk focusing on EU Exit - reported January 2021, moderate assurance, completion of management actions tracked in audit tracker by ARAC. Standing item on SMT weekly minutes - EU Exit update - reported in minutes.
						Regulatory model Development work being undertaken to become a more data-driven risk based regulator as part of the HTA Development Programme.					X			Preventative		
						Other Strengthening horizon scanning arrangements					X			Preventative		

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2	**Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:** • **relating to an activity we regulate (such as retention of tissue or serious injury or death to a person resulting from a treatment involving processes regulated by the HTA)** • **caused by deficiency in the HTA's regulation or operation** • **where we need to regulate, such as with emergency mortuaries** • **that causes business continuity issues** **(Risk to all Delivery Development and Deployment objectives)** Risk owner: **Nicky Harrison**	_Cause_ • _Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management)_ • _Failure to recognise the potential risk caused by an incident (for instance poor decision making, lack of understanding of sector, poor horizon scanning)_ • _Failure to work effectively with partners/other organisations_ • _Breach of data security_ • _IT failure or attack incident affecting access to HTA office_ • _External factors such as terrorist incident, large scale infrastructure failure or pandemic_ _Effect_ • _Loss of public confidence_ • _Reputational damage_ • _Legal action against the HTA_ • _Intervention by sponsor_	5	4	Future but increased likelihood over next few months	Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff	3	3		6	X X		Preventative	Policies etc. reviewed annually, training specification and notes after incident reviews	Subject to internal audit reported to ARAC in February 2020 Version 19 of CIRP published July 2019. CIRP deployed in March 2020 to manage coronavirus pandemic. CIRP used as framework for managing Sandpiper critical incident. Business Continuity and Critical Incident Response Plans updated and approved by SMT on 10 June 2021.
						All specific roles identified in the Critical Incident Response Plan are filled.					1 2 3 X	Preventative	Evidence of regular review and updating of the CIRP and no specific CIRP roles left vacant or, if role is vacant, cover arrangements put in place.	CIRP reviewed and updated to version 19 in July 2019. Further minor changes proposed February 2020 updated roles following staff changes. Business Continuity and Critical Incident Response Plans updated and approved by SMT on 10 June 2021.
						Media handling policy and guidance in place and Critical Incident Response Plan includes requirement to involve Comms team. Comms Team have embedded media handling and development of lines to take into business as usual.			Comms Team maintain close working relationships with colleagues across the business and proactively raise awareness of the need for Comms role in shaping lines and dealing with media. Experience of engaging and managing a contract with Crisis comms consultants to support the HTA on a specific critical incident.		X	Preventative	Policy reviewed as scheduled. Reports on any key media issues and activity in the Chief Executive's Report. Evidence of active Comms Team participation in issues with potential for media or public interest.	Media issues are included in the quarterly Board reporting as they arise and as relevant. Media enquiries successfully managed during critical incident phase of Sandpiper.
						Availability of legal advice					X	Preventative	Lawyers specified in Critical Incident Response Plan, SMT updates	In place
						Fit for purpose Police Referrals Policy			Engagement with other potential investigatory authorities, such as NHS Counter Fraud Authority		X	Preventative	Annual review of policy (minimum), usage recorded in SMT minutes	Police referral process used regularly by SMT and captured in SMT minutes. Police referral process shown to have been effective in 2020/21 with a referral to police for a potential breach of the HT Act being taken forward in an active investigation. Police referral policy being updated - considered by the Board November 2021 and on the agenda for finalisation February 2022.
						Onward delegation scheme and decision making framework agreed by the Board					X X	Preventative	Standing Orders and Board minutes	Standing Orders published May 2017, updated at Board meeting in November 2021.
						Regulatory decision making framework			Regulatory Decision Making process and SOP regularly reviewed and disseminated to staff.		X	Preventative	Reports to Board of key decisions in Chief Executive's Report to the Board.	Number of Regulatory Decision Meetings detailed in monthly management performance pack, for review by SMT. Regulatory Decision Making SOP reviewed and updated March 2020 with the next review due by March 2022.
						IT security controls and information risk management					X X	All	SIRO annual review and report Internal audit reports	Cyber security review - standing agenda item at ARAC - last discussed June 2020. Cyber Security has been a standing agenda item in the form of a dashboard report at each ARAC meeting.
						Critical incident response plan regularly reviewed and tested			Actions associated with the internal audit reported in February 2020.		X X	Preventative	Critical Incident Response Plan and notes of test, reported to SMT Use of CIRP reported to SMT.	CIRP used to manage response to coronavirus pandemic from March 2020. CIRP deployed for a short period in May / June 2021 to deal with confidential matter. CIRP used as basis for Sandpiper response planning in Autumn 2021.
						Evaluate test exercise of incident and feedback to all staff.			Question over whether a test of the Plan is required in light of the recent stress test presented by the coronavirus pandemic and more recently in the HTA's response to Sandpiper, managed as a critical incident.		X	Preventative	SMT content that activation and use of CIRP during first wave and first lockdown superseded the need for a test. SMT note CIRP framework used in managing the HTA's planning for and response to the critical incident arising from the police investigation codenamed 'Sandpiper'.	Noted in ARAC Audit Tracker.
						Ensure DIs (or equivalent in ODT sector) are aware of and follow the incident reporting procedure for incidents reportable to the HTA.			Awareness raised of PM sector reporting requirement (HTARIs) at external training events, e.g. 9 April 2021 - Level 3 Diploma (Anatomical Pathology Technology) trainee APT HTA lecture, 18 September 2020 - Level 3 Diploma (Anatomical Pathology Technology) trainee APT HTA lecture Quarterly meeting with NHSBT to review ODT SAEARs cases over 90 days and any complex cases. Publication of quarterly incident numbers in the professional e-newsletter may remind establishments to report. HTA website COVID-19 guidance emphasises that all licensed research and anatomy establishments should have an internal system for reporting adverse events and asked them to consider how best to handle adverse events during the pandemic.		X	Preventative / Detective / Monitoring	Inspections (and audits for ODT) include assessment of licensed establishments' knowledge and use of the relevant HTA incident reporting process. For example, as part of the current VRAs in the HA sector, we are specifically looking at each establishment's incident logs to check a) that they recoding incidents locally, and b) that incidents that should have been reported as SAEARs, were. Annual SARE (Serious Adverse Reactions and Events) HA SAEARs data reported to European Directorate for the Quality of Medicines (EDQM). Monitoring establishments' reporting of incidents through the HTARI, HA SAEARs and ODT SAEARs groups and advice, guidance and CAPAs regarding those incidents.	Findings at inspection (onsite or VRAs). Minutes of quarterly meeting with NHSBT to review SAEARs cases in ODT sector - latest meeting was December 2021. Most recent SARE report submitted summer 2021. Publication of closed SAEAR and HTARI incident summaries included in the HTA publication scheme - published quarterly - and reporting in the Board's data annex. Publication of incident numbers in the regular (bimonthly) Professional Newsletter.
						Management of any risk of incidents likely to arise from the end of the 6 months post-Transition Period grace period for EEA/GB import / export licensing continues to be managed through the defined UK Transition project. The Director of Regulation is SRO, with a dedicated project manager and project resource and close continuing engagement with DHSC.			Continuing engagement with DHSC on ongoing aspects of the UK Transition Period Project, including the Northern Ireland Protocol (and engagement with NI Executive Department of Health).			Preventative / Detective / Monitoring	Director-level oversight as SRO (Director of Regulation), weekly Project meetings, 'stand-up' over the 6 weeks either side of 31/12/20, regular reporting to SMT through standing agenda item and specific papers for key decisions.	Regular reports to SMT - standing item on SMT agenda from February 2020. Internal Audit 2019/20 (Moderate assurance and management actions completed by Autumn 2021). Project formally closed October 2021 and remaining actions handed over to business. Pending clarification of whether any further changes might arise from any changes to the Northern Ireland Protocol.

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			I	L			I	L			1	2	3			
3		**_Cause_** **_External factors_** • _No scheduled review of Human Tissue Act and associated regulations, or Quality and Safety Regulations (other than for EU Exit)_ • _Rapidly advancing life sciences_ • _Potential move away from the UK as base for some regulated establishments/sectors due to EU Exit and changes in exchange rates_ • _Introduction of deemed consent for Organ donation in England_ • _Uncertainty posed by EU Exit, and misperceptions stemming from a 'no-deal' scenario_ **_Matters which certain stakeholder groups believe require review_** • _Scope of relevant material e.g. waste products_ • _Licensing requirements e.g. transplantation research_ • _Regulation relating to child bone marrow donors_ • _Issues raised by emergence of social media e.g. non-related donors_ • _Strengthening of civil sanctions for non-compliance_	4	3	Ongoing	Horizon scanning process in place that creates and maintains an up to date log of issues known to the HTA with respect to the legislation (updates, amendments or emerging issues) to inform DH and manage messages	3	3		9			X		Monitoring	Ongoing log	Log in place and shared with Board in outline at the Strategic planning session in 2021.
	Failure to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach **_(Risk to Delivery objective e, and Development c)_** _Risk Owner:_ **_Louise Dineley_**	**_Matters which stakeholders/public may expect to be inside regulatory scope_** • _Efficacy of clinical treatment from banked tissue and treatments carried out in a single surgical procedure_ • _Police holdings_ • _Products of conception and fetal remains_ • _Data generated from human tissue_ • _Funeral directors_ • _Forensic research facilities_ • _Cryonics_ • _Body stores / Taphonomy_ • _Imported material_ • _Clinical waste_ • **_Other_** • _Inadequate stakeholder management_ **_Effect_** • _Diminished professional confidence in the adequacy of the legislation_ • _Reduced public confidence in regulation of matters relating to human tissue_ • _Reputational damage_				Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope			_Comms & Engagement strategy under development to strengthen the HTA's approach and impact of stakeholder engagement. Updated C&E Strategy planned for Q4._		X			Preventative/ Detective	_Stakeholder Group meeting minutes Authority minutes (including Public Authority Meeting) TAG and HWG meetings Evidence of engagement with other relevant stakeholder forums, not necessarily organised by HTA._	_Last Stakeholder and Fees Group meeting in October 2019; Histopathology Working Group February 2020; Transplant Advisory Group October 2019. Public Authority Meeting in July 2021 - held virtually. Professional newsletters issued regularly - last one September 2021. Sector-specific engagement e.g. with anatomy sector webinars and engagement with the post-mortem sector through multi-agency forums (Death Investigation Group, Excess Deaths Working Group)._
						Active management of issues raised by the media – including the development of the HTA position on issues			_Lines currently under review and update_		X			Preventative/ Detective	_Quarterly reports to Board on communication (including media) activities_	_Last report to November Board meeting (2021)._
						Regular reporting to DHSC sponsorship and policy team on matters which risk public and professional confidence						X		Monitoring	_Quarterly Accountability meetings with DH superseded during the pandemic by DHSC attendance at Board meetings for assurance plus DHSC sponsor team's engagement with HTA._	_Most recent confirmation in letter from Marina Pappa of DHSC Sponsorship Team to AMS dated 21 July 2021 re Quarter 1 2021/22. AMS met with Sponsorship team regularly during 2021._
						Action where we believe it will support public confidence					X			Preventative	_Updated guidance in response to the coronavirus emergency published on the website, further sector specific guidance_	Update to the Board and DHSC at Board meeting July 2021.
						Clear view of use of s.15 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge			_Demonstrate ongoing engagement of Devolved Assembly in Wales and N Ireland. Effective engagement and collaboration demonstrated through the revision of Code D._		X			Preventative	_Duty and its uses understood by SMT and Chair_	_Advice and guidance continues to be provided, for example on the Private Members Bill - Organ Tourism and Cadavers on Display, first introduced into Parliament in 2020 and reintroduced in 2021. Engagement with DHSC over Sandpiper issues - advice submitted to Secretary of State 15 December 2021. Also engagement with Welsh Government officials on this matter. Ongoing engagement with NI Executive over NI Deemed Consent and need for HTA to update its Code of Practice (F) in recognition of this._
						No further changes to HTA's Standards since significant changes launched April 2017. Significant activity to update Codes of Practice for Organ Donation and Transplantation (and consent) to support the introduction of deemed consent (May 2020).			_Further work planned in 2021/22 to review and update codes of practice. Focus will be on factual update._		X			Preventative	_Updated draft guidance produced for revised Code D. Updated draft of Codes of Practice D to enhance consent expectations for imported bodies and body parts for public display._	_Draft revised Code of Practice D (Public Display) to align consent expectations for imported bodies and body parts with those for material originating in England, Wales and Northern Ireland received Parliamentary approval in July 2021._
						Extensive Professional Evaluation Survey undertaken in Q4 2019/20, reported to Board in July 2020 and used to inform further developments.			_Further work planned in Q3 & 4 to pilot new approaches to stakeholder engagement_		X			Preventative	_Evidence from Professional Evaluation used as an evidence and information source to inform and drive improvements_	_Evidence from Professional Evaluation presented to the Board in July 2019._
						Communications work package set up as part of UK Transition project to ensure we are managing our licensed establishments' expectations of what is required at the end of the transition period. As part of this WP we will also attempt to reach out to unknown end users to make them aware of their new regulatory licensing requirements and timelines.			_UK Transition Communications Plan updated several times during the life of the project. RM taking responsibility for leading stakeholder engagement and coordinating activities of RM Stakeholder Managers._					Preventative	Weekly UK Transition Project meetings - standard agenda item is discussion of Communications Work Package.	UK Transition project documents (in dedicated Teams channel), weekly meeting agendas and action points plus weekly updates to SMT. UK Transition project closed October 2021.
						Regular meetings with DHSC policy team and attendance at other departmental meetings (ALB delivery partners) to inform planning for key pressures such as ongoing response to Covid-19; winter pressures, Transition Period and the period after 31 December 2020. In the last 6 months the HTA has demonstrated its role in strategic and partnership working as part of the wider Life Sciences & regulatory system and has demonstrated a responsiveness to legislative amendments and updates.			_Ongoing engagement with partner organisations to build opportunities for collaboration and support to the life sciences sector._		x			Preventative	_Development programme workstream Strengthening of Horizon scanning has identified 4 areas to progress in 2021/22._	_Regular reporting to SMT and through formal routes_

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL I	RESIDUAL L	ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
4	*Failure to utilise people, data and business technology capabilities effectively* **(Risk to Delivery objectives a-e, Development a-d Deployment a, c and d)** Risk Owner: **Louise Dineley**	• *Cause* *Lack of knowledge about individuals' expertise* • *Poor job and organisational design resulting in skills being under used* • *Poor line management practices* • *Poor project management practices* • *Poor leadership from SMT and Head* • *Loss of productivity as a result of the effects of changes to ways of working* • *Data holdings poorly managed and under-exploited* • *Inadequate business technology or training in the technology available* • *Lack of ring-fenced resource for 'no-deal' EU Exit* *Effect* • *Poor deployment of staff leading to inefficient working* • *Disaffected staff* • *Increased turnover leading to loss of staff* • *Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed* • *Poor use of technology resulting in inefficient ways of working* • *Inadequate balance between serving Delivery and Development objectives*	3	4		**People capability**	4	2	All major projects have project management rigour further enhanced through benefits realisation and plans to assess ROI at year end.	9					
						People Strategy for the period 2019 to 2021 is in effect			Recruitment to identified vacancies and skills gaps completed. Succession planning and future skills needs to be developed further as part of a workforce model. Work planned for Q3 & 4.		X	X		Preventative/ Monitoring	Board approval of the Strategy	Board approved the Strategy at its meeting in February 2019 and is provided with regular updates on all facets of its progress in quarterly board reporting. Most recently in July 2021
						Full suite of people policies and procedures (including performance management)					X			Preventative/ Monitoring	Full suite of policies in place and available on Wave	https://intranet.hta.gov.uk/pages/polici es_forms
						External assessment of utilisation of capabilities							X	Monitoring/ Detective	Internal audit 'Utilisation of capability' provided moderate assurance in July 2019	ARAC received the audit report and monitors progress against recommendations - most recently June 2021.
						Adherence to the HTA Workforce Capability Development Framework					X			Preventative	SMT approved the Framework in September 2020 - as a response to internal audit recommendations	ARAC to receive update on the Framework at its meeting in October 2020
						Investment in the development of the HTA leadership team					X			Preventative	External consultants engaged to assess team and individual development needs and design appropriate interventions	The current programme of work was completed in June 2021.
						Handover process is formalised via a checklist to ensure corporate knowledge is retained					X			Preventative/ Monitoring	Handover checklist is in place and in operation.	Evidence provided to internal audit June 2021.
									More formal assessment of future capability needs and how these should be met including through better knowledge of internal skills. Work to adopt a portfolio management approach to support more effective resource deployment and identification of skills required.		X	X		Preventative/ Monitoring	Director and Head of HR assessing capability needs as part of future operating model HTA Workforce Capability Development Framework sets out how capability needs will be met Head of HR has implemented a register of skills within the HTA	SMT will be agreeing its approach to filling specific immediate capability needs in October Development Programme is picking up medium to long term capability needs.
									Establish a formal role within SMT terms of reference to look holistically at people and capability issues across the organisation focussing on short and long term impacts and deliverables.			X		Preventative/ Monitoring	SMT terms of reference and SMT minutes	SMT ToRs revised and approved. HMT ToRs in development HTAMG ToRs to be revised subsequently
						Data capability										
						Data relating to establishments securely stored with the Customer Relationship Management System (CRM)			Ongoing development of the electronic management of all information and records. Phase 1 complete. Phase 2 underway.		X		X	Preventative/ Monitoring	Upgrades to CRM, closely managed changes to CMR development. Internal audit of personal data security.	CRM upgrade completed successfully in March 2019
						Appropriate procedures to manage personal data including GDPR compliance.					X		X	Preventative/ Monitoring	Internal audit on GDPR compliance provided moderate assurance.	Internal audit report in March 2019. Part of ongoing Cyber and data security and SIRO reporting. Now absorbed in BAU Information Governance and Cyber Security work
						Business technology capability										
						Staff training in key business systems and mandatory training on policies and required controls.					X			Preventative	Systems training forms part of the induction process for new starters	Ongoing records of all new starters trained in key business systems. New remote induction programme was launched in Summer 2020.
						IT systems protected and assurances received from 3rd party suppliers that protection is up to date			Reporting to ARAC on Cyber Security and system security in place.		X	X	X	Preventative/ Monitoring	Quarterly assurance reports from suppliers. MontAMSy operational cyber risk assessments. Annual SIRO report	Annual SIRO report agreed SMT June 2021
						Business technology										
									Identify refresher training and targeted software specific training needs.		X			Preventative	Evidence of targeted training in last quarter to support the roll out and adoption of EDRMS. Further strengthening of core training requirements included in updated induction programme.	
						System performance analytics available and reported monthly			Use of data analytics to inform and drive changes in practice.						Analytics provide assurance on system performance and support targeted intervention with members of staff as necessary.	

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT RISK PRIORITY I	INHERENT RISK PRIORITY L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK PRIORITY I	RESIDUAL RISK PRIORITY L	ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
5	Insufficient, or ineffective management of, financial resources (Risk to Deployment objective b Risk Owner: Richard Sydee	**_Cause_** • Fee payers unable to pay licence fees - • The number of licenced establishments changes, leading to reduced fee income • Management fail to set licence fees at a level that recover sufficient income to meet resource requirements • Failure to estimate resource required to meet our regulatory activity • Poor budget and/or cash-flow management • Unexpected increases in regulatory responsibilities • Unforeseeable price increases / reductions in GIA • Fraudulent activity detected too late **_Effect_** • Payments to suppliers and/or staff delayed • Compensatory reductions in staff and other expenditure budgets • Increased licence fees • Requests for further public funding • Draw on reserves • Failure to adhere to Cabinet Office Functional Standards **_Leading to:_** • Inability to deliver operations and carry out statutory remit • Reputational damage and non payment of fees	5	4	Ongoing	Budget management framework to control and review spend and take early action	2	3		3	X	X		All	Budgetary control policy reviewed annually and agreed by SMT	Revised version reviewed by SMT in November 2020. AUD 16b/21. Next review March 2022 post audit.
						Financial projections, cash flow forecasting and monitoring					X			Monitoring	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report to Board in November 2021
						Licence fee modelling								Preventative	Annual update to fees model	No change to fees agreed by the Board November 2021 meeting
						Rigorous debt recovery procedure					X			Preventative	Monthly finance reports to SMT and quarterly to Authority	Level of outstanding debt is being reduced. Older debt are being collected. Although we maintain a tight grip on our position, the overall environment is more uncertain than normal.
						Reserves policy and levels reserves					X			Monitoring	Reserves policy reviewed annually and agreed by ARAC	Last agreed by ARAC October 2021
						Delegation letters set out responsibilities					X	X		Preventative	Delegation letters issued annually	Issued in April 2021
						Fees model provides cost/income information for planning					X			Preventative	Annual review of fees model, reported to SMT and Authority	Went to the Board November 2021
						Annual external audit							X	Detective	NAO report annually	Unqualified Accounts produced June 2021
									Monitoring of income and expenditure (RS) **Ongoing**				X	Detective	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report October 2021
									Horizon scanning for changes to DH Grant-in-aid levels and arrangements (RS) **Ongoing**		X	X		Detective	Quarterly Finance Directors and Accountability meetings	FD from NHS Resolution, HRA, NICE and CQC maintain contact over common issues weekly. Quarterly meetings with DHSC which cover finance and non-finance issues/risks.
									Action plan to move from rudimentary to Basic level of maturity on the GovS 013 Functional Standards		X	X		Preventative	Counter fraud Strategy and Action Plan developed and presented to ARAC Oct-19. Annual training of staff completed n Q4	Cabinet Office - CDR submissions made quarterly last submission April 2021 (Q4 2020/21). Counter-fraud activities now part of BAU.

Risk 6

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL		ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L			1	2	3			
6	*Failure to achieve the full benefits of the HTA Development Programme* *(Development objectives a-d)* *Risk owner* *Louise Dineley*	**Causes** • *Uncertainty of funding* • *Programme and project benefits poorly defined and understood* • *Inadequate programme and project governance arrangements* • *Poorly specified programme and projects* • *Insufficient programme, project and change management skills* • *Inadequate leadership of change* • *Inability to access the necessary skills required at a affordable cost* • *Lack of staff buy-in to change* • *Management and Head stretch of delivering transformation alongside business as usual and other development activity* • *Insufficient agility in (re)deploying people to change projects* • *Poorly specified procurement and inadequate contract management* • *Realisation of single points of failure for DDAT and People Strategy* **Effects** • *Wasted public money* • *Failure to achieve the central strategic intent of the Authority* • *Distracts senior management from operations at a time when demands have increased* • *Reputational damage* • *Unaffordable cost over run* • *Staff demotivation* • *Data remains under-utilised* • *Technology inadequate to meet future needs (cost, functionality)* • *Limited ability to achieve improvements in efficiency and effectiveness* • *Pace of change is inadequate and impacts negatively on other work*	3	3		SMT experience of organisational change, programme and project management.	3	3	*Change Manager appointed in August 2020. Ongoing organisational preparedness remains a key workstream in the 21/22 plan.*	9	X			Preventative	Recruitment of an HTA Programme Director	The Director of Data, Technology and Development appointed in October 2019 will act as Programme Director.
						HTA approach to the management of change projects *(underpinned by project management methodologies)*					X			Preventative	Dedicated permanent project manager appointed	PM in place an operating effectively
						A number of trained project managers among HTA staff			*Project Management skills further strengthened by introduction of a toolkit and induction session by PM*		X			Preventative		
						Experience of procurement and contract management					X			Preventative		
						Existing mechanisms for engaging staff			*Plans developing for strengthening internal communications function*		X			Preventative		
						Well established corporate governance arrangements and financial controls						X		Monitoring	Internal audit of key controls	Assurance provided by Internal Audit of adequacy of key financial controls
						Agreement to a phased delivery approach to avoid all or nothing investment and align with available funding			*Further alignment of projects on the business plan to strengthen phasing of actions, resource deployment and consolidation of actions to encourage smarter working.*		X			Preventative	Progamme plan in place	Update reported to July Board meeting
						Project management rigour including benefits to be realised.			Embed Benefits Realisation Management methodology within programme		X			Preventative		
						Monthly reporting to SRO in place			Introduce a Programme Management function		X			Preventative		*Ongoing focus in 21/22 to embed PMO skills and build wider capability across the business*
									Board approval to proceed at key Gateway decision points			X		Monitoring		
									Training plan to encompass project and change management and HTA approach		X			Preventative		*Change management training activity is now in progress following the appointment of the HTA Change Manager. Mandatory all staff sessions were undertaken in quarter 3. Further osu planned in Q4*
						Strengthened planning supports a single message and focus on an agreed set of priorities			Development of procurement plan to deliver the DDAT Strategy		X			Preventative		*Plan in place, work ongoing in 2020/21.*
									SROs identified for Programme and individual projects		X			Preventative		*High level plan in place for 2021/22*
						Project management includes a monitoring of costs			Schedule a regular programme of staff engagement events		X			Preventative		*Reset and relaunch event planned in Q4 providing focus to developments over the next 15 months. Review of stakeholder engagement also extends to inviting a wider contribution to future development plans.*
						Scope of projects aims to deliver benefits including on a phased and incremental design			Establish an external stakeholder communications and engagement plan		X			Preventative		*Work progressed in Q4 20/21*
									Recruitment of new Board Member(s) with digital and organisational change experience			X		Monitoring		
						Agreed priorities in Business Plan and underpinning foundations for future strategy maintain required pace							X	Monitoring/ Detective		
						Identified success measures and benefits to be realised for the Development Programme and individual projects							X	Preventative		

**Human Tissue Authority
Board meeting**

Date: 5 May 2022

Paper reference: HTA 14/22

Agenda item: 6

Authors: Louise Dineley, Sandra Croser, Audrey Jessiman, Shirley Dent

OFFICIAL

HTA Communications and Engagement Strategy

Purpose of paper

1. To seek HTA Board approval of the Communications and Engagement Strategy.

Decision making to date

2. The SMT discussed the Communications and Engagement Strategy on 12 April and agreed the paper be submitted to the HTA Board.

Action required

3. The HTA Board is asked to consider and give approval to the attached Communications and Engagement Strategy and comment on the underpinning indicative actions outlined for FY 22/23 in the associated draft Action Plan.

4. The HTA Board is asked to note that the Action Plan will be finalised during Q1 following discussion with relevant staff, and a review by the new Head of Communications, who joined HTA on 25 April. The Action Plan will be updated and revised on a quarterly basis to ensure alignment with the Business Plan and prioritisation of tasks, given available staffing levels and budget for FY 22/23

Introduction / Background

5. An outline strategy was presented to the HTA Board in February 2022. Following that, in March we completed a detailed stakeholder mapping and engagement exercise, assisted by a communications and stakeholder management agency, Luther Pendragon (LP). Using the evidence and feedback from their research, and aligning that with our overarching strategic aims, we have developed a renewed Communications and Engagement strategy.

6. The renewed draft strategy is appended at **Annex A** and a short summary of the underpinning research is attached for Board awareness at **Annex B**.

7. Key findings of interest from the focus groups and stakeholder survey conducted by LP include:

   - Our stakeholders perceive us as an authoritative, helpful, and professional regulator. A potential challenge is that depending on whom a stakeholder engages with, the HTA tone of voice can vary between emails, website, and phone contact. Going forward, we want to focus on iron out any inconsistencies.
   - Stakeholders feel communication at times is one-way and would welcome more opportunities for engagement with us, for example through events and one-to-one meetings. We are keen to develop such engagement.
   - Respondents from the research sector, in particular, felt that there was not enough relevant content for them on the HTA website compared to other sector groups. We will review this.
   - Increasing awareness of the HTA among the public is favoured by some stakeholders, but it was indicated that this does not need to be a major awareness campaign: a steady drumbeat of social media content, posters, and leaflets in meaningful locations etc., was seen as useful.
   - A number of respondents said they'd like the HTA to be more proactive in the policy space, saying it could do more to ensure that regulation is fit for purpose. Whilst HTA is an independent regulator, more active work in the policy space would of course need to be in support of and in concert with DHSC, our sponsor Department which has the lead policy responsibility, and taking account of the devolved adminstrations.

8. The draft Communications and Engagement Strategy was discussed with staff in a workshop during April.

Strategic direction

9. The overarching ambition driving this renewed strategy is that the HTA improves how we communicate; in a way that is more on the front foot and exploiting suitable opportunities to better engage with our stakeholders. This is consistent with the goal that the HTA should be an excellent, modern, accountable regulator that works in collaboration with others whilst maintaining its independence.

10. Effective communication for a regulator is essential to relay the details of the regulatory environment, to highlight to licensed establishments "what good looks like," to listen to feedback from those we regulate, to explain our regulatory decisions and to tune in to new emerging issues that must be navigated by the regulator.

11. We are seeking to be both excellent at how we assure public confidence today and in the future. Achieving this will require active communication and engagement, as we seek to be both an effective regulator and, more effective as a sector leader for the areas we regulate, responding to both existing needs and the emerging requirements of the sectors we regulate. This role will involve providing advice to the DHSC Secretary of State about any identified gaps or potential improvements to legislation as our regulated sectors evolve, taking account of government expectations for improved regulation as outlined in the Regulators' Code and the Better Regulation Framework.

12. Effective two-way communication is also consistent with the provisions in the Regulators Code, that regulators should have a range of mechanisms to enable and regularly invite, receive, and take on board feedback from those they regulate.

13. To that end, and building on our engagement and research, we are focusing our renewed approach around **four strategic principles** on which to base future communications and engagement activity. These are:

- **Be present***:* Ensure that the HTA is a regulator that is present with its stakeholders; that it is visible and accessible, from events and working groups through to social and traditional media.
- **Be relevant**: Provide communications and content that is tailored and relevant to specific audiences.
- **Be proactive***:* Be more proactive when communicating and engaging with groups of stakeholders, initiating advisory groups, convening round table discussions, and signalling that the HTA is open to collaboration and dialogue.
- **Be clear and consistent***:* Clear and consistent communication and engagement must be at the heart of the HTA's strategy.

Areas of Activity

14. To bring the strategy to life, we have identified a series of communication and engagement activities underneath each of these priorities, which are outlined in the appended strategy and include:

- Building a more balanced presence in the media.
- Developing content to be shared with the public.
- Where possible, tailor the HTA's communications to specific audiences
- Build a greater social media presence and use digital platforms more regularly.
- Provide spokespeople relevant to the audience.
- Develop a programme of roundtable stakeholder engagement events.
- Work to create a tone and style across our communications, so that all content and communications that issue, are clearly seen and understood as having a consistent HTA voice.
- Communicate key messages through our website homepage.
- More and better targeted face-to-face engagement including HTA presence at industry events.
- Working more closely with other organisations.

15. The ambition of increasing the impact HTA can make as a sector leader for the areas we regulate on behalf of DHSC and devolved administrations – and the consequential communications and engagement approaches that are needed to support that – requires a shift in our thinking. In doing so, we will wish to work closely with the DHSC sponsorship team, so they are fully aware of any emerging findings, given the Department holds overall policy responsibility. Leadership from

the SMT will be critical in supporting staff to embrace new ways of working. Planned internal reviews of HTA culture and ways of working, aligned with updates to HTA's expectations on behaviour and values, will also provide support to better position staff to embrace new ways of working.

16. It is recommended that a separate but linked internal corporate policy document is developed which is consistent with the externally focused Communications & Engagement Strategy. That will enable specific action areas, expected behaviours, targets and ways of working to also be aligned with individual staff Performance Development Plans.

Action Plan 22/23

17. There are more things that we could do in support of the strategy than we have the staff or finances to support. Hence, there is a need to prioritise on an annual basis through an Action Plan that can be monitored against progress.

18. An indicative Action Plan for FY 22/23 is appended to the Communications and Stakeholder Engagement Strategy in **Annex A**. As noted in paragraph 3, this Action Plan will be finalised during Q1 and will be updated and revised on a quarterly basis to ensure ongoing alignment with the Business Plan and available resources. Delivery of the Action Plan will not only require careful planning and prioritisation by the Communications Team but also requires input from across the organisation.

19. Some additional resources may also be required, including external design work (e.g., infographics) to support explanation of our regulatory remit, and externally supported media training for key staff.

Next Steps

20. Subject to the HTA Board agreeing the attached Communications and Engagement Strategy and any comments on the related indicative 22/23 Action Plan, next steps are:

- Assess the skills and resources required to deliver the plan and assign responsibilities.

- Finalise the indicative one-year Action Plan and commence implementation of targeted actions to enable more proactive communication and stakeholder engagement activities,
- Agree, prior to implementation how this work will be evaluated to determine and assess impact.
- Develop an associated internal communications corporate policy document.

Recommendation

21. The HTA Board is asked to consider and give approval to the attached Communications and Engagement Strategy and comment on the underpinning indicative actions outlined for FY 22/23 in the associated draft Action Plan.

Annex A

Communications & Engagement Strategy - May 2022

Introduction

This document is a renewed Communications and Engagement Strategy for the Human Tissue Authority (HTA). It has been developed with input from staff and stakeholders and with technical assistance from an external communications consultancy. It reflects feedback received from our external stakeholders on how we are currently perceived by them, as well as addressing areas we can do more on regarding communication and engagement. It has been developed taking information and research from different sources to help the HTA arrive at a revised approach to communication and engagement.

Effective communication and engagement are central to the operation of the organisation and a great deal of the Human Tissue Authority's success depends on its proficiency and effective application of communications and engagement with a diverse group of stakeholders. That can be a particular challenge for the HTA as a small organisation with finite resources whilst needing to communicate across not just one but several different sectors dealing with both living and deceased human tissue.

Enabling our Strategic Priorities

Strategic Direction: The HTA is a proactive, innovative and highly respected sector leader and regulator

Operational Delivery: HTA is a trusted, excellent, modern and efficient regulator.

People & Capability: Our culture, values and behaviours, reflect what is needed for us to excel.

Moving forward: HTA has a modern approach to how we regulate, through better use of data and analytics and more risk-based prioritisation.

Communication & Engagement Strategy enables achievement of the Strategic Priorities through activities and targets aimed at:

Encouraging effective, open and supported internal and external communication and engagement with colleagues, stakeholders and the wider public.

Supporting through greater internal communication and engagement, our colleagues to be proactive and agile, high-performing and engaged, enabling them to see the big picture and how they can best contribute to the organisations priorities and objectives.

Identifying increased opportunities to engage and communicate on joint activities with other regulators and relevant parties.

Distinguishing communication and engagement

In a strategy for both communications and engagement, there are times when the two overlap. Within this strategy, we have used the following broad definitions:

- **Communication**: Activities where we articulate or 'position' the HTA and when the HTA broadcasts information using the channels available, for example posting news on the website.

- **Engagement**: Activity whereby communication is two-way, involving dialogue or exchange between two or more entities or people, for example the HTA responding to a social media post or someone responding to a HTA social media post.

This strategy largely focuses on how we will Communicate and Engage with our external stakeholders, but similar approaches will apply to communication and engagement <u>internally</u> across the organisation.

Upon agreement of this strategy, we will develop a separate, internal corporate policy document seeking to have an internal focus by reviewing and refreshing the related guidance, to include for example: our new style guide, how to communicate effectively with government (taking account of the DHSC Framework Agreement), guidance on contact with the media, media training etc. That internal piece will align with our culture / behaviour / values expectations at a future point once our work in those areas has been completed.

The HTA's audience

The HTA has a broad range of **external stakeholders** that will need to be communicated and engaged with. These include:

- **The public**, amongst whom it is essential to maintain trust and confidence in the activities of the HTA and of the individual sectors we regulate.
- **Living donors** who are affected by the impact of our regulatory remit, and in the case of deceased donors, their families.
- **DHSC** (as sponsor department) **and devolved administrations** in Wales and Northern Ireland, and to a lesser extent Scotland.
- The **associations and organisations** that fall within the areas the HTA regulates, including HTA Licensed Establishments.
- **Health Regulators closely linked to HTA** and others that might become relevant in the future.
- **International Health Regulators**, including the EU, so the HTA can keep abreast of developments internationally, particularly across Europe, to ensure more effective cross-border activities.
- **Opinion formers** – including professional representatives.

Overarching strategic principles

Aligned with, and in support of, our broader revised HTA strategic priorities, our Communication and Engagement Strategy is underpinned by an ethos that the HTA should become a more active communicator; one that is on the front foot and increasingly looking for opportunities to communicate and engage with our stakeholders, in a manner that reflects our status as an independent regulator and as a sector leader. This is consistent with the goal that HTA be an excellent, modern, accountable regulator that works innovatively and in collaboration with others whilst maintaining our independence. Of course, as a Non-Departmental Public Body (NDPB), the policy lead for the sectors we regulate is our parent department, DHSC, working also with devolved administrations; and hence our communications and stakeholder engagement must therefore be cognisant of those governance arrangements.

Our goal is to achieve excellence in how we assure public confidence today, and in the future, in being an effective regulator and, in addition, a sector leader for the areas we regulate.

Communication & Engagement Strategic Principles

Be Present
HTA is increasingly visible and accessible across all of our stakeholder groups, involved in the right conversations at the right time.

Be Relevant
Content and communications are tailored and relevant to specific audiences. Messaging and content are relevant to the current agenda of news, events and topical developments.

Be Proactive
HTA has a proactive approach to collaborating and engaging with our stakeholders, developing opportunities for thought leadership.

Be Clear & Consistent
We are consistent in the tone and delivery of our communications. Communication and engagement is evidence-based, underpinning our credibility and authority

Our renewed approach to communication and engagement is built around **4 strategic principles: Be Present, Be Relevant, Be Proactive, Be Clear and Consistent**

Rationale for these priorities

A recurring theme from the feedback to the consultation process conducted by the external body, was that our stakeholders do see the HTA as an expert in the role we perform, and stakeholder groups want to learn from us: some feel we have a role as an educating presence. Our renewed strategy, focusing on three of these principles, Be Present, Be Relevant and Be Proactive, recognises and reinforces the visibility we already have, but will push us to do more

and ensure we're engaging with the full breadth of our key stakeholder groups – not just our sector specific establishments – in the right way at the right time.

Increasing our visibility means we also need to ensure that the content we produce for our communications and engagement, is tailored and relevant to our diverse stakeholder group. The principles Be Relevant, Be Proactive and Be Clear & Consistent, are focused on ensuring that as we better position ourselves as a future focused sector leader enabling us to make more effective contributions in policy areas in support of our sponsor Department that has lead policy responsibility. In communication terms, we will need to ensure that our content is relevant to the current agenda of news, events, and topical developments. This will require thinking laterally and outside-of-the-box on some topics, recognising that events in a separate regulatory sector or environment or wider generic government initiatives for better regulation may have implications for HTA.

A key component of the HTA's overarching strategic priority is to be more proactive, and this is expressly aligned with the 'Be Proactive' priority for the renewed communications strategy. Collaboration with our stakeholder groups does take place, but traditionally this has been driven by an immediate requirement, or in the course of our core work as a regulator. Increasingly, we will move to proactive engagement with our stakeholders, initiating, convening, and leading advisory groups, round-table discussions. Through these collaborations, we can further develop opportunities for better sector leadership, using the insights and perspectives gained to help inform policy work important to us and to our stakeholders, not least DHSC, given our responsibility to provide relevant advice to the Secretary of State, and the DAs.

Central to all our activities is a need for clear and consistent messaging. This is distinctly different to the principle of being relevant and of tailoring our communications. As we increase the level of engagement and communication we have with our stakeholders, HTA will need to ensure that there is consistency in what our stakeholders hear, regardless of which part of the HTA communicates or engages with them. This has emerged as a particular challenge in relation to our written communication, which some stakeholders feel is out of step with our verbal communication, creating an impression of inconsistency and that HTA doesn't always speak with one shared voice.

Applying the four principles

These principles form the foundation of our future communications and engagement work, guiding the decisions we make and allowing us to plan and prioritise effectively. By applying and fully embedding these 4 principles in how we work on a day-to-day basis, the HTA can build further awareness levels and address the perception that we have become overly inward-focused. They will also address other communications issues identified in the consultation engagement report, such as clarity of our regulatory role and consistency of tone. HTA is already perceived as regularly communicating with our stakeholders, but all would welcome

greater levels of engagement. There are also varying experiences in the nature of the engagement, with HTA seen as regularly in 'broadcast' rather than 'receive' mode.

Set out, below, are a series of high-level target activities in support of the 4 guiding principles, in relation to both the communications, and the engagement activities. Given our overarching strategic aims of becoming an innovative and respected sector leader and regulator, activities here will look at options and opportunities to move from a 'broadcast' mode to an 'engaged and actively receiving' mode.

The activities and actions indicated here are further developed, refined, and detailed in the related Action Plan, together with timelines, targets and indicative KPIs. It should be noted that these actions and activities predominantly focus on our approach in relation to our external stakeholders. We are conscious that our internal stakeholders are an equally important audience to which these principles also apply. Work on a separate, but linked, internal guidance and policy document, will better help to frame how these principles will be internally applied, and the behaviours, expectations and targets required to enable success.

Strategic Principle: Be Present

Be Present
HTA is increasingly visible and accessible across all of our stakeholder groups, involved in the right conversations at the right time.

In our Communications we will:

- *Build a more balanced presence in the media.*
- *Expand our presence and role beyond our core prevention activities*
- *Develop focused content to be shared with the public*
- *Keep under review our stakeholder groups and how we are communicating with them*

In our Engagement we will:

- *Increase our visibility and engagement at industry events and conferences*
- *Increase the number and type of engagement activities we hold with our sector Licensed Establishments*
- *Develop approaches to increase engagement with other Non Departmental Public Bodies and international regulators*

Rationale for these activities:

Currently, the HTA's media coverage tends to arise following reports on regulatory failings and/or enforcement actions. Through our renewed C&ES (Communication & Engagement Strategy), we will proactively work to increase our presence and visibility in the media, with stories that support the HTA's narrative. Building relationships with key media targets and journalists, will better ensure that if stories arise where the HTA may have a position, commentators already have an understanding of our work, enabling our views and positions to be more accurately reflected.

There is an opportunity – and amongst our stakeholder group, an increasing expectation – that aside our role as a regulator, we also compass a more effective role as a sector-leader and enabler of new and innovative approaches to the use of human tissue for research, medical treatment, and education. Increased proactive engagement with our stakeholders, alongside shifting our external focus to include the broader environment in which HTA operates, will help identify those areas where we can, and should, look to carve out that presence.

Although HTA predominantly deals with licensed establishments, there is a growing perception that we could do more to communicate in a targeted way with the wider general public. This will ensure consistency of information – as opposed to the public gathering information from e.g., licensed establishments – as well as helping to dispel any myths or inaccuracies about our role as a regulator. Suitably targeted increasing visibility may have additional benefits, e.g., in improving availability of living donor donations, if there is increased awareness of how this is regulated. We should create more content, using clear and simple language, on the HTA's social media platforms, and in leaflets etc. Additional work needs to be done to identify where the greatest salience for these materials exists, for example in hospitals, GP waiting rooms or other healthcare settings.

Advancing our communication plans must be aligned with an increase in our visibility at, and engagement during, key industry events and conferences. Proactively we also need to look at increasing the number and type of engagement activities that we hold with stakeholders with options for both in-person and virtual events being actioned.

HTA also needs to look at engagement beyond the traditional core priority areas of our sectors. Broader engagement is needed with other ALBs (Arms Length Bodies) in particular, but also with international colleagues and, where appropriate, with particularly regarding policy, strategy, and the impact of developing technologies on our role and remit.

Strategic Principle: Be Relevant

Be Relevant
Content and communications are tailored and relevant to specific audiences.
Messaging and content are relevant to the current agenda of news, events and
topical developments.

In our Communications we will:

- *Tailor HTA communications – both in content and in broader delivery mechanisms - to better reach specific audiences.*

- *Designate specific spokespeople across the organisation and provide improved guidance, support and media training to ensure consistency*

- *Build and lead a rolling programme of roundtable events that brings key stakeholders (e.g. our LEs) together, to discuss issues of mutual interest.*

In our Engagement we will:

- *Align our engagement to the specific needs of stakeholders – e.g. understanding best practice, potential policy changes, new regulations or emerging initiatives etc.*

- *Increase our use of social media to expand our reach and better share developments*

- *Work closely with other organisations and collaborate on issues of common interest to increase awareness raising and outreach opportunities.*

Rationale for these activities:

Every other month, the HTA issues a newsletter to designated individuals connected to our licensed establishments, and anyone who has signed up to receive a newsletter through our website: this can include members of the public, the media, other regulators, as well as other sector-specific individuals. This is a valuable communication tool, with a heavy focus on information from a sector specific perspective: there are however opportunities to include broader HTA wide information to increase its relevance and expand understanding of all HTA activities.

As we raise our profile, we will expect increased requests for official HTA comment, and risks will increase that any comment made by a HTA employee will be seen as an official positional stance. Our approach must enable our stakeholders to continue to receive key information and updates from those that they know, trust and respect, while we also ensure consistency and clarity of messaging, particularly on sensitive issues. We will provide updated internal guidance to key staff across the HTA, ensuring it is clear which communications need to be centrally cleared and who is designated to issue them. Clarity will be provided on who can speak with the press on specific issues, with suitable media training made available to those staff.

Half of the stakeholders surveyed as part of our consultation on this strategy, (51%) said that they were keen to hear from other HTA licensed establishments (LEs). Collaborating with other LE's gives opportunity to build advocacy as well as building engagement through further collaboration. As part of our renewed C&ES, as a sector leader, we will look at how best the roundtable events initiated during 2021 can be revised and refocused to better bring LE's together to discuss issues of mutual interest.

Strategic Principle: Be Proactive

Be Proactive

HTA has a proactive approach to collaborating and engaging with our stakeholders, developing opportunities for thought leadership.

In our Communications we will:	*In our Engagement we will:*
• *Increase HTAs presence across various social media platforms. Proactively use social media channels to support targeted and tailored communications.*	• *Be explicitly open to collaboration opportunities, clearly signposting ways to get involved and collaborate with us on our website and social media.*
• *Capitalise on national awareness days and milestone dates through all communication channels, to boost awareness of HTA activities*	• *Examine options for leading a research-specific membership group to increase their learning and support opportunities*
• *Designate specific spokespeople across the organisation and provide improved guidance, support and media training to ensure consistency*	• *Create different fora for engagement with our stakeholders, e.g. support or advisory groups for newer licensees.*

Rationale for these activities:

Social media is a key channel the HTA could make more use of to reach and engage audiences, but the right content is needed to drive this (which we will address through our 'Be Relevant' principle). Most communication via these channels is currently focused on what the HTA does, offering little incentive to grow followers or for some to remain 'tuned in' to the HTA. Reshaping content to reflect what is going on in the world and using it to share HTA thoughts and positioning, will be a significant shift change. There are opportunities for HTA to capitalise on national awareness days and milestones in the media. For example, issuing tweets / social media communications on International Women's Day and connecting this to the work of women in the sector, leads to greater engagement and more public interest.

HTA will build capability to harness topics of broad interest and relevance to increase its renewed proactive presence through media channels. These issues could include, for example, advancements in treatments of cancer, as this would drive general interest in the HTA and the wider debates surrounding the areas it regulates.

The HTA can enhance stakeholder engagement by clearly signposting information about ways to get involved and collaborate with the HTA on the website and social media. We can then use the HTA website to showcase where successful collaborations have taken place. Several regulators, including NICE, the MHRA (Medicines and Healthcare product Regulatory Agency)

and the CQC (Care Quality Commission), advertise opportunities for the public and other stakeholders to engage through initiatives such as giving opinion on new guidance or attending workshops and events. Listening to and engaging with the public more often would support the HTA's public interest remit.

HTA can also look at creating other fora to increase collaboration and engagement. A membership-driven, research-specific group is one area that stakeholders have highlighted could be helpful. We will explore this as we consider what executive level working groups or task and finish groups involving stakeholders, we should develop for specific areas of HTA business.

Strategic Principle: Be Clear & Consistent

Be Clear & Consistent
We are consistent in the tone and delivery of our communications. Communication and engagement is evidence-based, underpinning our credibility and authority

In our Communications we will:	*In our Engagement we will:*
• *Define and refine the HTA's tone of voice and style, to ensure consistency across all platforms and outputs.*	• *Ensure there is clear understanding of the HTA's function and role – particularly as we explore more opportunities as a thought leader – amongst our stakeholders.*
• *Avoid the use of jargon or overly legalistic language.*	• *Closely monitor high-profile media cases that could impact on HTA, proactively engaging with the media to ensure understanding of our regulatory role*
• *Avoid being non-committal in responses.*	
• *Be clear in what we do – and what we don't do.*	
• *Create easy graphics as guides to help stakeholders know where our remit ends and/or aligns with those of other NDPBs and ALBs*	

Rationale for these activities:

The feedback from stakeholders is that when interacting with the HTA the organisation is consistently friendly and approachable. However, in contrast, it is felt that in written communications the HTA is very different. People find the language used across channels such as the website and direct mail are too legalistic. It is perceived that written communication seems to repeat codes of conduct rather than explain them and can be "non-committal." Any inconsistency in the communication approach can create confusion.

Stakeholder interviews reveal that there is also some confusion about where the HTA's remit starts and where it finishes. This is perhaps not surprising given the complexity of some of these issues, however, as we move to being more proactive there are risks that this confusion could grow. It will be important that the HTA is definitive about where its role ends and where others begin, equally how we might develop advice to DHSC about the areas where regulation is limited, for example, where no regulator has any role, but one may be needed, or in emerging technological areas where lines between existing regulatory authorities are becoming blurred.

Implementing and Embedding the Renewed Strategy

This renewed Communications & Engagement Strategy has been developed at a time when HTA - as with many ALBs and the broader public sector – faces resource pressures. As such, the actions that will be undertaken to advance work on the strategy over the coming years, whilst ambitious, seek to take account of the existing staffing levels and existing priorities.

Several key activities and suggested actions outlined in this Strategy require collaboration with other Non-Departmental Public Bodies and ALBs. The HTA will reach out to those key regulatory bodies - just as NHSBT (NHS Blood and Transplant) has with the HTA on their strategic priorities – to ensure they are aware of our overarching strategic direction, and to ensure coherence between our approaches.

An indicative Action Plan to give effect to the priorities outlined in this strategy document is outlined below at Appendix 1. This will be an iterative document and will be reviewed and updated annually to ensure activities are best positioned to align with, and support achievement of, the HTAs Annual Business Plans.

It will be important to evaluate the impact the new strategy and the related activities are having. The annually agreed Action Plan will be reviewed internally by HTA on a quarterly basis.

Appendix 1 – Action Plan activities for 22/23 (DRAFT)

This is an indicative outline of activities and approaches to be advanced in discussion with the new Head of Comms and when taking overall priorities into account.

These actions are consistent with the HTA's overarching strategic goals, but the ambition must be balanced with the current financial and staffing resources, and it is clear not all the possible areas for action list below can be progressed in 2022/23.

Areas will be selected from the following long list of actions which are consistent with the strategy:

Draft Indicative Action Plan for 2022/23 (subject to available resources)

C&E Strategic Priority	Action / Activity	To be undertaken by (Note this section may need a sub section identifying who is lead / who is supporting activities)	Timeframe	Expected Outcome / KPI [how we will measure success]
Be Present	Build relationships with identified media targets.	Head of Comms/ Comms team		Increase in number and nature of contacts by media to HTA Increased awareness within media contacts of HTA / activities, more proactivity on their part in contacting us
	Identify key media targets in main UK news outlets (BBC, ITV, C4 etc.)	Head of Comms		Contacts established
	Identify issues HTA should be commenting on	Head of Policy & Development, Head of Comms, Heads of Regulation		Internal process in place to identify issues. Regular alerts and reviews each month via horizon scanning on issues.
	Identify opportunities for HTA attendance (conferences, workshops etc.) for attendance by CEO and SMT	SMT Deputy Director P&CG Head of Policy Heads of Reg		Annual calendar of events Increase in number of events HTA invited to attend HTA invited to contribute to events.
	Create suitable targeted programme of awareness raising, for example, with opinion makers / formers	Deputy Director P&CG Head of Policy		Increased awareness of HTA by opinion formers, with HTA referred to more accurately / increasing references to HTA.
Be Relevant	Bimonthly newsletter reviewed for content – new sections / elements added. Newsletter added to website	Head of Comms with Heads of Reg & Head of Policy. Additional inputs from other Heads and Deputy Director Strategy		Positive feedback on newsletter Increase in subscriptions to receive newsletter. Increase in requests to HTA for material for inclusion in future issues
	Review website content and structure – tailor information searches and drop-down menus	Chief Technology & Info Officer, Head of Comms, Head of Regs		Increase / volume of web traffic to specific sites. Increased awareness among stakeholders (esp. sectors) on key information. Feedback on website from stakeholders.

Draft Indicative Action Plan for 2022/23 (subject to available resources)

C&E Strategic Priority	Action / Activity	To be undertaken by (Note this section may need a sub section identifying who is lead / who is supporting activities)	Timeframe	Expected Outcome / KPI [how we will measure success]
				Increase in type of visitor to our site (i.e., more media / more ALBs / more public versus sectors/LEs)
	Renew roundtable events	Policy Team with Heads of Reg		Roundtable events held Follow up from roundtable generates positive feedback Information from roundtables feeds into business planning and strategic prioritisation across all teams.
	Identify nominated spokespeople for HTA & provide media training			Heads of Regs, specified RMs trained. SMT, Deputy Director Strategy, Head of Comms and any other nominated spokespeople media trained
	Develop internal policy guidance, processes and supports to guide staff on contact with media and use of social media	Head of Comms with Head of Policy and Chief Technology & Info Officer		Clear understanding across staff base of when / what can be posted and what may need to route via Comms
Be Proactive	Expand HTA's presence on social media – create and/or update HTA accounts across usual social media platforms. Explore international / EU based platforms to expand reach with other regulators	Head of Comms & Chief Technology & Info Officer Comms team		Increase in HTA activity and reforwarding / reposting of activity
	Include a 'collaborate with us' area on the HTA website & showcase recent collaborations			
	Create a membership-based research specific working group	Head of Research		
Be Clear & Consistent	Develop guidance / run internal training on written communication styles, to better	Head of Comms – inputs from Heads & Deputy Director P&CG		

Draft Indicative Action Plan for 2022/23 (subject to available resources)				
C&E Strategic Priority	**Action / Activity**	**To be undertaken by** (Note this section may need a sub section identifying who is lead / who is supporting activities)	**Timeframe**	**Expected Outcome / KPI [how we will measure success]**
	support staff in ensuring consistency and building confidence in corresponding with our stakeholders Develop specific guidance and training on correspondence with government / parliament			
	Provide clear internal guidance for all staff on future direction of HTA as a thought leader, with clarity on a sector-by-sector basis on what we do / don't do, and areas we provide positioning on / areas we collaborate on	Deputy Director P&CG with Head of Policy – inputs from Heads of Regs		
	Review all external content (sector by sector basis) for consistency of tone / language and clarity of messaging	Head of Comms with each Head of Regulation		

Human Tissue Authority
Board meeting

Date: 5 May 2022

Paper reference: HTA 14b/22

Agenda item: 6

Author: Audrey Jessiman

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Annex B: Summary of Luther Pendragon's findings about the HTA's Stakeholder Engagement

Introduction

1. The Human Tissue Authority has a substantial number of stakeholder relationships: government- including the devolved nations; other healthcare regulators and related non-Departmental Public Bodies; Arm's Length Bodies; and organisations within the sectors we regulate. The HTA commissioned Luther Pendragon to undertake a programme of internal and external engagement and research, to better understand current stakeholder perceptions of the HTA levels of engagement and provide recommendations as to what the future of HTA stakeholder engagement should look like.

2. That research identified a number of gaps in how we currently engage and communicate with our stakeholders and identified possible steps that could be taken to address them. This paper outlines in summary form, the main findings from the Luther Pendragon research.

3. The HTA would like to thank all the stakeholders who took part for their honest and constructive feedback. The HTA's renewed Communications and Engagement Strategy has been informed by the research findings provided.

Methodology

4. To understand current stakeholder perceptions, levels of engagement and what stakeholders would like engagement from the HTA to look like going forward, Luther Pendragon conducted three key phases of research.

    Phase 1: Desk research. This included reviewing HTA mentions by stakeholders across media, social media, parliamentary archives from the last two years, as well as reviewing communication from other regulators and the previous HTA stakeholder report, to understand the stakeholder perceptions which are in the public domain.

Phase 2: Stakeholder survey. This was an online survey from 9 March to 21 March 2022, sent to many key stakeholders of the HTA. This survey, which ran simultaneously to the stakeholder interviews, returned 117 responses, out of 618 stakeholders who received the link. Of those who responded, 91% were HTA licensed establishments (LEs); 54% of respondents worked for organisations in research, and 52% in healthcare (more than one option could be selected).

Phase 3: Interviews and focus groups. Luther Pendragon undertook 10 interviews with internal and external stakeholders and facilitated two focus groups (one internal and one external) to better understand stakeholder relationships.

Stakeholder Model & Map

5. Based on the findings from the desk research, interviews, focus groups and the online survey, Luther Pendragon mapped the current status of what they saw as key HTA stakeholder groups, into four categories of engagement. Each category represents an increasing impact on the HTA, necessitating an increased level of engagement.

1. **Monitor**
2. **Keep Informed and consult as necessary**
3. **Keep satisfied – keep up to date and be responsive**
4. **Work with - actively engage and regularly consult**

Engagement - current state of play
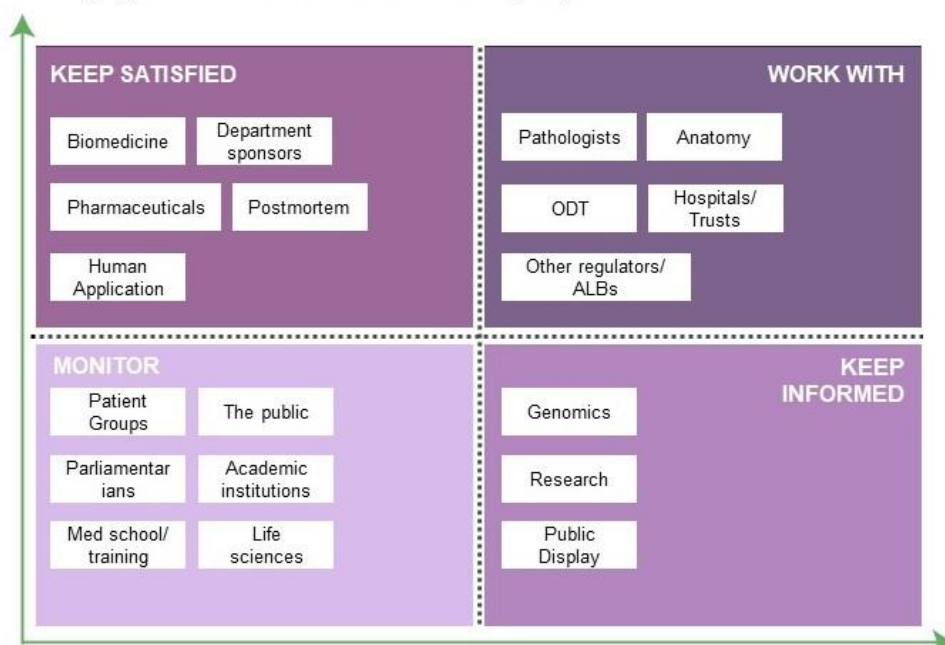
6.   Luther Pendragon also mapped how they considered this model should look, based on the reflections from the research and consideration of both the interest and influence of these stakeholders in relation to the HTA. We took account of these views but were not bound by them as we developed the draft HTA Comms and Stakeholder strategy.

Engagement – where we want to be
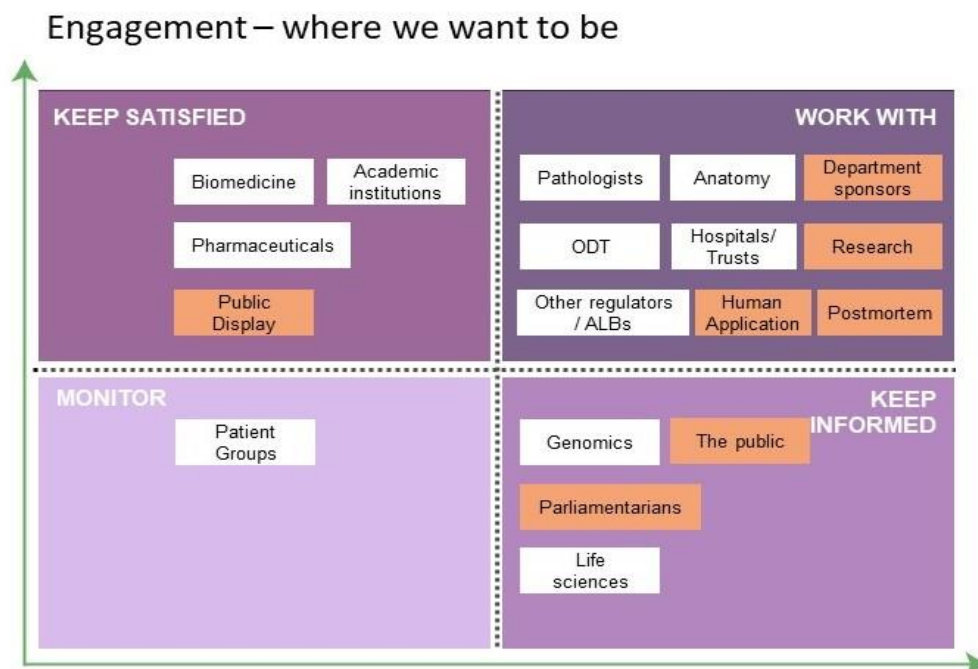
7.   Key changes and perceived strategic gaps in the HTA's current stakeholder engagement, and the groups that should be prioritised for additional engagement are highlighted in the map of where we want to be. This has been informed by the findings from the interviews and survey work.

8.   It was recommended that this stakeholder map should be reviewed and updated on a 6-monthly basis to reflect the strategic priorities of the HTA, and the changing nature of stakeholder relationships.

Conclusions

9.   Based on three phases of research, the following conclusions were drawn by LF about current stakeholder perceptions, and desired levels of engagement among HTA stakeholders:

i.   The predominant impression of the HTA is based on its regulatory function. Across the three strands of research, it is seen as authoritative and expert in what it does. It is, however, seen to have a softer side, with many stakeholders viewing it as friendly and compassionate. This could be an issue, as some stakeholders suggest that the HTA has different tones of voice

dependent on who you speak to and how. For example, stakeholders reported that tone varies between emails, website content, and phone contact.

ii.   While most HTA stakeholders feel engaged with the HTA, they would prefer higher levels of engagement, particularly more events and one-to-one meetings. This suggests a tailored approach to engagement, as opposed to the HTA focusing all its resources on general awareness raising or generic content. Some stakeholders who were members of recent or predecessor advisory groups were keen to see these return and would have liked more communication about the groups and the HTA activities they covered during the pandemic.

iii.   The HTA does receive some mention by parliamentarians and in the media, suggesting its role is known and understood at the parliamentary/ devolved administration level and by the media on relevant issues. Some stakeholders felt the HTA should be more proactive in the policy space and felt it could be doing more to ensure that regulation is fit for purpose. They would like the HTA to be more consultative with stakeholders in this regard. This is an area for HTA to explore whilst recognising that DHSC has policy lead responsibility and any work in this area must be completed with the full support of our DHSC Sponsor team.

iv.   The Research sector has been identified as an area for improvement in terms of stakeholder engagement. Stakeholders felt there was not enough relevant content for them on the HTA website compared to other areas of the HTA's focus, and noted that, as in other areas of the HTA's work, there is no advisory group for Research at the moment.

v.   Although the public is not a primary audience for HTA engagement the HTA still needs to inform the public about its work. Internal stakeholders felt that this is where the main misperceptions about the HTA came from.

vi.   There are some key issues on which stakeholders, internally and externally, feel the HTA should be more active. This includes live organ donation and public display.

Human Tissue Authority
Board meeting

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Agenda item:	7
Author:	Ranjan Sen, Audrey Jessiman, Paul Clements

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Development Programme Annual Report

Purpose of paper

1. The purpose of this paper is to provide the HTA Board with an Annual Report on the work of the Development Programme, outlining progress made over the last 12 months. This Report also outlines some lessons learnt, along with suggestions for how best to take forward its aims in a way that aligns with and supports achievement of our Business Plan.

Decision making to date

2. The SMT on 12 April, reviewed and noted progress on the last Board update (dated 10 February 2022).

Action required

3. The HTA Board is asked to note this Annual Report, and to agree the recommendation approved by the SMT, that the HTA take this opportunity to pause current activities to enable a review of the current focus and structure of the Development Programme. It is intended that a further paper on the findings of that

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review, outlining recommendations on how to take work forward, will be submitted to the July Board meeting.

Background

4. The HTA's vision and strategy is centred on achieving greater sustainability, agility, and resilience in our operations. In 2020, the HTA took the opportunity afforded by the Covid-19 pandemic, to take stock of how we were operating and set in train several connected projects to examine how we can most effectively deliver our services going forward. These related projects were collectively known as the Development Programme.

5. The current Programme consists of 6 inter-connected workstreams or projects, that articulate more modern ways of working:

Key elements of the Development Programme

Better Use of Data & Intelligence
- Improve the quality of data to better inform risk-based prioritisation
- Develop a Regulatory Insight Model & Index (RIMI)

Target Operating Model
- The framework within which our future ways of working are specified. Informed by our approach and needs on data and our operational platforms

Horizon Scanning
- Proactively review the wider landscape to respond to emerging regulatory requirements or policy opportunities

Organisational Preparedness
- Ensure all staff have the requisite tools and skills

Electronic Content Management System (ECMS)
- A robust record management system to ensure we can readily track, locate and report on data

Optimising Microsoft M365 Platform Functionality
- Exploit M365 platforms and functionality to improve collaboration

6. These projects aimed to address known challenges within the HTA regarding e.g., access to real time information on the breadth, accuracy, and timeliness of data, and of the ability of data to provide useful management information and insight. Projects were also aimed at facilitating a more outwardly focused HTA, with greater advance line-of-sight on areas of interest to HTA.

7. The Senior Responsible Owner (SRO) for the Development Programme is the Director of Data, Technology and Development. Progress is reported on a regular basis at SMT with progress reports given at ARAC and the Board. There are no additional project or programme-level governance boards.

8. It was envisaged that the overarching Programme would be governed by the following principles:
   - The Senior Responsible Officer (SRO) would be responsible for benefit realization - i.e., the realisation of Return on Investment and associated measures.
   - The Project (Programme) Manager would oversee delivery of cross-project success measures. They would also collate Monthly Reports for the SRO and review progress against success measures, that would support reporting across and up the organisation.
   - Individual Project Leads would be responsible for each of their allocated project's deliverables.

9. The structure provided the right level of oversight and control to the programme over Q1 and Q2. As progress of work required join up with wider business and its operation, challenges were encountered regarding resource allocation (people and budget). This in turn required rescoping and refreshing of programme deliverables for Q3 and Q4. Regular reporting to Board and ARAC continued, however, slowing and pausing of projects placed greater reliance on SRO to govern, direct and be responsible to delivery.

Progress over the past year

10. During 2021, progress was made on Horizon Scanning, with a Horizon Scanning Working Group established and details for staff on how to add to the Horizon Scanning Log made available through WAVE, the staff intranet site. Resourcing constraints however, consistently slowed progress across several other projects.
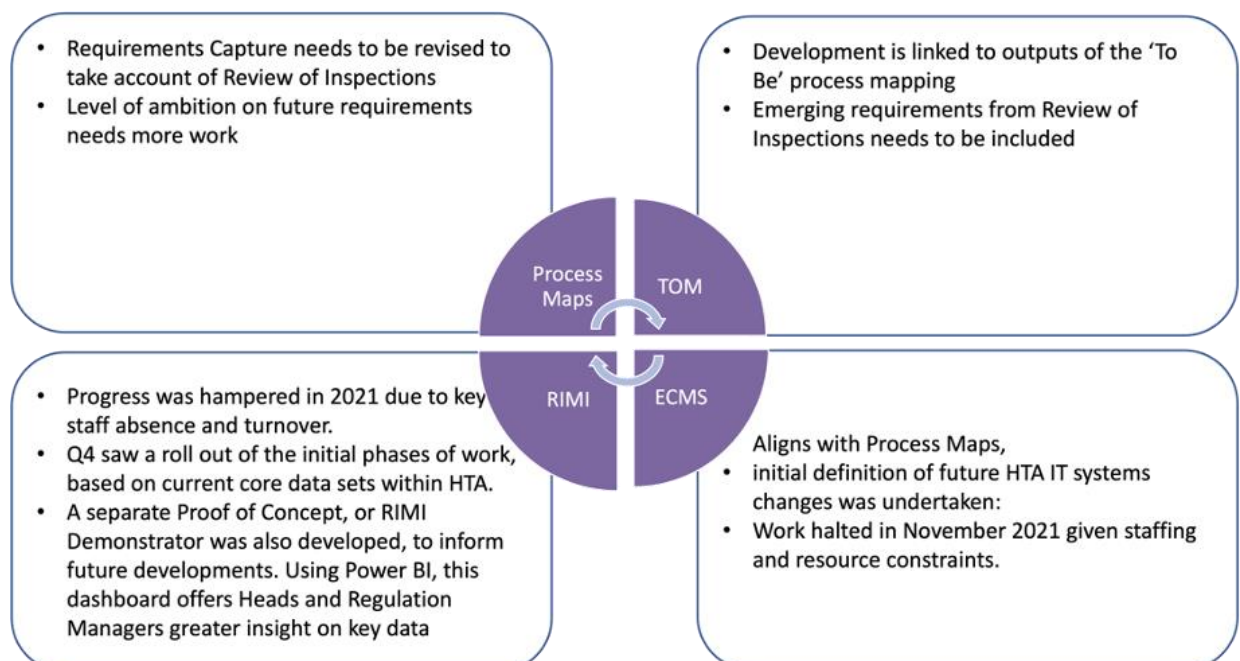
This negative impact was so acute, that towards the end of the year, SMT directed the programme to focus on just 3 priority projects:

I. The drafting of a Target Operating Model.
II. The development of the HTA's Data and Intelligence systems, so that future capability could be developed to fully adopt a more risk-based approach to oversight and regulatory action.
III. The establishment and further adoption of components of the Enterprise Content Management System.

11. Considering this re-prioritisation, progress over the last 12 months has largely been on the following four components:

I. Further evolution of the Target Operating Model (TOM): Status Amber
II. A package of "As-Is" and "To-Be" Process Maps, Data Flow Diagrams and Narratives that form the basis of our TOM. Status Red
III. Regulatory Insight Model & Index (RIMI) – updated version: Status Amber / Red.
IV. Design phase of the Transition Architecture for the Enterprise Content Management System (ECMS): Status Red

12. Whilst noting modest achievements in 21/22, it is recognised that these have been achieved in a very challenging fluid environment that led to a continual refresh of the programme. As such, not all the intended benefits and ROI have been realised. A summary of the progress made on these components is outlined in the image below.

- Requirements Capture needs to be revised to take account of Review of Inspections
- Level of ambition on future requirements needs more work

- Development is linked to outputs of the 'To Be' process mapping
- Emerging requirements from Review of Inspections needs to be included

Process Maps | TOM
RIMI | ECMS

- Progress was hampered in 2021 due to key staff absence and turnover.
- Q4 saw a roll out of the initial phases of work, based on current core data sets within HTA.
- A separate Proof of Concept, or RIMI Demonstrator was also developed, to inform future developments. Using Power BI, this dashboard offers Heads and Regulation Managers greater insight on key data

Aligns with Process Maps,
- initial definition of future HTA IT systems changes was undertaken:
- Work halted in November 2021 given staffing and resource constraints.

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13. Additionally, work continued on the planning of two supporting areas of work:

   I.   ***Target Workforce Skills Map to inform workforce development and future operating model: Status N/S (not started)***
        Due to the dependency on process mapping this project of work hadn't commenced. As with other projects, planning for what needs to be done has continued, including the approach to a Skills Audit and alignment with the Target Operating Model. This work and its delivery will commence once there are outputs from the 'To-Be' business process mapping that provide insight into the future skills needs of the organisation.

   II. ***Stakeholder Engagement (internal and external): Status: Amber***
        It has been necessary in Q2 and Q3 to prioritise and deploy the Communications and Engagement Team's resources to the Website Redevelopment project. In Q4, a commission was issued to Luther Pendragon to conduct a Stakeholder Mapping Project. This work has provided a stakeholder model which identifies gaps in current engagement that will be addressed through the renewed Communication and Engagement Strategy (HTA 14/22 agenda item 6).

14. The Business Plan for 22/23, has placed Development Programme projects in the pipeline, ostensibly pausing this portfolio of work. This is reflective of the view of the SMT that in its current state, clarity is needed before progressing with the projects.

Lessons Learnt

15. The Development Programme's breadth of ambition through its multiple interlinked projects is significant. The degree to which those projects are however aligned, understood, have been accurately scoped and resourced, have been sequenced in their roll-out, and supported across the broader staff base of HTA is far less clear. Some key lessons emerging to date are:

   I.   Consistent resource allocation to projects has been a significant challenge. Budget allocations have been limited and when called upon have not been available for use due to conflicting organisation priorities or requirement for further clarity regarding expected outputs from spend. A review of the

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5

appropriateness of skills, capabilities and numbers of staff allocated to Programme work, would also be beneficial.

II. Internally, there have been significant changes and turnover in staff: while that has resulted in a loss of critical corporate knowledge, newly arrived staff bring different skillsets, creating opportunities to exploit fresh and alternative thinking. This could help to provide a level of refocus on how best to advance needed reform and change within available fiscal and staffing constraints. Staff turnover will continue during 22/23, with some key staff aligned to this project already scheduled to leave, or on short Fixed Term Contracts.

III. Awareness and knowledge across the organisation on the breadth, value and benefits the Programme can deliver is variable. Resource constraints reinforce, rather than address, disconnects between the needs and requirements of core delivery side (e.g., Regulation team) and those working on the Programme.

IV. Greater clarity is needed on scope definition, resource requirements, updated user and business requirements, prioritisation, and reprioritisation of Programme work. This would better inform cost estimation, sequencing and monitoring of delivery timeframes and monitoring of targets. Updated risk and cost-benefit assessments would help inform decision-making and better help address e.g., funding constraints, and the potential impact of any emerging or new external requirements.

V. While multiple documents relating to elements of the Programme have been historically developed, there is an absence of a coherent overarching 'live' document, readily accessible by key project staff. The degree to which the broader SMT and Board support and engage with the Programme is unclear. Internally, a Wave intranet page has been established for the Programme, but messages on focus, objectives, targets, and rationale are not clearly visible.

VI. Our professional service teams (HR, Finance, Policy, IT, etc.) are proportional for our modest c50 FTE overall headcount, but the breadth of services they cover on a daily basis is just as extensive as an organisation 10x our size. This leaves the teams stretched beyond their reasonable capabilities and experience. The HTA is therefore carrying significant inherent risk and needs to address this as a priority within 22/23. Early conversations with much larger members of the wider Health & Social Care family should be started with a view to potentially buying a more comprehensive range of shared services within the year.

Going Forward – Opportunity for Review

16. Since the Development Programme was formulated, the broader context in which it is operating has changed. For example, advances in how data is collected as part of the VRA and ODT data and collection exercise, have not yet been reflected within the thinking of the Data and Intelligence project. Similarly, the Review of Inspections which will take place during 22/23, will impact on the development of the TOM and process mapping components.

17. Our digital maturity is still low, with known gaps and inconsistencies in how data is collected, reported on, and utilised by our technical teams. The sustainable long-term provision of our IT support services also needs to be urgently explored. This is likely to include examination of developing a shared service or partnering arrangement, for example with another health body, who has critical mass of the modern skills and experiences that HTA urgently needs.

18. Considering the lessons learnt to date and the changing internal and external environment, a review of the Development Programme, following programme and project management methodology best practices, would afford an opportunity to ensure that its current scope of work, activities, resource allocation and schedule remain appropriate.

Next Steps

19. It is recommended that a review of the Development Programme is conducted between May and June 2022 (Q1). Project reviews are an integral component of effective project management: as such, a review at this point would be in-line with best-practice. A review affords an opportunity, to take account of the lessons learnt to date, to identify any areas that require attention, and to refine where needed, any of the activities and delivery schedule of the Development Programme. A review would also enable a check to ensure that the objectives and aims remain optimal and aligned to the HTA's overarching strategic priorities.

20. The details regarding the staffing, structure and scope of the review will be set out in a Terms of Reference for agreement by the SMT. The findings and recommendations of the Review will be presented to the July board meeting.

Recommendation

21. The recommendation, based on this Annual Report, is that the HTA take this opportunity to pause activities and review during Q1 (May and June) the current focus and structure of the Development Programme. The findings and recommendations of that review will be submitted to the July Board meeting.

Human Tissue Authority Board Meeting

Date: 5 May 2022

Paper reference: HTA 16/22

Agenda item: 8

Author: Dr Colin Sullivan and Sandra Croser

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Remuneration Committee Terms of Reference

Purpose of paper

1. To inform the HTA Board of and gain agreement for proposed changes to the Terms of Reference (ToR) of the board's Remuneration Committee (RemCo).

Decision making prior to Board

2. The SMT agreed this paper on 12 April 2022 for submission to the HTA Board.

Action required

3. The HTA Board is asked to note, consider, and approve the changes to the Terms of Reference of the Remuneration Committee (and to also approve that Appendix 5 of the standing orders be amended to reflect the changes to the RemCo ToRs).

What is proposed

4. The Remuneration Committee is a standing sub-committee of the HTA Board. The Terms of Reference for the Remuneration Committee form an annex to the HTA standing orders and hence Board approval is needed for any amendments to the ToRs.

5. Article 95 of HTA's standing orders states 'The Board will keep under review the structure and remit of its Committees. To date, the role of the Remuneration Committee has been focused around agreeing the HTA's remuneration strategy on behalf of the HTA Board. The Remuneration Committee (RemCo) can achieve this by ensuring that the strategy is compliant with government policy on remuneration in arm's length bodies (ALBs), and that it meets the needs of the organisation in relation to recruitment and retention. In reviewing the RemCo terms of reference, we have worked with colleagues in DHSC to ensure the attached version includes all aspects of the latest requirements expected of ALBs by the DHSC Remuneration Committee and the DHSC sponsor team, this includes in respect of the recruitment of the Chief Executive and any other posts at the ESM (Executive Senior Management) pay grades.

6. In addition to updating the ToRs in respect of the ALB remuneration strategy requirements, it is proposed that the HTA RemCo be assigned a second informal role to also serve as a sounding board/support for the CEO as the Accounting Officer (AO) on people and cultural issues. In this regard, RemCo can support the CEO in working through the culture review designed to help ensure the approaches and behaviours of staff reflect and are consistent with the HTA's refreshed values, so as to optimise the successful delivery of the vision and mission and our underpinning objectives.

7. Whilst recognising RemCo is the main forum for the HTA Board to consider HR and People matters ahead of discussions at a full Board meeting, risks faced by the HTA which relate to people issues such as, Equality, Diversity, and Inclusion (EDI), culture or behaviour issues may be raised at meetings of the Audit & Risk Committee (ARAC). With this in mind, it is proposed that the Chair of ARAC will be updated on the discussion at RemCo meetings. In addition, at least one Board Member, must be a member of both the Remuneration Committee and the Audit and Risk Assurance Committee, with that person not being the Chair of either sub-committee.

8. Article 94 of HTA's Standing Orders states 'The frequency of Committee meetings will be defined in the Terms of Reference, which must be agreed by the Board'. With two distinct roles for a renewed RemCo, both the formal duties in respect of the remuneration strategy and recruitment of senior posts in line with DHSC requirements, and the informal sounding board/support for CEO as AO on people and cultural issues; it is proposed that the frequency of meetings be increased

from the previous expectation of a minimum of one meeting per year to two
meetings per year.

9. The next meeting of RemCo, working to the revised ToRs, is proposed for June
    with a further discussion following on soon after the November HTA Board
    meeting. In 2023 and beyond when HTA Board meetings move to a cycle of
    March, June, September, and December; RemCo meetings are proposed for May
    and November. Subject to agreement by the RemCo Chair, it is proposed that
    these meetings will be held virtually.

Recommendation

10. The HTA Board is asked to note, consider, and approve the changes to the Terms
    of Reference of the HTA Remuneration Committee (and to also approve that
    Appendix 5 of the standing orders be amended to reflect the changes to the
    RemCo ToRs).

Annex 1

Review of the Terms of Reference for the Remuneration Committee

The Terms of Reference for the Remuneration Committee were last updated and approved on 1 August 2021 with a review date set of 31 July 2023, during the process of updating the HTA's standing orders. These ToRs are included as Appendix 5 of the standing orders.

If approved, the version below will replace these ToRs and the newly constituted Remuneration Committee can consider if any revisions are required with a review date not later than May 2024.

Appendix 5: Terms of Reference for the Remuneration Committee

Reference number	HTA-TOR-002	**Version**	22.0
Owner	Resources Directorate	**Date approved**	5 May 2022 (tbc)
Author(s)	Sandra Crosser	**Next review date**	31 May 2024
Reviewed by	Colin Sullivan	**Distribution**	Internal and external
Approved by	HTA Board		

Constitution

The Human Tissues Authority (HTA) has established a Remuneration Committee (known to HTA as RemCo) with the formal role of agreeing the remuneration strategy on behalf of the board. The Remuneration Committee will achieve this by ensuring that the strategy is compliant with government policy on remuneration in arm's length bodies (ALBs), and that the needs of the organisation in relation to recruitment and retention are fully considered.

In addition, separate from the formal governance responsibilities of RemCo (as set out above) the board consider RemCo to be a suitable forum to offer informal support and act as a sounding board, to the Chief Executive, on the wider culture and people issues.

Duties and functions

The duties of the Remuneration Committee are twofold.

The first, the formal responsibilities of a Remuneration Committee as determined by the Department of Health and Social Care (DHSC), are as follows:

a. determine and agree the HTA's remuneration strategy, taking into account affordability, recruitment and retention, comparability with other ALBs' remuneration and Government policy on remuneration.
b. approve the annual pay award for the HTA;
c. approve recommendations for early retirement and any other extraordinary remuneration, including non-contractual termination arrangements or compensation for all staff;
d. have regard to the annual civil service pay guidance, the civil service reward principles and all other relevant codes, laws, and regulations.

e. ensure that the remuneration report for staff and HTA Board Members that appears in the annual report and accounts (ARA – which are overseen by ARAC) is consistent with the HTA's remuneration strategy;

f. determine the remuneration of the Chief Executive within the Government's policy for remuneration of very senior staff;

g. when required, have oversight of the recruitment of the Chief Executive ensuring the actions taken are fully compliant with the DHSC 'ALB ESM Pay Framework' and ensuring all responsibilities falling to the DHSC Remuneration Committee are appropriately adhered to.

h. Ensure DHSC Remuneration Committee prior approval is obtained for recruitment to any roles with a total salary package of a set threshold (the threshold is currently set at £150,000) and above.

i. Ensure DHSC approval is obtained prior to increasing the 'Director' level structure for the HTA. The structure should be determined by DHSC and a business case must be submitted and approved prior to such recruitment commencing.

j. Please Note: The decision-making authority to increase headcount at the senior levels (Director and CEO) resides with the DHSC and not the HTA Remco.

The second area of responsibility is to provide informal but informed guidance and support to the Chief Executive, as the Accounting Officer, on any matters relating to People and Culture. This includes:

k. Being a forum for more in-depth discussions than are possible at the Board about the values, behaviours, inclusivity, and underlying culture of the organisation.

l. Considering the HTA staff engagement and satisfaction survey scores and reflecting on any issues arising from these.

m. Providing the CEO with ideas and guidance in relation to People and Culture interventions, where requested.

n. Consider and discuss progress against the HTA's equality, inclusion, and diversity strategy (EDI) and offer any professional support and insights to support the Chief Executive that enables the objectives of the EDI strategy to be progressed.

Rights
In respect of its formal areas of responsibility, the Remuneration Committee has the following rights:

a. it may commission independent specialist advice at the expense of the HTA, subject to budgets agreed by the Board (and with the agreement of the Accounting Officer);

b.   it will be consulted in advance on the procurement of any external advice being sought on its behalf;

c.   it may secure the attendance of outsiders with relevant experience and expertise in order to discharge its formal responsibilities.

Information requirements
The Remuneration Committee will be provided with information about pay award proposals and any other papers deemed necessary for each meeting.

Reporting to the Authority
The Remuneration Committee will formally report back (either verbally or in writing) to the HTA Board after each meeting.

The Remuneration Committee will ensure the Chair of the Audit and Risk Assurance Committee is updated (either verbally or in writing) regarding identified risks from EDI, Culture or behaviour discussions or reports.

Reviewing effectiveness
The Remuneration Committee will undertake annual reviews of its own effectiveness and agree actions for improvement. The Remuneration Committee will report the results of the review to the HTA Board.

Recruitment and membership
The Remuneration Committee will be chaired by a lay Board Member, who is not the HTA Board Chair, and who preferably has relevant experience and expertise.

The Remuneration Committee will be made up of no fewer than three, and no more than five, other Board Members, one of whom will be the HTA Board Chair.

At least one Board Member, who is not the Chair, must be a member of both the Remuneration Committee (RemCo) and the Audit & Risk Assurance Committee (ARAC).

Recruitment of Board Members to the Remuneration Committee will be through 'expressions of interest' with personal statements in application. The applications will be reviewed by the Chair and the Chief Executive, who will decide on the appointments. Should an insufficient number of expressions of interest be received to fill an available role, the HTA Board Chair will appoint the Member who has the most appropriate skills and experience to the role.

Remuneration Committee members will be appointed for a set term of 3 years, which will not exceed their tenure as HTA Board Members. This term may be extended in accordance with business need.

Members of the Remuneration Committee must disclose the existence and nature of any personal or material interest before the discussion of that interest at any meeting. They must be free of any relationship that may compromise their independence or interfere with the exercise of their judgement.

Attendance

A minimum of two members of the Remuneration Committee (excluding the Chair) will be present for the meeting to be deemed quorate.

Committee members will be expected to attend every meeting. If a member is not able to attend a meeting, they should provide apologies to the RemCo Secretary in advance of the meeting. If a member does not attend more than two consecutive meetings the Chair will arrange a meeting with the member to discuss their attendance and whether they wish to continue their membership of the Committee.

Board Members who are not members of the Remuneration Committee have the right of attendance. Board Members attending meetings will be entitled to speak with the permission of the Chair of the meeting, but in no case will they be entitled to vote.

The Chief Executive, the Director of Resources and the Head of HR will attend meetings of the Remuneration Committee, except when matters relating to their own remuneration are under consideration.

The Remuneration Committee may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters.

Frequency of meetings

The Remuneration Committee will meet at least twice per calendar year will be scheduled to ensure that deadlines relating to remuneration are met and to facilitate timely reporting to the HTA Board.

Following the expansion of the role to also consider, informally, the People and Culture of the HTA, a greater frequency is envisaged. The Chair of the Remuneration Committee may convene additional meetings as they deem necessary.

The Accounting Officer or the HTA Board may ask the Remuneration Committee to convene further meetings to discuss particular issues on which the Committee's advice is sought.

Secretariat responsibilities

Secretariat responsibility for the Committee will fall to the HTA Private Office.

The agenda, minutes from the previous meeting and any meeting papers for consideration will be distributed to the group **at least** one week before each meeting.

Minutes and action points from each meeting will be circulated as soon as possible, within one month of the meeting. Members will be required to provide any comments on accuracy of the minutes by email. This will ensure the key areas of discussion and action points are captured accurately.

Minutes of the Remuneration Committee are confidential and will not be published on the HTA website.

Version history

These Terms of Reference will be reviewed annually by the Remuneration Committee and will be approved by the Authority following that review.

Latest version	Date	Comments	Reviewed by	Approved by
15.0	24 February 2015	Updated to ensure factual accuracy, update membership information, and add version control.	Amy Gelsthorpe-Hill	Authority Members
16.0	4 May 2017	Scheduled review	Diane Galbraith	Authority Members
21.0	1 August 2021	Fundamental review as part of the review of the Board's Standing Orders.	Allan Marriott-Smith	Were held in draft and not brought to Board

| 22.0 | 10 March 2022 | Draft for consideration by HTA Chair and Board | Colin Sullivan | tbc |

HTA
Human Tissue Authority

Minutes of the Ninety-Ninth meeting of the Human Tissue Authority Board

Date: 10 February 2022

Time: 10.00-12.00

Venue: Zoom

Protective Marking: OFFICIAL

Attendees:

Board Members
Lynne Berry, HTA Chair
Professor Gary Crowe
Dr Stuart Dollow
Dr Charmaine Griffiths
Glenn Houston
Professor Penney Lewis
Jan Williams
Dr Lorna Williamson
Ellen Donovan

Apologies
Professor Deborah Bowman
Maria Nyberg, Deputy Director Health Ethics, DHSC

Observers
Jacky Cooper, Team Leader Human Tissue Policy, and Ethics of Consent

HTA attendees
Dr Colin Sullivan, Chief Executive
Louise Dineley, Director of Data, Technology and Development
Nicolette Harrison, Director of Regulation
Richard Sydee, Director of Resources
Kelly Sherlock, Head of Regulation
TJ O'Conner, Executive Assistant
Alison Margrave, Board Support (minutes)
Sarjana Tharin, Data Analyst (item 4)
Shirley Dent, Head of Communications (item 5)
Dr Julie Edgeworth, Interim Head of Development (items 9 and 10)

Item 1 – Welcome and apologies

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

Item 2 – Declarations of interest

2. The Chair asked Members if there were any new declarations of interest; none was declared

Item 3 – Chair's Report

3. The Chair provided an oral update on the following items:

    Induction of CEO. The Chair thanked Board members for assisting with the induction of Dr Colin Sullivan. On behalf of the Board, she expressed thanks to the Senior Management Team for their work during the interim period.

    Fuller Inquiry. HTA has provided feedback on the proposed terms of reference for the Independent Inquiry led by Sir Jonathan Michael and offered its support for the inquiry.

    Department of Health and Social Care. The Board noted that there had been meetings regarding HTA Board Member recruitment and renewals and the Fuller Inquiry.

    One-to-one review meetings. The Chair reminded the Board that their review and objective setting meetings would be held shortly.

Item 4 – Chief Executive's Report

4. Dr Colin Sullivan introduced the report and thanked the Board and SMT for his warm welcome. He highlighted that he had already attended an inspection visit and this had been invaluable for his understanding of the work of HTA.

5. Colin informed the Board of the exercise which had been undertaken to utilise resources for Q4. This had been helpful both to progress Q4 activity and for objective setting for the 22/23 business plan. He also highlighted his proposal to reintroduce Key Performance Indicators, to review how inspections are conducted from an overall systems perspective and to enhance the statistical information provided to the Board. He outlined the initial changes to the data annex and the information provided to the Board. The Board welcomed this

additional information, especially regarding statistical process control charts and suggested that narrative would be developed to accompany them.

6. He spoke to the Risk Summary and Strategic Risk Register and spoke to the risks which were above tolerance. Whilst cyber security is included within risk two and four it was questioned whether it should be a separate risk. It was noted that ARAC receives a report on cyber security at each of their meetings.

7. The Board discussed the level of debtors and were informed of the steps being taken by HTA to reduce these. The surplus in Q3 was discussed with the commissioning of work taking place in Q4. The underspend on training was mainly attributed to online training events rather than face-to-face events.

8. The Board noted the report.

Item 5 – Communication and Engagement Strategy (HTA 2/22)

9. Louise Dineley introduced the report

10. She noted that HTA's previous strategy had centred on face-to-face contact with a specialist group of stakeholders and social media was very limited. Extensive work has been done to increase HTA's social media outreach and to provide a base which future development can be measured.

11. The role of round-table events was discussed, and it was noted that these would not necessarily replace Working Groups but be an additional form of outreach.

12. The Board discussed the idea of sector themed approach for engagement and the need to measure success and deliverables for the strategy.

13. The Board noted the report.

Item 6 – Business Plan 2022/23 (HTA 3/22)

14. Richard Sydee introduced the report provided an overview of the planned process to compile and agree the HTA Business Plan for 2022/23

15. He highlighted the guidance which HTA had received from the Department on priorities for 2022/23 and confirmed HTA would adhere to this in producing the Business Plan.

Action one

16. The Board noted the proposed roadmap for the 2022/23 Business Plan and agreed to review the pre-publication business plan in correspondence during March 2022

Item 7 – Audit and Risk Assurance Committee Terms of Reference (HTA 4/22)

17. Richard Sydee introduced the report and informed the Board that during its meeting on 27 January 2022, ARAC had discussed the amended Terms of Reference.

18. The Committee were supportive of the amendments made to align nomenclature between governance documents and they did not propose any further changes to the terms of reference.

19. The Chair spoke about the need to update the terms of reference for the Remuneration Committee to encompass a wider "people" approach.

Action two

20. The Board agreed the proposed Terms of Reference for the Audit and Risk Assurance Committee and further agreed that HTA's governance documents to be updated accordingly

Action three

21. The Board agreed that the Terms of Reference for the Remuneration Committee should be brought to the May Board meeting for approval.

Item 8 – Police Referral Policy (HTA 5/22 and HTA 5a/22)

22. Nicolette Harrison introduced the report and highlighted her thanks to Professor Penney Lewis for all her assistance in this regard.

23. She referred to her email to Board members with additional proposed amendments to the policy and the proposal that this should now be called "Police Referral and Warrants Policy".

24. The Board discussed the importance of receiving specialist legal advice with experience in relevant statutory regimes and in devolution. The Executive were encouraged to challenge the legal advice if they felt it was not correct.

Action four
25. The Board agreed the revised Police Referral and Warrants Policy document and the amendment to the Standing Orders.

Item 9 – Horizon Scanning (HTA 6/22)

26. Louise Dineley introduced the report

27. The process that HTA follows to develop the Horizon Scanning log and register was explained. It was stressed that this is not a standalone piece of work but that it crosses over many areas in which HTA operates and provides HTA with further insight into emerging themes and supports HTA's strategies.

28. The Board spoke of the importance of this work and appreciated the clarity of accountability and management leads within it. The role of this work being linked to strategic priorities in the business plan was discussed.

29. The Board questioned whether this exercise captures the developments in commercial operators and in the priorities of the Department of Health and Social Care. Louise Dineley responded that HTA's approach captures best practice and has been shared with other organisations. She stated that HTA employs a range of different methods to gather data and this helps build resilience in HTA's ability to capture future pressing issues.

30. The Board noted the report.

Item 10 – Deemed Consent NI (HTA 7/22)

31. Louise Dineley introduced the report.

32. She reported on the stakeholder engagement work that had been undertaken in Northern Ireland and the rest of the UK and the various touchpoints for managing the process and for developing relationships further.

33. The revised Code of Practice F would be brought back to the Board in July before being laid before Parliament.

34. The Board were pleased with how far this legislation had come in Northern Ireland and thanked all those who supported and guided it through the process so far.

Action five
35. The Board agreed that HTA should proceed with the proposed review of the Code of Practice F.

Item 11 – Audit and Rick Assurance Committee Update (HTA 8/22)

36. Professor Gary Crowe introduced the report and provided updates on its discussions.

37. The Audit and Risk Assurance Committee had discussed the progress of internal audit and noted that these are expected to be delivered on time. The Committee also noted the progress of the external audit, being undertaken by KMPG.

38. The Board were reminded that Cyber Security is a standing item on ARAC's agenda, and they pay close attention to this item.

39. The Board noted the report.

Item 12 – Minutes of 4 November 2021 (HTA 9/22)

40. The Board noted the proposed amended minutes of the meeting of 4 November 2021 and agreed these.

Item 13 – Matters arising from 4 November 2021 (HTA 10/22)

41. The Board noted the progress which had been made against the actions from the previous meeting.

Item 14 – Development Programme Update (HTA 11/22)

42. The Board noted the information report on the Development Programme.

Item 15 – Any other business

43. The Chair informed the Board that the next meeting would be held in the morning of 5 May at the HTA Office and would be held in public. Board members were asked to reserve time in the afternoon for a Board workshop.

44. The Chair took the opportunity to thank those members who were reaching the end of their term. She thanked each of them individually for their contribution to the work of the HTA. Each retiring Board member in turn spoke of their experience with HTA.

45. There being no further items the Chair officially closed the ninety-ninth meeting of the HTA Board.

Date of Next Meeting

5 May 2022 at HTA Office

Meeting actions

Action one
The Board noted the proposed roadmap for the 2022/23 Business Plan and agreed to review the pre-publication business plan in correspondence during March 2022

Action two

The Board agreed the proposed Terms of Reference for the Audit and Rick Committee and further agreed that HTA's governance documents to be updated accordingly

Action three

The Board agreed that the Terms of Reference for the Remuneration Committee should be brought to the May Board meeting for approval.

Action four

The Board agreed the revised Police Referral and Warrants Policy document and the amendment to the Standing Orders.

Action five

The Board agreed that HTA should proceed with the proposed review of the Code of Practice F.

![HTA Human Tissue Authority logo]

Human Tissue Authority
Board meeting

Date: 5 May 2022

Paper reference: HTA 18/22

Agenda item: 10

Author: Alison Margrave, Board Support

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Matters Arising from HTA Board meeting 10 February 2022

Date Added	Action	Target date	Revised date	Status
Feb 22	The Board noted the proposed roadmap for the 2022/23 Business Plan and agreed to review the pre-publication business plan out of committee during March 2022	Mar 22		Completed
Feb 22	The Board agreed the proposed Terms of Reference for the Audit and Rick Committee and further agreed that HTA's governance documents to be updated accordingly	May 22		Completed
Feb 22	The Board agreed that the Terms of Reference for the Remuneration Committee should be brought to the May Board meeting for approval.	May 22		See agenda item 8
Feb 22	The Board agreed the revised Police Referral and Warrants Policy document and the amendment to the Standing Orders.	May 22		Completed
Feb 22	The Board agreed that HTA should proceed with the proposed review of the Code of Practice F.	July 22		In progress

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

Human Tissue Authority
Board meeting

Date: 5 May 2022

Paper reference: HTA 19/22

Agenda item: 11

Author: Dr Julie Edgeworth

OFFICIAL

Deemed Consent Northern Ireland

Purpose of paper

1. To provide the HTA Board with an update on revising Code of Practice F, Part Two, to reflect the legislative change to deemed consent for deceased organ and tissue donation in Northern Ireland (NI).

Decision making to date

2. The SMT agreed this paper on 12 April 2022 for submission to the HTA Board.

3. At the February Board meeting, a paper (HTA 7/22) on deemed consent in NI was presented for consideration. The HTA Board agreed revisions could be made to Code of Practice F, Part two, to reflect the changes in legislation on deceased organ and tissue donation in NI.

4. The purpose of this paper is to update the HTA Board on progress.

Action required

5. For the HTA Board to note the progress to date and plans to undertake consultation and engagement on the revisions to the Code prior to the July Board meeting.

Background

6. The Organ and Tissue Donation (Deemed Consent) Act 2022 was passed by the Northern Ireland Assembly in February 2022 and received Royal Assent on 30 March 2022. The Act, when it comes into force in Spring of 2023, will amend the definition of 'appropriate consent' as set out in the Human Tissue Act 2004 for NI and introduce an 'opt-out' system for deceased organ and tissue donation.

7. To date, deemed consent has not applied in NI and this is reflected in the current version of Code of Practice F, Part Two, which offers practical advice and guidance to practitioners.

8. The Act will introduce deemed consent in NI, and as such the HTA has agreed with the Department of Health in NI to amend the Code to reflect the changes relating to deemed consent.

9. On 4 April, the HTA was invited by the NI Department of Health to nominate a representative to the newly established project board that will oversee the implementation of the new legislation on deemed consent in NI. The Head of Regulation for Organ Donation and Transplantation will fulfil this role. The new project board will oversee planning for, and implementation of, the law change. The project board is likely to meet on a quarterly basis from May 2022 for a period of approximately 18 months.

Progress to date

10. A draft of the revised Code was sent to the HTA Board for comment by correspondence in March.

11. Comments received from HTA Board Members were reviewed and the Head of Regulation for Organ Donation and Transplantation provided responses to the questions raised directly to the Board Members.

12. In addition, stakeholder engagement has been initiated through the HTA website to create awareness of the forthcoming consultation. Direct communications about the consultation have been sent to stakeholders across the UK, encouraging engagement and providing those with an interest, the opportunity to respond.

13. The NI Clinical Advisory Group (CAG, which has HTA representation) requested a review of the draft revised Code prior to the broader consultation process. To accommodate this request, whilst also ensuring we could retain the CAG as consultees, NI colleagues agreed to identify two members to act as reviewers. The draft Code, embargoed for wider distribution, was sent to the identified members on 7 April for comment.

14. Due to the movement of organs for transplantation between NI and the Republic of Ireland (ROI), engagement with colleagues in ROI was initiated to provide them with awareness of the upcoming stakeholder roundtables and public consultation on revisions to the Code. HTA understands that ROI has commenced work to introduce Deemed Consent provisions, though this is at an early development stage. We will keep ROI colleagues appraised of feedback from our consultation.

15. Invitations have been issued to key stakeholders to attend roundtable consultation events between 10 and 18 May. This will enable key stakeholders, including colleagues in Devolved Administrations, the Clinical Advisory Group for NI deemed consent, and other relevant stakeholders in NI, as well as the rest of the UK, an opportunity to discuss the changes being made to the Code. These roundtable events are in addition to the online public consultation that will take place between 6 May and 24 June.

Going Forward

16. Roundtable events with key stakeholders will be held to ensure the Code clearly reflects the legislative change and provides clarity on the changes.

17. There will be engagement with wider stakeholders through our website, providing information on the consultation and a dedicated email inbox to submit comments.

18. We will provide a summary of the feedback received from the consultation and engagement events on the revised Code, along with a revised draft Code to NI colleagues to review and comment.

19. We will present a final revised version of the Code to the HTA Board in July for approval.

Recommendation

20. For the HTA Board to note the progress to date and plans to undertake consultation and engagement on the revisions to the Code prior to the July Board meeting.

![HTA Human Tissue Authority logo]

Annex A

The move to deemed consent for deceased organ and tissue donation across the four nations of the UK.

Wales:

Wales was the first UK country to introduce deemed consent. This came into force on 1 December 2015, following the implementation of the [Human Transplantation (Wales) Act 2013](#). The HTA was asked by colleagues in Welsh Government to draft a [Code of Practice](#) to reflect the law.

England:

England introduced deemed consent on 20 May 2020, following the implementation of the [Organ Donation (Deemed Consent) Act 2019](#). The existing HTA [Code of Practice F, Part Two](#), was extensively revised to reflect the change in law.

Scotland:

Scotland introduced deemed authorisation on 26 March 2021, following the implementation of the [Human Tissue (Authorisation) (Scotland) Act 2019](#). The HTA does not regulate under this piece of legislation, so HTA Codes of Practice do not apply to Scotland. The HTA does however regulate establishments in Scotland that hold a licence in the Organ Donation and Transplantation sector, under the Quality and Safety of Organs Intended for Transplantation Regulations 2012.

Northern Ireland:

[The Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022](#) received Royal Assent on 30 March 2022 and will come into force in Spring 2023. As this paper sets out, the current Code of Practice F, Part two, will be amended to reflect this change in law.

Organs continue to be shared nationally. Given the cross-border / all-island status in Ireland, we do not expect any impact on organ sharing with the Republic of Ireland as a result of the forthcoming implementation of the law change in NI.