Ninety-Seventh meeting of the Human Tissue Authority Board

Date: 15 July 2021

Time: 10.00-12.00

Venue: Zoom

Protective Marking: OFFICIAL

Agenda

1. Welcome and apologies
2. Declarations of interest
3. Minutes of 6 May 2021 meeting (HTA 12/21)
4. Matters arising from 6 May 2021 meeting (HTA 13/21)

Regular reporting

5. Chair's Report (Oral)
6. Chief Executive's Report (HTA 14/21)

   Annex A- Risk Summary (HTA 14a/21)
   Annex B- Strategic risk register (HTA 14b/21)
   Annex C- Board Supplementary Data Annex) (HTA 14c/21)

Incidents

7. Incident Analysis and Surveillance Presentation – Dr Chris Birkett and Dr Robert Watson (HTA 15/21)

Committee and Working Groups

8. Membership to Committees and Working Groups (Oral)
9. Audit and Risk Assurance Committee Update (HTA 16/21)

Development Programme

10. Development Programme Update (HTA 17/21)

Post-COVID operations

11. The HTA Beyond COVID-19 Restrictions- Richard Sydee (HTA 18/21)

Questions from Observers

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

Any Other Business

13. Any Other Business (Oral)

Meeting Close 12.00

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

Date: 6 May 2021

Time: 10.00 – 11.40

Venue: Zoom

Protective Marking: OFFICIAL

Attendees:

Board Members

Lynne Berry, CBE (HTA Chair)
Dr Charmaine Griffiths
Professor Gary Crowe
Professor Penney Lewis
Jan Williams
Professor Deborah Bowman
Dr Lorna Williamson
Glenn Houston
Dr Stuart Dollow
Ellen Donovan

HTA attendees

Allan Marriott-Smith, CEO
Louise Dineley, Director of Data Technology and Development
Richard Sydee, Director of Resources
Nicolette Harrison, Director of Regulation
Dr Julie Edgeworth, Policy Manager
Morounke Akingbola, Head of Finance and Governance
Nima Sharma, Board Secretary (minutes)

Apologies

None

Observers

Marina Pappa, Deputy Director, Department of Health and Social Care (DHSC)

Item 1 – Welcome and apologies

1. The Chair welcomed Members, the Executive, and observers to the ninety-sixth meeting of the Board.

2. The Chair welcomed Ellen Donovan, to her first Board meeting since her appointment on 1 April 2021.

Item 2 – Declarations of interest

3. The Chair asked Members to declare any personal or pecuniary interests that they may have in relation to the meeting's agenda.

4. Deborah Bowman asked that consultancy work with the Professional Standards Authority on ethical experiences of practitioners during the pandemic be noted.

5. No other interests were raised.

Item 3 – Minutes of 11 February 2021 meeting [HTA 07/21]

6. The Chair asked Members for any comments on the minutes from the last meeting.

7. None were raised and the minutes were accepted as an accurate record of the meeting.

Item 4 – Matters Arising from the 11 February 2021 meeting [HTA 08/21]

8. The Chair asked Members to note the matters arising from the previous meeting, most of which would be covered during the meeting and asked if there were any comments on these.

9. Regarding action two, it was agreed that the Executive would provide a summarised analysis of trends and associated learning and actions from incidents reported to the HTA and from ongoing surveillance over the previous year. This would be presented at the next Board meeting in July.

Action 1: ANH to provide a summarised analysis report to the Board of trends and related learning and actions from incidents reported to the HTA and from ongoing surveillance over the previous year.

Item 5- Chair's Report [Oral]

10. The Chair provided an update to the Board on the following issues:

11. The Board was informed that Glenn Houston's term of office had been extended for a further year and that discussion was underway with the Department of Health and Social Care (DHSC) regarding succession planning for Members leaving in March 2022.

12. The Chair and CEO had attended a meeting hosted by Lord Bethell [Parliamentary Under Secretary of State (Minister for Innovation)], bringing together the systems and professional regulators for health and social care. The Minister tasked those attending with developing a vision for how regulators should adapt to provide a system-wide approach to regulation which protects public confidence and patient safety while also promoting innovation in the life sciences. Louise Dineley will be the HTA lead on this work.

Item 6 – Chief Executive's Report [HTA 09/21]

13. Allan Marriott-Smith presented the report to the Board.

14. A number of clarifications were provided based on questions raised on the report prior to the Board Meeting. It was confirmed that the HTA is recruiting to 10.5 (full time equivalent) permanent roles, alongside a small number of interim and contract positions which address short-term capability needs.

15. Following the Board Strategy session, the revised Strategy would be produced during May and agreed by the Board in correspondence in June. The business plan would also be shared with the Board for information in June (this would not require Board approval).

16. Work continues to establish the most appropriate membership of ARAC and the Remuneration Committee, and on the future shape of the HTA's advisory committee and stakeholder engagement arrangements. It is anticipated that proposals would be brought to the July meeting for Board approval.

17. Nicky Harrison provided and update on the progress made with Virtual Regulatory Assessments (VRAs). Following the pilot of ten VRAs in the Human Application sector, this approach is being extended to other sectors with VRAs scheduled to be undertaken in the research and post-mortem sectors in the first quarter of 2021/22 with the aim of VRAs becoming a routine part of the HTA's regulatory toolkit.

18. Members were informed that the HTA continues to support Public Health England's post-mortem COVID surveillance programme by licensing a small number of Funeral Directors for the removal of swab samples from the deceased.

19. Questions were raised about Corrective and Preventative Action Plans (CAPAs), particularly the trends over the past year and the number of cases open for over 12 months. It was noted that numbers of CAPAs being opened had increased in the latter part of the year because of VRAs and virtual licence application assessments. Members were keen to understand more about these trends in regulatory data in the Board Supplementary Data Annex at the July meeting.

20. Members were updated on the website accessibility project and noted that some areas of non-compliance were identified by NHSX which will need correcting before the HTA's new website can go live.

21. Richard Sydee informed the Board that the interim financial year-end position, was £150,000 surplus due to additional income from grant in aid and an increase in the volume of licence applications.

22. It was noted that the variance under the Government Internal Audit (GIA) costs in table 1 would be amended in the papers published on the website.

23. Members were provided with an overview of the treatment of budget surplus in government accounting.

24. Members were asked to note that the HTA is confident that it would recover debts owed by NHS organisations.

25. Members noted that the actual cost for legal advice exceeded the budgeted costs because the HTA has sought a large amount of legal advice in the last year.

26. An update was provided on the plans to return to office working. There would be no obligation for staff to return to office working in the immediate future. Work is being undertaken to map out a comprehensive plan (including decision making) for how the HTA should respond across its operations to the easing of lockdown restrictions.

27. Following on from the discussion with the Board earlier in the year on risk appetite and tolerance, the new risk summary was presented to the Board along with the updated HTA's strategic risk register. The purpose of the summary page is to provide an overview of the risks as they currently stand, with explicit tolerance levels and a summary of work being undertaken to mitigate those risks. The Board was informed that this would be presented to the Audit and Risk Assurance Committee following any comments from the Board.

28. Board Members approved the new format of the strategic risk register and risk summary.

29. The content of this report was noted.

Item 7 – Development Programme [HTA 10/21]

30. Louise Dineley presented this paper to the Board.

31. A high-level overview was provided of the milestones achieved in quarter four milestones, with a particular emphasis on the migration from IMPACT to the new Electronic Document Records Management System (Sharepoint); a system which offers better interoperability. It was also highlighted that the move to Teams and Microsoft Office 365 has encouraged increased communication amongst staff, visible through analysis.

32. A power point slide was presented to the Board, sharing details about the incremental development expected over the next 12 months, with key deliverables for each quarter. This slide would be shared with Board Members following the meeting.

33. The Board thanked Louise for her work and posed a number of questions. Members questioned whether the staff of the HTA understand the change journey for the HTA and what this will mean for them. The Board was informed that staff are, and will continue to be, informed of the changes. A change specialist had been employed to prepare the organisation for change and that further resource would be put into embedding change and into adopting a portfolio management approach to ensure successful deployment of resources to core business and projects.

34. Members also asked about the horizon scanning function and how the Board would contribute to this. The Board was informed that this is an area for further development, as the Executive has completed a review and refresh of the horizon scanning group and its responsibilities.

35. The Board noted the update.

Action 2: The power point slide of the Road Map for the Development Programme to be shared with the Board.

Item 8 – HTA Code of Practice D Update [HTA 11/21]

36. Louise Dineley presented this paper to the Board.

37. Members were provided with background information to the changes required to Code D. This review was a result of differences in legislative consent requirements for the public display of bodies imported into England, Wales and Northern Ireland, relative to those for domestic bodies. As a result, a series of round table discussions were undertaken, and legal advice sought. Thanks were extended to Penney Lewis for her support in reviewing the Code, specifically for providing additional comments to simplify the beginning of paragraph 64.

38. Lorna Williamson asked if the Royal College of Pathologist (RCPath) had been consulted as part of the stakeholder engagement and confirmed that she would inform RCPath.

39. The Board noted that Nicky Harrison had been leading on planning for implementation and will ensure there is updated training and guidance for Regulation Managers to take account of this change. More generally, this change would also be shared with stakeholders, including RCPath, to ensure that they are aware of the changes.

40. The Board approved the changes made to Code D and noted the content of this paper.

Item 9- Any Other Business [Oral]

41. There was no other business raised.

HTA Board Meeting

Matters Arising from the May 2021 meeting

Meeting	Action	Update
May 2021	**Action 1:** ANH to provide a summarised analysis report to the Board of trends and related learning and actions from incidents reported to the HTA and from ongoing surveillance over the previous year.	**Progress** To be presented as part of agenda item 7.
May 2021	**Action 2:** The power point slide of the Road Map for the Development Programme to be shared with the Board.	**Progress** This was Circulated to Members.

Human Tissue Authority
Board meeting

Date: 15 July 2021

Paper reference: HTA 14/21

Agenda item: 6

Author: Allan Marriott-Smith
CEO

OFFICIAL

Chief Executive's Report

Purpose of paper

1. This paper gives an overview of the HTA's performance during the period April to June 2021 (quarter one).

2. The report provides an account of our core regulatory business, progress on development projects, the financial position at the end of quarter one, 2021/22 and a summary of people and other operational issues arising since the last Board meeting.

Decision Making

3. The CEO approved this paper for presentation to the Board on 7 July 2021.

Action

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

Strategic risk

5. The Risk Summary document is at Annex A and the Strategic Risk Register is at Annex B to this paper.

6. In its May assessment of Strategic Risks, the SMT concluded that four of the six risks were at tolerance (risks one, two, three and six) and two of the risks were above tolerance (risks four and five).

7. Regarding risk one, routine site visit inspections are still suspended. Work is underway to prepare for their reintroduction when the current COVID-19 restrictions are lifted, and the HTA's Virtual Regulatory Assessment model has now been embedded as business-as-usual and is used alongside other regulatory tools to ensure continued compliance with HTA standards.

Regulatory overview

8. Annex C to this paper contains a summary of regulatory activity during quarter one.

9. Virtual Regulatory Assessments (VRAs) are now becoming embedded as part of our regulatory toolkit, having continued in the Human Application sector and been expanded into the Post-Mortem, Research and Anatomy sectors over the past quarter in a further stage of piloting.

10. The suspension of routine site visits since the onset of COVID-19 has led to a changing profile of regulatory activity. This has resulted in a reduction in the number of Corrective and Preventative Action Plans (CAPAs) opened and has enabled greater focus on progressing existing CAPAs to closure. The trend in opening and closure of CAPAs during 2020/21 and into the first quarter of 2021/22 is shown in Table three of the Supplementary Data Annex. Several long-standing CAPAs in the Human Application (HA) sector have been closed, with continuing regulatory action being progressed on the reduced number of these older CAPAs.

11. Five licence revocations took place in quarter one and ten new licence applications were received. Seven of these applications were received in the HA sector, two applications were received in the Research sector and one received in the Anatomy sector.

12. Work continued to support licensing changes as we approached the end of the six-month period for issuing new import and export licences following the end of the Transition Period following the UK's exit from the European Union. Of the seven HA applications mentioned, four were associated with transition.

13. Four Regulatory Decision Meetings (RDMs) were held in quarter one. These were in three sectors and resulted in a range of regulatory action, including an unannounced site visit.

14. Living donation cases continue to increase but have not returned to pre-pandemic levels of activity. The Head of Regulation for this sector continues to meet monthly with the Lead Nurse for living donation at NHS Blood and Transplant to understand the national picture.

15. Work has also continued to support a police investigation of a case referred by the HTA in quarter one of the 2020/21 business year.

Development and change

Development Programme

16. Good progress has been made on the projects within the Development Programme. More detail on the Programme is provided in paper (HTA 17/21, agenda item 10).

HTA Website Redevelopment Project

17. On 10 June 2021 the HTA launched its new website. The launch of the public beta site represents a significant milestone in the redevelopment project and development of an accessible website. Over the next six months we will be monitoring the website to assess user experience and to identify any further development that may be required in advance of a "go live" assessment with NHSX.

Finance

Table one Financial position for Q1 2021/22

Human Tissue Authority

Summary Management Accounts for the three months ended 30 June 2021

	Actual	Budget	Variance	
	£	£	£	%
INCOME				
Grant in Aid	193,000	192,000	1,000	0.52
Non-cash cover	19,531	19,531	0	0
Licence Fee income	1,510,063	1,486,426	23,637	1.59
Devolved Governments	133,572	133,572	0	0
Other Income	12,564	12,565	(1)	0
TOTAL INCOME	**1,868,730**	**1,844,094**	**24,636**	**1.34**
OPERATING COSTS				
Staff costs (salaries etc)	754,086	809,132	(55,046)	(6.81)
Other staff costs (excl Inspections)	19,060	30,475	(11,415)	(37.46)
Board Costs	30,843	39,500	(8,657)	(21.92)
Inspection Costs	66	6,000	(5,934)	(98.90)
Living Organ Donation and Transplantation costs	318	0	318	0
Communication Costs	1,852	2,250	(398)	(17.69)
IT and Telecoms	136,170	101,250	34,920	34.49
Office and Administration Costs	9,782	27,447	(17,665)	(64.36)
Other costs	6,660	59,250	(52,590)	(88.76)
Legal and Professional	86,309	34,805	51,504	147.98
Accommodation costs	52,824	55,242	(2,418)	(4.38)
Non-cash costs	16,018	19,531	(3,513)	(17.99)
Total operating costs	**1,113,988**	**1,184,882**	**(70,894)**	**(5.99)**
Net Income/(expenditure)	**754,742**	**659,212**	**95,530**	**14.50**

18. Table one provides a summary of our financial position at the end of the first quarter of the 2021/22 business year. We are posting a surplus against budget of **£96k** before any adjustments. The components that make up our net position are described in more detail below (paragraphs 20 to 30).

Income

Table two Income summary

Human Tissue Authority
Income Summary
For the Three Months Ending 30 June 2021

	Actuals	Budget	Variance	
	£	£'	£	%
Grant in Aid	193,000	192,000	1,000	0.52
Non-cash	19,531	19,531	0	0
Sub-Total	**212,531**	**211,531**	**1,000**	**0.48**
Licence Fees				
Application Fees	25,380	0	25,380	0
Human Application	1,484,683	1,486,426	(1,743)	(0.12)
Sub-Total	**1,510,063**	**1,486,426**	**23,637**	**1.59**
Other				
Secondees	12,564	12,565	(1)	(0.01)
Devolved Assemblies	133,572	133,572	0	0
Sub-Total	**146,136**	**146,137**	**(1)**	**0**
Total Income	**1,868,730**	**1,844,094**	**24,637**	**1.34**

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

- Grant in aid – is £1k higher than budgeted due to profiling.
- Licence fees – are above budget by **£24k**, which is largely due to application fees which are not budgeted for. The other sectors are to be billed in September and have therefore been excluded from the table.
- Other income – is on budget. To note there is no rental income as this ceased when the HTA relocated to its new offices in Stratford.

Expenditure

20. **Staff costs (salaries)** – are under budget (£55k) due to vacancies across the organisation which are being recruited to.

21. **Other staff costs (excl. inspection)** – are under budget by £11k. Most of this underspend relates to recruitment costs which are underspent by £2.4k and training costs which are underspent by £8k. The balance being small over and underspends in non-inspection travel.

22. **Board costs** – include Member allowances, travel and venue hire. The underspend (£8.6k) relates mainly to travel and venue costs where all meetings have been held virtually.

23. **Inspection costs** – as expected remain under budget as site visits have been suspended to later in the financial year due to the COVID-19 pandemic restrictions.

24. **Living Organ Donation, Transplantation and Communications costs** – in total are on budget, however within Communications, there is a small underspent against our media monitoring service.

25. **IT and Telecom costs** – as at the end of June we are overspent by £35k. The majority of this relates to development consultancy (£33k overspend) which is an aspect of the Development Programme where budgets are yet to be fully delegated and overspends within the IT Support Contract (£6k) which relates to the cost of more expensive IT support and maintenance (£7k). The overspend is offset by underspends within consumables; software licences and telephone totalling £11k

26. **Office and Administration costs** – are £16k under budget; this includes costs for office relocation, bad debts written off and other office administration costs. The most significant variance is for the office relocation (£22k) which covers additional travel costs for staff which due to restrictions have not materialised. This is offset by an overspend (£5k) against printing and publications costs which were not profiled for in this quarter.

27. **Other costs** – are under budget by £52k and is due to an underspend on the Website project which is one of the work packages for the Development Programme. We now anticipate these costs will occur later in the year and this budget will be re-profiled.

28. **Legal and professional costs** – are significantly over budget (£52k). Legal fees are over budget by £2k. In addition, we are overspending against our Consultancy costs (£50k) of which £47k relates to support to cover vacancies in our business planning roles.

29. **Accommodation costs** – are under budget by £2.4k. The underspend relates mainly to the rent and service charges for 2 Redman Place. The budget being based on figures provided in March. We have now signed the final Memorandum and Terms of Occupation (MOTO) with DHSC which included slightly more favourable changes to the HTA costs.

30. **Non-cash costs** – underspend of £3.5k represented by depreciation and amortisation costs of our tangible and intangible assets. This underspend will continue as the original budget was set prior to the major write-off of obsolete assets at the end of last year. These costs are provided for through "Ring-fenced RDEL" funding provided by the DHSC which we will reduce in future years.

Forecast outturn

31. We are currently forecasting a break even, however, a detailed review will be undertaken in July, taking into account any changes in planning for the rest of the financial year.

32. Work relating to the finalisation and delegation of the Development programme budget will conclude shortly and this will allow for more accurate profiling which will in turn provide more accurate variance analysis to inform performance monitoring.

Other key performance indicators

Debtors

33. At the end of June 2021, the total value of our debtors was **£476k** represented by **68** accounts. This is a small increase on the same period in 2020/21 where debts were £441k.

34. The table below gives a breakdown by sector.

Table three Debtors by sector

Sector	Number of establishments	Value of debt £	%ge
NHS	36	£234,158	49
Government Bodies	3	£133,572	28
Non-Government Bodies[1]	29	£108,698	23
Total	**68**	**£476,428**	**100**

35. Of the 36 NHS accounts, 6 (£12k) have been outstanding since the 2019/20 billing run. We are in contact with each organisation and expect to clear these in this new business year. Of the remainder, 16 (£94k) relate to the 2020/21 business year and 14 (£129k) to the current year.

36. Of the 29 Non-Government Bodies, 13 (£12k) relate to the 2019/20 and prior business year, 7 (£27k) to the 2020/21 year and the remainder 9 (£70k) to this business year. As with the NHS organisations, we are actively pursuing these debts and expect resolution in 2021/22.

[1] Includes Universities and private organisations

People

People

COVID-19 response

37. Staff continue to be encouraged to discuss with their Line Manager and HR any changes they may require because of the impact of the pandemic, although most staff are now working their core hours with little or no adjustment required.

38. Heads of Function continue to have a standing agenda item at each bi-weekly Heads Management Team (HMT) meeting to review and raise any wellbeing or mental health concerns within their teams.

New ways of working / Return to office-based working

39. Due to the Government's extension of restrictions until further review on the 19 July, the HTA has continued to work from home in line with Government guidelines. Access to the office in Stratford is available on request but, to date, no staff member has requested this.

40. A Return to Office Working Survey was completed, with a response rate of 83%. This has highlighted several areas of concern for staff, including travel to the office and the safety of the working environment in the office. Both of these issues will be addressed with additional communication in the coming weeks via the Engagement team, internal communication channels and team meetings.

41. An HR Engagement Team across the Stratford co-located Arms-Length Bodies (ALBs) has been initiated, with the first meeting taking place in June. It was agreed by representatives from each ALB that an HR Engagement Team would facilitate development and networking opportunities. The next meeting will be in July where the Terms of Reference for the group will be agreed.

Wellbeing

42. Wellbeing continues to largely focus on our support to staff who are working from home or adopting new working patterns or who are otherwise impacted by the COVID-19 restrictions.

43. A Government Internal Audit Agency assessment of our wellbeing arrangements has been conducted with a 'Substantial' assurance rating given to all areas that were audited. The report made only one low level recommendation.

Recruitment and Retention

44. The recruitment programme is progressing well with seven of the 17 approved roles (excluding the CEO) now offered and accepted. The recruitment process is ongoing with seven other roles currently live and three roles to follow in quarter two.

Sickness absence

45. Sickness continues to be low relative to historic levels; this is being monitored to ensure that staff take proper time to recover if they are unwell.

Pulse Survey

46. As staff have been surveyed on Wellbeing and Return to Office in quarter one, the Pulse survey has been postponed and will be conducted next in July.

Other Issues

Quarter Four Accountability

47. We continue to meet our accountability requirements to the DHSC differently in the short term. DHSC colleagues have agreed to scrutinise Board papers as part of their accountability review and follow up with supplementary questions where required.

48. The Department wrote to us in June to confirm that they had no governance concerns for quarter four and that the HTA's financial position was balanced. They commended the HTA on the way it had responded to a number of challenges in quarter four. The HTA also received a letter of thanks from the Minister on its work to revise Code D.

Freedom of Information requests

49. During quarter one, the HTA received five requests for information under the Freedom of Information Act (FOIA). We publish FOIA responses on our website.

Complaints

50. In quarter one, one formal complaint was received by the HTA and has been resolved.

Latest review date – 27/05/2021

Strategic risk register 2021/22
Risk summary: high to medium 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**	At tolerance	⇔⇔⇔⇔
R2: Failure to manage an incident	Delivery, Development and Deployment objectives	**6 - Medium**	At 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)	**12 - High**	Above 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 transformation programme	Development (a-d) objectives	**6 - Medium**	At tolerance	⇔⇧⇔⇔

* Strategic objectives 2019-2022:
** This column tracks the four most recent reviews by SMT (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**	**5**	**10 - Medium**
Tolerance threshold:					**10 - Medium**

Commentary
At tolerance. We have a good regulatory framework for normal times, with a strong assured position on our key regulatory processes from an Internal Audit review within the past 18 months. We coped well with the novel challenges and intensity of increased activity in the PM sector during the peak of the pandemic but continue to face new challenges arising from this new context, particularly the suspension of one key regulatory process, routine site visits, across all sectors since mid-March 2020. Activity in the PM sector is now stable, although many emergency mortuary licences are being renewed and there is a limited expansion of licencing of funeral directors' premises to support national public health COVID-19 surveillance. Having developed and piloted Virtual Regulatory Assessments (VRAs) in the Human Application (HA) sector in 2020/21, these are becoming embedded into business-as-usual in that sector and are now being extended to Human Tissue Act sectors. The schedule of VRAs for quarter one includes HA, Research and Post-Mortem sectors, with a view to scaling up use of this tool across all sectors over the remainder of the year. Our inability to meet our legal obligation to undertake biennial site visits in the HA sector since mid-March 2020 has been managed as an issue, of which the Board and Department of Health and Social Care (DHSC) sponsors are aware. The continuing absence of routine site visit inspections by the HTA may result in an increase in this risk, or perception of this risk by external stakeholders, although this may vary by sector. Whilst routine site visits have been suspended since the onset of initial pandemic restrictions, we retained the option to undertake short or no-notice site visits if we felt this was justified by risk. Our plans for undertaking site visits safely, which have included the provision of PPE kits to all relevant staff in Regulation Directorate, were successfully tested in an unannounced site visit undertaken in May 2021. Plans for re-initiating routine site visits are being developed as part of our plans for the anticipated lifting of COVID-19 restrictions. 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 our ongoing engagement with our regulated sectors, with investigations and active regulatory action continuing throughout the pandemic restrictions.

The Senior Management Team have agreed a tolerance of 10 as an interim position. This is higher than the indicative appetite agreed with the Board, but it is felt that the current operating environment limits the impact of further internal mitigation. The exit from current restrictions coupled with the roll out of developing activities should allow this to be reduced further in due course.

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**
3	5	15 - High	**3**	**2**	**6 - Medium**
Tolerance threshold:					**6 - Medium**

Commentary
At tolerance. The HTA believes that our incident management response plans were well tested and found to be robust and effective through their deployment in managing the impact of the pandemic and related restrictions over the past 15 months as well as their adaptation for use in managing the potential impacts of the European Union (EU) at the end of the Transition Period. Although there is a demonstrable link between risks one and two, in that a business continuity issue could destabilise the ability to regulate, this risk is focused on our ability to respond. As such the Executive have set this risk at a lower tolerance level as our ability to respond appropriately is within the direct locus of control of the HTA. SMT believe this risk is stable at tolerance level. The remaining concern would be continuation of the challenges of the pandemic alongside the emergence of another significant incident that could compound management stretch.

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	**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 and stakeholders about emerging issues and we provide clear lines to the media when necessary. Communicating on an issue which is not within remit, but which may adversely impact on public confidence is challenging. 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 proactive approach went live in quarter four of 2020/21 and will continue to be embedded in 2021/22.

Following the end of the Transition Period for the UK's exit from the (EU) on 31 December 2020, the HTA's UK Transition Project has been proactively managing the regulatory changes, some of which do not take effect until 1 July 2021, engaging with establishments and representative bodies to ensure those affected by these changes are aware of and can meet their new obligations, providing advice and guidance through a variety of routes. This has also included some changes to regulatory processes. Plans have been made to manage anticipated resource pressures approaching the deadline for some changes at the end of June 2021.

The HTA has responded to ongoing concerns, including from Members of the House of Lords, concerning the consent provisions for material imported for the purposes of public display. As a result, the HTA has reviewed and updated Code D. The revised Code D is due to be laid before Parliament on 7 June 2021 with the potential adoption by the end of July.

Work has continued to support Public Health England in its pilot project to undertake post-mortem surveillance sampling for COVID-19 through the licensing of Funeral Directors, with several more applications now expected in the next phase of this project.

All these matters are being actively managed, and there has at this stage been no detrimental impact on the HTA's reputation.
SMT believe this risk is stable in May 2021.

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**
3	4	12 - High	**3**		**12 – High**
Tolerance threshold:					**9 - Medium**

Commentary
Above tolerance. Recruitment to permanent roles was put on hold from quarter one 2020/21 while development work was ongoing to ensure more flexible access to the necessary capabilities associated with change and to allow us to identify and plan for filling capability gaps. Resulting gaps were mostly filled by interim or temporary contracts throughout 2020/21. 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 10 posts including that of a Deputy Director adding further support and resilience to the Senior Management Team. It will be proposed to the Audit and Risk Assurance Committee in June that the outstanding recommendations on the past records management audit are closed. This proposal reflects the completion of the planned developments in quarter four 2020/21 with the implementation of the new Electronic Document Record Management system and the future development and adoption of an eEnterprise Content Management system in 2021/22. As a result, the inherent risk has reduced and will reduce further as new systems are developed and embedded. In the meantime, the HTA will tolerate a higher level of residual risk. In designing the new system the recommendations of the previous audit on records management and standards of good practice have been considered. The move to a more digital way of working means that management of our information, data and records is critical and the requirements to do this well extend beyond the audit recommendations. It is suggested that Records Management is reaudited in early 2022/23 following the completion of the planned developments. Outline Business Cases for further investment in the Development Programme have been agreed and external consultants engaged to help manage the governance around the full range of business plan deliverables. At its April review SMT considered the current tolerance level as temporary, accepting a higher tolerance as an interim whilst plans are firmed up and we continue to progress the projects and deliverables under the Development Programme. The impending departure of the Chief Executive expected in quarter three is being managed with mitigations to avoid a gap in senior leadership.

SMT believe that the risk tolerance has not changed whilst good progress is being made and plans are being executed. It is expected that the tolerance level will reduce as plans increasingly translate into action.

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

Commentary
Above tolerance. Planning for 2021/22 is now complete. DHSC have confirmed GIA funding for the new financial year and we expect additional funding for ongoing EU transition activities. With anticipated cost reductions from our estate, and the impact of ongoing restrictions on normal site visit and meetings/events likely to continue to reduce expenditure, we have allocated funds for the continuation of our development activities. Further discussions with DHSC on accessing reserves to fund our development priorities are in train and we are hopeful of some limited flexibility this financial year. Tolerance for the risk is low, in line with Board agreed appetite in this area. There are future pressures around the 2021 Spending Review where organisations will be required to make savings. This may have an impact on our fees for 22/23. Added to this are the in-year pressures including our ambitious plans. Although the medium term impact of the pandemic on our licensed establishments remains difficult to predict, we will consider emerging trends as we start the 2022/23 fees work in May/June 2021 and would anticipate that this risk will reach tolerance once this work is finalised.

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**	**2**	**6- Medium**
Tolerance threshold:					**6 - Medium**

Commentary
At tolerance. The removal of costs associated with site visit inspection along with the pause in recruitment has provided some headroom for development investment within the existing budget for 2020/21 and will continue to do so in 2021/22. The office move project is complete and closed, 151BPR will be formally returned to GPA at the end of February 2021 and the new premises were ready for occupation on 18 January. Some activity relating to IT, records digitisation and resumption of office working will continue outside the project. The successful delivery of a number of projects to the end of the 2019/20 business year (HTA Intranet, Office 365 upgrade, adoption of remote working, future EDRMS requirements and data and intelligence review) has led to a downgrading of the impact and likelihood score for this risk - now 3/3. There is still more to do, but the work to date represents a significant proportion of the "must do" element of this programme. SMT believe this risk is stable in March 2021. April 2021 – The executive proposes to close this risk in its current form. Large elements of this work is now complete, and it is felt that a risks in this area relate to the failure to derive the benefits from our Development programme and recruitment plans and that we fail to keep pace with wider developments in the Governments approach to the regulatory sphere we operate. We anticipate bringing this new risk for consideration by ARAC in June 2021 and then to the Board meeting currently scheduled for July 2021. May 2021 – The risk has been reviewed and reframed to reflect the successful delivery of the office move and a range of IT projects that represent a transformation in the way that the HTA operates. The risk has been reframed to focus on the Development Programme and the realisation of the intended benefits and return on the investment of resources. The Development Programme is incremental in its delivery with identified success measures and benefits to be realised at a key points. This incremental approach supports the inherent and residual risk scores and anticipate the realisation of benefits across the programme. The risk is to the realisation of the full benefits not to no benefits.

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 in May and June respectively. Particular to note, is the relationship between risks 1 and 2 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 6, 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 2021

The above risk summary was reviewed by SMT, and it was agreed that the risk scorings have remained stable. Risk 4 was discussed in detail in light of the change in senior staff that will take place in quarter 3 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.

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

IMPACT	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%)**

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 particular 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	2	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***	***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**	**5**	**2**		**10**	1	2	3			
						Regulatory model comprising a mixture of proactive regulatory assessment (eg 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.			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, now being incorporated into business as usual. 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.		X			Preventative	Board developed and approved the current HTA Strategy and is aware of the risks and opportunities associated with the suspension of routine site visit inspections during Covid restrictions and how VRAs are being incorporated into BAU. Board 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. 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 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. VRAs being incorporated into BAU in HA sector from Quarter 4 2020/21, with plans to expand into all sectors during Quarters 1 and 2 or 2021/22, as evidenced in Business Plan. Internal Audit late Quarter 3 / early Quarter 4 2020/21 on 'Inspection Process during Covid-19' - draft report agreed late May 2021. Moderate assurance; to be considered by ARAC early June 2021. Renewal of emergency mortuary licences and expansion of Funeral Director licensing for removal of tissue for PHE post-mortem public health surveillance for Covid-19. Police referral made late 2019/20 being actively investigated by the police, with ongoing input (Witness Statements) from HTA.
						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 of key decisions in Board Reporting.	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 eg 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	Latest update of HTA Strategy published November 2020. Annual Board Strategy session 27 April 2021 to consider annual strategy refresh.
						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.			Following the departure of the Head of Planning and Performance, SMT and their Heads have ensured there is regular review and updating of the operational business plan and monthly performance pack.		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 was produced in Quarter 1 2020/21 and published during Quarter 2 (delayed by Covid). 2021/22 narrative Business Plan is currently under development.	Quarterly reporting to Board and DHSC has continued in the modified form adopted at the onset of the pandemic, with assurance being gained from the papers submitted to the regular Board Meetings, most recently 6 May 2021. DHSC have confirmed they are content with this approach to assurance and with assurances gained this way. [Most recent confirmation in letter from Marina Pappa of DHSC Sponsorship Team to AMS dated 25 Feb 2021 re Quarter 3 2020/21.] Agendas and minutes of SMT meetings.
						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. Detailed evaluation carried out prior to adoption and expansion. Following Internal Audit on the Inspection Process during Covid, some further management actions are being undertaken, principally to ensure other regulatory processes and documentation (SOPs) are 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 largely complete - to be considered by ARAC June 2021.	Final report received April 2019 and showed substantial assurance. The two 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.
						Quality management systems										
						HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model			Following the departure of the Quality Manager in 2019/20, a Regulation Manager with experience in QMS has overseen and coordinated 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 is expected to transfer to a newly created role during Quarter 2 2021/22.	Limitations in QMS still remain. Scheduled reviews have now been re-instated following the departure of the quality manager with a schedule of activity in place. 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.	HR report included in Chief Executive's report to the Board at the May 2021 meeting. End-of-year reviews completed during Quarter 1 2021.
						Training and development of professional competence					X			Preventative	Annual PDPs, Corporate Training Programme (led by Head of HR), RM Training programme, Career Investment Scheme proposals to SMT	Evidence of corporate training programme, including quarterly mandatory training. Regulation-led Training sessions focusing on Change and VRAs. '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. 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.
						EU Exit (End of Transition period and HTA Exit Sls '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 and stakeholders during the transition period. HA Guide, ODT Framework and other external guidance being updated inline 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		

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			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
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***	***3***	Future, should event occur	Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff	***3***	***2***		***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. 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 X	2	3	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.		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.
						Availability of legal advice					X			Preventative	Lawyers specified in Critical Incident Response Plan, SMT updates	In place
						Fit for purpose Police Referrals Policy					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.
						Onward delegation scheme and decision making framework agreed by the Board					X	X		Preventative	Standing Orders and Board minutes	Standing Orders published May 2017, due to be updated before Board meeting in June 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
						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.
						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.		X			Preventative	SMT content that activation and use of CIRP during first wave and first lockdown superseded the need for a test.	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, eg 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 24 March 2021. Most recent SARE report submitted June 2020. 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. Smooth management of the end of the transition period at 31/12/20 through the regular stand-ups (based on the CIRP) and project oversight. SMT paper 14 January agreed scope of next phase to 30 June 2021 with project closure expected by 31 July 2021. Internal Audit 2019/20 (Moderate assurance and most management actions completed by the end of May 2021).

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK I	RESIDUAL RISK 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
3	**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***	***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* ***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*	*5*	*4*	*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	*4*	*3*		**9**	*1*	*2* *X*	*3*	*Monitoring*	*Ongoing log*	*Log in place and shared with Board in outline at the Strategic planning session in 2021.*
						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 May 2019. Professional newsletters issued regularly - last one May 2021. Sector-specific engagement eg 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					*X*			*Preventative/ Detective*	*Quarterly reports to Board on communication (including media) activities*	*Last report July 2020*
						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 25 Feb 2021 re Quarter 3 2020/21.*
						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 also published. These publications reflect the importance of ongoing publications and updates to specific conditions.*	Update to the Board and DHSC at Board meeting May 2020. Professional newsletter May 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					*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.*
						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 submitted to DHSC May 2021 for laying in Parliament.*
						Extensive Professional Evaluation Survey undertaken in Q4 2019/20, reported to Board in July 2020 and used to inform further developments.					*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 [YEAR?].*
						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.

					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 and the progress of the MMD Bill.				x			Preventative	*Development programme workstream Stengthening 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**	3	4		9	1	2	3			
						People Strategy for the period 2019 to 2021 is in effect					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 2020.*
						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/policies_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 2020*
						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*	*Interventions have commenced including full leadership team workshop in September 2020*
						Handover process is formalised via a checklist to ensure corporate knowledge is retained					X			*Preventative/ Monitoring*	*Handover checklist is in place and in operation.*	
									More formal assessment of future capability needs and how these should be met including through better knowledge of internal skills		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 review is in process supported by external advisers.*
						Data capability										
						Data relating to establishments securely stored with the Customer Relationship Management System (CRM)					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.
						Business technology capability										
						Staff training in key business systems					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					X	X	X	Preventative/ Monitoring	Quarterly assurance reports from suppliers. MontAMSy operational cyber risk assessments. Annual SIRO report	Annual SIRO report to be presented to SMT June 2021
									Business technology							

							Identify refresher training and targeted software specific training needs.		X			Preventative	Evidence of targeted training in last quarte to support the roll out and adoption of EDRMS. Further strengthening of core training requirements included in updated induction programme.	

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.
						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 May 2021
						Licence fee modelling								Preventative	Annual update to fees model	No change to fees agreed by the Board November 2020 meeting
						Rigorous debt recovery procedure					X			Preventative	Monthly finance reports to SMT and quarterly to Authority	Level of outstsnding 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 2020
						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	Will go to the Board November 2021
						Annual external audit							X	Detective	NAO report annually	Last report in June 2020 - clean opinion expected 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 May 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-finace 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 devleoped 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

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
								3			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*	5	4		SMT experience of organisational change, programme and project management.	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 communciations 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
									Embed Benefits Realisation Management methodology within programme		X			Preventative		
									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 incemental 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 indiviudal projects							X	Preventative		

Human Tissue Authority
Board meeting

Date: 15 July 2021

Paper reference: HTA 14c/21 (Board Supplementary Data Annex)

Agenda item: 6

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OFFICIAL

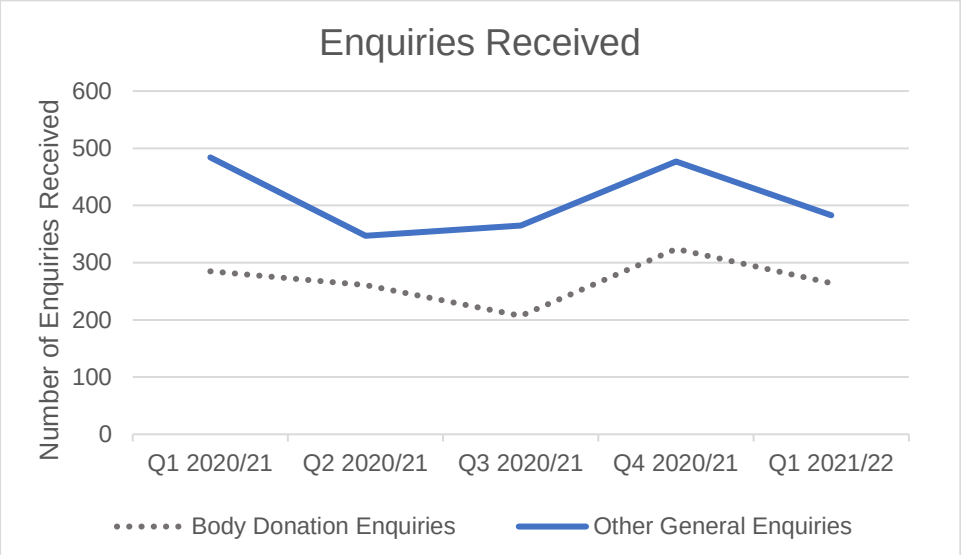
Purpose of Report

1. This report sets out a high-level overview of activity in quarter one 2021/22.

Enquiries

2. Figure 1 below displays the total number of body donation enquiries and other general enquiries received. In quarter one, 383 General Enquiries and 264 Body Donation Enquiries were received.

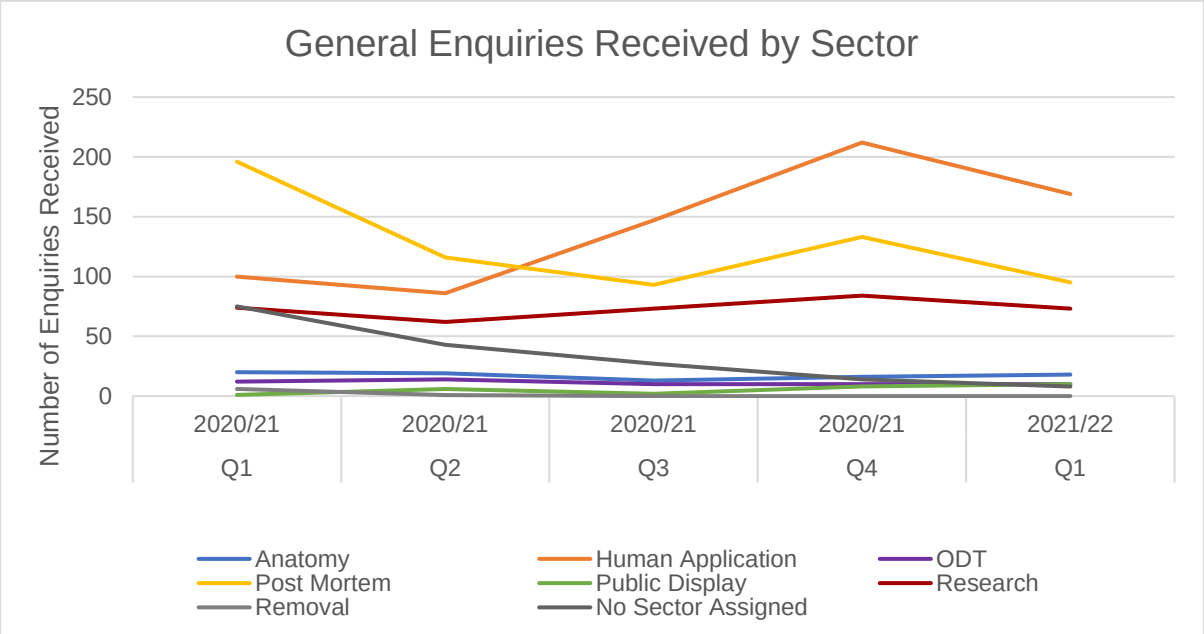
Figure 1: Number of body donation and other general enquiries received each quarter



3. Figure 2 displays the number of general enquiries received for each sector (excluding body donation enquiries).

4. The trends in the Human Application and Post Mortem sectors correlate with known periods of increased activity. PM enquiries are reducing following increased activity in the early part of the COVID-19 outbreak and Human Application sector enquiries remain high (compared to previous quarters) in line with UK Transition licensing engagement work.

Figure 2: Number of body donation and other general enquiries received each quarter



Licensing

5. Table 1 displays the number of new licence applications, new licences offered, satellite additions and revocations in quarter one.

Table 1: New licence applications, new licences offered, satellite additions and revocations in quarter one

Sector	New Licence Application	No. of Licence Applications with Decision Made	Satellite Additions	Revocations	Satellite Revocations
Anatomy	1	1	0	0	0

Human Application	7	1	6	1	2
Organ Donation and Transplantation	0	1	0	0	0
Post Mortem	0	0	4	3	0
Public Display	0	0	0	0	1
Research	2	1	0	1	0
Total	10	4	10	5	3

6. Ten new licence applications were received in quarter one 2021/22. For comparison, in 2020/21 we received ten applications per quarter on average.

7. Seven applications were received in the Human Application sector, of which two were from establishments based in Northern Ireland applying for import licences. Two applications were also received in the Research sector and one received in the Anatomy sector.

8. Decisions were made on four applications, of which all four were granted (one in the Human Application sector, one in the Post Mortem sector, one in the Research sector and one in the Anatomy sector).

9. There were ten satellite additions (six in the Human Application sector and four in the Post-Mortem sector).

10. Five revocations took place (one in the Human Application sector, three in the Post-Mortem sector and one in the Research sector).

11. Three satellite revocations took place in quarter one.

Licensing Variations

12. Figure 3 displays the total number of licensing variations received each quarter. A total of 196 licensing variations were received in quarter one. Compared to the peak received in quarter one 2020/21 (during the start of the COVID-19 pandemic), numbers have returned to the average before this period.

13. Licensing variations received by sector are displayed in Figure 4.

Figure 3: Total number of licensing variations received each quarter

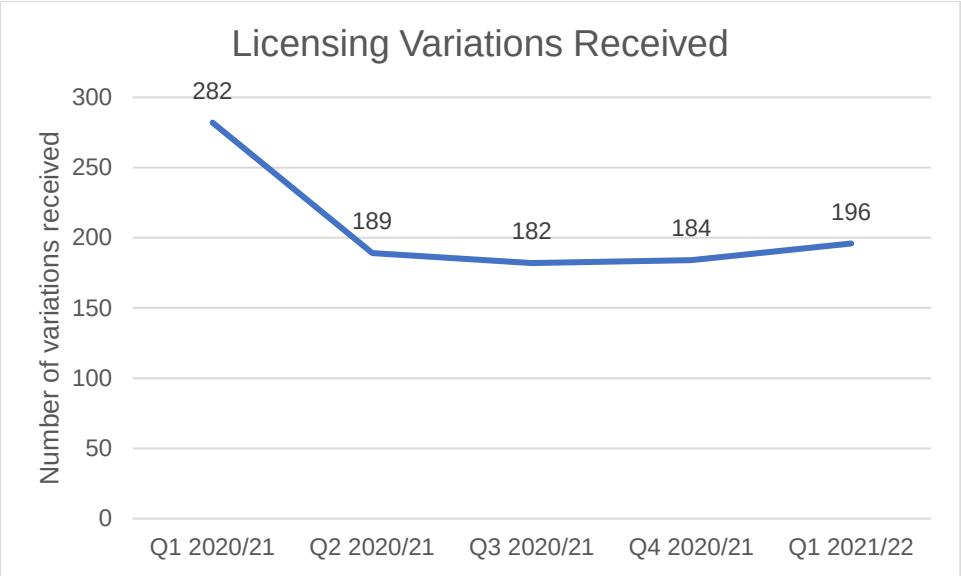
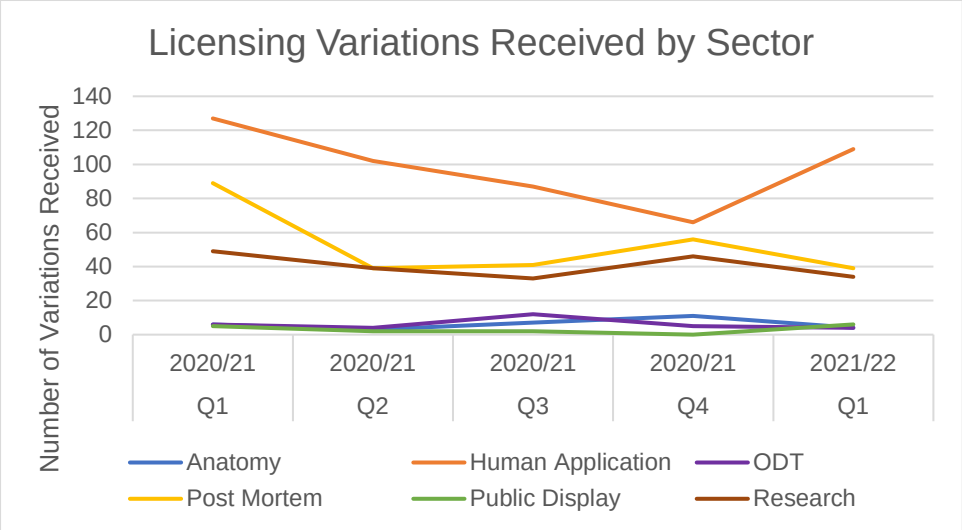


Figure 4: Total number of licensing variations by sector

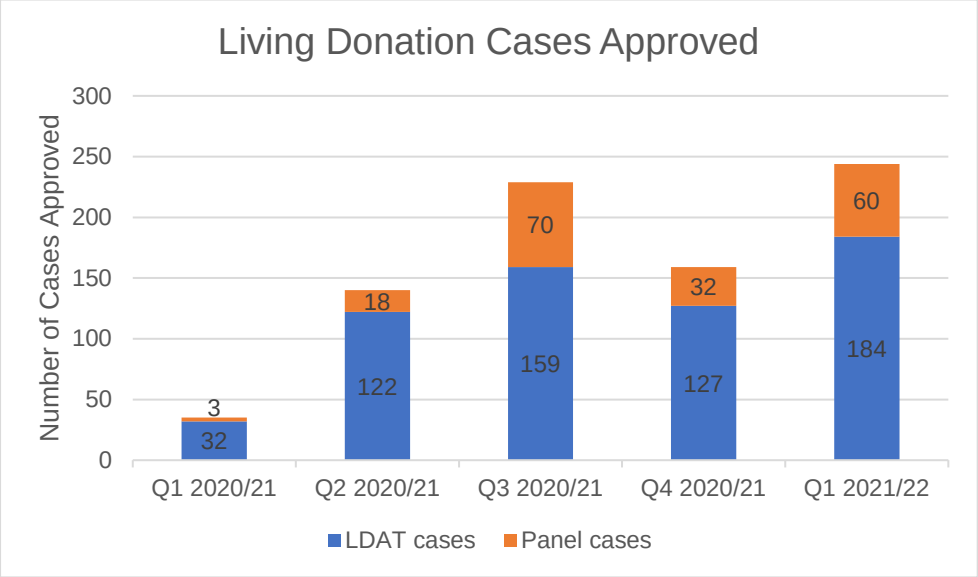


Living Donation

14. Figure 5 shows the total number of living donation cases approved by the Living Donation Assessment Team (LDAT) and HTA panels.

15. In quarter one, 184 cases were approved by the LDAT and 60 cases were approved by the panel. The total number of cases approved also includes those using the emergency out-of-hours processes.

Figure 5: Number of living donation cases approved per quarter



16. Table 2 below shows the total number of bone marrow and peripheral blood stem cell (PBSC) cases approved in quarter one compared to preceding quarters.

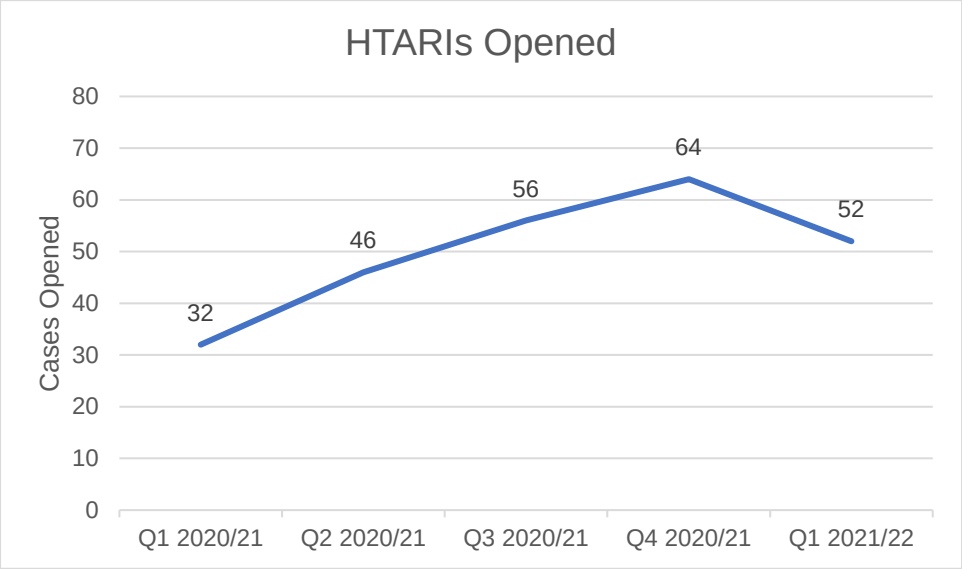
Table 2: Total number of bone marrow and PBSC cases approved

	Q1 2020/21	Q2 2020/21	Q3 2020/21	Q4 2020/21	Q1 2021/22	2019/20 Total	2020/21 Total
Bone Marrow/PBSC Cases Approved	16	15	17	14	12	66	62

Incidents – HTA Reportable Incidents (HTARIs)

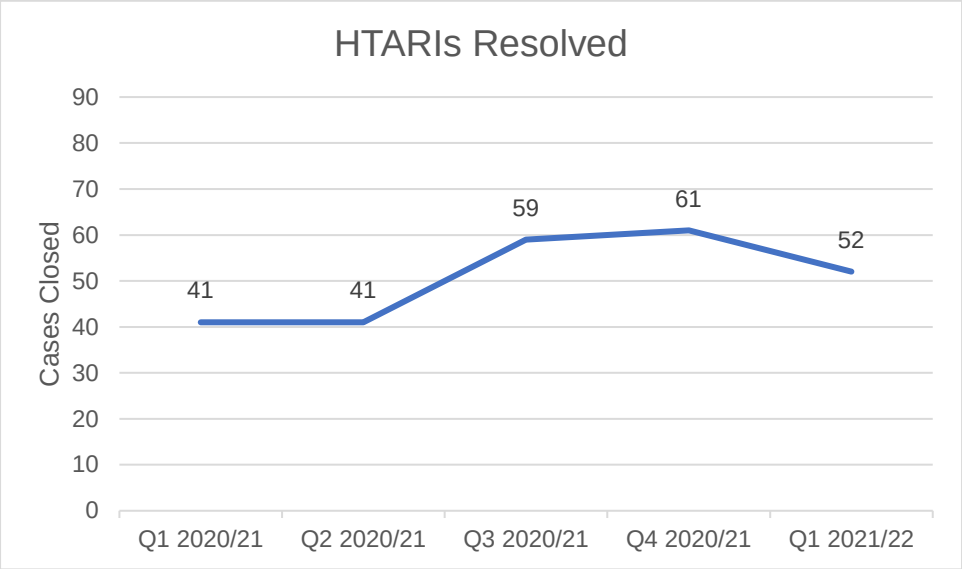
17. Figure 6 displays the number of reported HTARIs in quarter one compared to preceding quarters. This also includes any near misses and incidents that may, on investigation, be found not to be reportable incidents. In quarter one, 54 HTARI cases were opened, compared to 64 cases opened in the previous quarter.

Figure 6: HTARI cases opened during quarter in the Post-Mortem sector



18. Figure 7 displays the number of HTARIs resolved in quarter one compared to the preceding quarters. 52 HTARIs were resolved in quarter one, compared to 61 resolved in the previous quarter.

Figure 7: HTARI cases resolved during quarter in the Post-Mortem sector

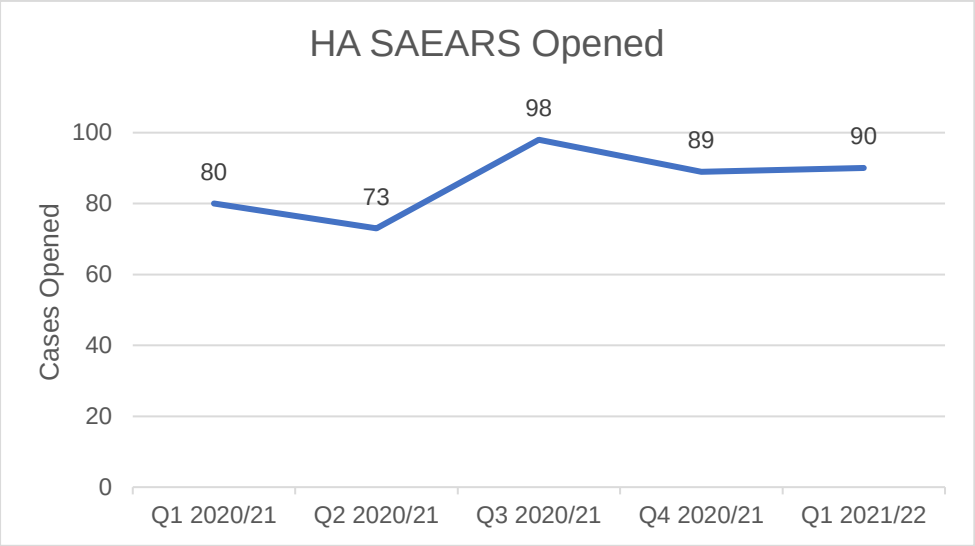


Incidents – Human Application Serious Adverse Events and Reactions (HA SAEARs)

19. Figure 8 below displays the number of reported HA SAEARs in quarter one compared to preceding quarters. This also includes any near misses and incidents that may, on investigation, be found not to fit the criteria of a

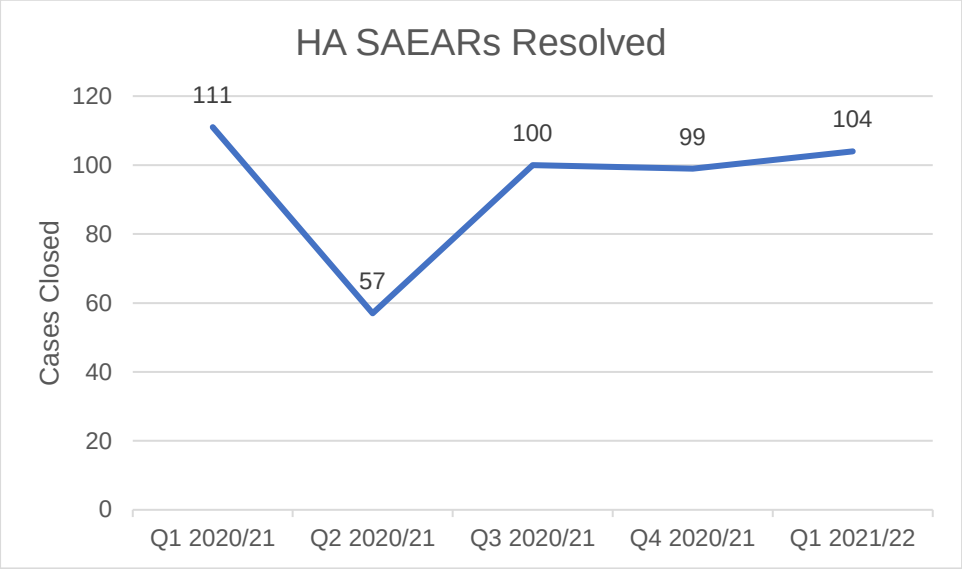
SAEAR. In quarter one, 90 HA SAEARs cases were opened, compared to 89 cases opened in the previous quarter.

Figure 8: SAEARs opened during quarter one in the Human Application sector



20. Figure 9 displays the number of HA SAEARs resolved in quarter one compared to preceding quarters. 104 HA SAEARs cases were resolved in quarter one, compared to 99 cases resolved in quarter four.

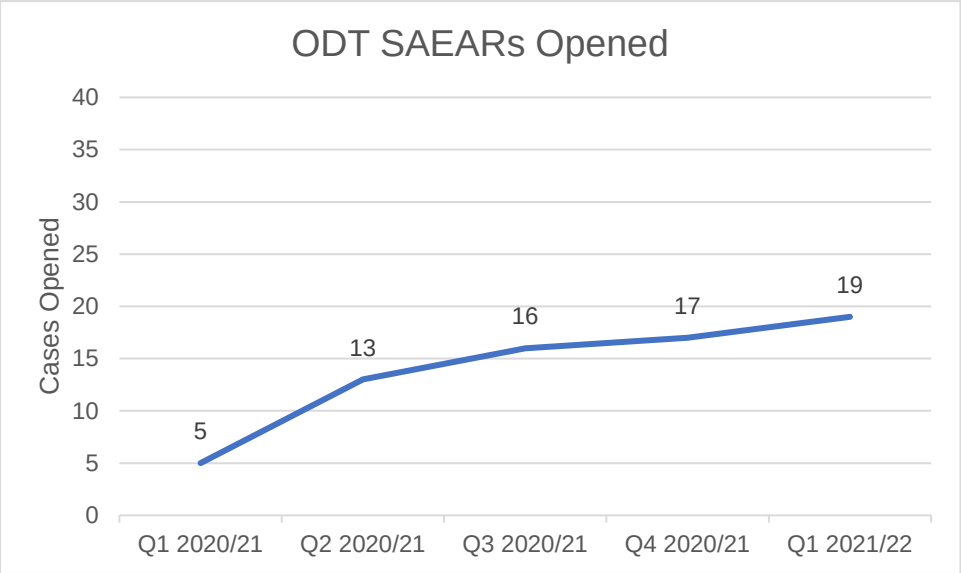
Figure 9: SAEARs resolved during quarter one in the Human Application sector



Incidents – Organ Donation and Transplantation Serious Adverse Events and Reactions (ODT SAEARs)

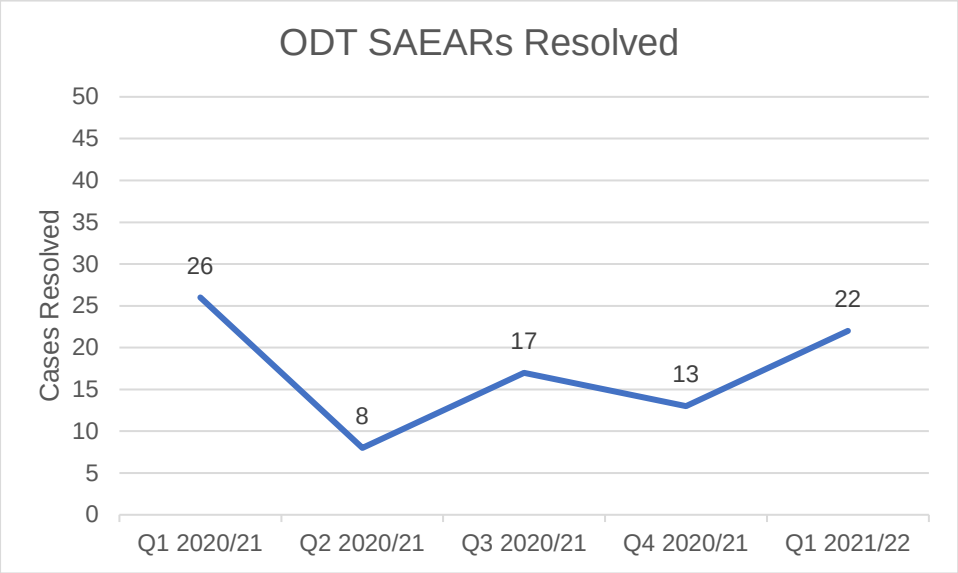
21. Figure 10 below displays the number of reported ODT SAEARs in quarter one compared to preceding quarters. In quarter one, 19 ODT SAEARs cases were opened, compared to 17 cases opened in the previous quarter.

Figure 10: SAEARs opened during quarter one in the Organ Donation and Transplantation sector



22. Figure 11 below displays the number of ODT SAEARs resolved in quarter one compared to preceding quarters. 22 ODT SAEARs cases were resolved in quarter one, compared to 13 cases resolved in the previous quarter.

Figure 11: SAEARs resolved during quarter one in the Organ Donation and Transplantation sector



Corrective and Preventative Action Plans (CAPAs)

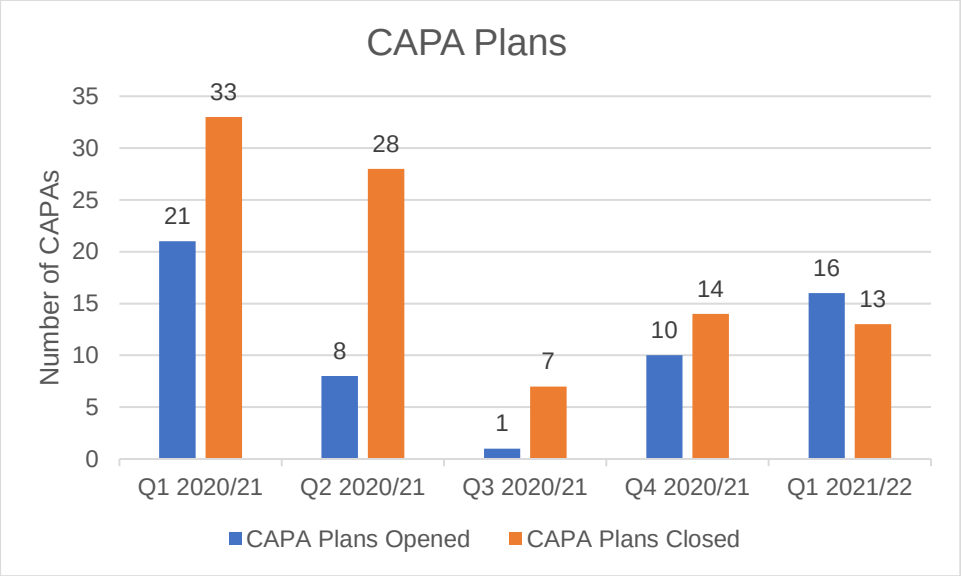
23. Figure 12 displays the number of CAPA plans opened and closed during quarter one, compared to previous quarters. The number of CAPA plans opened includes those opened as part of new licences offered and investigations.

24. The distribution in Figure 12 demonstrates the correlation between higher rates of CAPA plan opening with higher levels of assessment and licensing activities as a result of VRAs and UK Transition-related licensing work. Also clear is the impact of our increased drive to close CAPA plans during the period of national restrictions.

25. A total of 16 new CAPA plans were opened in quarter one. This includes 12 opened in the Human Application sector, two opened in the Anatomy sector and two opened in the Research sector.

26. A total of 13 CAPA plans were closed in quarter one. This includes nine in the Human Application sector and four in the Post-Mortem sector.

Figure 12: Number of CAPA Plans opened and closed during quarter



27. Table 3 shows all open CAPA plans at the end of quarter one and the length of time they have been open.

28. There was a total of 24 open CAPA plans at the end of quarter one. 16 CAPA plans have been open for less than six months, one has been open between

six to 12 months and seven CAPA plans have been open for longer than 12 months.

Table 3: All Open CAPA plans

Open CAPA Plans	Anatomy	Post Mortem	Human Application	Research	Public Display	ODT	Total
< 6 months	0	0	14	2	0	0	16
6-12 months	0	1	0	0	0	0	1
> 12 months	0	1	6	0	0	0	7
Total	0	2	20	2	0	0	24

Website Analytics

29. These analytics compare website activity during quarter one of 2021/22 with quarter one of 2020/21, as this represents the best direct comparison.

Table 4: Audience Size

	Q1 2021/22	Q1 2020/21
Visits	51,578	50,554
Sessions	73,124	70,811

30. Traffic has continued to recover after it was reduced during Q2-Q3 2020/21 due to a fall in traffic on body donation pages. This fall was a result of many establishments no longer accepting donations because of COVID-9.

Table 5: Engagement

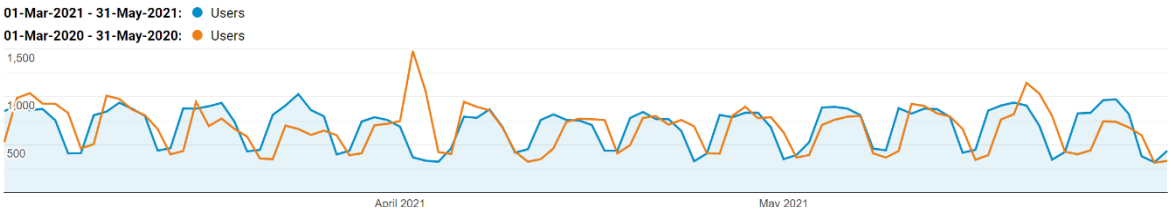
	2021/22	2020/20
Average time on page	3min 2s	2min 33s
Bounce rate	42.91%	42.95%

31. Average time on page is much higher this quarter with bounce rate remaining at comparable levels.

Popular Pages

32. The body donation page has roughly comparable traffic to the previous Q4 data, suggesting that users are returning to these pages. Pages such as the Homepage, Codes of Practice and Human Tissue Act all have significant increases.

Comparison graph (users over time)



(HTA 15/21)

Incident Analysis and Surveillance Report

Board meeting 15 July 2021

Chris Birkett and Rob Watson

HTA
Human Tissue Authority

Aim

To provide an overview to the Board of our analysis of incident data and our learning and responses to them in 2021/21

Incidents by sector

- Statutory requirement to report incidents in Organ Donation Transplantation (ODT) and Human Application (HA) sectors

- Since 2010 - HTA mandatory reporting system for the Post Mortem sector (HTARIs)

- Other sectors:
  - Standards – incidents should be investigated promptly
  - Guidance – Designated Individuals encouraged to contact us

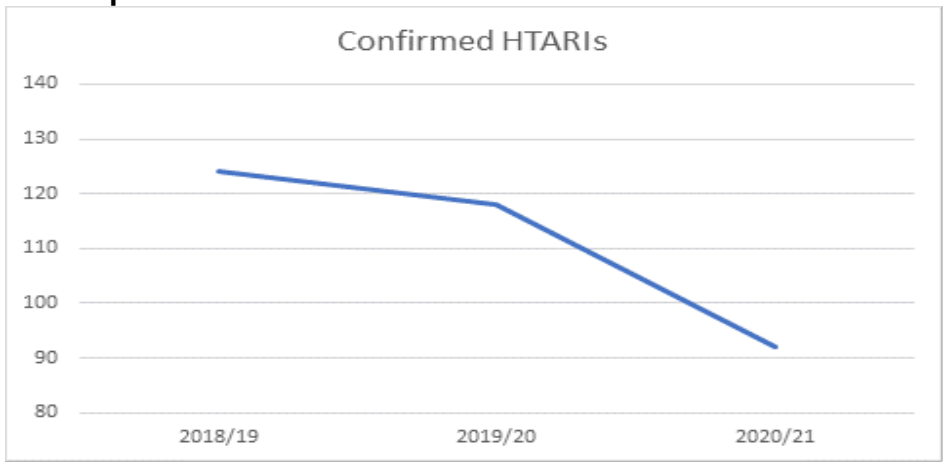
Incident Trending - Approaches

- Incident trends are identified:
  - during SAEARs (HA/ODT) and HTARI (PM) team meetings
  - by reviewing monthly data reports (all sectors)
  - via the annual SAEARs reporting exercise (HA sector)

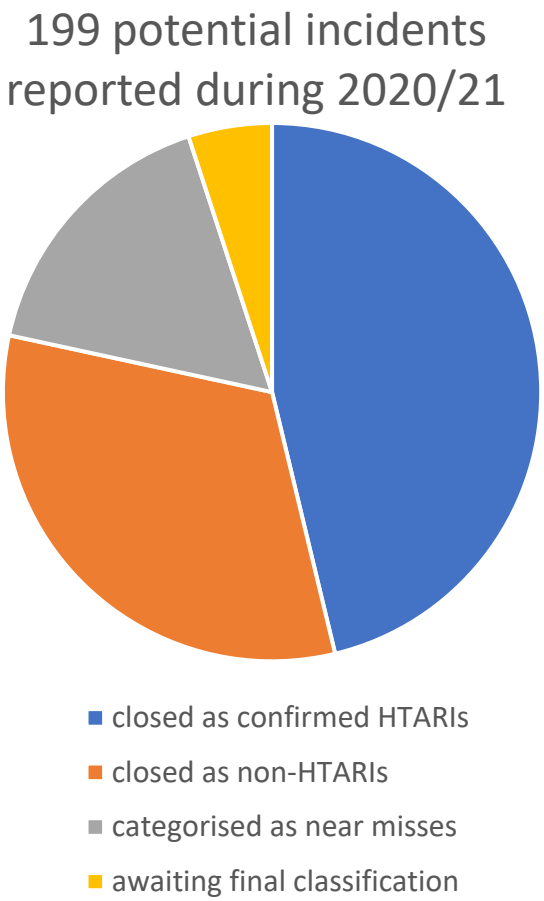
- Current approaches enable us to identify trends:
  - across the sector (i.e. a change in volume) or reported by a particular establishment
  - by activity
  - by the subtype of incident (e.g. contamination of a sample; release of the wrong body)

Incidents: Post mortem sector - HTARIs (HTA Reportable Incidents)

- Low threshold for reporting (contact encouraged)
  - 1 in 3 reports are non-HTARIs
- Downward trend in numbers of HTARIs over the last three years - COVID-19 impact?



- Specific reductions in serious security breaches and ‘Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence’.
  - monitor - genuine trends?



Incidents – HTARIs - Trends

- HTARI numbers very small compared to scale of activities (but important)

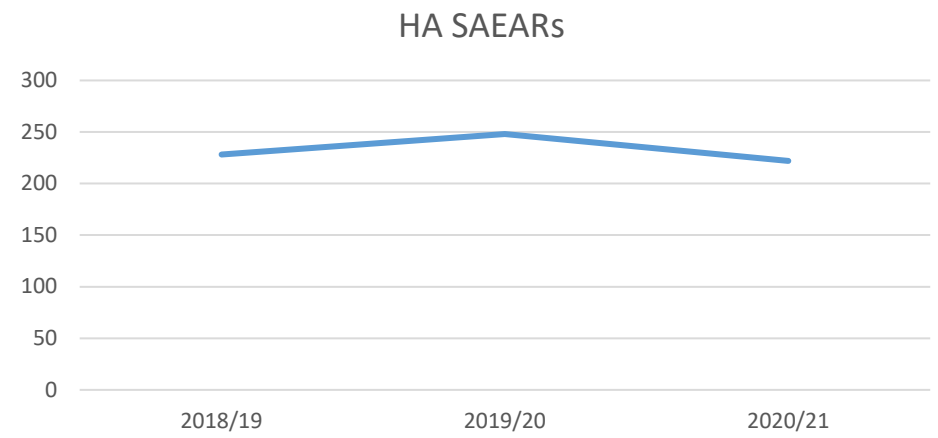
- Two HTARI categories recognised in 2020 as relatively consistent in terms of numbers:
  - release of the wrong body
  - loss of an organ or tissue

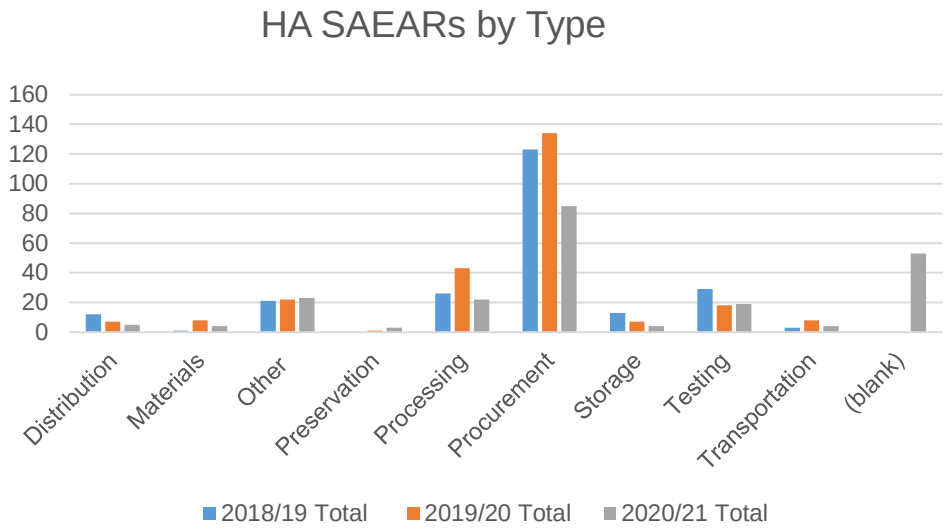
  - Both categories relate to how traceability is maintained
  - We developed and published guidance on traceability and addressing the root causes that might lead to release of the wrong body

- From monitoring HTARI reports and enquiries, we also issued guidance on **contingency storage** and **removal of relevant material from the deceased**.

  - continuing to monitor for any impacts and further trends
  - considering webinars

Human Application (HA) sector Serious Adverse Events / Adverse Reactions (SAEARs)





- Numbers and distribution of SAEARs relatively stable over last three years
- Majority of SAEARs are linked to procurement
- 2020 SAEARs that have not been categorised are listed as ‘Blank’ – these will be resolved when the SAEAR is closed

HA SAEARs – Trends in procurement SAEARs - examples

Bone marrow contamination during procurement

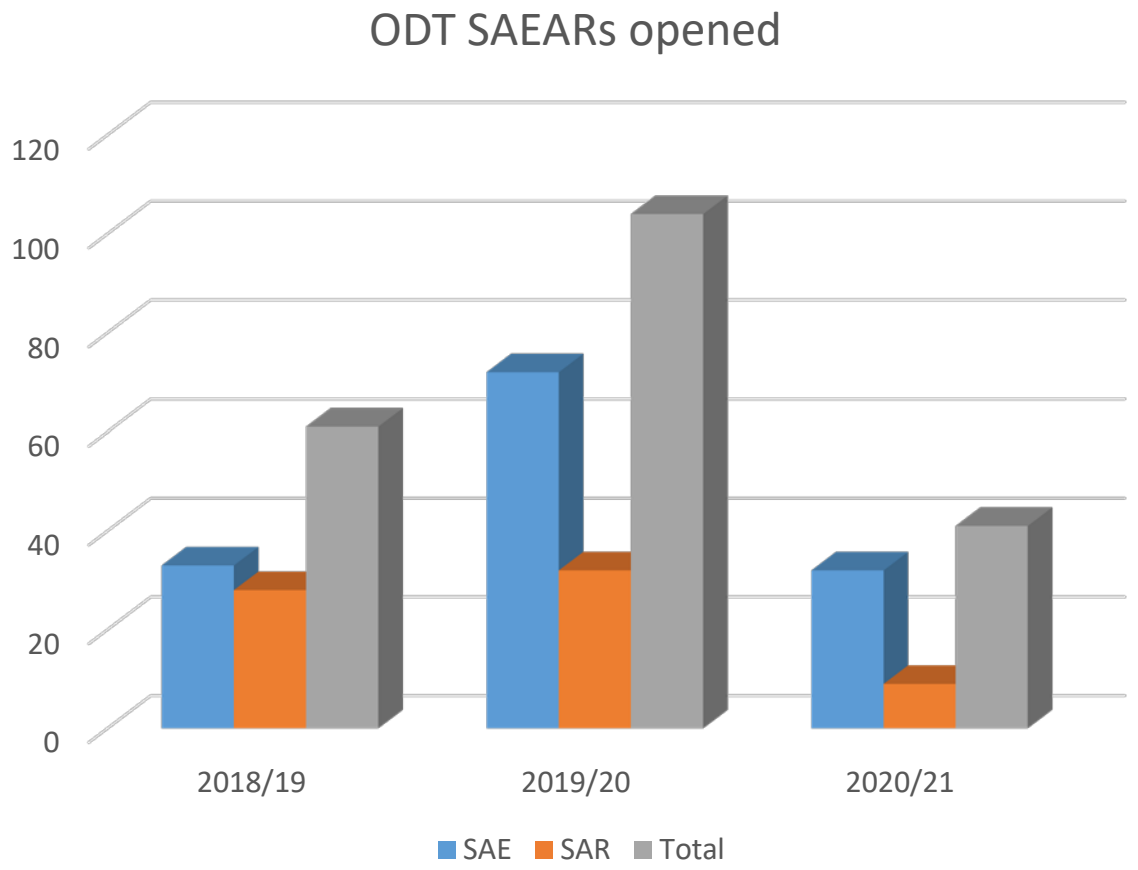
- Significant proportion of procurement SAEARs linked to contamination of bone marrow samples
- We have shared best practice in an attempt to reduce the frequency of such events
- We are also currently reviewing reporting requirements to ensure an appropriate level of regulatory oversight.

Unlicensed procurement of cord blood

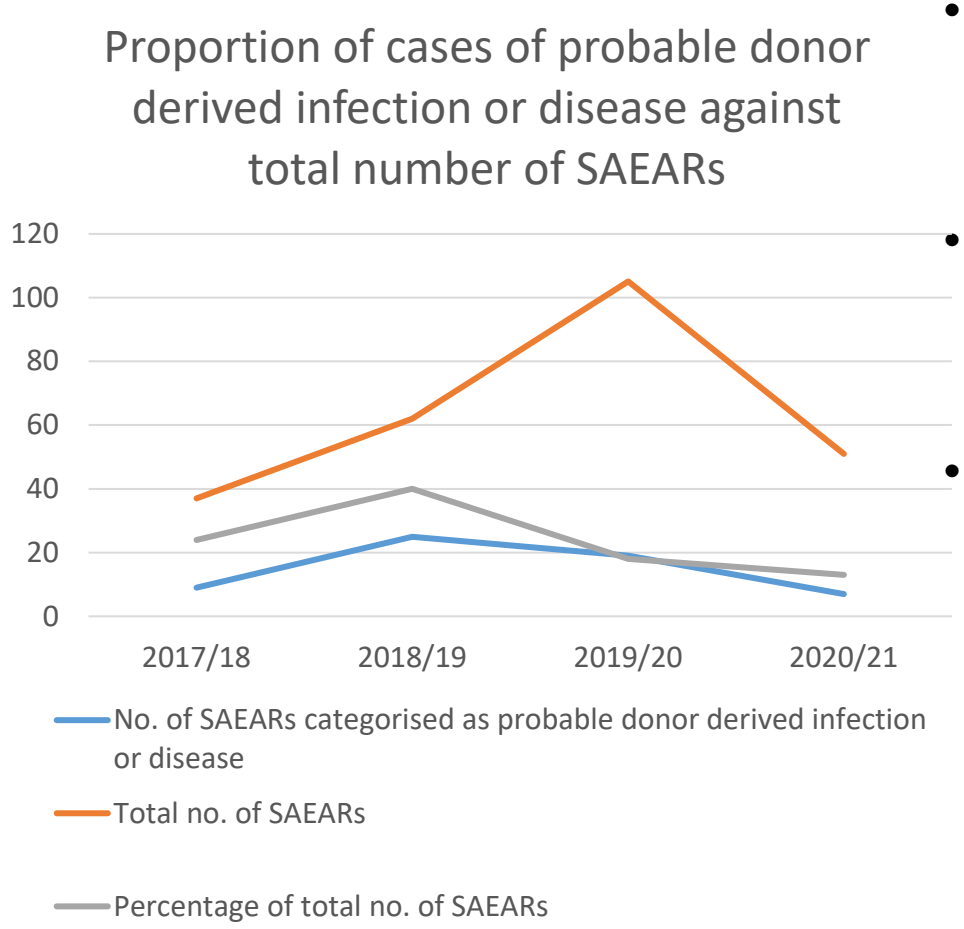
- Significant increase in such events due to COVID-related access restrictions in maternity wards
- Guidance issued to private tissue banks and we continue to work with them to explore alternative procurement models
- Considering contacting healthcare professionals via appropriate professional bodies

Organ Donation & Transplantation sector Serious Adverse Events / Adverse Reactions (SAEARs)

- Regular and senior oversight by HTA of NHS Blood and Transplant (NHSBT) investigation of SAEARs
- Review of all cases open for more than 90 days
- Sharp decline in SAEARs reports last year, reflecting significant decrease in donation and transplantation activity due to Covid-19
- Retrieval damage to organs remains the leading cause of SAE. These incidents are shared and discussed with retrieval teams by NHSBT for learning and improvement.



Incidents – ODT SAEARs - Trends



- This graph demonstrates the trend we have seen in cases of probable donor derived infection or disease incidents since 2017
- Usually these are transmissible infections that are not, or cannot be, effectively screened for at the point of deceased organ donation, for example human herpes virus 8 (HHV-8)
- HTA is participating in cross-sector specialist advisory group reviewing this issue

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Human Tissue Authority

Questions...

Human Tissue Authority
Board meeting

Date: 15 July 2021

Paper reference: HTA 16/21

Agenda item: 9

Author:
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Richard Sydee
Director Resources

OFFICIAL

ARAC update

Purpose of paper

1. This paper provides an overview of the business of the Audit, Risk and Assurance Committee (ARAC) meeting held on 17 June 2021.

Decision Making

2. The CEO approved this paper for presentation to the Board on 7 July 2021.

Action required

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

Background

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

Internal Audit

5. The Committee noted the three reports that concluded the 2020/21 audit plan. These covered: risk management; accounts payable; and the adequacy of Virtual Regulatory Assessments. The committee received the draft internal audit opinion for 2020/21 from Jo Charlton, Head of Internal Audit, which concluded that an overall rating of moderate assurance could be provided. This was in keeping with previous years.

6. The Committee noted the audit plan for the business year 2021/22 had been endorsed by all ARAC members in correspondence.

Annual Report and Accounts 2021/21

7. The Director of Resources presented the Annual Report and Accounts for the 2021/21 financial year report to the Committee. The Committee then received the draft External Audit completion report from Mike Surman of the National Audit Office. The committee noted that there were no material errors found or audit adjustments recommended and that the opinion was for the accounts to be unqualified.

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

Other items

9. The Committee received an update on Cyber Security from David Thompson, Head of Business Technology, and noted the annual report from the Senior Information Risk Owner. The Committee will continue to scrutinise this area and have requested further updates on staff training and awareness of cyber and information risk.

10. The Committee also reviewed revisions to the HTA's Critical Incident Response Plan and Business Continuity plan, received an update on the Development Programme and updates on standing agenda items relating to Gifts and Hospitality register and incidents.

Human Tissue Authority
Board meeting

Date: 15 July 2021

Paper reference: HTA 17/21

Agenda item: 10

Author: Louise Dineley
Director of Data, Technology and Development

OFFICIAL

Development Programme Update

1. The purpose of this paper is to provide the Board with:

   i. A look back over the quarter at progress against the Programme plan.
   ii. A forward look at Programme deliverables in the next quarter.

2. A more detailed report supplemented with details of success measures and benefits to be realised was shared with the Audit and Risk Assurance Committee (ARAC) at its June meeting.

Decision Making

3. The CEO approved this paper for presentation to the Board on 7 July 2021.

Action required

4. The Board is asked to:

   i. Note the update on the quarter one deliverables.

ii. Note the deliverables for quarter two.

Background

5. Over the last 12 months, the outputs of the Development Programme have focussed on establishing the foundations for the year ahead and the move from the conceptual to the delivery of change and the realisation of business benefits.

6. The HTA has agreed three priority projects for 2021/22. These are:

- The establishment and adoption of an Enterprise Content Management System.
- The development of the HTA's data and intelligence systems and future capability to strengthen the evidence underpinning our risk-based approach to oversight and regulatory action.
- The implementation of a Target Operating Model.

7. In addition to these priority projects, there are a number of projects and targeted pieces of work that will enable and support achievement of the priorities. These include:

- Ongoing organisational preparedness e.g. change readiness training
- Developing the HTA's workforce with the identification of future skills required, core competencies and business critical roles.
- Implementation of a revised Communications & Engagement Strategy that seeks to strengthen stakeholder engagement and build a function that recognises the HTA as a valued and authoritative voice in the Life Sciences sector.

8. We intend to learn and adapt in light of experience: the Development Programme will be actively informed by learning from the roll out of Virtual Regulatory Assessments and an agile approach to user informed design, development and testing of process and systems changes.

9. In parallel to the HTA's Development Programme, the HTA is involved in a number of external initiatives within the wider health and care system. Examples include, the Data Alliance Partnership, actions arising from the Regulators

roundtable and involvement with the Regulators Innovation Network (for example as an observer to projects on Anticipatory Regulation and Artificial Intelligence).

Quarter one 2021/22 – update on deliverables

10. The deliverables for the three priority projects in the quarter are outlined below along with a forecast assessment.

Overall project deliverables

11. *Agreement of Business Cases for the investment of people and financial resources to the Development programme in 2021/22*.
Status: GREEN - Business cases for Data and Intelligence and the ECMS projects agreed.

12. *Recruitment of Business Analyst to support a shared action of business process mapping and set the foundations for future business architecture design and build.*
Status: GREEN – Interim Business Analyst is in post focused on the production of "as is" and "to be" business process maps that meet HTA business requirements. Recruitment to the fixed term role is complete with the Business Analyst in post.

13. *Integrated programme plan, resource model and timeline*
Status: GREEN – detailed project plans in place for each core project with interdependencies and shared deliverables mapped at a programme level. Operational resource with identified subject matter experts effective from 1 June 2021.

Enterprise Content Management System

14. *Document a review of current HTA systems*
Status: GREEN – this review is underway and will continue into quarter two running in parallel to the "as is" business process mapping. The review aims to capture the functionality of the system, the relationships between different parts of the systems and the information flows through the system.

15. *Develop a target data architecture*
Status: GREEN – the development of the data architecture demands an understanding of business processes, how the systems and processes operate

and are used and the identification of business owners. These requirements will be captured in the design of workshops that commenced in early July.

Strengthening the use of Data & Intelligence

16. *Complete the evaluation of the proof of concept model*
    Status: GREEN – Evaluation of the proof of concept completed with report received.

17. *Data collection pilot*
    Status: AMBER – the planned development and deployment of a pilot has been rescoped and realigned to deliverables in quarter two. The revised plan does not impact on overall deliverables or longer-term timelines.

18. *Interoperability of systems and opportunities to optimise existing systems*
    Status: GREEN – the early scoping of requirements and systems developments support the potential and future use of Power Apps and Power BI (a business analytics service by Microsoft) for future data collections and management. There is a critical interdependency with the mapping of processes, in particular data flows, the design of the target data architecture and a quarter two deliverable of the Regulatory Insight Model & Index (version 1.0).

Development of a Target Operating Model

19. *Agreement of a draft HTA Operating Model*
    Status: GREEN – an outline of an HTA Target Operating Model has been agreed. This outline confirms core functions referred to as “domains”, the relationship (actual and potential) between them which will form the basis of future mapping, relationships to be established and options for future targeted improvements.

20. *Mapping of “as is” and “to be” state for core processes*
    Status: GREEN – the mapping of the current and future state of the core functions of licensing, data and intelligence and regulatory assessment is ongoing. These high-level maps will be used to inform the detailed business process mapping planned into quarter two.

Quarter Two 2021/22 Deliverables

21. The Development Programme has been designed to support incremental development, change and improvement. The deliverables in quarter two will continue and build on outputs from quarter one. By the end of quarter two we aim to have delivered:

- A data collection pilot
- A version of the Regulatory Insight Model and Index (RIMI)
- A documented “as is” and “to be” model supported by detailed business process maps in line with business requirements.
- The transition architecture for the ECMS to be built in quarter three
- Plans for targeted developments to agreed activities in the Target Operating Model
- A first draft of future workforce requirements to inform wider organisational preparedness and the options to develop or access core skill sets.

Measuring Success

22. The Development Programme delivery in 2021/22 will be supported by a newly developed framework of success measures and benefits to be realised as part of projects and programmes. The framework also aims to complete an initial assessment of return on investment (ROI) for the programme overall. The framework sets out the approach to be adopted to monitor, review, track and support the progress of the Programme. The detail of this monitoring will be shared as part of the report to the Audit Risk & Assurance Committee and form part of an annual report at the end March 2022.

(HTA 18/21)

HTA Beyond COVID-19 Restrictions

15 July 2021

HTA
Human Tissue Authority

Overview and contents

This document provides a high level overview of the HTA's planned approach to the lifting of COVID-19 restrictions

Contents:

- Readiness of 2 Redman Place
- A return to office based working
- Future use of our office space
- Plans to resume routine site visits

Readiness of 2 Redman Place

Our new office location is shared with 4 Health ALBs and has been in use since early 2021

- HTA's new offices at 2 Redman Place are available for use, albeit currently at 50% desk capacity (11 of 22 desks) and no use of meeting rooms due to extant social distancing requirements. The HTA has to this point restricted attendance to essential activity only.

- Other resident organisations have been using the space for some time with very positive feedback

- Some limited re-testing of IT connectivity and document unpacking will be required, but otherwise the site is fully operational

Plans for a return to office based working

The executive team have been discussing regularly its approach to any easing of restrictions

- HTA's SMT met on 9 July 2021 and agreed that it would support the full re-opening of 2 Redman Place following any Government announcement that removed formal social distancing requirements

- The Cross ALB programme board discuss and agree all changes to the availability of 2 Redman Place, they met on 13 July 2021 to discuss a joint response to the Government's announcement of 12 July 2021.

Future use of our office space

A number of new ways of working were envisaged and implemented during the last 18 months, how far we return to pre pandemic practices remains under discussion

- Following a consultation in 2020 the majority HTA staff now have home based contracts, they will attend the HTA's offices only for occasional meetings and events
- The for those staff who have retained an office based contracts there is a required minimum attendance at 2 Redman Place of 1 day a week - although more regular attendance is anticipated
- Decisions still need to be made regarding In person or virtual attendance at HTA Board and other governance meetings going forward, whether this be mandatory or voluntary and the regularity of such mandatory meetings