Ninety-Ninth meeting of the Human Tissue Authority Board

Date: 10 February 2022

Time: 10.00 -12.00 (Main meeting)

12.00 - 12.30 (Private session - Board and Chief Executive)

Venue: Zoom

Protective Marking: OFFICIAL – Draft

Agenda

Meeting administration

1. Welcome and apologies (LB) (10.00-10.05)

2. Declarations of interest (LB)

Regular reporting

3. Chair's Report (Oral) (LB) (10.05-10.15)

4. Chief Executive's Report (HTA 1/22) (CS) (10.15-10.35)

   Annex A- Board Supplementary Data Annex (HTA 1a/22)
   Annex B- Risk Summary (HTA 1b/22)
   Annex C- Strategic risk register (HTA 1c/22)

Items for discussion

5. Communication and Engagement Strategy (HTA 2/22) (10.35-10.45)

6. Business Plan 2022/23 (HTA 3/22) (10.45-10.55)

7. ARAC Terms of Reference (HTA 4/22) (10.55-11.05)
   Annex A – Draft ARAC Terms of Reference (HTA4a/22)

8. Police Referral Policy (HTA 5/22) (11.05-11.15)
   Annex A – Policy Referral Policy (HTA5a/22)

9. Horizon Scanning (HTA 6/22) (11.15-11.25)
   Annex 1 Horizon Scanning Log (HTA 6a/22)
   Annex 2 Horizon Scanning Register (HTA 6b/22)

10. Deemed consent Northern Ireland (HTA 7/22) (11.25-11.35

Committee and Working Groups

11. Audit and Risk Assurance Committee Update (HTA 8/22) (11.35-11.45)

Items for information only (11.45-11.55)

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

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

14. Development Programme Update (HTA 11/22)

Any Other Business (11.55-12.00)

15. Any Other Business (Oral) (LB)

Meeting Close 12.00

This version 26 January 2022

Human Tissue Authority Board meeting

Date: 10 February 2022

Paper reference: HTA 1/22

Agenda item: 4

Author: Colin Sullivan
Chief Executive

OFFICIAL

Chief Executive's Report

Action required

1. The Board is asked to note and comment on the content of this report.

Introduction

2. I would like to start, this my first CEO Report to the Board, by extending my thanks to HTA staff, Board members, the DHSC sponsor team and our stakeholders for a warm welcome and for spending time with me to outline the finer details of the Human Tissue Authority's remit. I am delighted to have joined the organisation as CEO in January. For me, this is a return to the health sector after a decade and more in the civil service and, since appointment, my time has been focused on getting to know how we currently do regulation, the ambition and coverage of our development programme and how we might or should change going forward. The latter remains work in progress as I continue to listen and learn but what is clear is the organisation's strong commitment to excellence and to ensuring that public confidence is maintained in how human tissue and organs are retained and used – safely, ethically, and with proper consent.

3. Whilst Covid restrictions and the requirement in early to mid-January to work from home when possible have impacted my ability to meet colleagues in person, I have enjoyed a wide-ranging induction phase with many virtual discussions and I

have been impressed with the wealth of expertise in this ALB. More recently, I had the opportunity to join an inspection visit which covered the Human Application sector. This was invaluable and, going forward, I look forward to the opportunity to learn more about our inspection and assessment activities. I will be very keen to work with other health regulators to support one another in terms of resilience and on other areas of mutual benefit and, in this respect, I have already held introductory conversations with the CEOs of CQC, HRA and HFEA with more meetings with other health regulators planned.

4. During my induction, limitations with the current legislation that governs human tissue use have frequently been mentioned. Whilst the HTA team are seeking to regulate to a high standard under the current legislation they are increasingly being asked to provide advice to licence-holders as new issues, arising from advances in life sciences, need to be addressed.

5. Going forward, I will be keen to ensure we get the balance right between being the regulator for the sector, with clear independence of thought and action to maintain public trust, whilst also seeking to work constructively with those licensed establishments that are highly compliant to enable them to tackle new regulatory challenges arising from advances in human tissue usage.

6. We must always seek to be efficient with the public money we administer and, in addition, deploy resources effectively between our different roles as the independent regulator and provider of advice for the sector. Hence, I am keen early in my tenure to review and refine, in conversations with the Board and staff members, our vision and strategic goals so that I can best marry resource planning and allocation to the priorities that meet the Board's ambitions.

Purpose of Paper

7. This paper gives an overview of the HTA's performance during the period 1 October 2021 to 31 December 2021 (Q3).

8. The report provides an account of our core regulatory business, progress on development projects, the financial position at the end of Q3 2021/22 and a summary of people and other operational issues arising since the last Board meeting held in November 2021.

Decision making to date

9. The Senior Management Team approved this report for presentation to the Board during their meeting on 20 January 2022.

Regulatory overview

10. **Annex A** to this paper contains a summary of regulatory activity during Q3. I am conscious that in recent times the Supplementary Data Annex has not provided as much analysis as any of us would have liked. However, as we seek to work post-Covid we are embarking on a journey to make this report of more benefit to the Board by enabling better scrutiny. In this first revised iteration, some data sets have been presented in a different format compared to previous reports. Data have also been presented over a longer time period to give two full years of data pre-Covid, demonstrating the impact of Covid and to enable longer-term trends, as opposed to normal random fluctuations, to be more easily observed. These data have also been expanded to include inspection numbers, which in previous years was captured through Key Performance Indicator monitoring. As we go into 22/23, I am seeking to re-introduce KPI monitoring which will in turn enable more detailed reporting and scrutiny.

11. The HTA's Safe Site Visits project, which implemented a strategy for returning to site visit inspections, developed individual risk assessments for staff, and secured and provided suitable PPE for staff, enabled a return to routine site visit inspections during Q3. The HTA has now embedded Virtual Regulatory Assessments (VRA) as part of its regulatory toolkit, allowing us to blend remote and on-site inspection methodologies to address the risk profile presented by each establishment. As such, inspections may comprise solely a VRA or be a 'hybrid', determined in accordance with the recently developed Inspection Assessment Decision-Making Framework. A forward plan of inspections for the remainder of this year, and an outline plan for a full inspection schedule for the next business year, was also developed during Q3.

12. The HTA has continued to monitor government Covid guidance and obligations, including from the Devolved Administrations, to ensure any site visits are in line with current advice.

13. The resumption of routine site visits is enabling the HTA to start to return to compliance with its statutory obligation to undertake site visit inspections at least every two years in the Human Application sector. The initial programme of inspections is being targeted at those considered higher risk and hence there will be an ongoing shortfall to meet the statutory obligation for some establishments for a period.

14. A new Head of Regulation and three new Regulation Managers joined the HTA during the latter part of Q2 and the early part of Q3, bringing the Regulation Directorate back to its current target staffing complement. The six month induction has been adapted, having previously been heavily office-based and reliant on face-to-face contact. The new structured virtual process, supported by observation and then support and leadership of inspections (VRAs and site visits), is progressing well.

15. Five licence revocations took place in Q3, four in the PM sector and one in the HA sector. There were eight new licence applications, two in the HA sector, four in the Research sector, one in the PM sector and one in the Anatomy sector.

16. The HTA's UK Transition Project was formally closed in Q3, with a small number of ongoing actions handed over to the business. The HTA is prepared to respond if there are any changes to the Northern Ireland Protocol (NIP) and maintains regular contact with the DHSC NIP lead for substances of human origin. The HTA continues to support DHSC by responding to ad-hoc commissions to inform policy design and scoping work related to NIP.

17. Five Regulatory Decision Meetings (RDMs) were held in Q3, four in the Human Application (HA) sector and one in the Post-Mortem sector.

18. There were 2 police referral considerations by SMT during Q3. Neither of these resulted in a referral to the police.

19. Living donation case numbers remain steady. A total of 260 cases were approved in Q3 compared to 270 in Q2. The Head of Regulation for this sector continues to meet monthly with the Lead Nurse for living donation at NHS Blood and Transplant (NHSBT).

20. Extensive engagement has taken place with NHSBT in relation to several complex enquiries in the ODT sector. These have mainly been to support and

facilitate innovation and planning, particularly where an issue appears to cut across the HA and ODT sectors, creating uncertainty about which regulatory framework a specific proposal may fall under.

21. There has been good progress on several novel regulatory matters that arose during Q3 or previously, across a range of sectors. These included serious incidents concerning loss of traceability, a failure to arrange for HTA approvals in certain cases where this was mandatory, and a novel public display proposal for which the HTA that raised issues of the adequacy of consent. These have all now either been satisfactorily resolved or there is ongoing regulatory oversight through Corrective and Preventative Actions. One of these matters resulted in a police referral consideration.

22. The HTA used its Critical Incident Response Plan for managing its response to the trial of David Fuller, which placed into the public domain information about his serious sexual offending against bodies at Maidstone and Tunbridge Wells Hospital mortuary. In December, the HTA provided initial advice on relevant matters to the Secretary of State for Health & Social Care and we are continuing to support DHSC and other stakeholders who are taking action as a result of this matter and as they feed into the Independent Inquiry that has now been launched.

Development

Communications & Engagement

23. Agenda item 5 (HTA 2/22) provides an update on communications and engagement activities in Q3 and an overview of the strategic development of the function including alternative approached adopted. Communications and engagement activity in the last quarter has been diverse encompassing new forms of engagement through focused stakeholder round tables, partnership working including new stakeholder relationships across the wider health family and responsive media activity and enquiries.

Development Programme

24. Agenda item 14 (HTA 11/22) provides a detailed update on the development programme. Progress has been slower than anticipated in the last quarter although confirmed investment in Q4 is expected to assist recovery.

HTA Website Redevelopment Project

25. In June 2021, the HTA launched its public beta website following a successful assessment by NHS X. Since "go live" of the beta site the website redevelopment project team have continued to seek feedback from the public and professional users of the site on their experience. Our aim has been to continually improve accessibility and user experience and to use feedback and formal testing to inform further developments. The project is currently preparing for the "live" assessment with NHS X at the end March.

COVID-19 Inquiry

26. In December 2021, Baroness Hallett was confirmed as the Chair to the upcoming UK public inquiry. Currently Scotland is the only devolved nation to have announced an additional inquiry. The terms of reference for the inquiry had not been published at the time of writing this paper. The HTA has started to collate information against an anticipated scope and will further refine this once further details relating to the inquiry have been confirmed.

Strategic risk

27. The Risk Summary document is at **Annex B** and the Strategic Risk Register is at **Annex C** to this paper.

28. In its January assessment of Strategic Risks, SMT concluded that 3 of the 6 risks were at tolerance (risks 1, 3 and 6) and three of the risks remained above tolerance (risks 2, 4 and 5).

29. The residual risk scoring for Risk 2, failure to manage an incident, has been reduced to reflect the move from incident management to inquiry preparation in relation to the Fuller case. Although this remains above tolerance this now scores as a medium risk and we anticipate further reduction in the coming months.

30. SMT also reduced the residual risk level for Risk 4, Failure to utilise our resources effectively, this reflects the review of Q4 activity plans to ensure sufficient resourcing and the successful filling of some vacancies.

31. SMT will undertake a review of the risks within strategic risk register once strategic business objectives for 2022/23 are finalised.

Finance

Table 1 - Financial position for Q3 2021/22

Human Tissue Authority
Summary Management Accounts for the nine months ended 31 December

	Actual	Budget	Variance	
	£	£	£	%
INCOME				
Grant in Aid	713,000	578,000	135,000	23.36
Non-cash cover	58,592	58,592	0	0
Licence Fee income	4,050,934	3,951,321	99,614	2.52
Devolved Governments	133,572	133,572	0	0
Other Income	37,693	37,694	(1)	0
TOTAL INCOME	**4,993,791**	**4,759,178**	**234,613**	**4.93**
OPERATING COSTS				
Staff costs (salaries etc)	2,485,145	2,427,397	57,749	2.38
Other staff costs (excl. inspections)	85,845	102,275	(16,430)	(16.06)
Board Costs	92,528	132,500	(39,572)	(30.17)
Inspection Costs	8,785	42,000	(33,215)	(79.08)
Living Organ Donation and Transplantation costs	624	7,000	(6,376)	(91.09)
Communication Costs	6,686	21,750	(15,064)	(69.26)
IT and Telecoms	305,710	273,750	31,960	11.67
Office and Administration Costs	17,004	90,342	(73,338)	(81.18)
Other costs	54,503	115,600	(61,097)	(52.85)
Legal and Professional	382,437	84,415	298,022	353.04
Accommodation costs	159,802	165,725	(5,924)	(3.57)
Non-cash costs	44,897	58,592	(13,695)	(23.37)
Total operating costs	**3,643,966**	**3,521,347**	**122,619**	**3.49**
Net Income/(expenditure)	**1,349,825**	**1,237,831**	**111,994**	**9.05**

32. Table 1 provides a summary of our financial position at the end of Q3 of 2021/22 business year. We are posting a surplus against budget of **£112k** before any adjustments. Below is a breakdown of the components that make up our net position.

Table 2 - Income summary

Human Tissue Authority
Income Summary
For the Nine Months Ending 31 December 2021

	Actuals	Budget	Variance	
	£	£'	£	%
Grant in Aid	713,000	578,000	135,000	23.36
Non-cash	58,592	58,592	0	0
Sub-Total	**771,592**	**636,592**	**135,000**	**21.21**
Licence Fees				
Application Fees	74,455	0	74,455	0
Anatomy	112,430	109,880	2,550	2.32
Human Application	1,484,683	1,486,426	(1,743)	(0.12)
ODT	317,125	310,360	6,765	2.18
Post-mortem	1,280,215	1,285,180	(4,965)	(0.39)
Public Display	20,035	20,360	(325)	(1.60)
Research	761,991	739,115	22,876	3.10
Sub-Total	**4,050,934**	**3,951,321**	**99,613**	**2.53**
Other				
Secondees	37,693	37,694	(1)	0
Devolved Assemblies	133,572	133,572	0	0
Sub-Total	**171,265**	**158,701**	**(1)**	**0**
Total Income	**4,993,791**	**4,759,179**	**234,612**	**1.38**

33. Table 2 provides a breakdown of our income for the year. Key variances are as follows:
    a. Grant in aid – is £135k higher than budgeted due to drawdown of EU funding and budget profiling.
    b. Licence fees – including application fees are above budget by **£99.6k**, which is largely due to application fees which are not budgeted for and an increase in Research income.
    c. Other income – is on budget.

Expenditure

34. **Staff costs (salaries)** – are over budget (£58k) due to the use of contract staff to fill permanent roles being recruited to.

35. **Other staff costs (excl inspection)** – are under budget by £16k. Most of this underspend relates to training costs which are underspent by £20k. The balance being small over and underspends in travel, non-inspection travel and overspend within recruitment of £18k.

36. **Board costs** – include Member allowances, travel and venue hire. The underspend (£40k) relates to vacancies at board level (£19.9k) and the balance relates to travel and venue costs where all meetings have been held virtually totalling £20k.

37. **Inspection costs** – remain under budget (£33k) as there have been fewer site visits due to the COVID-19 restrictions and virtual inspections incurring little or no cost.

38. **Living Organ Donation, Transplantation** – is under budget (£6k). The lack of training of Independent and Accredited Assessors is the cause of this variance.

39. **Communications costs –** are under budget (£15k). There has been no spend against; Business Planning, Strategic and Business Planning production, Staff Engagement, Stakeholder Engagement and DI Engagement totalling £14k. The balance is represented by small over and underspends within other areas such as Digital subscriptions and our Media Monitoring service.

40. **IT and Telecom costs** – as at the end of quarter three we are overspent by £32k. This is represented by overspends within IT Maintenance (£18k), Consultancy (£40k) offset by underspends within Consumables (£9k) and Telephone costs (£17k).

41. **Office and Administration costs** – £73k 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 (£68k) which covers additional travel costs for staff which due to restrictions have not materialised. Added to this are small underspends against printing, postage and stationery, publications costs totalling £5k.

42. **Other costs** – are under budget by £61k due to an underspend on the Website project (£58.4k) which is one of the work packages for the Development Programme. Costs were expected but are yet to materialise and this may be due to the bulk of the work being completed last year, however at the time of budgeting, we expected there to be additional costs. The small balance is an underspend in stationery.

43. **Legal and professional costs** – are significantly over budget (£298k). Legal fees are slightly under budget by £1k. We are overspending on internal audit costs (£13k). In addition, we are overspending against our Consultancy costs (£286k) of which £264k relates to the work were doing around our portfolio business planning and the same supplier was engaged to carry out work relating to the Development Programme.

44. **Accommodation costs** – are under budget by £6k. The underspend relates mainly to the rates for 2 Redman Place. The budget was based upon figures provided at the end of 2020/21, but the initial bills received from DHSC were lower.

45. **Non-cash costs** – underspend of £14k 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 covered by the ring-fenced RDEL provided by the DHSC.

Forecast outturn

Table 3: summary

	Actual	Budget	Forecast
	£	£	£
INCOME			
Grant in aid	713,000	578,000	911,000
Licence fees and other income	4,222,199	4,122,586	4,234,763
Non-cash cover	58,592	58,592	78,123
Total income	**4,933,791**	**4,759,178**	**5,223,886**
EXPENDITURE			
Salaries including Authority costs	2,577,673	2,559,897	3,534,592
Non-staff	1,066,293	961,450	1,689,294
Total Expenditure	**3,643,966**	**3,521,347**	**5,223,886**
Net income/(expenditure)	**1,289,825**	**1,237,831**	**0**

46. We are currently forecasting a break-even. A detailed review with teams was undertaken in January and changes for the last quarter of the business year such as additional staff payments have been factored in.

47. We have allocated funds to the development programme and other priority activities over the last quarter of this business year. This expenditure, in the region of £250k, is profiled to be spent across the last quarter but there is some possibility that not all activity will not complete as planned.

Other key performance indicators

Debtors

48. At the end of quarter 3, the total value of our debtors was **£0.4m** represented by **82** accounts. This is a significant reduction on the same period in 2020/21 where our debtors were **£0.7m**. This reduction is the result of a push within our credit control process.

49. The table below gives a breakdown by sector.

Table 4: Debtors by sector

Sector	Number of establishments	Value of debt £	%ge
NHS	42	£268,820	61
Government Bodies[1]	5	£31,615	7
Local Authorities	2	£13,030	3
Non-Government Bodies[2]	33	£129,306	29
Total	**82**	**£442,771**	**100**

50. Of the 42 NHS accounts, 1 (£7k) has been outstanding since the 2019/20 billing run. The trust is a Scottish one and we are still pursuing them. The remaining accounts all relate to the 2021/22 business year.

51. Of the 33 Non-Government Bodies, 2 (£1k) are over three years old and are universities, 11 (£10k) relate to the 2019/20 business year, 6 (£24k) to the 2020/21 year and the remainder are for this business year. As with the NHS organisations, we are actively pursuing these debts and expect resolution by the end of 2021/22.

52. Within the Government Bodies there is one outstanding account for one of the Devolved Assemblies who have since been in contact and have promised payment by early February (£25k)

Financial risks and mitigations

53. Financial risks are monitored on an ongoing basis. Below is a table of the current key risks identified and the mitigating actions and controls taken to minimise them. The financial risks in this summary are linked to one or more of the six high-level strategic risks that SMT has identified and is managing. The strategic risk five – insufficient, or ineffective management of financial resources – at the end of December is rated yellow (medium) as we are forecasting a break even and a surplus at the end of Q3.

[1] Includes ALBs, museums

[2] Includes Universities and private organisations

Risk	Mitigating actions and controls
Risk that we cannot maintain continuity of payments and salaries	Regular review of cashflow and maintenance of agreed level of reserves.
Establishments change their profile resulting in a reduction in hubs and satellites, and licensed activities, leading to a reduction in fee income	Periodic review of current licences and expected income. Budgets are adjusted accordingly.
An overspend or significant underspend may lead to a lack of stakeholder confidence in HTA's ability to manage resources effectively.	Monthly review of financial position and quarterly re-forecasting. Review of activities that can be deferred.
Unexpected increases in regulatory responsibilities	Prioritisation when work requirements change. DHSC funding if appropriate.
Management fail to set licence fees at a level that recovers sufficient income	Financial projections and cash flow forecasting and monitoring.

Governance

54. On coming into post, I have been considering with executive colleagues the structure and content of standing papers that we bring to the Board and how we might refine the content. These discussions will include the Chair and we are likely to see reports evolving over several meetings. We are of course open to feedback at any stage from Board members. Also in the governance space, it is hoped the dates for the 2023 Board and ARAC meetings can be confirmed soon.

People

COVID-19 response

55. As a result of the Omicron surge and government guidance, we again indicated to staff to work from home in January, unless they had an approved business need or wellbeing or health reason to attend. Staff were encouraged to discuss with their Line Manager and HR any adaption they may require arising from the impact of the pandemic. Currently all staff are working a 'standard' day with no adjustments required. We again communicated to staff with the further changes in UKG advice that staff can return to offices with effect from 20th January. We have advised staff that although mask wearing is no long mandatory in most settings, it

is still required on TFL and the London Underground. We have also advised staff that mask wearing is recommended in office communal spaces and it is a matter of personal choice to wear more widely. Additionally, staff have been informed that SMT will consider the implications of this latest guidance for our Ways of Working and on-site inspections over the coming weeks.

56. Heads of Function continue to have a standing agenda item at each fortnightly Heads Management Meeting (HMT) to review and raise any wellbeing or mental health concerns within their teams.

New ways of working / Return to office-based working

57. During the period of September to December a small but growing number of staff were choosing to work from the Redman Place office one or two days a week. Many of those using the office reported an increase in their general wellbeing and a positive reaction to the office space and layout. For many, the concerns highlighted in the April / May Office Working survey appeared to reduce with the main area of remaining concern being travel on public transport.

58. More detailed work on Ways of Working in a hybrid world have been paused to allow for a cultural review of our values and approach to working which I will lead over the coming months, flowing from the review and refinement of the vision and strategic goals.

Wellbeing

59. Over the last two quarters, the Wellbeing offering has included general wellbeing and mindfulness supplementing the focus on our response to the impact of COVID-19.

60. The monthly topics which have included Reflection and Strength and Renew and Nurture have encouraged staff to take time out and manage their own Wellbeing.

Sandpiper / Fuller Independent Inquiry

61. Additional resources were made available to all staff, following the disclosure of the Sandpiper case, at the beginning of November. Particular attention was given around the dates of the court case in early November and the sentencing hearing on 15 December, encouraging staff to access help if they felt the need. In early

November Cherry Tree Therapy led 2 separate support sessions, the first focused on Leading Through Traumatic Events, this was specifically targeted for Heads of Function, Line Managers and SMT, and the second, Guiding Through Traumatic Events, provided support and guidance for our trained Mental Health First Aiders.

62. Peer Support groups were developed with an identified Head of Function as lead to encourage staff to come together and discuss any topic of their choice. These weekly sessions were appreciated by staff with good attendance and positive feedback. Attendance at these sessions has now significantly reduced, indicating this support is no longer needed in addition to the various other 'drop in' sessions available throughout the month. The plan is to pause these sessions from January until or if the need arises again.

Recruitment and Retention

63. Retention on a rolling year stands with 10 leavers, (79%). However, four (8.5%), were fixed term contractors. Taking only permanent staff who have left the HTA over the last 12 months our attrition stands at six leavers (13%) giving an overall retention rate of 87%. We have lost 3 permanent members of staff since 1 July 2021, including the CEO. All three had between 4.5 and 11 years' service. Whilst this does represents a loss of knowledge, it also demonstrates that many staff are happy to remain with the HTA for notable periods of their career.

64. The recruitment programme over the last two quarters has been very active with both permanent and interim posts being filled. Currently we have two live permanent positions being actively recruited for with another two or three expected in the coming weeks

Sickness absence

65. 49.5 days of sickness were reported between 1 July 2021 and 31 December 2021. There were 17 members of staff with an average of 1.7 days each recording sick leave during this period. Nearly half of these were recorded as cold/flu. No members of staff have breached the Bradford score threshold. A small number of staff have reported a positive test for COVID during this period. There is a significant increase in the number of staff who have recorded sick leave compared to the same period in 2020 (5) and 2019 (8). The average number of days taken is higher than in the same period before the pandemic in 2019 (0.97) but lower than in the same period 2020 (2.5).

66. The increase in sick days during 2021 is not unexpected due to the wider environmental implications of the pandemic. There was a recognised increase in general seasonal viruses and an increase in the transmission of COVID itself.

Pulse Survey

67. We conducted a Pulse Survey in July and again in October. The participation rate for the July survey (64%) and October survey (60%) was down on the February pulse survey (74%). However, of those that responded, 93% said they have a neutral to good understanding of expectations of them and this is an increase from July at 89% and February at 75%.

Equality, Diversity, and Inclusion

68. As I arrive in post, I am pleased to see that we continue to build EDI into our HR offering and wider activity. All HR related policies contain an EDI statement of intent, and we have made small improvements to the diversity of the HTA workforce. Our gender imbalance has reduced with our female contingent down from 74% to 68%. We have also improved our ethnically diverse representation from 18% to 27% of non-white British members of staff.

69. There is a GIAA internal audit underway, which was due to report before Christmas. Unfortunately, due to illness, this has been delayed and will report by the end of January 2022.

Freedom of Information requests

70. During Q3, the HTA received 9 requests for information under the Freedom of Information Act (FOIA). We publish FOIA responses on our website.

Complaints

71. In Q3, no complaints were received by the HTA.

Action required

72. The Board is asked to note and comment on the content of this report.

Human Tissue Authority
Board meeting

Date:	10 February 2022
Paper reference:	HTA 1a/22 (Board Supplementary Data Annex A)
Agenda item:	06
Author:	Nicolette Harrison Director of Regulation

OFFICIAL

Purpose of Report

1. This report sets out a high-level overview of activity in Q3 2021/22 and signifies the start of a journey to refine how we present information to the Board.

Statistical Process Control (SPC) charts

2. The report uses Statistical Process Control (SPC) charts to differentiate between special cause variation and common cause variation.

3. A sensitivity of three standard deviations has been used to calculate the Upper Control Limit (UCL) and the Lower Control Limit (LCL). Standard deviation is a statistical measurement of variability. It gives an indication of how dispersed a set of values are in relation to the mean. A low standard deviation indicates data is clustered around the mean value, while a higher standard deviation indicates data is more spread out. Three standard deviations is most typically used in SPC charts as this empirically provides a balance in the risk of showing false signals and concealing true signals.

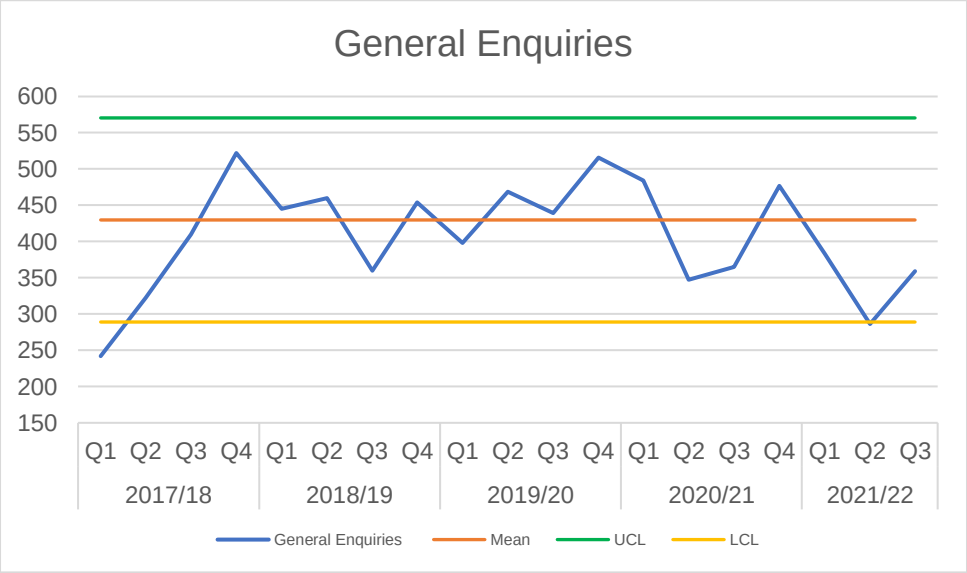
4. Data points that fall outside the Upper Control Limit (UCL) and Lower Control Limit (LCL) indicate variation that is irregular and outside the norm. Data points that fall between the two limits indicates common cause variation that is natural and expected. Data from 2018/19 has been selected as our comparative year to calculate the mean and the limits, as this was the last typical year before Covid-19.

5. Scatter graphs have also been included to facilitate better identification and visualisation of long-term trends. Linear regression has been used to determine the line of best fit.

Enquiries

6. Figures 1 and 2 below display the total number of general enquiries and body donation enquiries received each quarter. 359 general enquiries and 174 body donation enquiries were received in Q3 2021/22. Body donation enquiries has continued on a downward trend this quarter. This is likely due to improved body donation guidance available online, reducing the number of requests for information through enquiries.

Figure 1: General enquiries received each quarter (excluding body donation enquiries)



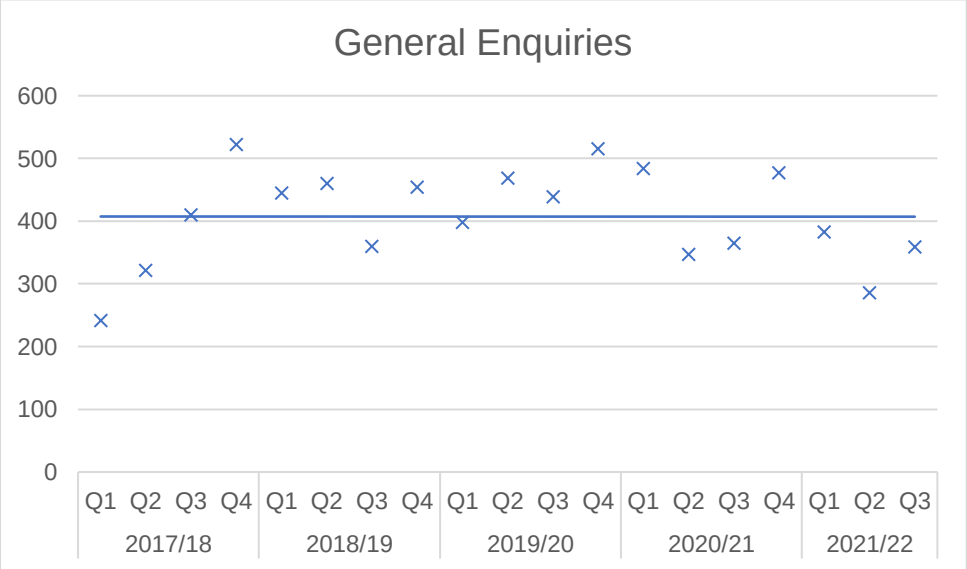
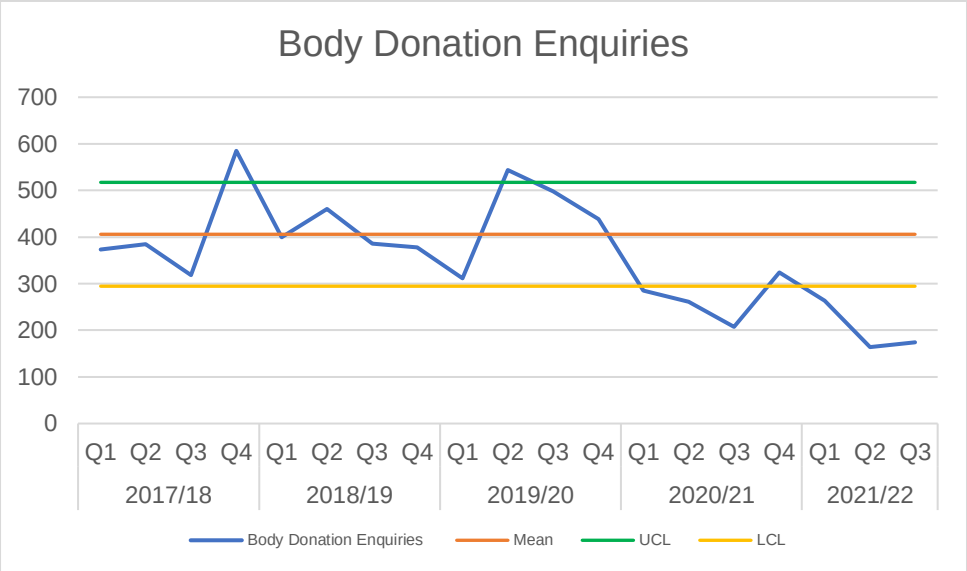
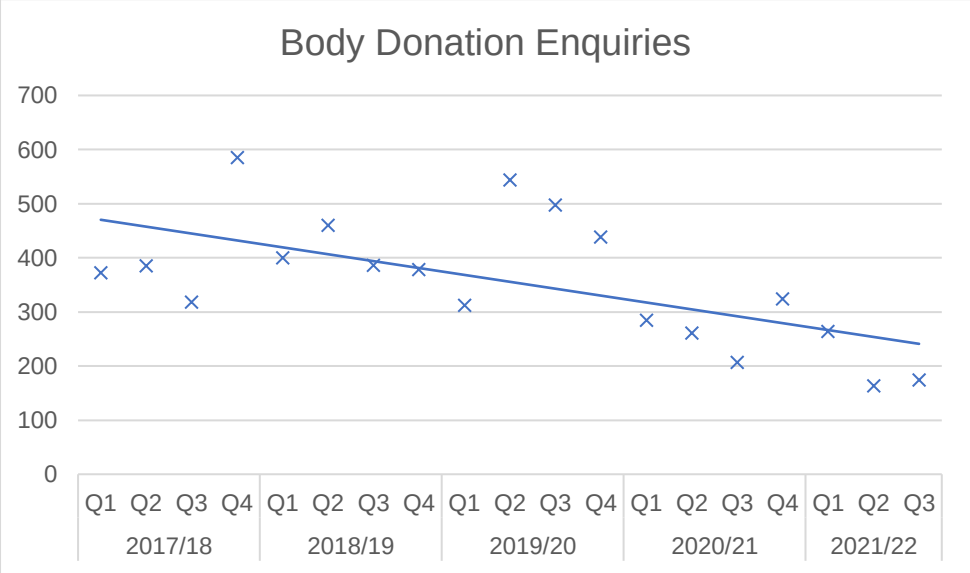


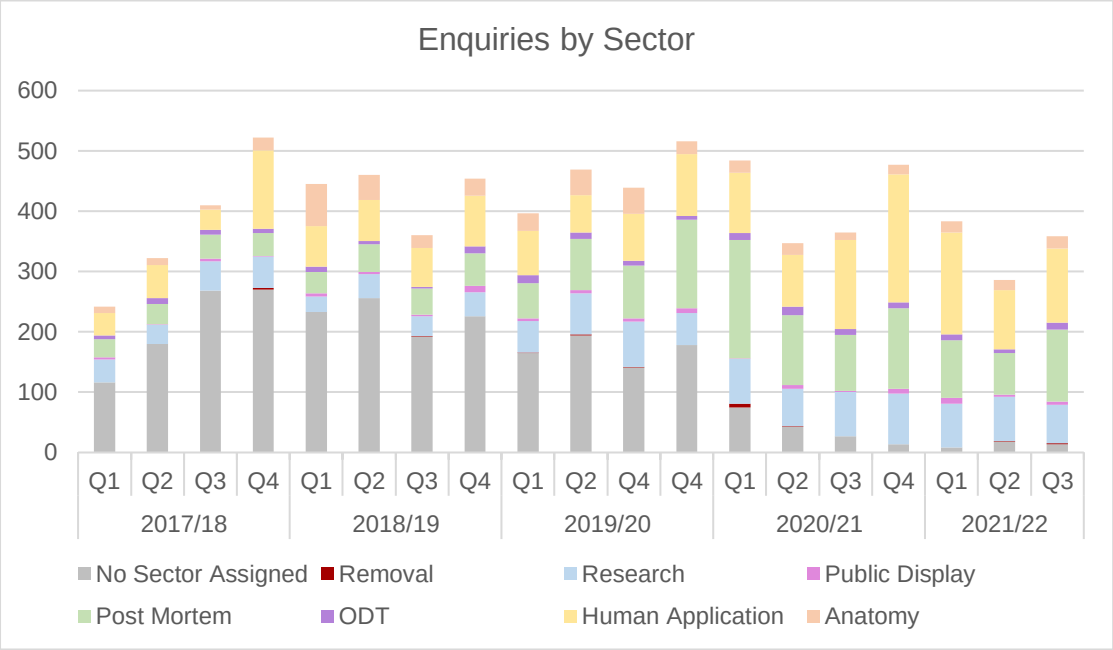
Figure 2: Body Donation enquiries received each quarter





7. Figure 3 displays the breakdown of enquiries by sector. In Q3 2021/22, the majority of enquiries were related to the Human Application sector (34%) and the Post Mortem sector (33%). The drive to increase data completeness of records can be seen from Q1 2020, with the steep reduction in the number of enquiries with no sector assigned.

Figure 3: Enquiries received by sector (excluding body donation enquiries)



Licensing

8. Figures 4 and 5 display the number of main and satellite licences in each sector at the start of each year.

9. Figure 6 displays the trends in the number of licences in each sector. Over the past 5 years, there has been a slight upward trend in the number of licences held in the Research, Human Application and Anatomy sectors. Numbers in all other sectors has remained relatively consistent each year.

Figure 4: Total number of main licences per year

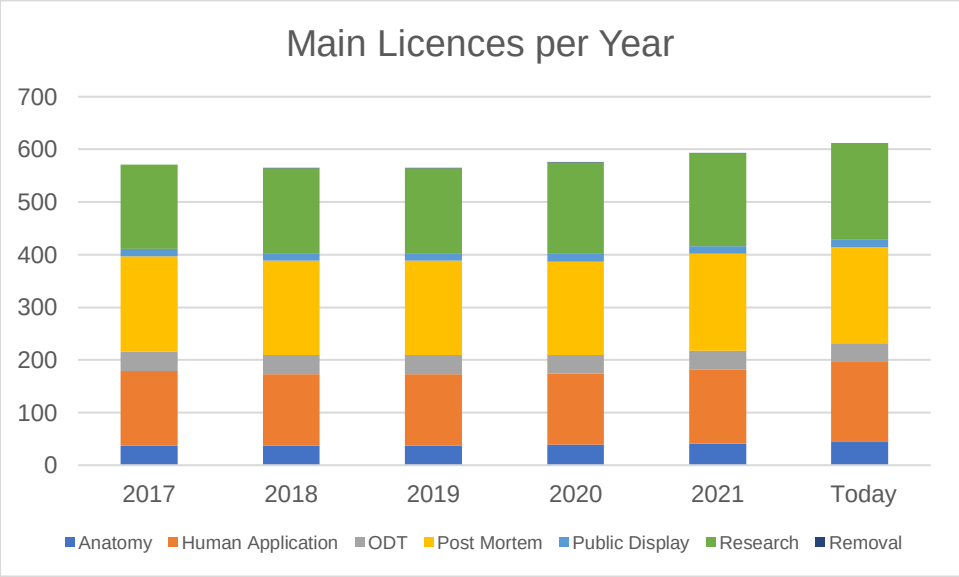


Figure 5: Total number of satellite licences per year

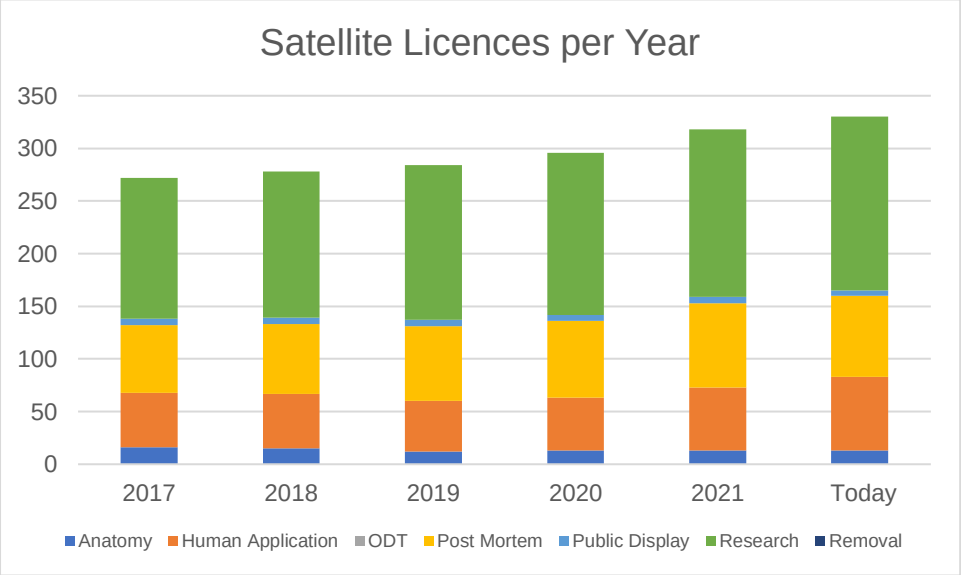
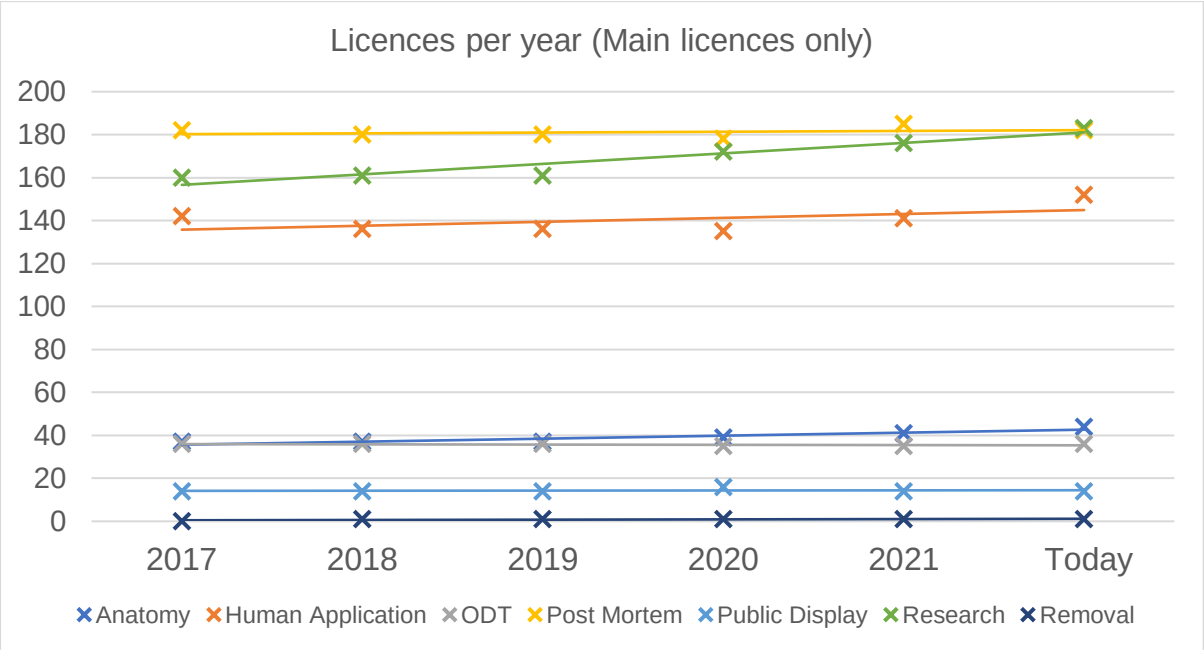


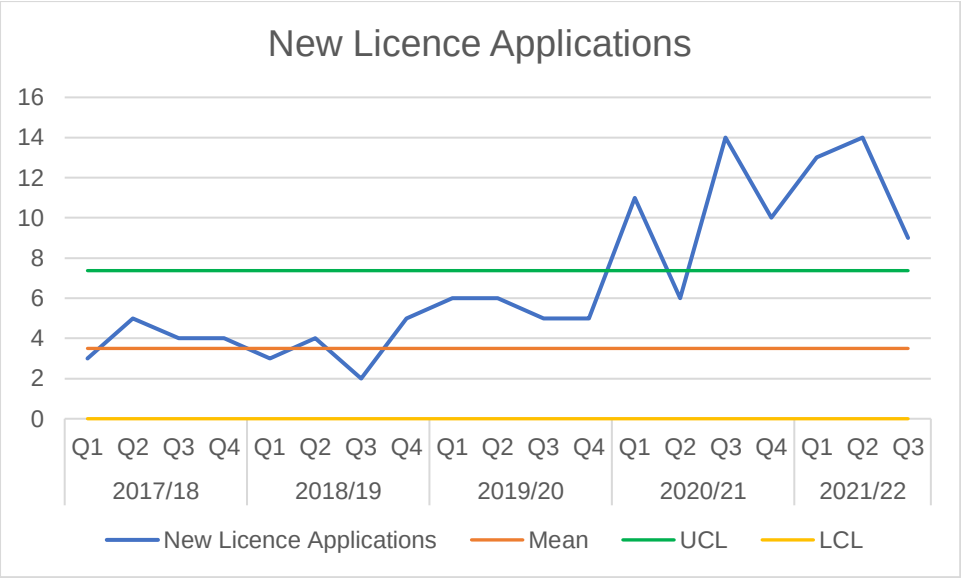
Figure 6: Trends in the number of main licences per year

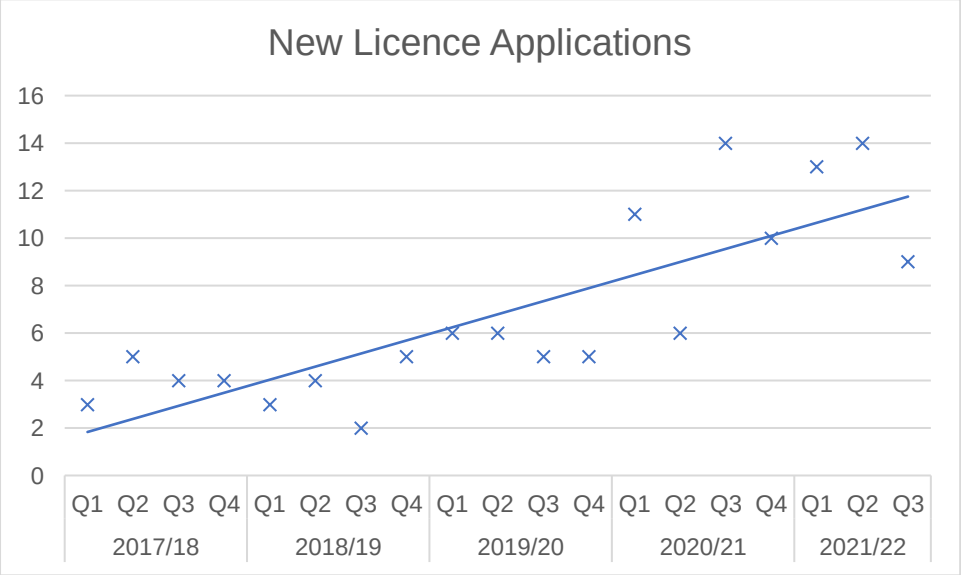


10. Figure 7 displays the number of new licence applications received each quarter. Since Q1 2020/21, there has been a general increase in the number of new applications received each quarter. Emergency mortuary licensing and UK transition related licences are the biggest contributors to this increase in licensing activity. Although Figure 7 displays an increase in activity in processing applications, this does not necessarily reflect an increase in the number of licences in each sector. This is because not all applications are granted and revocations of licences also impact the total number of licences

held. Total numbers of main and satellite licences were shown in Figures 4 and 5 above.

Figure 7: New licence applications received each quarter





11. Table 1 displays the number of new licence applications, new licences offered, satellite additions and revocations in Q3 2021/22.

Table 1: New licence applications, new licences offered, satellite additions and revocations in Q3 2021/22

Sector	New Licence Application	No. of Licence Applications with Decision Made	Satellite Additions	Revocations	Satellite Revocations
Anatomy	1	2	0	0	0
Human Application	3	5	1	1	0
Organ Donation and Transplantation	0	0	0	0	0
Post-Mortem	1	0	1	4	0
Public Display	0	0	0	0	0
Research	4	4	2	0	2
Total	9	11	4	5	2

12. Nine new licence applications were received in Q3 2021/22. For comparison, in 2020/21 we received ten applications per quarter on average.

13. Four applications were received in the Research sector, three applications were received in the Human Application sector, one in the Anatomy sector and one in the Post-mortem sector.

14. Decisions were made on 11 applications, all of which were granted (five in the Human Application sector, four in the Research sector and two in the Anatomy sector).

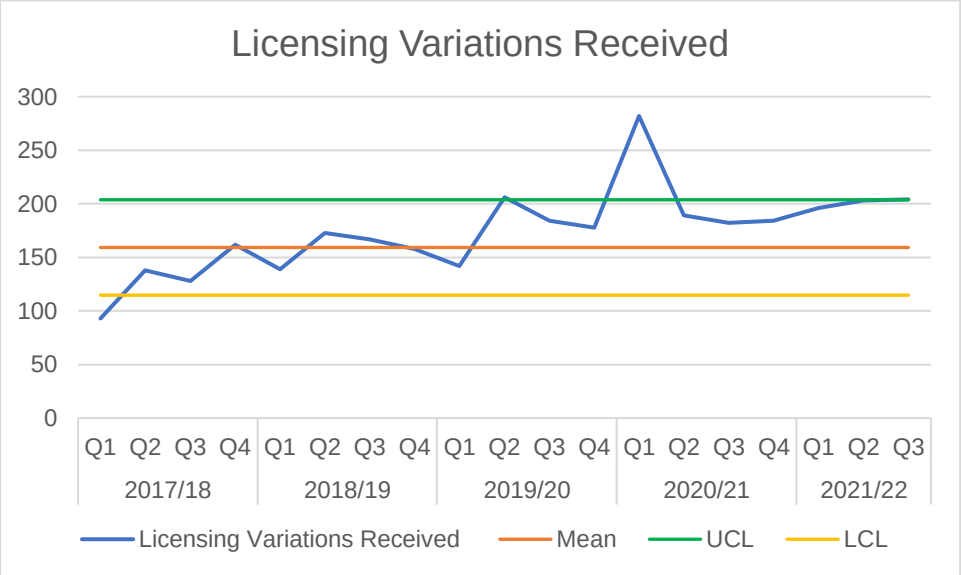
15. There were four satellite additions (two in the Research sector, one in the Human Application sector and one in the Post Mortem sector).

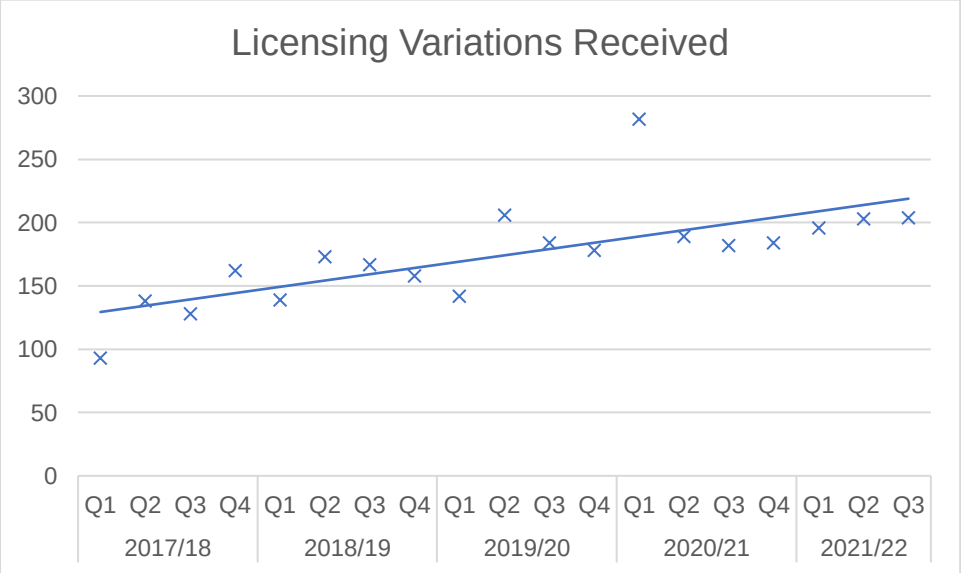
16. Five revocations took place. This included four in the Post Mortem sector and one in the Human Application sector. Two satellite revocations also took place in the Research sector.

Licensing Variations

17. Figure 8 displays the total number of licensing variations received each quarter. A total of 204 licensing variations were received in Q3 2021/22. Volume of licensing variation requests continues to steadily rise this quarter.

Figure 8: Total number of licensing variations received each quarter





Living Donation

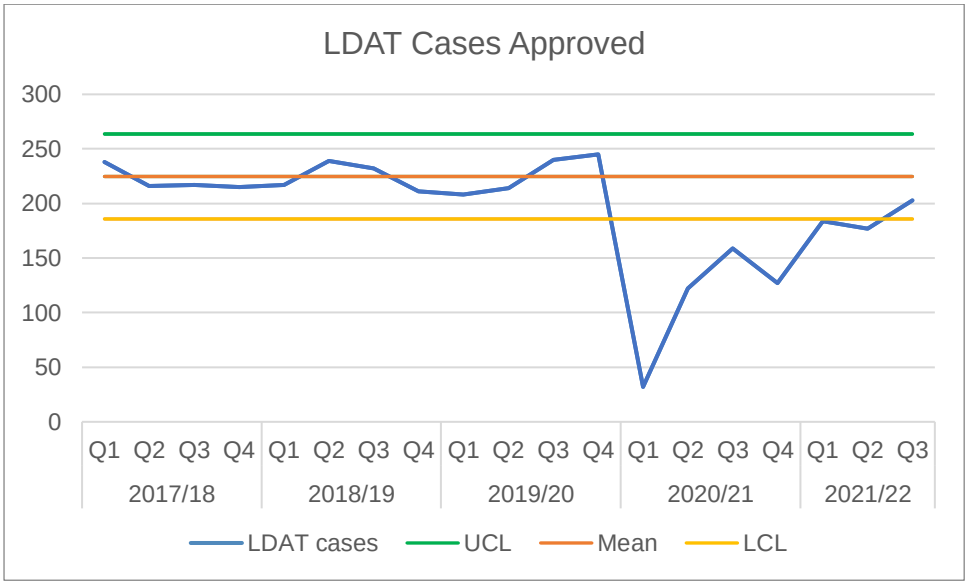
18. Figures 9 and 10 show the total number of living donation cases approved by the Living Donation Assessment Team (LDAT) and panel.

19. In Q3 2021/22, 203 cases were approved by the LDAT and 58 cases were approved by panel. The total number of cases approved also includes those using the emergency out-of-hours process. Both the number of LDAT cases and panel cases approved have continued an upward trend this quarter,

compared to the dip in Q1 2020 at the onset of Covid-19. Case numbers are now close to returning to pre-Covid levels. This is expected to continue as increasing the number of living organ donations is a strategic priority for NHSBT to address the issue of organ supply, as set out in its recently published 10-year strategy.

20. We continue to receive some short notice requests for shorter turnaround times for panel cases. This is primarily to accommodate the deadlines for the NHSBT matching runs where for non-directed altruistic donors, HTA approval is required before the donor can be included in the matching run.

Figure 9: Number of LDAT cases approved per quarter



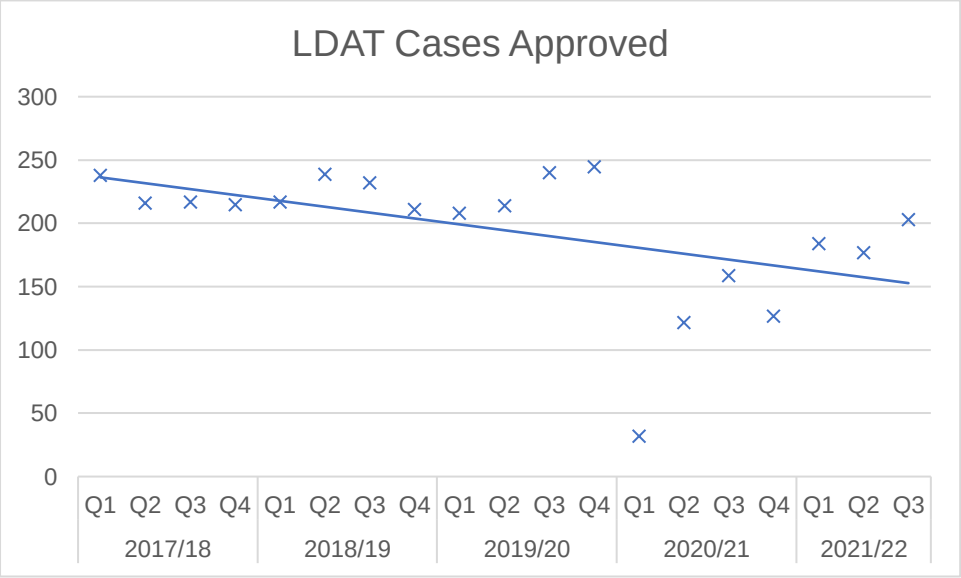
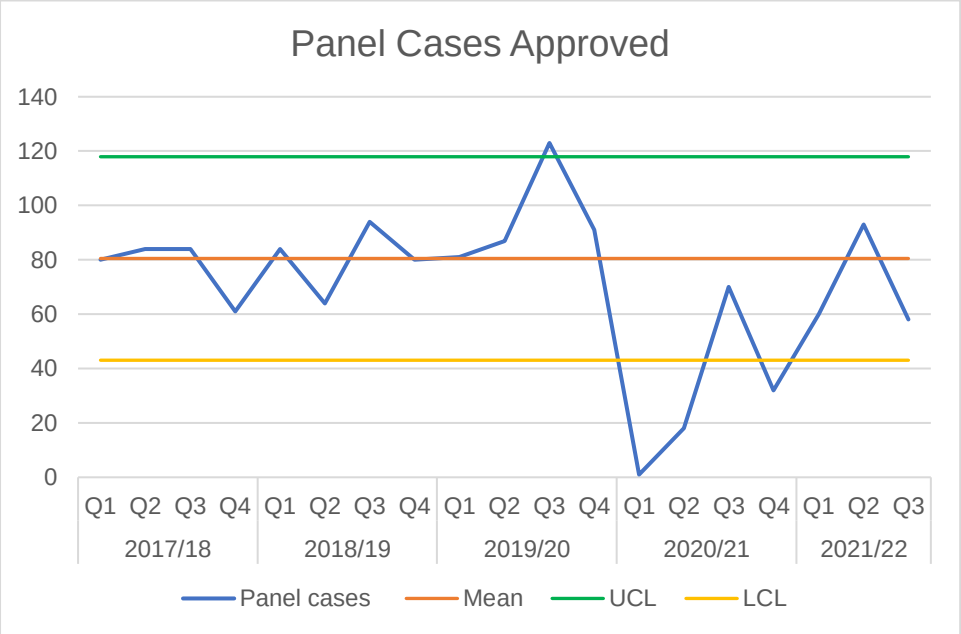
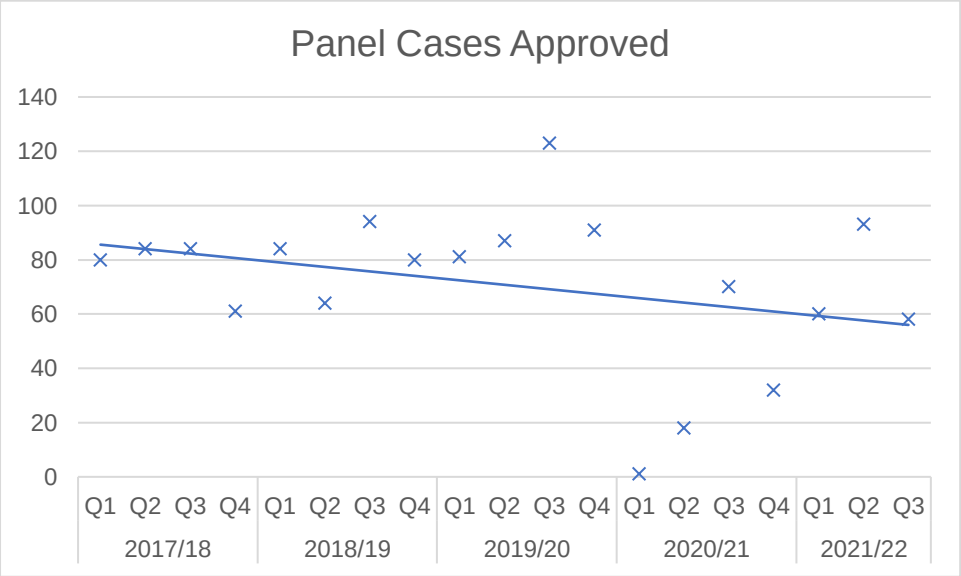


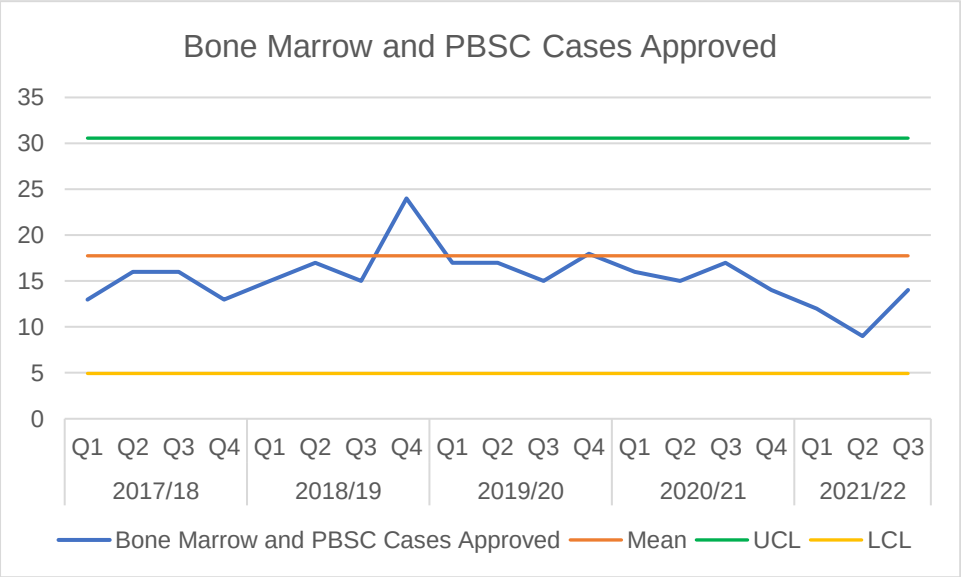
Figure 10: Number of panel cases approved per quarter

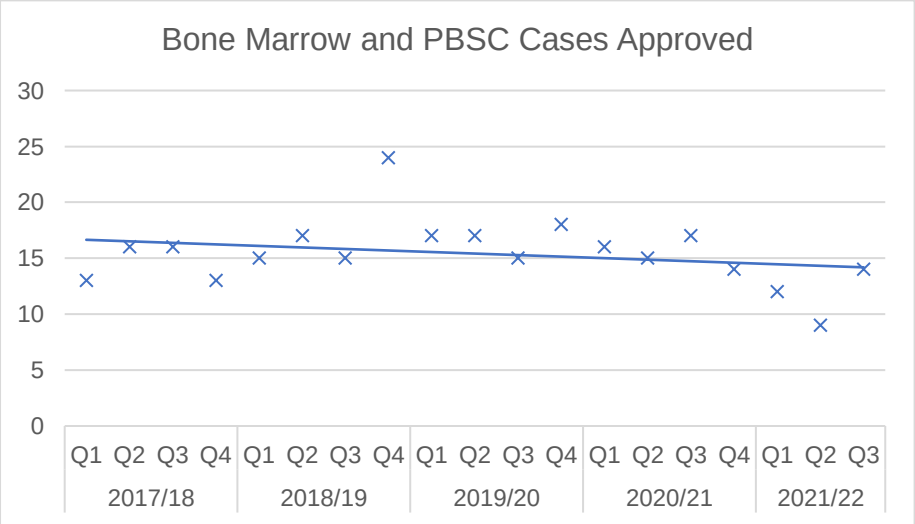




21. Figure 11 shows the total number of bone marrow and peripheral blood stem cell (PBSC) cases approved in Q3 2021/22 compared to preceding quarters. We have seen a slight downward trend in numbers during the pandemic.

Figure 11: Total number of bone marrow and PBSC cases approved



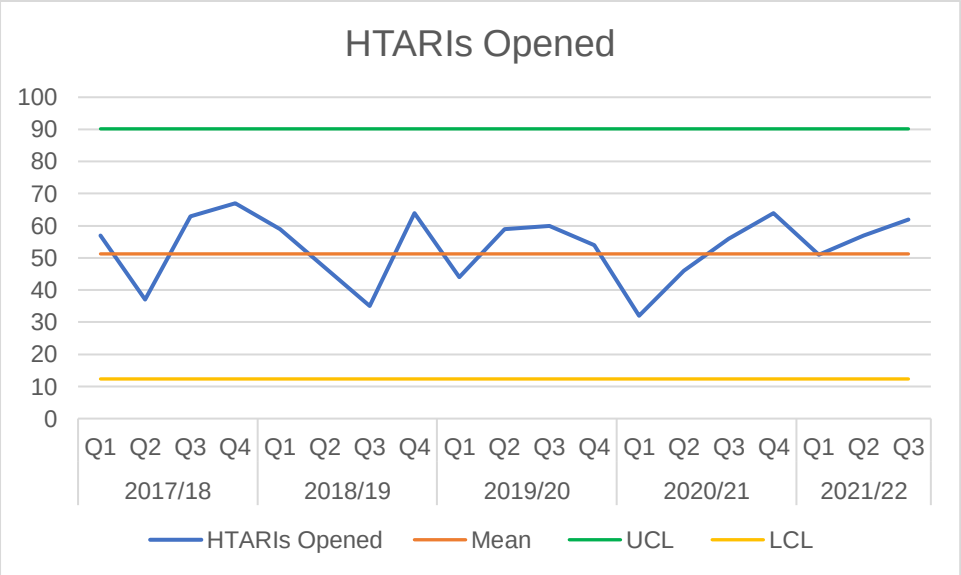


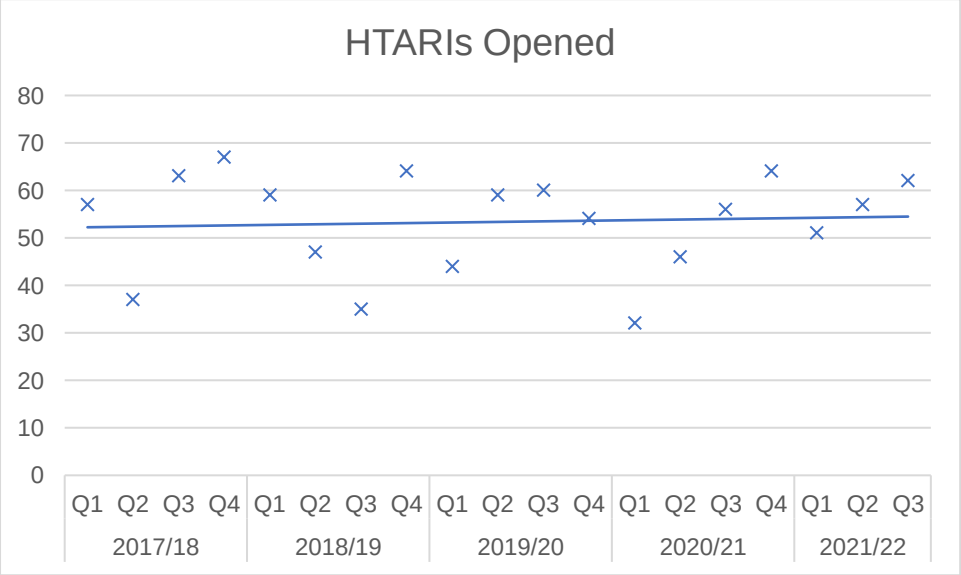
Incidents – HTA Reportable Incidents (HTARIs)

22. Figure 12 displays the number of reported HTARIs in Q3 2021/22 compared to preceding quarters. This also includes any near misses and incidents that may, on investigation, be found not to be reportable incidents. In Q3 2021/22, 62 HTARI cases were opened, compared to 57 cases in the previous quarter.

23. At the end of Q3 2021/22, there were 66 open HTARI cases. Of these, four have been open for longer than six months, the median age of which is eight months.

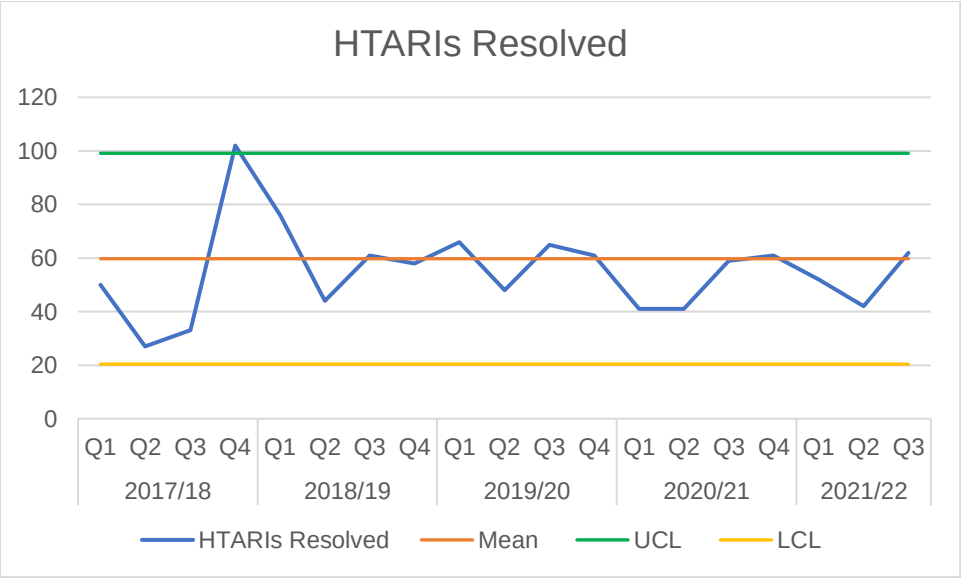
Figure 12: HTARI cases opened during quarter in the Post Mortem sector

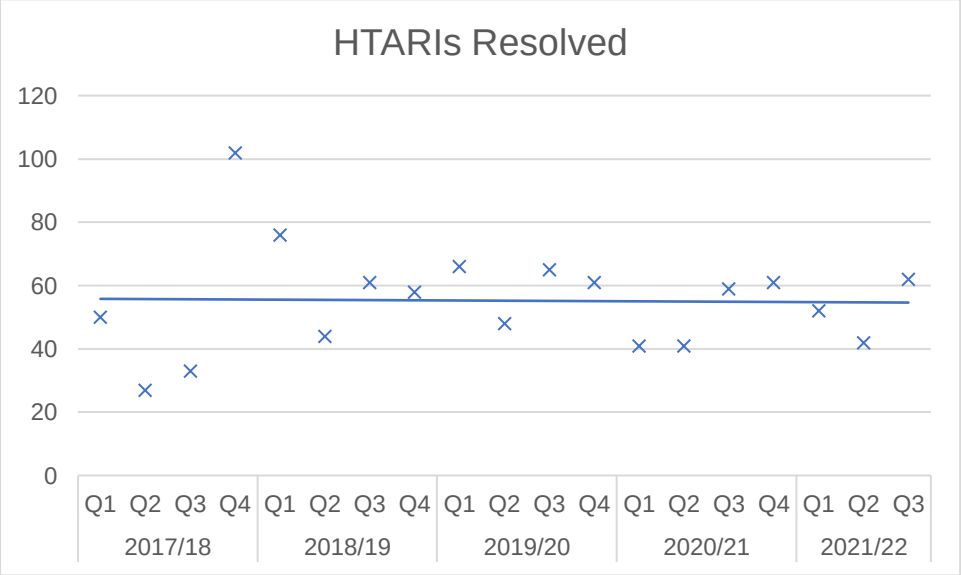




24. Figure 13 displays the number of HTARIs resolved in Q3 2021/22 compared to preceding quarters. 62 HTARIs were resolved in Q3 2021/22, compared to 42 in the previous quarter.

Figure 13: HTARI cases resolved during quarter in the Post Mortem sector



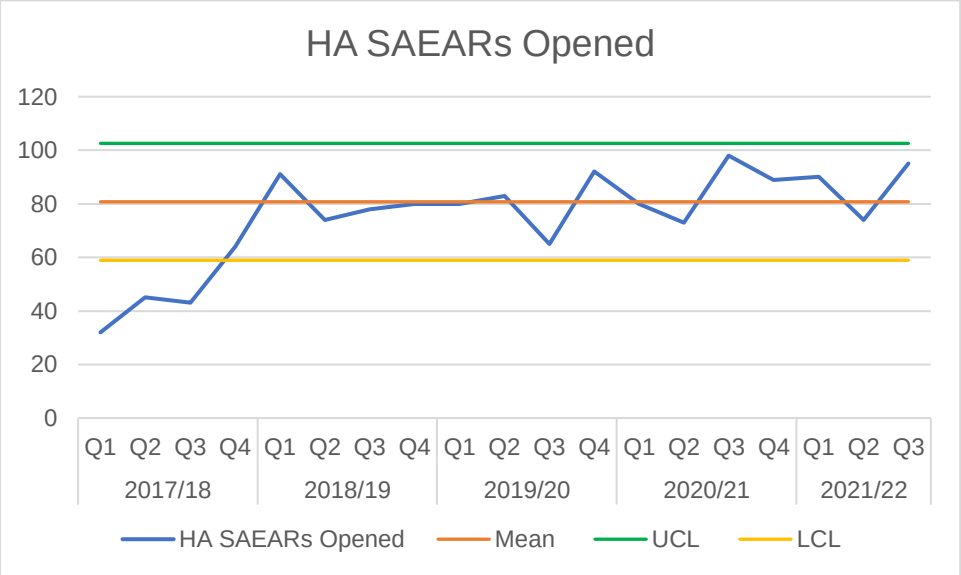


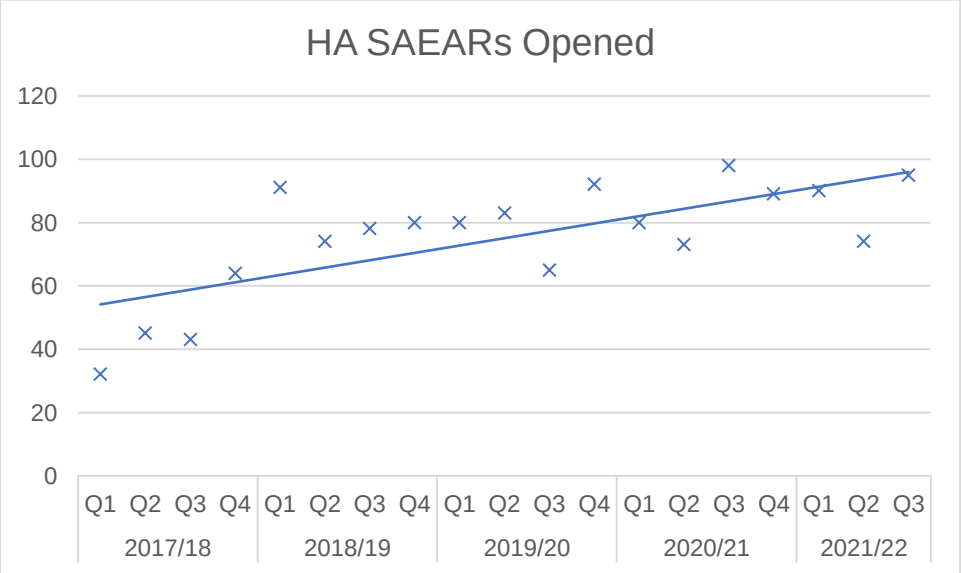
Incidents – Human Application Serious Adverse Events and Reactions (HA SAEARs)

25. Figure 14 displays the number of reported HA SAEARs in Q3 2021/22 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 Q3 2021/22, 95 HA SAEARs cases were opened, compared to 74 cases in the previous quarter.

26. At the end of Q3 2021/22, there were 163 open HA SAEARs cases. Of these, 45 have been open for longer than six months, the median age of these cases is 13.5 months.

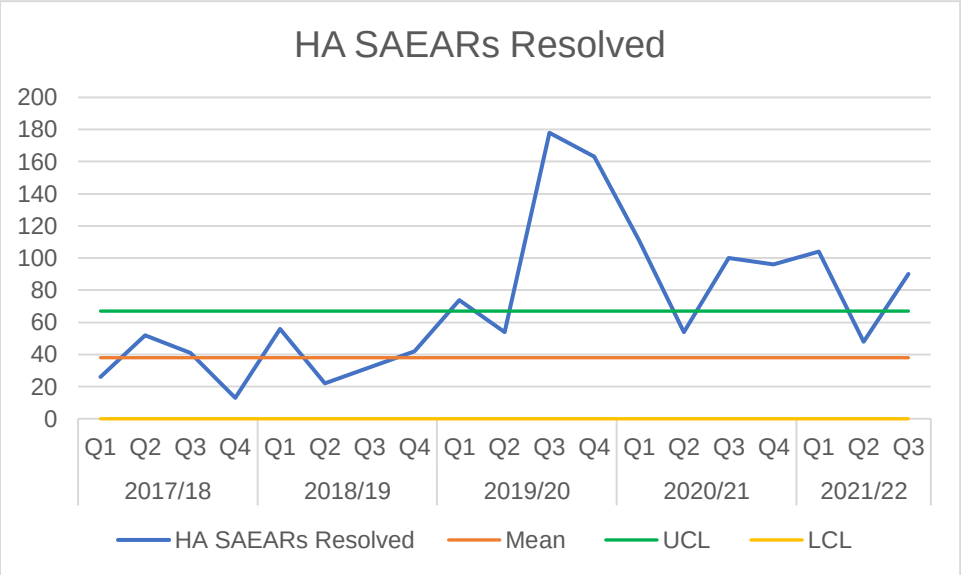
Figure 14: SAEARs opened during quarter in the Human Application sector

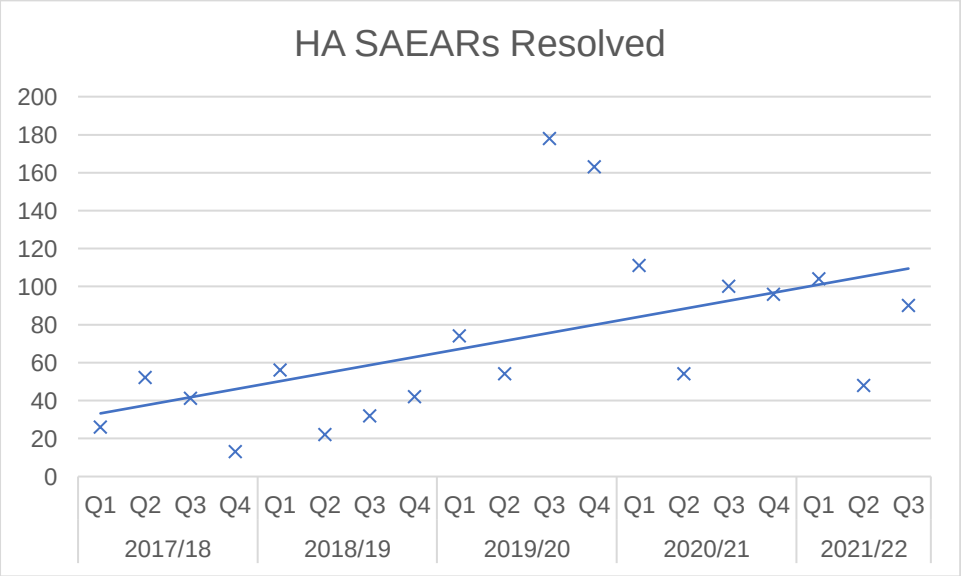




27. Figure 15 displays the number of HA SAEARs resolved Q3 2021/22 compared to preceding quarters. 90 HA SAEARs cases were resolved in Q3 2021/22, compared to 50 cases in the previous quarter.

Figure 15: SAEARs resolved during quarter in the Human Application sector



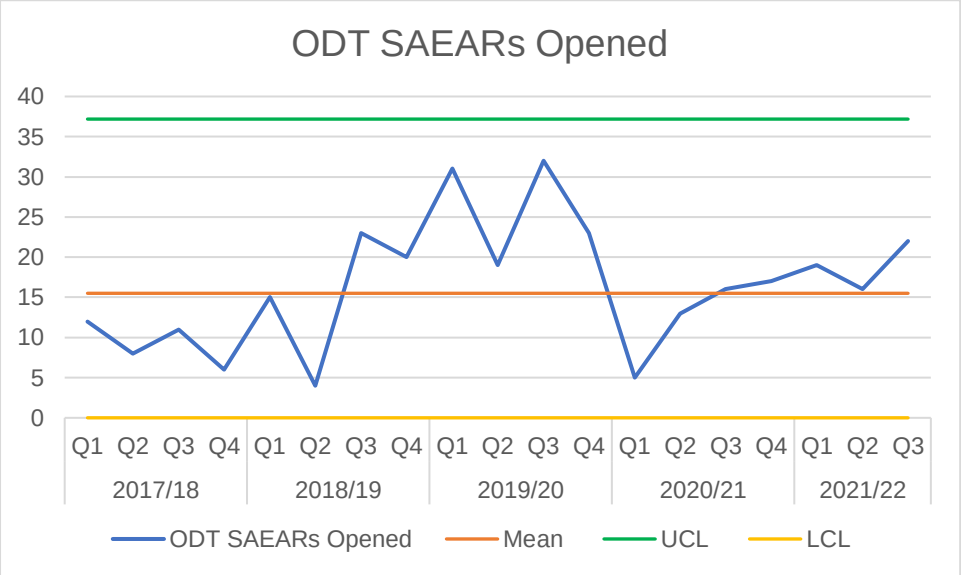


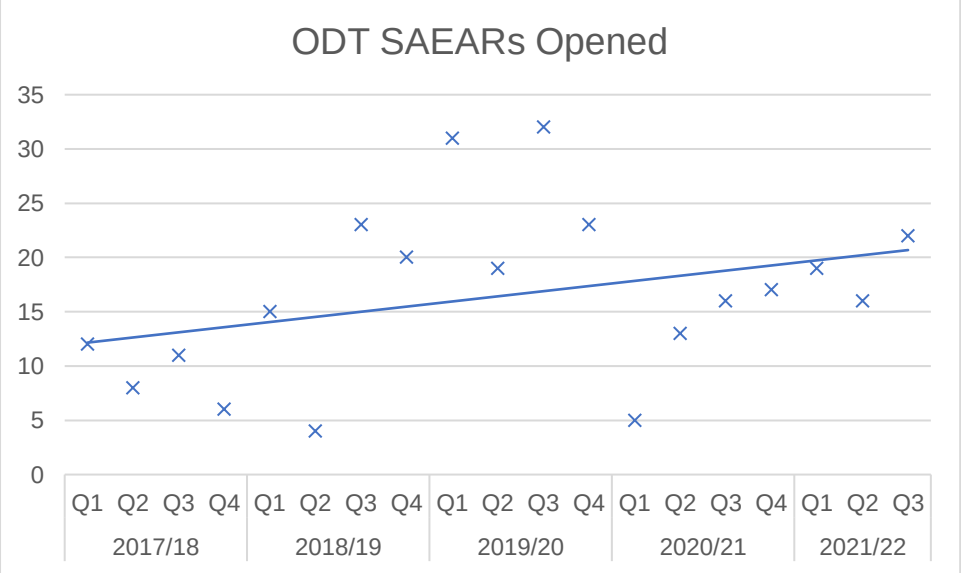
Incidents – Organ Donation and Transplantation Serious Adverse Events and Reactions (ODT SAEARs)

28. Figure 16 displays the number of reported ODT SAEARs in Q3 2021/22 compared to preceding quarters. In Q3 2021/22, 22 ODT SAEARs cases were opened, compared to 16 cases in the previous quarter.

29. At the end of Q3 2021/22, there were 27 open ODT SAEARs cases. Of these, one has been open for longer than six months, the age of which is 10 months.

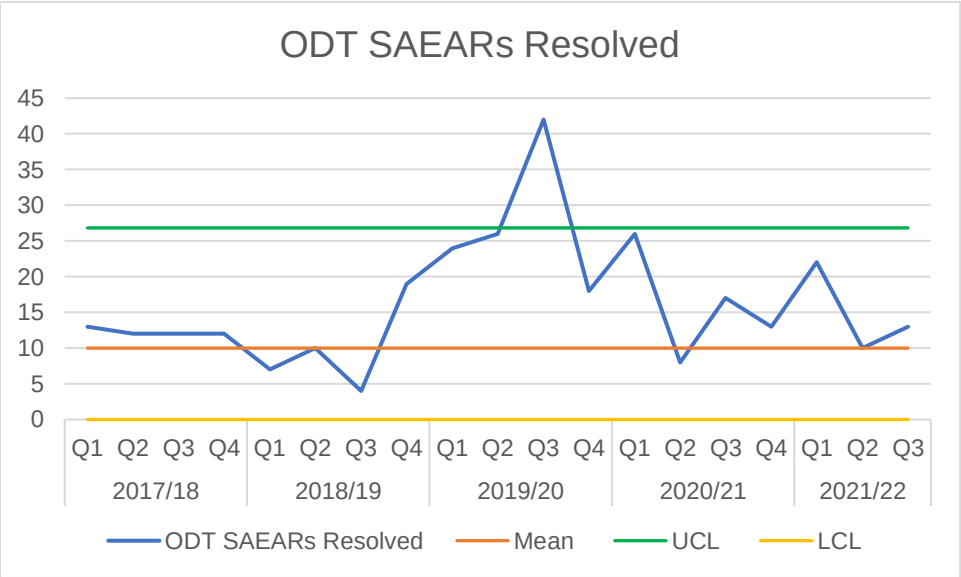
Figure 16: SAEARs opened during quarter in the Organ Donation and Transplantation sector

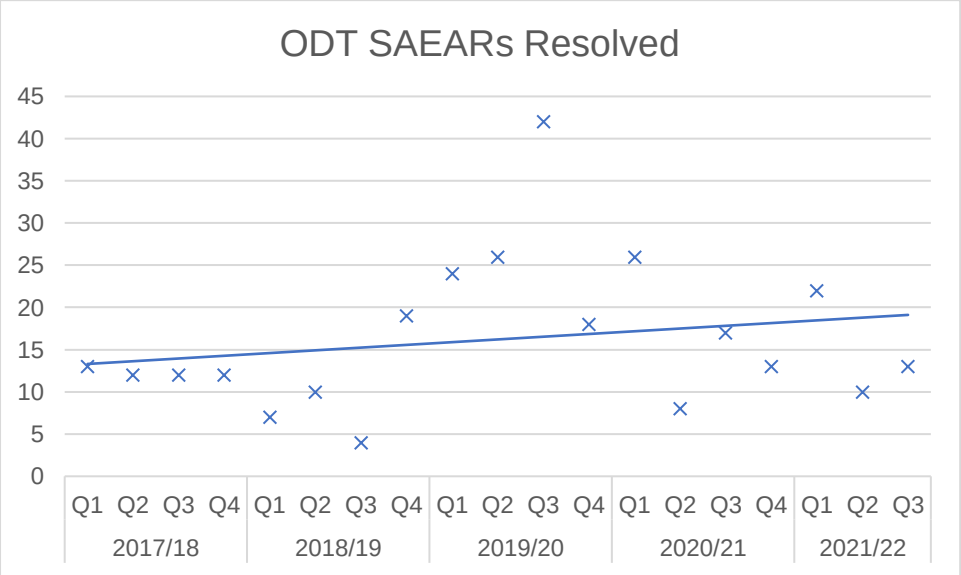




30. Figure 17 displays the number of ODT SAEARs resolved in Q3 2021/22 compared to preceding quarters. 13 ODT SAEARs cases were resolved in Q3 2021/22, compared to 10 cases in the previous quarter.

Figure 17: SAEARs resolved during quarter in the Organ Donation and Transplantation sector

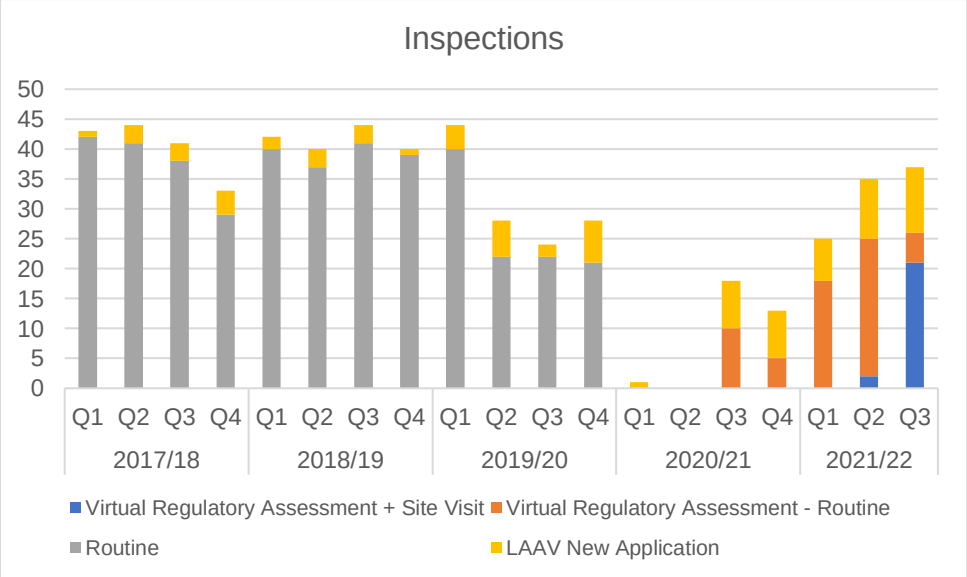




Inspections

31. Figure 18 displays the number of inspections, including Virtual Regulatory Assessments (VRA's), conducted each quarter. The number of inspections conducted this quarter is getting close to pre-Covid levels. In addition, this quarter the number of inspections with a site visit component has increased compared to the previous quarter. Routine site visits are those scheduled in advance in accordance with our internal risk profiling, as opposed to short-notice or unannounced site visits or inspections that may be undertaken to address specific risks, outside of the routine scheduling process.

Figure 18: Inspections carried out each quarter



Corrective and Preventative Action Plans (CAPAs)

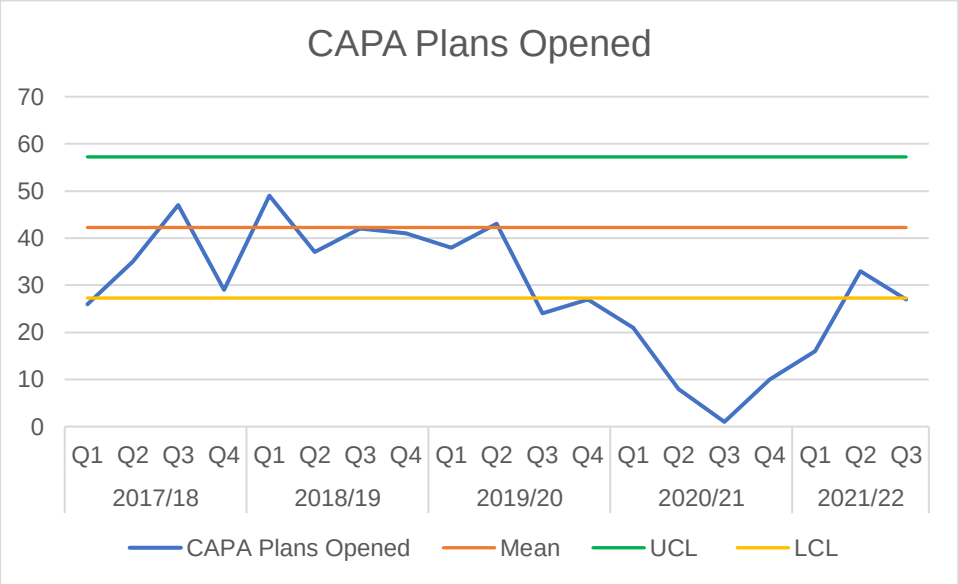
32. Figure 19 and Figure 20 displays the number of CAPA plans opened and closed during Q3 2021/22, compared to previous quarters. The number of CAPA plans opened includes those opened as part of new licences offered, and investigations.

33. A total of 27 new CAPA plans were opened this quarter. This includes 18 opened in the Human Application sector, five opened in the Post-Mortem sector, three opened in the Research sector and one opened in the Anatomy sector.

34. The distribution in Figure 16 demonstrates the correlation between higher rates of CAPA plan opening with higher levels of assessment and licensing activities as a result of inspections and UK Transition-related licensing work.

35. A total of 15 CAPA plans were closed in Q3 2021/22 including ten in the Human Application sector, two in the Post-Mortem sector, two in the Research sector and one in the Anatomy sector.

Figure 19: Number of CAPA Plans opened during quarter



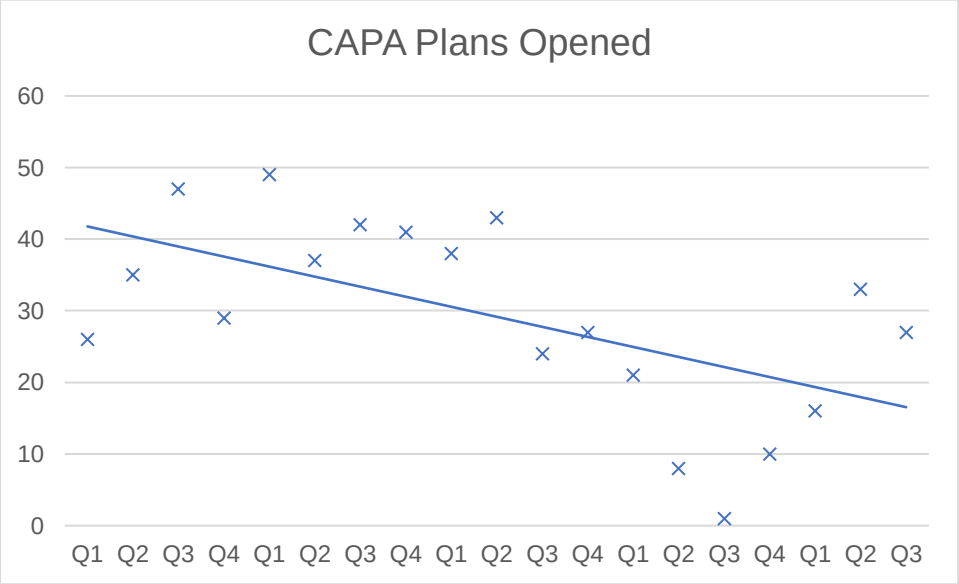
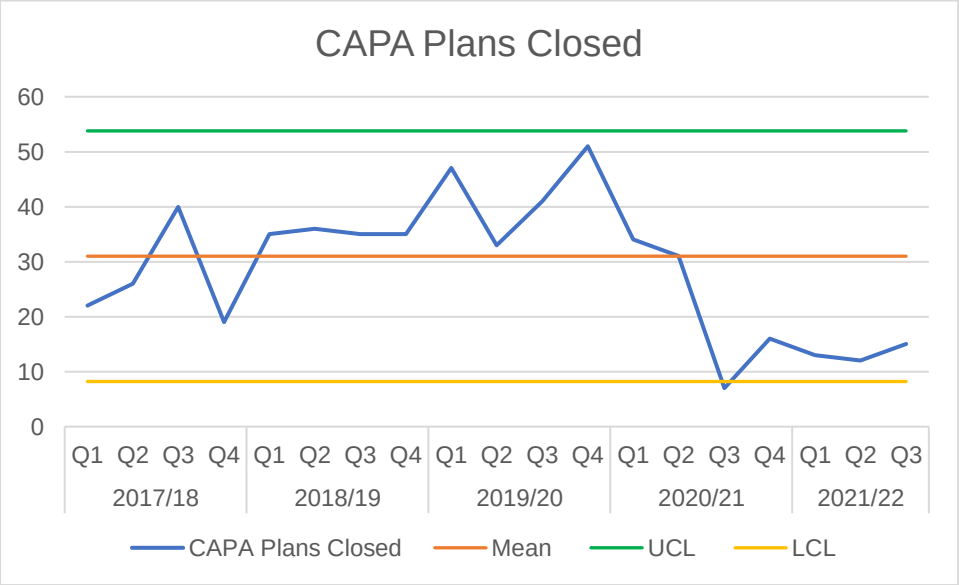
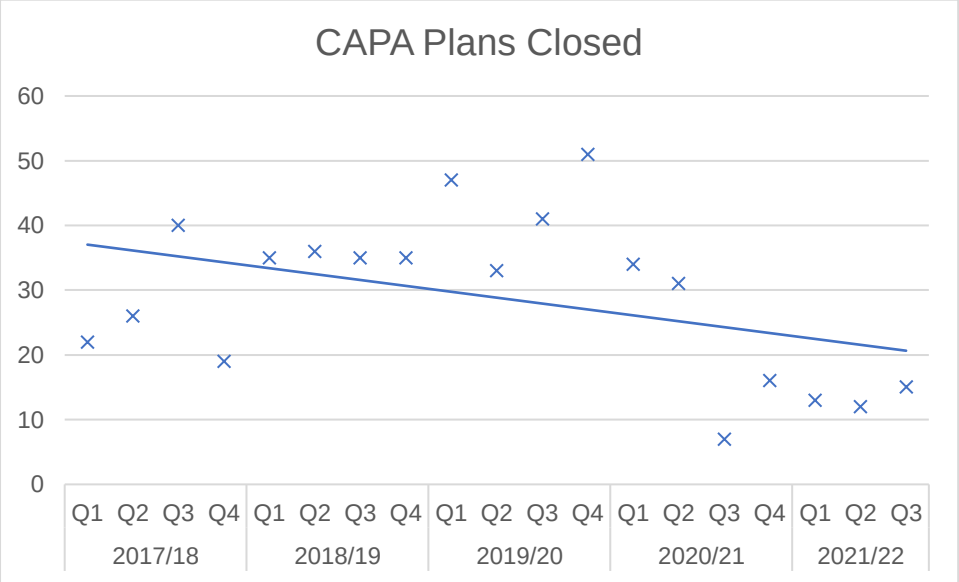


Figure 20: Number of CAPA Plans closed during quarter





36. Table 2 shows all open CAPA plans at the end of Q3 2021/22 and the length of time they have been open.

37. There were a total of 50 CAPA plans open at the end of Q3 2021/22. 41 CAPA plans have been open for less than six months, the median age of which was one month. Four CAPA plans have been open between 6-12 months, the median age of which was six months. Five CAPA plans have been open for longer than 12 months, the median age of which is 22 months.

Table 2: All Open CAPA plans

Open CAPA Plans	Anatomy	Post-Mortem	Human Application	Research	Public Display	ODT	Total	Median (months)
< 6 months	1	10	27	3	0	0	41	1
6-12 months	0	0	4	0	0	0	4	6
> 12 months	0	1	4	0	0	0	5	22
Total	1	11	35	3	0	0	50	N/A

Latest review date – 13/01/22

Strategic risk register 2021/22
Risk summary: residual risks

Risk area	Strategy link*	Residual risk	Status	Trend**
R1: Failure to regulate appropriately	Delivery (a-d & f) and Development (a-d) objectives	**10 – Medium**	At tolerance	⇔⇔⇔⇔
R2: Failure to manage an incident	Delivery, Development and Deployment objectives	**9 - Medium**	Above tolerance	⇧⇔⇔⇩
R3: Failure to manage expectations of regulation	Delivery e) and Development c)	**9 - Medium**	At tolerance	⇔⇔⇔⇔
R4: Failure to utilise our capabilities effectively	Delivery, Development and Deployment (a, c, and d)	**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 Development Programme	Development (a-d) objectives	**9 - Medium**	At tolerance	⇔⇔⇔⇔

* Strategic objectives 2019-2022:
** This column tracks the four most recent reviews by SMT (Senior Management Team) (e.g.⇧⇔⇩⇔).

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

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	5	15 - High	**2**	**5**	**10 - Medium**
Tolerance threshold:					**10 - Medium**

Commentary
At tolerance. We have a good regulatory framework, with a strong assured position on our key regulatory processes from an Internal Audit review within the past two years. Activity in the PM sector is now stable with no current activity on emergency mortuary licensing. The pilot temporary licensing of a very small number of funeral directors' premises to support national public health post-mortem Covid surveillance sampling has not expanded, with only 4 sites active. SMT are considering our approach to this pilot project. Quarter 3 has seen a full schedule of inspections, using either VRAs and / or site visits, this is broadly in line with pre-pandemic activity and this level of activity is planned to continue through quarter 4 We continue to use all other regulatory tools and processes, such as managing and responding to incident reports (Serious Adverse Events and Reactions and HTA Reportable Incidents), whistleblowing / informant information and ongoing engagement with our regulated sectors, with investigations and active regulatory action having continued. We continue to actively manage a small number of more unusual regulatory matters with establishments SMT believes this risk remains stable, at tolerance, in January 2022.

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

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

Commentary
This risk concerns our ability to respond to incidents irrespective of their nature or cause, which could be from matters outside the HTA's remit or control as well as matters for which we are directly responsible. The Executive has therefore set a lower tolerance level on this risk as our ability to respond appropriately is within the HTA's control. The HTA believes that our incident management response plans have been well tested and found to be robust and effective through their deployment in managing the impact of the pandemic and related restrictions and in their adaptation for use in managing the potential impacts of EU Exit following the end of the Transition Period. We have continued to use these arrangements in preparing and managing the potential consequences of an incident that occurred at an HTA-licensed establishment which, although not a regulatory matter, has required significant HTA resource. This incident has placed continued demands on senior management, particularly since the departure of the CEO at the end of October 2021. The incident also placed significant impact on our Communications / Media team, in addition to those leading the relevant sector. SMT notes that our arrangements have stood up well to the most critical phase of this incident although there have been inevitable impacts on the delivery of some strategic activities within the communications team. Having increased the risk scoring in July we are now of the opinion that the likelihood of this risk materialising has subsided – we now score this risk as 9 - Medium.

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

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

Commentary

At tolerance.

We continue to communicate our remit and advise where appropriate. There is ongoing dialogue with DHSC (Department of Health and Social Care) and stakeholders regarding the announced Independent inquiry and we provide clear lines to the media when necessary. Although this has been a challenging area of work, we believe it has been managed well over the last quarter.

In 2020/21, the Development programme included a specific workstream to strengthen horizon scanning on emerging changes to policy and activities where the HTA may be required to act or offer an authoritative voice. This approach has been embedded in 2021/22 alongside the piloting of alternative and additional approaches to engagement.
We continue to support the wider Government agenda to encourage development and innovation across UK life sciences and contribute to work looking at better regulation across all sectors of UK business. In late quarter 2/ early quarter 3 the HTA convened round table discussions with key external stakeholders. These sessions represented the first of a series of roundtables aimed at supporting innovation and growth in the life sciences sector. The first two roundtables were focused on issues raised over retention of tissue blocks and slides from coronial post-mortems for research and on supporting innovation in the Human Application sector.
The HTA have submitted areas of potential legislative change to the Department in response to requests and this, should it be taken forward, would clarify and strengthen the HTA's remit going forward.

The HTA supported the UK Health Security Agency's pilot project to test the feasibility of post-mortem surveillance sampling for COVID-19 through the licensing of a small number of Funeral Directors in one region. The HTA is in discussion with the UKHSA about the future direction of this work as most of these few fixed term licences are due to expire before 31 March 2022.
All these matters are being actively managed. SMT note that the critical incident, which could have led to significant misperception of the HTA's role has not so far done so and appears not to have had a detrimental impact on the HTA's reputation.

At their January meeting SMT agreed this risk remains unchanged, at tolerance.

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

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

Commentary

Above tolerance.

From Quarter one of 2021/22, the HTA started implementing a partial organisational redesign to address capability gaps identified during the previous year and has started an ambitious recruitment campaign for 10 posts including that of a Deputy Director adding further support and resilience to the Senior Management Team. By August 2021, appointments had been made to seven and a half posts, with plans to progress the recruitment to the remaining 2.5 Wte in Q3 2021/22. Progress in the recruitment to the remaining posts has been consciously paused to facilitate input from the incoming CEO to both roles and future organisational design.

Key vacancies remain relating to the planning and portfolio manager and Chief Information & Technology Officer. Interim appointments have been made to both posts and will be subject to a review and update in Quarter 4.

The combined pressures of the critical incident and vacancies led to the need to reprioritise activity across Quarter 3, as captured on other risks this has had some implication for strategic delivery in relation to communications and the development programme. A renewed focus on the business plan for Quarter 4 recognises and prioritises key activities across Quarter 4 that are either in direct support of current business activity or are dependencies for ongoing project activity which will continue in the next business year.

Recruitment and retention remain a key priority for the HTA. The HTA's new Chief Executive, Dr Colin Sullivan, began his new role on 1 January 2022 and this is clearly a key mitigator of some organisational risk. Although some key vacancies remain unfilled on a permanent basis progress continues to be made and key roles in Communications, Business Planning and IT have interim resource in place and activity is underway to continue with recruitment in quarter 4.

This risk was increased during Quarter 3, and although still above tolerance SMT believe this risk has reduced since the last review and will continue to do so over this quarter.

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

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
4	5	20 – High	**3**	**2**	**6- Medium**
Tolerance threshold:					**3 - Low**

Commentary
Above tolerance. Our financial review at the end of Quarter 3 provides assurance that expenditure for the full year will be in line with budgets. We forecast a balanced year end position, with risk more likely to see small underspends emerging if planned activity cannot progress as planned. We await a further commission from the Department regarding the 2021 Spending Review, we do not anticipate specific savings measures for 2022/23, but are mindful that some reductions in our Grant in Aid could be required across the SR period given the tight settlement provided for the core departmental and ALB activity. Recommendations on 2022/23 fees were discussed and Board agreement reached on fee levels at the November Board meeting. Although CPI has increased significantly since this agreement any upward pressure on the HTA's expenditure for 2022/23 will be dependent on the availability and scale of any public sector pay award remit in 2022. Continued inflation and current levels could result in more significant pressures from 2023 onwards. SMT have agreed that this risk is unchanged.

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

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

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

Reviews and revisions

(11/03/21) SMT review March 2021

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

(30/03/21) SMT review March 2021

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

(29/04/21) SMT review April 2021

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

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

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

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

(09/07/21) SMT review July 2021

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

(06/08/21) SMT review August 2021

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

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

(09/09/21) SMT review September 2021

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

(18/11/21) SMT review November 2021

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

(13/01/22) SMT review January 2022

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

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 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.

HTA 1c/22 Annex C - NEW - HTA Strategic Risk Register 2021-22

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 (e.g. through site visit inspections and sector engagement) and reactive tools (such as responding to incidents reported to the HTA, investigations of concerns raised etc). Process for consideration of police referral maintained and used. Annual collection of activity data in HA sector; biennial collection of compliance updates data from other sectors.			Following the suspension of routine site visit inspections at the onset of Covid-19 pandemic restrictions, work was undertaken in 2020/21 to develop a risk assessment and a virtual regulatory assessment tool. VRAs are now incorporated into business alongside a decision making framework to inform decisions about whether to undertake a site visit, VRA or hybrid inspection. Development Programme-led activity from 2020/21 to develop a new Target Operating Model to re-state and clarify the key elements in our approach to regulation. A full inspection timetable has been implemented from quarter 3 of the 21/22 business year.		X			Preventative	Board developed and approved the current HTA Strategy and was aware of the risks and opportunities associated with the suspension of routine site visit inspections during Covid restrictions and how VRAs were being incorporated into BAU. Board were aware of the issue of failing to meet the legal obligation to carry out a site visit of HA establishments at least once every two years because of the suspension of routine site visits during Covid. SMT agreed late May 2021 to resumption of routine site visits in HA sector once restrictions are lifted, alongside continuing use of VRAs. Routine site visit elements are now being included in HA inspections, although some are VRA only, determined on a risk-based approach. Continuing use of all other regulatory tools during the pandemic restrictions, including managing HTARIs and SAEARs, investigations, advice to regulated sectors (such as seminars in Anatomy sector, Professional Newsletters). Development and use of emergency mortuary licensing regime during the pandemic, including use of virtual assessment techniques.	In-depth evaluation of pilot programme of 10 x virtual regulatory assessments in the HA sector in quarter three 2020/21 carried out and reported to the HTA Board Meeting February 2021 and a further evaluation of the expansion into remaining sectors in summer 2021. VRAs incorporated into BAU in all sectors, as evidenced in Business Plan and inspection schedule. Internal Audit late Quarter 3 / early Quarter 4 2020/21 on 'Inspection Process during Covid-19' - report agreed late May 2021; Moderate assurance; considered by ARAC; all actions now complete (per ARAC Quarter 3 2021). Renewal of some emergency mortuary licences although most have now been revoked as no longer required. SMT consideration of request by UKHSA to extend the small number of Funeral Director removal licences (for post-mortem public health surveillance for Covid-19) agreed on basis of bringing them into a normal regulatory regime ie LAAV, open-ended licences funded by appropriate fees. (Head of Regulation written to UKHSA Project Lead 21 Dec. 2021.) Police referral made late 2019/20 has been investigated by the police, supporting Witness Statements provided by the HTA, decision pending with CPS.
						Regulatory decision making framework			Heads of Regulation using dashboards to track open cases and ensure there is effective follow-up, in accordance with the HTA's decision-making framework.		X			Preventative	Reports summarising numbers of Regulatory Decision Meetings included in monthly performance pack and recorded in CRM. Case Review Meetings all summarised in CRM.	Satisfactory Internal Audit Report (strong assurance) November 2020. Lessons learned from Regulatory Decision Meetings (RDMs) held January 2020 and used to inform update to Regulatory Decision Making SOP. Regulatory Decision Making SOP updated February 2020. Evidence of regulatory decision making framework being used in practice e.g. Case Review Meetings recorded in CRM, numbers of RDMs reported in monthly performance data pack.
						Annual scheduled review of Strategy					X	X		Preventative	Outputs from annual strategy review translate into revised annual Strategy	Annual Board Strategy session held 27 April 2021 informed annual strategy refresh. Latest update of HTA Strategy published November 2021.
						The HTA has produced a detailed business plan for the remainder of the year. These plans are approved by SMT and balance core regulatory functions, development priorities and resource deployment considerations.			In the continuing absence of a role with specific responsibility for the business plan, SMT and their respective Heads have ensured there is regular review and updating of the operational business plan and monthly performance pack. Consultancy-led review developed a portfolio management approach that SMT could adopt, including some initial tools. Interim Portfolio Planning Manager (contractor) appointed on short-term contract to develop and implement this new approach, between December 2021 and February 2022.		X	X		Preventative	Operational business plan for 2021/22 (using Excel spreadsheet template developed in 2020/21) in use and reviewed regularly by SMT. Contractors engaged Quarter 1 2021/22 to support development of business planning through adoption of a portfolio management approach. 2020/21 narrative Business Plan for 2021/22 published during Quarter 3 (Covid-related delay).	Progress on the Portfolio Management approach regularly discussed at SMT meetings. SMT receives monthly reports of Management Information for review and action. Interim Portfolio Planning Manager appointed December 2021.

				Well established processes support our core regulatory business.		Development and introduction of new regulatory process (VRA) managed as a project with Director of Regulation as SRO, Head of Regulation (for Research and Anatomy) as Deputy SRO, and a RM as Project Manager. Project now in process of closure with formal closure report to be discussed by SMT in January 2022. Post-closure actions are in hand. (December 2021.) Detailed evaluation carried out on two occasions, prior to adoption in HA sector and expansion into other sectors. Completion of further management actions identified by Internal Audit of effectiveness of the inspection process by Quarter 3 2021. (Reviewed by ARAC.) (Principally ensuring other regulatory processes and documentation (SOPs) were updated to take account of VRAs.)				X	Detective	Internal audit conducted on Key Regulatory Processes late 2018/19, receiving substantial assurance and noting good areas of best practice. Internal audit on the Inspection Process during Covid-19 conducted late 2020/21 - see R4. Moderate assurance and management actions complete, as noted by ARAC Quarter 3 2021.	Internal Audit 2019: Final report received April 2019 and showed substantial assurance. The 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. Internal Audit 2021: low priority actions all complete by Autumn 2021.
				Quality management systems								
				HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model		The HTA's Quality Manager left in 2019/20 and has not been replaced. This function has not been formally re-allocated. A Regulation Manager with experience in QMS continues to coordinate activities to ensure policies are reviewed and updated, with input and support from the Quality Forum as relevant.			X			Preventative/ Monitoring	Management oversight and reporting trough the monthly performance pack. This work had been expected to transfer to a newly created role during Quarter 2 2021/22 but this has not happened, hence the RM is still coordinating this work.	Limitations in QMS still remain. Scheduled reviews have now been re-instated by the RM who is covering this work following the departure of the quality manager in 2020/21. QMS and monthly performance reporting pack includes evidence of degree to which the documents are current.
				People								
				Adherence to the HTA People Strategy which has been substantially amended and approved by the Board					X			Preventative	Management information and assessment presented to the Board quarterly.	Chief Executive's report to the Board now includes HR report - last presented to November 2021 meeting. Mid-year reviews completed during Quarter 3 2021.
				Training and development of professional competence					X			Preventative	Annual PDPs, which include Development Objectives, Corporate Training Programme (led by Head of HR), Career Investment Scheme proposals to SMT, induction programme for new entrants, with a bespoke programme for RMs.	Evidence of corporate training programme, including quarterly mandatory training. Quarterly Regulation-led Training sessions held virtually in July 2021, September 2021 and scheduled for January 2022. 'Lunch and Learn' programme.
				Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas		As vacancies arise, SMT take the opportunity to review business requirements and target building capability and filling skills gaps. An organisational redesign for aspects of the HTA's work was developed during late 2020/21 to enable key gaps and capability issues to be addressed and a large-scale recruitment programme for 10 posts, including the redesign, initiated in Quarter 1 of 2021/22.			X	X		Preventative/ Monitoring	SMT assessment of skills requirements and gaps as vacancies occur. Organisational design. Recruitment policy.	Staffing levels and risks reported quarterly to the Board most recently July 2021. Large recruitment programme for 10 vacancies started May 2021, incorporating the new roles created by the organisational redesign of key support functions and search for key additional capability identified as required in the RM cadre. Recruitment policy reviewed by SMT May 2021 to be completed by autumn 2021.
				EU Exit (End of Transition period and HTA Exit SIs 'grace period')								
				Fortnightly Transition Period oversight meetings from February 2020 with+H4:Q16+H4:Q15 Close liaison with DHSC to ensure communications are in line with government policy and that appropriate arrangements are made to support DHSC and stakeholders during the transition period. HA Guide, ODT Framework and other external guidance being updated in line with new legislation to ensure we can regulate accordingly.		Weekly project meetings from Quarter 3 2020/21. Dedicated project manager (external contractor) and Regulation Directorate and comms team resource. Weekly Project Governance meetings from mid-January 2021 (after daily / thrice weekly stand-ups ceased). Continued close liaison with DHSC policy and communications teams and EU Exit and Trade teams, including participation in DHSC-led meetings with ALBs. Project maintaining active oversight of risks, issues, and resource requirements.			X	X		Preventive / Detective / Monitoring	Weekly reporting by ANH to SMT under standing item on SMT agenda. Internal Audit Quarter 3 of 2020/21 - moderate assurance. SMT lead for project - ANH (Director of Regulation). Formal project re-established from Quarter 3 2020/21. SMT papers for key decisions.	EU Exit - dedicated project manager (contractor) appointed Quarter 3 2020/21 until 31 July 2021. (Project due to be closed and handed over to business as usual by 31 July 2021.) EU Exit / UK Transition Project documentation and records in Teams Channel. Internal Audit on Risk focusing on EU Exit - reported January 2021, moderate assurance, completion of management actions tracked in audit tracker by ARAC. Standing item on SMT weekly minutes - EU Exit update - reported in minutes.
						Regulatory model								
						Development work being undertaken to become a more data-driven risk based regulator as part of the HTA Development Programme.			X			Preventative		
						Other								
						Strengthening horizon scanning arrangements			X			Preventative		

HTA 1c/22 Annex C - NEW - HTA Strategic Risk Register 2021-22

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***	***4***	*Future but increased likelihood over next few months*	Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff	***3***	***3***		***6***	X	X		Preventative	Policies etc. reviewed annually, training specification and notes after incident reviews	Subject to internal audit reported to ARAC in February 2020 Version 19 of CIRP published July 2019. CIRP deployed in March 2020 to manage coronavirus pandemic. CIRP used as framework for managing Sandpiper critical incident. Business Continuity and Critical Incident Response Plans updated and approved by SMT on 10 June 2021.
						All specific roles identified in the Critical Incident Response Plan are filled.					1 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. Experience of engaging and managing a contract with Crisis comms consultants		X			Preventative	Policy reviewed as scheduled. Reports on any key media issues and activity in the Chief Executive's Report. Evidence of active Comms Team participation in issues with potential for media or public interest.	Media issues are included in the quarterly Board reporting as they arise and as relevant. Media enquiries successfully managed during critical incident phase of Sandpiper.
						Availability of legal advice					X			Preventative	Lawyers specified in Critical Incident Response Plan. SMT updates	In place
						Fit for purpose Police Referrals Policy			Engagement with other potential investigatory authorities, such as NHS Counter Fraud Authority		X			Preventative	Annual review of policy (minimum), usage recorded in SMT minutes	Police referral process used regularly by SMT and captured in SMT minutes. Police referral process shown to have been effective in 2020/21 with a referral to police for a potential breach of the HT Act being taken forward in an active investigation. Police referral policy being updated - considered by the Board November 2021 and on the agenda for finalisation February 2022.
						Onward delegation scheme and decision making framework agreed by the Board					X	X		Preventative	Standing Orders and Board minutes	Standing Orders published May 2017, updated at Board meeting in November 2021.
						Regulatory decision making framework			Regulatory Decision Making process and SOP regularly reviewed and disseminated to staff.		X			Preventative	Reports to Board of key decisions in Chief Executive's Report to the Board.	Number of Regulatory Decision Meetings detailed in monthly management performance pack, for review by SMT. Regulatory Decision Making SOP reviewed and updated March 2020 with the next review due by March 2022.
						IT security controls and information risk management					X	X		All	SIRO annual review and report Internal audit reports	Cyber security review - standing agenda item at ARAC - last discussed June 2020. Cyber Security has been a standing agenda item in the form of a dashboard report at each ARAC meeting.
						Critical incident response plan regularly reviewed and tested			Actions associated with the internal audit reported in February 2020.		X	X		Preventative	Critical Incident Response Plan and notes of test, reported to SMT Use of CIRP reported to SMT.	CIRP used to manage response to coronavirus pandemic from March 2020. CIRP deployed for a short period in May / June 2021 to deal with confidential matter. CIRP used as basis for Sandpiper response planning in Autumn 2021.
						Evaluate test exercise of incident and feedback to all staff.			Question over whether a test of the Plan is required in light of the recent stress test presented by the coronavirus pandemic and more recently in the HTA's response to Sandpiper, managed as a critical incident.		X			Preventative	SMT content that activation and use of CIRP during first wave and first lockdown superseded the need for a test. SMT note CIRP framework used in managing the HTA's planning for and response to the critical incident arising from the police investigation codenamed 'Sandpiper'.	Noted in ARAC Audit Tracker.
						Ensure DIs (or equivalent in ODT sector) are aware of and follow the incident reporting procedure for incidents reportable to the HTA.			Awareness raised of PM sector reporting requirement (HTARIs) at external training events, 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 December 2021. Most recent SARE report submitted summer 2021. Publication of closed SAEAR and HTARI incident summaries included in the HTA publication scheme - published quarterly - and reporting in the Board's data annex. Publication of incident numbers in the regular (bimonthly) Professional Newsletter.
						Management of any risk of incidents likely to arise from the end of the 6 months post-Transition Period grace period for EEA/GB import / export licensing continues to be managed through the defined UK Transition project. The Director of Regulation is SRO, with a dedicated project manager and project resource and close continuing engagement with DHSC.			Continuing engagement with DHSC on ongoing aspects of the UK Transition Period Project, including the Northern Ireland Protocol (and engagement with NI Executive Department of Health).					Preventative / Detective / Monitoring	Director-level oversight as SRO (Director of Regulation), weekly Project meetings, 'stand-up' over the 6 weeks either side of 31/12/20, regular reporting to SMT through standing agenda item and specific papers for key decisions.	Regular reports to SMT - standing item on SMT agenda from February 2020. Internal Audit 2019/20 (Moderate assurance and management actions completed by Autumn 2021). Project formally closed October 2021 and remaining actions handed over to business. Pending clarification of whether any further changes might arise from any changes to the Northern Ireland Protocol.

HTA 1c/22 Annex C - NEW - HTA Strategic Risk Register 2021-22

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	I	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*	*4*	*3*	*Ongoing*	Horizon scanning process in place that creates and maintains an up to date log of issues known to the HTA with respect to the legislation (updates, amendments or emerging issues) to inform DH and manage messages	***3***	***3***		***9***	*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 July 2021 - held virtually. Professional newsletters issued regularly - last one September 2021. Sector-specific engagement e.g. with anatomy sector webinars and engagement with the post-mortem sector through multi-agency forums (Death Investigation Group, Excess Deaths Working Group).*
						Active management of issues raised by the media – including the development of the HTA position on issues			*Lines currently under review and update*		*X*			*Preventative/ Detective*	*Quarterly reports to Board on communication (including media) activities*	*Last report to November Board meeting (2021).*
						Regular reporting to DHSC sponsorship and policy team on matters which risk public and professional confidence						*X*		*Monitoring*	*Quarterly Accountability meetings with DH superseded during the pandemic by DHSC attendance at Board meetings for assurance plus DHSC sponsor team's engagement with HTA.*	*Most recent confirmation in letter from Marina Pappa of DHSC Sponsorship Team to AMS dated 21 July 2021 re Quarter 1 2021/22. AMS met with Sponsorship team regularly during 2021.*
						Action where we believe it will support public confidence					*X*			*Preventative*	*Updated guidance in response to the coronavirus emergency published on the website, further sector specific guidance*	Update to the Board and DHSC at Board meeting July 2021.
						Clear view of use of s.15 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge			*Demonstrate ongoing engagement of Devolved Assembly in Wales and N Ireland. Effective engagement and collaboration demonstrated through the revision of Code D.*		*X*			*Preventative*	*Duty and its uses understood by SMT and Chair*	*Advice and guidance continues to be provided, for example on the Private Members Bill - Organ Tourism and Cadavers on Display, first introduced into Parliament in 2020 and reintroduced in 2021. Engagement with DHSC over Sandpiper issues - advice submitted to Secretary of State 15 December 2021. Also engagement with Welsh Government officials on this matter. Ongoing engagement with NI Executive over NI Deemed Consent and need for HTA to update its Code of Practice (F) in recognition of this.*
						No further changes to HTA's Standards since significant changes launched April 2017. Significant activity to update Codes of Practice for Organ Donation and Transplantation (and consent) to support the introduction of deemed consent (May 2020).			Further work planned in 2021/22 to review and update codes of practice . Focus will be on factual update.		*X*			*Preventative*	*Updated draft guidance produced for revised Code D. Updated draft of Codes of Practice D to enhance consent expectations for imported bodies and body parts for public display.*	*Draft revised Code of Practice D (Public Display) to align consent expectations for imported bodies and body parts with those for material originating in England, Wales and Northern Ireland received Parliamentary approval in July 2021.*
						Extensive Professional Evaluation Survey undertaken in Q4 2019/20, reported to Board in July 2020 and used to inform further developments.			Further work planned in Q3 & 4 to pilot new approaches to stakeholder engagement		*X*			*Preventative*	*Evidence from Professional Evaluation used as an evidence and information source to inform and drive improvements*	*Evidence from Professional Evaluation presented to the Board in July 2019.*
						Communications work package set up as part of UK Transition project to ensure we are managing our licensed establishments' expectations of what is required at the end of the transition period. As part of this WP we will also attempt to reach out to unknown end users to make them aware of their new regulatory licensing requirements and timelines.			UK Transition Communications Plan updated several times during the life of the project. RM taking responsibility for leading stakeholder engagement and coordinating activities of RM Stakeholder Managers.					*Preventative*	Weekly UK Transition Project meetings - standard agenda item is discussion of Communications Work Package.	UK Transition project documents (in dedicated Teams channel), weekly meeting agendas and action points plus weekly updates to SMT. UK Transition project closed October 2021.
						Regular meetings with DHSC policy team and attendance at other departmental meetings (ALB delivery partners) to inform planning for key pressures such as ongoing response to Covid-19; winter pressures, Transition Period and the period after 31 December 2020. In the last 6 months the HTA has demonstrated its role in strategic and partnership working as part of the wider Life Sciences & regulatory system and has demonstrated a responsiveness to legislative amendments and updates.			*Ongoing engagement with partner organisations to build opportunities for collaboration and support to the life sciences sector.*		*x*			*Preventative*	*Development programme workstream Strengthening of Horizon scanning has identified 4 areas to progress in 2021/22.*	*Regular reporting to SMT and through formal routes*

HTA 1c/22 Annex C - NEW - HTA Strategic Risk Register 2021-22

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

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

HTA 1c/22 Annex C - NEW - HTA Strategic Risk Register 2021-22

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

Human Tissue Authority
Board meeting

Date: 10 February 2022

Paper reference: HTA 2/22

Agenda item: 5

Author: Shirley Dent

OFFICIAL

Communications and Engagement Strategy

Purpose of paper

1. This paper provides the Board with:
    a) The objectives outlined in the working Communications and Engagement Strategy shared with the Senior Management Team (SMT) in August 2021.
    b) An update on the Q3 communications and engagement activities detailed in this strategy.
    c) Learning from Q3 activities and how this will be used to inform and revise the HTA Communications & Engagement Strategy.

Decision making to date

2. This paper was approved by SMT (Senior Management Team) on 20 January 2022.

Action required

3. The Board is asked to note and comment on the update and information provided.

Background

4. In August 2021, SMT agreed a working Communications & Engagement Strategy. This working document represented and aimed to support a transition from the HTA's established approach to communications and engagement. The objectives of this strategy were to:
    a. Strengthen stakeholder engagement with the HTA and public confidence in sectors regulated by the HTA, situating the HTA as an authoritative and collaborative regulator.
    b. Position HTA as a health regulation thought-leader that supports excellence and innovation in UK healthcare and life sciences.
    c. Support and promote the measurable positive impact of the HTA's regulation across all relevant sectors.

5. The delivery of these objectives would require change to established ways of working including the use of existing and new communication channels and approaches. Activities identified included:
    a. Reviewing and revising our stakeholder engagement model to enhance and extend positive relationships with both HTA licensed establishments and the wider healthcare and life sciences sectors.
    b. Developing, and increasing output of, digital and social media content that effectively and appropriately informs and engages target audiences.
    c. Instigating and implementing an internal communications programme that supports the Development Programme and improved sharing and analysis of data and intelligence.

Q3 2021/22 – update on activities

6. Good progress has been made by the Communications Team in Q3 on developing and testing new approaches. These activities have provided a foundation to build on, and learn from, as we develop the longer-term Communications and Engagement Strategy.

Stakeholder mapping and engagement

7. The Communications Team completed an initial stakeholder mapping exercise with the Heads of Regulation in this quarter. Findings of this initial mapping show that while our engagement is very positive in distinct sectors and with discrete

groups and organisations, there are development areas for our stakeholder engagement with the wider healthcare, life sciences, and health policy ecosystem. This development is critical in supporting the HTA maintain an expert regulatory voice and in remaining sensitive to development and innovation in the life sciences arena.

8. The HTA's purpose highlights the importance of providing the public with confidence in the safe and consensual use of human tissue, cells, and organs. The refresh of our approach to stakeholder engagement will be mindful of this outcome and what this means in relation to opportunities for collaboration and partnership working with other organisations and further information that can be shared in the development of the HTA's authoritative voice. As part of our refreshed stakeholder engagement, we will implement a review of our established stakeholder groups and their future direction and input, particularly in relation to the HTA's Development Programme.

9. The HTA held two roundtable discussions in September engaging stakeholders with a depth of experience and interest in two challenging areas of our regulation: innovations in the use of tissues and cells in Advanced Therapy Medicinal Products (ATMPs) and the retention of tissue from Coroners' examinations for research and teaching purposes. This was a new format of engagement for the HTA which was positively received. Stakeholders who took part in the discussions were NHSBT (NHS Blood and Transplant), Anthony Nolan, the BMA (British Medical Association), and the Royal College of Pathologists. Both roundtables were open exchanges and positively moved the discussion on, with several recommendations on how to further work on these issues emerging from the meetings.

10. We aim to develop more roundtables in 2022 and will engage as early as possible with the communications teams of those stakeholders participating to ensure a collaborative and positive communications and promotion plan is in place.

11. In 2022 we will continue to develop the HTA's stakeholder and engagement model by:
    a. Producing an updated stakeholder map and strategy that supports the HTA's strategy 2021-2024. In addition to a set programme of engagement with stakeholders we will seek to identify opportunities for additional and targeted engagement sessions on known issues, as strategic think pieces or in response to other insight.

b. Delivering a range of stakeholder events that prioritise two-way exchange and intelligence sharing, including a programme of roundtable discussions, data, and intelligence workshops, and the HTA annual conference
c. Reframing and updating existing advisory groups in line with the HTA's strategic direction, purpose, and the operating environment.

Digital content and social media output

12. Significant progress has been made on the website redevelopment project and in strengthening social media output in this quarter.

13. In Q4, the website redevelopment project enters its final phase, with the NHSx live assessment scheduled for 24 March. Significant development has been achieved over the duration of the project to date to ensure the accessibility of the website and its content. Quantitative data indicates the impact user-focused changes have had on the HTA website performance. Against our public beta baseline (the metrics gathered in the first 8 weeks of the launch of the public beta website), our October – December metrics indicate that we are exceeding: our unique users base by 128% (10,620 v 24,246); our sessions base by 93% (18,363 v 35,421); and our page view base also by 93% (48,826 v 94,479). Our Google search metrics also show a strong October - December performance: the impression base was exceeded by 209% (128,000 v 395,780) and our search results click base by 316% (4,480 v 18,651). Over the coming weeks our focus will be on further embedding these changes through further testing with a focus on plain English and the conversion of HTA document templates across all business activities in line with accessibility standards.

14. We continued to increase social media output and enhance our visual presentation of posts, with significant year-on-year (by monthly comparison) increase in all metrics. We have increased output of posts from Q2 2021/22, when we were posting on average 1-2 times a week on our social media channels to posting at least twice a day on Twitter and once on LinkedIn, with all posts containing a visual element. The comparison of activity in September 2020 and September 2021 shows an increase across engagement metrics 19% for impressions (the number of times HTA content is displayed on social media accounts), 245% for engagements (the number of times users interact with HTA content by liking, sharing, or commenting), and 44% for click throughs (the

number of times users click on links in our social media posts to access HTA content).

15. We continue to develop our social media activity by exploring ways we can intelligently 'listen' and appropriately engage with pertinent discussions that can inform our wider regulatory and strategic understanding.

16. Going forward, we will explore how innovative (while appropriate) approaches to our digital and social media content can help engage target audiences. This content could include guest blogs (from appropriate partners), infographics, video explainers, and vlogs.

Internal communications

17. The Communications Team has continued to deliver BAU internal communications content while exploring new approaches and ways to engage and exchange information and ideas with staff across the organisation. As part of this development, we are continuing to develop and experiment with innovative and engaging content, including internal blogs and videos. We have worked with teams across the HTA, particularly HR, to ensure timely informative and supportive information is available to all staff, such as critical incident support. In 2022, we want to maintain this proactive approach to distilling information while encouraging more two-way exchange across all teams and staff, utilising a range of innovative and engaging formats, forums, and content.

18. To engage and embed Development Programme projects, the Communications Team explored, and are now implementing, project champions within teams, including Accessibility Champions and Data Dashboard Champions.

19. We are currently trialling several internal communications initiatives including weekly news reviews at the all-staff meeting with guest panellists from across the organisation and 'Get To Know You' short, light-hearted video interviews that will be posted to Wave (the HTA intranet).

Next steps

20. During Q4 the communications and engagement priorities will be to:
    a. Develop the HTA Communications and Engagement Strategy for SMT approval before Board paper submission in May

b. Continue to develop our stakeholder model and relationship management, including the use of advisory groups. This will include a dedicated quarter four engagement plan to include a year-long schedule of roundtable discussions and data and intelligence workshops, with the first of these events delivered in the quarter.
c. Review, in liaison with teams across the organisation, our established stakeholder groups, making recommendations for the groups' future direction in the Communications and Engagement Strategy.
d. Prepare for a successful NHSx live assessment, including an accessibility audit and final UAT and development sprints.
e. Rollout the internationally recognised Web Content Accessibility Guidelines (WCAG 2.1 AA) compliant templates and internal accessibility training materials.
f. Provide communications support for the Northern Ireland deemed consent Code amendments consultation.
g. Develop and trial video content for the Wave intranet.
h. Plan and implement internal communication for Development Programme products and initiatives, including the HTA data model.
i. Embed Accessibility and Data Dashboard champions in teams across the organisation.
j. Establish an annual conference working group and start to plan the 2022 stakeholder conference.

21. Over the next 3 months the HTA Communications & Engagement Strategy will be further developed and revised. During this time, we hope to seek the engagement and feedback of Board members and to use this to inform the drafting the final strategy. This strategy will be brought back to the Board in May for approval.

Human Tissue Authority
Board meeting

Date: 10 February 2022

Paper reference: HTA 3/22

Agenda item: 6

Author: Richard Sydee

OFFICIAL

Business Plan 2022/23

Purpose of paper

1. The purpose of this paper is to provide an overview of the planned process to compile and agree the HTA Business Plan for 2022/23

Decision making to date

2. This paper was approved by SMT (Senior Management Team) on 20 January 2022.

Action required

3. The Board is asked to note the proposed roadmap for the 2022/23 Business Plan and agree to review the pre-publication business plan out of committee during March 2022.

Background

4. Following the late publication of the HTA's 2021/22 Business Plan we have undertaken a review of the process for compiling and finalising the HTA's future strategic and operational business plans.

5. The HTA received guidance on 2022/23 business plan priorities from the Department shortly before the Christmas break. ALBs are asked to ensure they set out where and how the ALB is contributing to departmental objectives. Key matters of importance that ALBs are asked to consider in their business plan narratives, where relevant to their remit, are:

    - Consideration of response to COVID-19

    - Any relevant cross-system work from:
        - The NHS Long-Term plan (LTP)
        - Manifesto commitments
        - The five strategic Missions for Government
        - The DHSC Outcome Delivery Plan
        - the UK's future relationships with the EU and the rest of the world

    - Contribution to the Government's levelling up agenda
        - Places for growth
        - Health inequality reduction

6. Although it does not provide an absolute deadline for submission, it outlines an expectation that ALBs should be able to publish their 2022/23 Business Plan in March or April 2022.

7. The high-level summary below sets out the broad areas of activity that will be undertaken over the last quarter of this business year to agree activities and support the drafting of the narrative strategic plan for Departmental approval and publication. The 2022/23 plan will build on the Q4 business plan that was approved by the Executive on 18 January 2022.

8. As the Board will not meet again until May 2022, it is proposed that the draft plan be discussed and agreed with the Chair and Board at the end of March 2022, ahead of submission to the Department for approval for publication.

HTA
Human Tissue Authority

2022/2023- Business Planning Roadmap

Output		January 2022	February 2022	March 2022
Business Planning	Projects/ Additional Activities	**w/c 17th & 24th Jan** Business Portfolio Manager to facilitate a series of workshops for Teams/Directorates to identify all activities that need to commence/be delivered within 22/23. This will need to be supported with information on resource requirements (FTE, finances etc). ***Deliverable*** – complete list of all known projects/activities in each directorate to take place in 22/23 and any potential items in pipeline.	SMT to discuss and agree all identified activities. This will include Portfolio prioritisation and pipeline. ***Deliverable***- agreed plan for 22/23 to include all agreed activities and pipelines. SMT to provide assurance that this is achievable and that this aligns with strategic objectives.	Agreed activities to be incorporated in the formal Business Plan for 22/23. ***Deliverable*** - Directors and/or CEO to provide narrative for the Business plan detailing key activities and how to support delivery of organisations strategic objectives Board sign off on 22/23 Business Plan
	Business as usual activities	**w/c 17th & 24th Jan** Teams/Directorates to agree Key performance indicators for all Business as usual activities. ***Deliverable***-	SMT to agree KPIs, SLAs etc. ***Deliverable*** – a set of tangible KPIs to be referenced in the Business Plan and used in monthly portfolio reporting.	Business Plan to reflect all KPIs against BAU activities. ***Deliverable***- Board sign off on 22/23 Business Plan
Portfolio Management	Develop Reporting pack and processes	**w/c 31st Jan** Develop reporting pack using Q4 business plan including existing data reports as baseline and identify processes that will be followed to ensure information is cascaded monthly and avoids duplication of effort ***Deliverable***-clearly defined governance structure to support portfolio performance reviews	Incorporated agreed KPIs etc into reporting pack to monitor trends, progress and support decision making (where applicable for Q4) ***Deliverable*** - First pack to be sent to SMT for feedback as a dry run before first portfolio Management board in March 2022.	First portfolio Management board to take place with full portfolio reporting pack. The Business Plan will be kept as a standstill document (reviewed quarterly). ***Deliverable***- Full set of meeting documentation (reporting pack, minutes and actions from PMB) which can be shared with HTA Board.

Terms of reference

Audit and Risk Assurance Committee (ARAC)

Reference number	HTA-TOR-001	**Version**	15.~~43~~
Owner	Resources Directorate	**Date approved**	~~18 September 2018~~ Insert date when approved 2022
Author(s)	~~Morounke Akingbola~~ Head of Finance and Governance	**Next review date**	~~18 September 2021~~ month 2025
Reviewed by	~~Morounke Akingbola / Nima Sharma~~ Head of Finance and Governance/ Executive Assistant	**Distribution**	Internal and external
Approved by	HTA Authority		

Constitution

1. The Authority has established an Audit and Risk Assurance Committee (known to Human Tissue Authority (HTA) staff as ARAC) to support it in its responsibilities for risk management and governance. The ARAC will achieve this by advising the ~~Authority~~ Board and the Accounting Officer on the exercise of their responsibilities, ensuring the comprehensiveness of assurances that these responsibilities are being met and reviewing the reliability and integrity of these assurances.

2. The ARAC will make recommendations to the Board ~~Authority~~ regarding the adoption of the Annual Report and Accounts.

Duties and functions

3. The ARAC will advise the Accounting Officer and ~~Authority~~ Board on:

a. the strategic processes for risk, control and governance and the Annual Governance Statement;

b. the accounting policies, the accounts, and the annual reports of the HTA. This includes the process for review of the accounts prior to submission for audit, levels of error identified, and management's letter of representation to External Audit;

c. the planned activity and results of both Internal and External Audit;

d. adequacy of management response to issues identified by audit activity, including External Audit's audit completion report;

e. assurance relating to corporate governance requirements for the HTA;

f. ensure that the remuneration report for staff and Members in the annual report and accounts reflects the strategy (permanently delegated to ARAC by the Remuneration Committee);

g. (where appropriate) proposals for tendering for either Internal or External Audit services or for purchase of non–audit services from contractors who provide audit services; and

h. where necessary, anti–fraud policies, whistle–blowing processes, organisational culture and arrangements for special investigations.

Rights

4. The ARAC has the following rights:

a. it may co-opt additional participants, for a period not exceeding a year, to provide specialist skills, knowledge and experience (these additional participants must be recruited in line with paragraph 15 of this document);

b. it may procure independent specialist ad–hoc advice, at the expense of the HTA, subject to budgets agreed by the ~~Authority~~Board; and

c. it may seek any information it requires from HTA staff, who are expected to assist the Committee in the conduct of any enquiries.

Access

5. Internal and External Audit will have free and confidential access to the Chair of the ARAC. In addition, a confidential session with Internal and External Auditors for ARAC members will be scheduled each year.

Information requirements

6. As appropriate to the meeting the ARAC will be provided with:

    a. a report summarising any significant changes to the organisation's Risk Register;

    b. a progress report from Internal Audit summarising: work performed (and a comparison with work planned); key issues emerging from Internal Audit work;

    c. management response to audit recommendations;

    d. changes to the Internal Audit Plan;

    e. details of any resourcing issues affecting the delivery of Internal Audit objectives. Requests for work and reports received will be channelled through the Accounting Officer, to whom Internal Audit reports;

    f. a progress report from the External Audit representative summarising work done and emerging findings; and

    g. progress reports from the Executive, including periodic in-depth reports on areas of potential uncontrolled risk as identified by the ARAC.

7. As and when appropriate the ARAC will also be provided with:

    a. the Internal Audit Plan;

    b. Internal Audit's annual opinion and report;

    c. External Audit's annual report and opinion

    d. the draft accounts of the organisation;

    e. the draft Annual Governance Statement;

    f. a report on any changes to accounting policies;

    g. a report on any proposals to tender for audit functions;

    h. a report on co–operation between Internal and External Audit; and

    i. a report on any fraud or financial misdemeanour and any whistleblowing.

Reporting to the Authority

8. The ~~Authority~~ Board will receive the minutes of meetings of the ARAC for information. The circulation of any confidential minutes will be at the discretion of the Committee Chair.

9. The ARAC will formally report back (either verbally or in writing) to the ~~Authority~~ Board after each of its meetings.

10. The ARAC will provide the ~~Authority~~ Board with an Annual Report, timed to support the finalisation of the accounts and the Annual Governance Statement. The report will summarise the conclusions from the work it has undertaken during the year.

Reviewing effectiveness

11. The ARAC will use the National Audit Office's self-assessment checklist for Audit Committees in order to undertake annual reviews of its own effectiveness and agree actions for improvement. The ARAC will report the results of the review to the Authority.

Recruitment and membership

12. The ARAC will be chaired by a lay ~~Authority~~ Board Member, who is not the Authority Chair, and who preferably has relevant experience and expertise.

13. All other members of the Committee should be ~~Authority~~ Board Members, but not ~~Authority~~ the Board Chair. Including the ARAC Chair, there will be a minimum of three ~~Authority~~ Board Members and a maximum of five ~~Authority~~ Board Members on the Committee at any time.

14. At least one ~~Authority~~ Board Member, who is not the ARAC Chair, must be a member of both the ARAC and the Remuneration Committee, to provide assurance over remuneration matters.

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

16. The ARAC Chair and the other ARAC members will be appointed for a set term of three years, which will not exceed their tenure as ~~Authority~~ Board Members. It should be noted that ~~Authority~~ Board Members may be reappointed to the ARAC in accordance with the HTA's business needs.

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

Attendance

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

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

20. ~~Authority~~ Board Members who are not members of the ARAC have the right of attendance at Committee meetings. ~~Authority~~ Board Members attending meetings shall be entitled to speak with the permission of the Chair of the meeting, but in no case shall they be entitled to vote.

21. If the ARAC Chair is not present at a meeting, an alternative ~~Authority~~ Board member will be co-opted to chair that meeting.

22. The Chair of the ~~Authority~~ Board may attend Committee meetings, say once per year and not so frequently as to compromise the independence of the Committee. ~~An Authority~~A Board Member who is not a member of the ARAC may be co-opted as a member of the ARAC for a specific meeting if necessary to ensure a meeting is quorate.

23. The Chief Executive in his or her role as Accounting Officer (as defined in the Framework Agreement), the Director of Resources, and any other officer (at the discretion of the Chair) and Internal and External Audit (or equivalents) will also attend meetings of the Committee.

24. Up to two observers from the Department of Health and Social Care will normally be invited to attend meetings of the Committee.

25. The ARAC may ask any other officials of the Authority to attend to assist it with its discussions on any particular matter.

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

Frequency of meetings

27. The ARAC will meet three times per calendar year, with meetings timed to ensure effective and timely conduct of business and reporting to the ~~Authority~~Board.

28. The Chair of the ARAC may convene additional meetings as they deem necessary.

29. External Audit may request a meeting of the Committee if they consider one necessary.

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

Secretariat responsibilities

31. The ~~Board Secretary~~Executive Assistant ~~-~~will have secretariat responsibility for the Committee.

32. The Secretary must ensure Committee meeting dates are scheduled, meeting venues are booked and that Committee members are invited to attend all meetings.

33. The Secretary will liaise with the Committee Chair to create the agenda and will be responsible for collating and distributing the papers relating to the meeting. The agenda, minutes from the last meeting and the meeting papers for consideration will be distributed to the Committee one week before each meeting.

34. The Secretary will be responsible for taking minutes of meetings and recording action points. The draft minutes and action points from each meeting will be circulated as soon as possible, within one month of the meeting. Committee members will be asked to provide any comments on accuracy of the minutes by email within a time frame set by the ARAC Chair. This will ensure the key areas of discussion and action points are captured accurately.

35. The minutes will be approved by the ARAC Chair prior to being published on the HTA website. The Secretary will be responsible for ensuring that minutes are published on the website no later than two months after each meeting.

36. The Secretary will write a short summary of the issues discussed at each meeting for publication in the next staff newsletter and e-newsletter. This note will be drafted within one week of each meeting and approved by the Committee's Chair prior to being sent to the Head of Communications for publication.

Version history

37. These Terms of Reference will be reviewed annually by the ARAC and will be approved by the ~~Authority~~ Board following that review.

Latest version	Date	Comments	Reviewed by	Approved by
15.0	24 February 2015	Updated to ensure factual accuracy, update membership information and add version control.	Sue Gallone / Amy Gelsthorpe-Hill	Authority Members
15.1	18 October 2016	Amendment to secretariat and updated forward plan as per May 2016 minutes	Sue Gallone / Morounke Akingbola	
15.2	2 November 2016	Updated per November 2016 minutes	Morounke Akingbola	ARAC Members 09-11-2017
15.3	18 September 2018 (reviewed again 13 July 2020)	Amend role to Board Secretary	Morounke Akingbola	Board Members
15.4	January 2022	Updated to align with other governance documents	Morounke Akingbola	Board Members

~~*Further review to be undertaken by new ARAC Chair in 2021~~.

Human Tissue Authority
Board meeting

Date: 10 February 2022

Paper reference: 5/22

Agenda item: 8

Author: Nicolette Harrison / Kelly Sherlock

OFFICIAL

HTA Police Referral Policy

Purpose of paper

1. To seek HTA Board approval of:
    a. a revised HTA Police Referral Policy; and
    b. reinstatement of reference to the Police Referral Policy in the scheme of delegation of the Standing Orders.

Decision making to date

2. HTA considered a previous version of the HTA's Police Referral Policy at its meeting on 4 November 2021, paper reference HTA 26/21 refers.

3. Following that meeting, further amends have been made, on which legal advice has been obtained.

4. The revised Police Referral Policy is Annexed with changes highlighted.

5. In reviewing this revision to the Police Referral Policy, it became apparent that reference to it has been inadvertently deleted from the most recent version of the scheme of delegation in the Standard Orders.

6. The relevant section is on page 22 of the standing orders.

7. We propose that the table should be amended to reinstate the reference to a Police Referral, as distinct from a decision to authorise a warrant, as shown in italics below.

Decision Class	Decision Description	Delegation level
Decisions on referral to the police	*Police Referral*	*Senior Management Team*
Decisions on duly authorising a warrant	Any decision to 'duly authorise' a police officer (or officers) to obtain and use a warrant under the provisions set out in section 48 and Schedule 5 of the Human Tissue Act 2004 or regulation 23 of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (entry, search, and seizure in connection with a suspected offence).	Senior Management Team

Action required

8. The Board is invited to approve the updated Police Referral Policy.

9. The Board is invited to approve the amendment to the Standard Orders.

HTA 5a/22 Annex A - Police Referral Policy Document

Policy for managing and referring potential criminal breaches of human tissue legislation

Version	17.4	**Last reviewed on**	10 February 2022
Reference number	HTA-POL-023	**Next review due**	On next use
Author(s)	Nicolette Harrison	**Owner**	Dr Colin Sullivan
Approved by	Authority	**Distribution**	HTA Executive HTA Authority Members

Aim

1. This policy is primarily intended to assist HTA decision makers in reaching a view on whether or not to refer an apparent criminal breach of human tissue legislation to the police for investigation.

Purpose

2. This policy sets out how the HTA decides whether to refer apparent breaches of human tissue legislation to the police where those breaches may amount to criminal offences. It also covers decisions relating to the authorisation of the police to obtain and execute a search warrant under the Human Tissue Act 2004.

3. When we refer to human tissue legislation, we mean human tissue legislation that is within the HTA's remit. This currently includes (but may not be limited to in the future):

   a) The Human Tissue Act 2004 ("the Act")
   b) The Human Transplantation (Wales) Act 2013
   c) The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) ("the 2007 Regulations")

Commented [NH1]: Section on warrants added in previous draft version considered by the Board at their meeting on 4 November 2021; now at paras 39-53.

Commented [NH2]: Explanation expanded for clarity.

Commented [NH3]: Added to list.

Commented [NH4]: "…(as amended)" inserted post UK Exit from the EU.

d) The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended) ("the 2012 Regulations")
e) Additionally, the Scottish Government has delegated certain functions to the HTA under The Human Tissue (Scotland) Act 2006.

4. The criminal offences under the Act and the Regulations are summarised in Appendix 1.

Background

5. Human tissue legislation sets out the activities that constitute criminal offences if they are not undertaken lawfully. Specifically, some activities are made lawful:

- when appropriate consent is in place;
- under the authority of a licence from the HTA;
- through the HTA disapplying a legal prohibition e.g. living organ donation; or
- through HTA powers to issue Directions e.g. non-consensual DNA analysis.

Other activities are unlawful under any circumstances; trafficking in transplantable material being an example. The offences created by human tissue legislation are included in Appendix 1.

6. In undertaking its statutory functions, the HTA has a number of mechanisms by which it can identify breaches of legislation. The HTA has statutory power to carry out inspections and investigations, including the power to enter premises and seize documents. In some situations, regulatory action may be sufficient to deter or avoid any potential criminal breach of human tissue legislation.

7. In the course of its regulatory activity the HTA may uncover evidence suggesting offences may have been committed under human tissue legislation or other legislation e.g. human trafficking offences. This policy only relates to referral to the police in circumstances where the police would not, other than by the actions of the HTA, be informed that an offence may have been committed.

8. This policy relates to the management and referral of potential offences committed under the human tissue legislation within the HTA's remit, as set out in paragraph 3 above. The HTA's remit under the 2007 and 2012 Regulations applies to the whole of the UK.

9. Where the HTA identifies potential offences committed under Scottish human tissue legislation for which the Scottish Government has delegated some functions to the HTA, e.g. decision making on all relevant living donations, the HTA will inform the appropriate officials in the Scottish Government to agree if

Commented [NH5]: "…(as amended)" inserted post UK Exit from the EU.

Commented [NH6]: Added to list.

Commented [NH7]: Replaced "set out" with "summarised".

Commented [NH8]: Amended for clarity – it had previously only mentioned offences in England, Wales and Northern Ireland and made outdated reference in the footnote to the UK as a Competence Authority for the whole of the UK in relation to the 2007 and 2012 Regulations.

Commented [NH9]: Added in for clarity.

and by whom any referral will be made to Police Scotland. The HTA recognises that as for the police in England, Police Scotland are unlikely to be familiar with human tissue offences and hence it may be more efficient in practice to refer directly to the Procurator Fiscal (Crown Office and Procurator Fiscal Service ("COPFS").

Commented [NH10]: This section has been amended and expanded for clarity. It has incorporated previous reference to how referrals for offences in Scotland will be dealt with and updated and corrected these.

Legal Considerations relevant to the HTA's role

10. Although the Authority's licensing role and its regulatory powers are clearly defined in human tissue legislation, the scope of the Authority's role in relation to investigating and prosecuting offences is not expressly set out. Accordingly, the Authority has to determine what its role should be. In making that decision, the following factors have been taken into account.

- Paragraph 3, Schedule 5 of the Act stipulates that a person duly authorised by the Authority and by signed warrant has power to enter any premises (not only licensed premises), by force if necessary, and to search them where there are reasonable grounds to believe that an offence under Parts 1 or 2 of the Act or under the Human Transplantation (Wales) Act 2013 is being or has been committed. A similar power is contained within the 2007 Regulations for offences contained within those Regulations (Regulation 23).
- Under paragraph 5(2), Schedule 5, a duly authorised person also has the power to seize anything that he or she has reasonable grounds to believe may be required as evidence in proceedings for such an offence. This suggests that the Authority may have a role to play in gathering evidence to support the investigation of a potential criminal offence whether or not it has been referred to the police by the HTA.
- The Act contains legal requirements and offences that the HTA has no regulatory power to enforce, and which it may never come across through its regulatory activities, such as those relating to the non-consensual analysis of DNA.

Commented [NH11]: Amendments highlighted and shown in tracked changes were added for clarity, including statutory references where appropriate.

Commented [NH12]: Note: the previous version had a subsequent bullet point, now deleted, that discussed the HTA's view on conducting interviews under caution. This was considered not relevant for the Police Referral Policy. Instead, this will be incorporated into the HTA Investigation Policy and further legal advice is being sought on interviews under caution.

11. Some of the offences under the Act require the consent of the Director of Public Prosecutions ("the DPP") in order to prosecute (section 50 of the Act). For practical reasons, and as a consequence of section 1(7) of the Prosecution of Offences Act 1985, in England and Wales, this will involve the Crown Prosecution Service ("CPS"). In Northern Ireland, the consent of the DPP for Northern Ireland is required, and the Public Prosecution Service ("PPS") of Northern Ireland would be involved. There is no such consent requirement in Scotland.

Commented [NH13]: This section has been expanded to include reference to how offences requiring consent to prosecute are dealt with in England and Wales and in Northern Ireland and to note that this is not a requirement in Scotland.

12. Taking all these factors into account, and in view of the HTA's lack of expertise to investigate, interview or gather evidence to a standard that would be required for criminal prosecution, the HTA has determined that its policy will be to refer

potential breaches of human tissue legislation to the appropriate police force for investigation, where this is indicated. The HTA will use its limited powers of investigation to assist the police where this is required. The police force will undertake liaison with the relevant prosecuting authority (CPS, PPS or COPFS).

13. In making a decision about referral to the police for investigation, the HTA considers the impact that any offence, and its severity, has on the public interest (see indicative factors in para 28 - 29). The CPS in England and Wales, PPS in Northern Ireland, and COPFS in Scotland, in deciding whether or not to bring a prosecution, will consider: (i) whether there is enough evidence to provide a realistic prospect of conviction; and (ii) whether doing so is in the public interest.

14. The HTA aims that this policy will be supported by a protocol to be agreed with the National Police Chiefs' Council (NPCC).

Principles

Discharge of responsibilities

15. The Authority's functions as set out in section 15 of the Act include superintending, in relation to activities within its remit, compliance with requirements of Parts I and II of the Act. Establishing an agreed process whereby offences under the Act are referred to the police for investigation contributes to the discharge by the Authority of its duties under the Act. The Authority must exercise its discretion to refer to the police for investigation in a rational and reasoned way.

    The manner in which that discretion is exercised is crucial. As a public body, the Authority's decisions are subject to scrutiny by means of judicial review to consider whether the Authority's discretionary powers have been exercised lawfully, rationally and with procedural fairness. One of the key grounds for judicial review in this context is failure to take into account a relevant fact or factor or having taken into account an irrelevant fact or factor. Decision-making, therefore, needs to be properly reasoned and documented. This applies equally to decisions to refer as well as decisions not to refer.

    In the event that further evidence or relevant factors come to light or where circumstances suggest that a further review is appropriate, a decision not to refer may be revisited.

Consistency

16. There is also a need for the Authority's decision making to be consistent. This does not mean, however, that the Authority should decide to refer every case in

Commented [NH14]: Paras 28-29 – Factors for and against referral now separated into two paragraphs for clarity.

Commented [NH15]: Updated text to make reference to prosecuting authorities in Northern Ireland and in Scotland.

Commented [NH16]: Note – deleted former paragraph 12 which covered factors the HTA will take into account when making a decision about referring to the police for investigation. This content is now in paras 28-29.

Commented [NH17]: Amended text to clearly specify the two aspects that would be considered by a prosecuting authority.

Commented [NH18]: This text was included in the draft version considered by the HTA Board on 4 November 2021.

Commented [NH19]: Wording has been clarified and made more precise in relation to the references to factors relevant to Judicial Review.
A preamble sentence has been deleted as redundant, being implicitly covered in the factors for and against referral at paras 28-29. That sentence was:
"Even where there is evidence of a criminal offence, the Authority retains discretion not to refer a case for investigation by the police, for example in the circumstances described in paragraph 22."

Commented [NH20]: As above, this sentence has been rephrased to make the point clearer.

which there is an alleged criminal breach of a particular section of the Act or Regulations to the police. The HTA strives to achieve consistency by articulating and reasoning decisions using lists of indicative factors that point in favour of and against referral to the police.

17. Whilst the HTA will consider whether it holds any relevant evidence, the HTA is unlikely to make any assessment as to the strength, credibility and/or admissibility of that evidence when deciding whether to make a referral. It is recognised that any referral to the police will be for the purpose of investigating whether there is sufficient evidence of an offence to support a decision to charge a suspect with that offence.

Commented [NH21]: Former paragraphs 17 and 18 have been merged and rephrased for clarity.

HTA decision making process

18. The HTA's Regulatory Decision Making Standard Operating Procedure (HTA-SOP-026) sets out the principles of decision making within the HTA and the delegation of decision making for possible police referrals.

Commented [NH22]: Inserted full title of the relevant Standard Operating Procedure and updated hyperlink to where this is located in our Electronic Document and Records Management System.

Notification of potential offence

19. The Authority may receive notification of a potential offence from a number of sources including:

- intelligence gained from someone in an establishment or in the sector
- inspection processes
- notification from a member of the public
- notification by the police
- notification from another body such as another regulator or a research ethics committee

The role of the Director of Regulation

20. The Director of Regulation has responsibility for oversight of all potential criminal cases which relate to offences under human tissue legislation. Under the schedule of delegation for decision making, decisions on referral to the police are taken by the Senior Management Team ("SMT").

Commented [NH23]: Inserted title in full before use of abbreviation.

21. When information is received to the effect that a criminal offence may have been committed, this will be managed initially by the Director of Regulation through the HTA's regulatory processes, where it is possible to do so. The aim will be to seek to establish the facts of the case and to gather enough information to reach a decision about whether the activity identified appears to constitute a criminal offence or is one which can be managed using regulatory tools. The Director of

Regulation will inform the HTA CEO of the potential criminal offence at the earliest opportunity.

22. The Director of Regulation has delegated responsibility for deciding whether the evidence indicates that an offence may have been committed, taking into account all of the information available. The Director of Regulation is responsible for deciding when to refer the case to SMT for decision but will inform SMT of the progress of the HTA's investigation and the reasons for any delay in referring a case.

23. The Director of Regulation's conclusions and decision with respect to delegated cases must be recorded. If a clear breach of the Act or the Regulations has been identified, the establishment concerned should normally be informed that the breach has been noted and that it will form part of the establishment's licensing history when considering the need for regulatory action on any future occasion.

24. In exceptional circumstances where urgent referral to the police may be required, either to protect public safety, or where there is a concern that a delay may result in evidence that may be relevant to a criminal proceeding being compromised, the Director of Regulation may, with reference to the Chief Executive or other Director if the Chief Executive is unavailable, make the referral to the police directly without an SMT decision.

The Senior Management Team

25. The Senior Management Team must be quorate to make a decision on police referral. An independent legal adviser and the appropriate Head of Regulation may also be present to offer advice if required.

26. The Senior Management Team will consider the information available by reference to the indicative factors set out below. SMT may defer making a decision until additional evidence is gathered. In the case of a potential organ trafficking offence which has come to light through the living donation assessment process, the referral would not usually be made until the right to reconsideration of the Authority's original decision had been exhausted.

27. Where a decision is made, a record should be made of this in the SMT minutes, whether it is to refer the case to the police or not, and the reasons for it. The Chair will be informed of the decision as soon as possible and a report made to the Authority at the next practicable Authority meeting.

Commented [NH24]: Inserted "HTA" for clarity.

Commented [NH25]: Shortened for clarity from "…making the judgement as to whether…".

Commented [NH26]: Rephrased from "…the timing of referral of the case…".

Indicative factors in deciding whether to refer to the police

Factors in favour of referral

28. The following non-exhaustive list contains public interest factors **in favour** of referral to the police:

a) The alleged offence poses a risk to public safety
b) The alleged offence has the potential to damage public confidence in the use of human tissue
c) Referral to the police for investigation would have a positive impact on maintaining public and/or professional confidence in the use of human tissue
d) A person committing the alleged offence concerned is or was in a position of authority or trust, for example a licence holder or designated individual
e) A person committing the alleged offence was a ringleader or an organiser of the events
f) The alleged offence may have been deliberate or steps have been taken to conceal the facts related to the alleged offence or to mislead anyone concerning the facts related to the alleged offence (including the falsification of any information in any document or delay in reporting the activity which may constitute an offence)
g) The alleged offence or other offences under human tissue legislation are likely to be continued or repeated, as indicated, for example, by a history of recurring conduct
h) The alleged offence was committed despite a warning being given that the conduct may amount to an offence or that a licence was required
i) The alleged offence continued over a significant period of time
j) The information indicating the alleged offence is assessed to be reliable

Commented [NH27]: Inserted "…non-exhaustive list" and replaced "…may be regarded as" with "contains".

Factors against referral

29. The following non-exhaustive list contains public interest factors **against** referral to the police:

a) The alleged offence poses no risk to public safety
b) The alleged offence has limited potential to damage public confidence in the use of human tissue
c) A person committing the alleged offence has already been subject to criminal proceedings relating to the specific events in the UK or abroad
d) A person committing the alleged offence concerned acknowledged the breach of human tissue legislation to the Authority and/or the person concerned has not attempted to conceal the matter

Commented [NH28]: Inserted "…non-exhaustive list" and replaced "…may be regarded as" with "contains".

e) The alleged offence related to an isolated incident, which is unlikely to be repeated, for example as a result of regulatory action or changes in governance arrangements at the establishment
f) It appears that committing the alleged offence was not a deliberate act and occurred as a result of a genuine mistake or misunderstanding
g) There has been a long delay since the alleged offence occurred
h) The information indicating the alleged offence is assessed to be unreliable

A reasoned approach

30. A referral will usually take place when the Senior Management Team is satisfied that the public interest factors in favour of referral outweigh those tending against.

Recording decisions

31. Any decision made by the Senior Management Team must be recorded. The record of the decision should include a summary of the available information, the decision of SMT and the reasons for the decision, by reference to the factors.

32. Any processing of personal data through the implementation of this policy will be undertaken in accordance with the HTA's Privacy Notice.

Process for referral to the police

33. SMT, upon deciding to refer, will delegate responsibility for making the police referral to the appropriate Head who will liaise with the Home Office, Scottish Government or national police contacts to identify the appropriate point of contact within the relevant police force or COPFS. The content and scope of the referral will be informed by advice and the circumstances of each case but will typically consist of some or all of the following:

a) a summary of the alleged offence
b) where the offence relates to a regulatory matter, an account of the investigation signed by the Chief Executive
c) where the offence relates to a regulatory matter, details of any regulatory action taken by the HTA
d) a chronology of events (where this is not already evident elsewhere)
e) a list of all retained documents, with confirmation this is subject to any legal requirements for privacy and data protection.
f) where it is required, the HTA impact assessment
g) whether this case has also been notified to the CPS.

Commented [NH29]: Deleted the word "report" after "investigation" as amended text to be less specific by using the phrase "an account of the investigation".

Commented [NH30]: Changes highlighted.

34. Where urgent referral to the police may be required, either to protect public safety, or where there is a concern that a delay may result in evidence that may be relevant to criminal proceedings being compromised, the referral may be made orally with the full paperwork provided subsequently.

35. Where the offence relates to a service being provided to the public and that service may be disrupted as a result of a referral, the HTA will conduct an impact assessment in line with its Decision-Making Framework. This will inform stakeholder engagement to minimise disruption to service delivery and maintain public confidence. The HTA will update this impact assessment on a fortnightly basis and send a further copy to the police after every review.

36. Section 5 (consent), section 32 (commercial dealings in transplantation) and section 33 (restrictions on living organ donation) of the Act include offences that require the consent of the DPP for prosecution. In relation to other offences for which such consent is not required, and given that there will be few opportunities for individual police forces to develop any expertise in relation to offences contained in human tissue legislation, the HTA will also consider whether to notify the CPS (or PPS) at the time of any such referral or liaise with the receiving force about which organisation is best placed to do so.

Commented [NH31]: Text amended to clarify this relates to offences for which consent to prosecute is not required and to rephrase the text about notifying the CPS (and inserting PPS), including deleting reference to "…Special Crime Division of the CPS".

37. During an investigation, the police may require formal statements from HTA members of staff or other types of information. These requests should be passed to the appropriate Head at the HTA.

38. The police may also require expert evidence from the HTA. Where such a request is made, the police and HTA will rely on the CPS *Guidance for Experts on Disclosure, Unused Material and Case Management* (see *Related documents*).

Commented [NH32]: Included full title of the reference booklet.

Authorisation of the police to obtain and execute a warrant

Commented [NH33]: Note: apart from the tracked changes now highlighted at para 52, the remainder of this section, paras 39-53 inclusive and the table of related documents, were highlighted as additions in the previous draft version of this Policy that the Board considered at their meeting on 4 November 2021.

39. In some cases, the police may need to obtain and execute a warrant under provisions set out in section 48 and Schedule 5 of the Act. Also relevant are the Human Tissue Act 2004 (Powers of Entry and Search: Supply of Information) Regulations 2006 (SI 2006/538) ("the HTA Entry and Search Regulations").

40. There are multiple references to a "duly authorised person" in Schedule 5 of the Act which covers powers of inspection, entry, search and seizure. There is no requirement for a duly authorised person to be an employee of the HTA or engaged by the HTA.

41. The Criminal Justice and Police Act 2001 (as amended) refers to parts of Schedule 5 of the Act and clearly anticipates that the police may be involved in the seizure and retention of material under this Schedule.

42. Paragraph 3 of Schedule 5 of the Act allows a Justice of the Peace (a magistrate) to authorise, by signed warrant "a duly authorised person to enter the premises, if need be, by force and search them." The HTA could authorise a police officer or officers to act for the purposes of paragraph 3. If seeking and executing a warrant, a formal statement - referred to in the legislation as "an appropriate statement" - must be prepared in accordance with the HTA Entry and Search Regulations.

43. Regulation 2 of the HTA Entry and Search Regulations sets out what an appropriate statement must contain and also, at Regulation 2(1)(c), defines the person who is a duly authorised person for the purposes of paragraph 3, Schedule 5 of the Act (entry and search in connection with suspected offence) and who is executing a warrant issued under that paragraph, as the "investigator".

44. The appropriate statement which the duly authorised person or investigator must give to the occupier (or leave at the premises when executing a warrant) must, in accordance with Regulation 2(2) of the HTA Entry and Search Regulations, contain the following information:
    a) a statement that the investigator has been authorised by the Authority for the purposes of paragraph 3 of Schedule 5 to the Act (entry and search in connection with suspected offence);
    b) a statement that the investigator's rights of entry and search are subject to his producing evidence of his entitlement to exercise them, if required;
    c) a statement that the investigator is entitled, if need be, to enter the premises by force;
    d) a description of the investigator's powers under paragraph 5(2) to (4), Schedule 5 of the Act in respect of seizure of property in the course of inspection and search;
    e) a description of the requirement under paragraph 5(5), Schedule 5 of the Act for the investigator to leave a statement giving particulars of what he has seized and stating that he has seized it;
    f) a description of the powers of the investigator
        i. under paragraph 6(1), Schedule 5 of the Act to bring with him such other persons and equipment as he considers necessary;
        ii. under paragraph 6(2), Schedule 5 of the Act to inspect equipment and inspect and take copies of records, and in the case of

premises in respect of which a licence is in force to observe the carrying on of licensed activity;

g) a description of the investigator's obligations under paragraph 7(2), Schedule 5 of the Act to prepare a written report of the search and, if requested to do so by the appropriate person, give him a copy of the report;
h) a statement that a person commits an offence under paragraph 8, Schedule 5 of the Act if—
    i. he fails without reasonable excuse to comply with a requirement under paragraph 6(3), Schedule 5 of the Act, or
    ii. he intentionally obstructs the exercise of any right under Schedule 5 of the Act.

45. The statement could be prepared by (or on behalf of) the duly authorised person and would not necessarily be prepared by the HTA. If the HTA does not prepare the statement, then a formal written document, letter of appointment or similar should be in place which confirms that a person is "duly authorised" by the Authority for the purposes of paragraph 3 of Schedule 5 of the Act (entry and search in connection with suspected offence). The duly authorised person should have this document with them on any search.

46. The mechanics of getting a warrant are that an application must be made to the Magistrates' Court and, certainly where the police are involved in its execution, should comply with the Police and Criminal Evidence Act 1984 ("PACE") Code of Practice B.

47. The application will require "sworn information" that there are reasonable grounds for believing that (a) an offence under Part 1 or 2 of the Act or under the Human Transplantation (Wales) Act 2013 is being, or has been, committed on any premises, and (b) any of the conditions in paragraph 3(2), Schedule 5 of the Act are met in relation to the premises.

48. The conditions referred to are:
    a) that entry to the premises has been, or is likely to be, refused and notice of the intention to apply for a warrant under this paragraph has been given to the occupier;
    b) that the premises are unoccupied;
    c) that the occupier is temporarily absent;
    d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.

49. The HTA and the police may choose to collaborate in relation to the sworn information. Whilst a sworn statement may be prepared by a senior member of the Authority (such as the Director of Regulation), this is not a requirement of the legislation and it may be prepared by an investigating police officer instead.

50. Execution of the warrant must take place while the warrant remains valid (within 31 days) and in compliance with the relevant provisions of Schedule 5 of the Act and the HTA Entry and Search Regulations. There is a requirement under paragraph 7, Schedule 5 of the Act that, as soon as reasonably practicable after having exercised a power to inspect or search premises, the duly authorised person shall (a) prepare a written report of the inspection or search, and (b) if requested to do so by the Designated Individual or occupier, provide a copy of the report.

51. Under section 21 of Schedule 2 of the Act, the Authority may delegate any of its functions (to such extent as it may determine)–
    a) to any member of the Authority,
    b) to any member of the staff of the Authority, or
    c) to a committee consisting of persons each of whom is:
        i. a member of the Authority, or
        ii. a member of the staff of the Authority

52. On these grounds, and in line with the police referral delegation set out in the Onward Delegation Scheme of the HTA's Standing Orders, the Senior Management Team can duly authorise a police officer (or officers) to act for the purposes of paragraph 3 of Schedule 5 of the Act.

Commented [NH34]: Inserted text for clarity to replace the deleted text later in this sentence.

53. Following a decision to so authorise, a letter of appointment should be prepared – which confirms the name/s of the person (or persons) authorised and the details of the warrant – and signed by the Chief Executive or on behalf of the Senior Management Team

Related documents

Document	Date
The Code for Crown Prosecutors (CPS, October 2018) https://www.cps.gov.uk/publication/code-crown-prosecutors	Last accessed 13 December 2021
Guidance for Experts on Disclosure, Unused Material and Case Management (CPS, September 2019)	Last accessed 13 December 2021

https://www.cps.gov.uk/legal-guidance/cps-guidance-experts-disclosure-unused-material-and-case-management	

Revision history

Date	Version	Comments
16 August 2011	0.1	For SMT review on 18 August 2011
13 September 2011	0.2	Incorporating SMT comments
21 February 2012	0.3	Redraft to incorporate elements of HTA/POL/023
23 February 2012	1.0	Version agreed by SMT
8 April 2014	2.0	Revised version amended by AMS in light of the legal advice provided by Mills and Reeve (21 November 2013)
28 January 2014	2.1	Revised in light of regulatory action relating to establishment operating without a licence
26 February 2015	15.0	Version ratified following police referral decision on 26 February. New version numbering scheme adopted
3 August 2016	16.0	Fundamental review of the policy to provide greater clarity on the HTA role in investigation and as a basis for beginning discussion with NPCC following the disbanding of ACPO.
7 October 2016	16.1	Revised in light of comments from SMT, Heads and Authority Member Bill Horne and Chair Sharmila Nebhrajani.
9 February 2017	17.0	Revised in light of comments received from Members on 1 November 2016 and in subsequent correspondence.
March 2019	17.1	Reviewed and updated for GDPR compliance.
June 2020	17.2	Reviewed and updated in light of police referral experience and legal advice relating to warrants under the HT Act 2004. Agreed by SMT 7 July 2020.
November 2021	17.3	Minor amends approved by SMT 22 October 2021 and considered but not approved by the Board 4 November 2021 having identified the need for further changes.
February 2022	17.4	Revised following input from the Board, further review by the HTA Executive and legal advice.

Appendix 1

Offences under the Human Tissue Act 2004

1. Various offences are created by the Human Tissue Act, 2004 (the Act). A summary of the offences is provided below.

a) Consent

- Section 5(1): Prohibition of Activities without consent;
- Section 5(2): Making of a false representation in relation to activities requiring consent;
- Section 5(3): Storage of body for use for anatomical examination without the relevant signed certificate;
- Section 5(5): Use of body for anatomical examination without the death of the person being registered; and
- Section 8(1): Restriction of activities in relation to donated material.

b) Licensing

- Section 25(1): Breach of licence requirement unless there is a reasonable belief that the activity is not a licensable activity or that the individual acts under the authority of a licence;
- Schedule 5 Paragraph 8 Enforcement Offences: failure without reasonable excuse to comply with Paragraph 1(1) (Production of Statutory Records for Inspection) or Paragraph 6(3) (Inspector's Supplementary Powers) or intentional obstruction of the exercise of an inspector's rights under Schedule 5 *(see Schedule 2 paragraph 1 for further explanation).*

c) Anatomical specimens

- Section 30: Possession of anatomical specimens away from licensed premises, subject to exceptions *(see Schedule 2 paragraph 2 for further explanation);*
- Section 31: Possession of former anatomical specimens away from licensed premises *(see Schedule 2 paragraph 3 for further explanation).*

d) Trafficking / Transplantations

- Section 32: Prohibition of commercial dealings in human material for transplantation *(see Schedule 2 paragraph 4 for further explanation);*
- Section 33: Restriction on transplants involving live donors *(see Schedule 2 paragraph 5 for further explanation);*

- Section 34(3): Failure to comply with the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 in relation to the supply of information about transplant operations or knowingly or recklessly supplying information which is false or misleading in a material respect.

e) DNA analysis

- Section 45: Non-consensual analysis of DNA, subject to exceptions *(see Schedule 2 paragraph 6 for further explanation)*

2. It is important to note that proceedings for offences under Sections 5, 32 or 33 of the Act (see above) may not be instituted except by or with the consent of the DPP (or in the case of Northern Ireland, the DPP for Northern Ireland).

3. Section 49 of the Act covers the offences that can be committed by corporate bodies. Section 49(1) provides that where an offence under the HT Act is committed by a body corporate and is proved to have been committed with the consent or the connivance of or to be attributable to any neglect on the part of:

   a) any director, manager, secretary or other similar officer of the body corporate, or
   b) any person who was purporting to act in such capacity,

   he (in addition to the body corporate) commits the offence and will be liable for prosecution.

Offences under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

4. In addition to offences created by the Act, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) (the 2007 Regulations) create offences which are summarised below. Offences under the 2007 Regulations may be committed by a person, body corporate or Scottish partnership.

   - breach of requirement to hold a licence or to act under a third-party agreement;
   - breach of confidentiality requirement; and
   - enforcement offences.

Commented [NH35]: Amended text to clarify the scope and purpose of s49 of the Human Tissue Act.

Commented [NH36]: Deleted a redundant reference to "neglect", which relates to s49 (para 3 above) and is already included in that paragraph.

Commented [NH37]: "…(as amended)" inserted post UK Exit from the EU.

Commented [NH38]: "…(as amended)" inserted post UK Exit from the EU.

Offences under the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended)

5. Offences under the 2012 Regulations (as amended) may be committed by a person or body corporate.

    - Undertaking organ procurement activities (donor characterisation; organ characterisation; preservation of an organ; making arrangements to transport an organ; or retrieval of an organ) without a licence.
    - Undertaking organ transplantation activities (organ characterisation; preservation of an organ; making arrangements to transport an organ; or implantation of an organ) without a licence.

Commented [NH39]: "…(as amended)" inserted post UK Exit from the EU.

Commented [NH40]: "…(as amended)" inserted post UK Exit from the EU.

Human Tissue Authority
Board meeting

Date: 10 February 2022

Paper reference: HTA 6/22

Agenda item: 9

Author: Louise Dineley

OFFICIAL

Horizon Scanning

Purpose of paper

1. The purpose of this paper is to provide the Board with an update on the HTA's approach to Horizon Scanning and to identify some emerging thinking on questions to consider at a Board Strategy session later in 2022.

Decision making to date

2. The Senior Management Team approved this report for presentation to the Board during their meeting on 20 January 2022.

Action required

3. The Board is asked to note and comment on the approach to Horizon Scanning and the identified emerging themes.

Background

4. Over the last 9 months, the HTA has reviewed and updated the approach it takes to horizon scanning. This update has attempted to embed horizon scanning into activities and outputs across all HTA functions. It also aims to complement and inform other processes and activities such as the existing legislative review log and the operational risk registers. Combined these sources of information help to inform the strategic risk register. The triangulation of these sources allows the HTA to consider risks, opportunities and proactively respond through strategic and operational planning.

5. There is a clear framework through which all areas of the business are able to contribute to horizon scanning. This framework includes a horizon scanning group with membership representing all activities at the HTA. This group contributes to the maintenance and updating of a horizon scanning log. This log is also accessible to all staff allowing anyone in the business to identify new or emerging issues for consideration.

6. Horizon scanning features as a standing agenda item on individual Team and the Heads Management Team meeting. It is an objective on all staff members personal development plans.

7. Horizon scanning group members are responsible for collating, adding and updating items on the log from their relevant business areas. A representative from each business area attends, on a rotational basis, a monthly meeting. This rotational attendance encourages cross area discussions. The group review updates for individual items, links and impacts identified for different business areas and potential emerging issues arising.

8. The log and its review feeds into a register managed by the Head of Development. The horizon scanning register reflects items where action including monitoring is proactively being taken. Items on the register and the recommended actions are reported to the SMT on a monthly basis for consideration and agreement. This reporting structure supports the identification of new and emerging issues, ensures any issues are appropriately considered and addressed and potential risks, threats and opportunities for the HTA are proactively managed.

Horizon Scanning Register and Log

9. At the time of writing this report, the last monthly update to the horizon scanning log and register was in December 2021. Annex 1 contains the current log which contains a range of issues largely from the perspective of regulatory activity. This bias is reflective of the previous focus of horizon scanning at the HTA. In Q3, the Policy Team have been targeting and encouraging contributions from non-regulatory teams. One example identified as an addition is the implications of remote working as the default position in the future business requirements for systems design, technology developments and information management. This is an example of an emerging issue which straddles operational risk.

10. Annex 2 contains the horizon scanning register. The register is generated through internal governance with discussions and outputs from the Horizon Scanning Group and the Heads Management Team meeting. It is this register and the supporting governance that underpins reporting and recommendations to the Executive on entries for proactive management. The current register identifies five entries that have been reported to SMT. These include:
    - Licensing of funeral directors – storage of bodies for a scheduled purpose
    - Licensing of funeral directors – public health surveillance scheme
    - Travelling for transplant otherwise known as “organ tourism”
    - Assessment and reconditioning centres
    - Mid- and long-term implications of Operation Sandpiper

11. Over Q4, the policy function will be continuing to develop the log and register and the collation of non regulatory entries as well as external factors covering the wider life sciences sector and development of regulation.

Emerging Themes

12. As previously mentioned, horizon scanning is an integral function serving risk identification and strategic planning. In April 2021, the Board Strategy session considered a number of questions generated from horizon scanning. As we prepare for the annual strategy session, we have identified several emerging themes for early consideration. These include:
    - The role and purpose of the HTA within the changing and evolving Life Sciences landscape.

- Scope of sectors and activities regulated and provided with oversight by the HTA.
- Supporting innovation and advancements in the use of human tissue, cells and organs for example in research and advanced therapies.
- Alternative models of oversight and / or advice to unregulated or potential new entrants to regulation.
- Response to and for legislative change to support the HTA in fulfilling its role and purpose.

13. The sample themes identified are not mutually exclusive and reflect multiple entries on the horizon scanning log and register. Using information gathered through horizon scanning we will seek to develop and explore a number of strategic questions with the Board which may include what type of regulator the HTA needs to be. Over the last two years, the landscape has changed and the activities regulated have evolved. For the HTA to remain effective as a regulator in the future and in supporting innovation a continual review and sense check of its role and purpose may provide a useful pillar for the next strategy refresh. Such a review is also helpful in providing assurance on the emergence and management of gaps in regulation. Similarly research and technical innovations are identifying novel and alternative uses for human tissues, cells and organs that have the potential to introduce new sectors and activities to regulation or that may benefit from an alternative model such as oversight and advice. Proactive consideration of what this means for not only who is regulated but how, is critical and raises discussion points around “event based” regulatory models, supporting and not limiting innovation and the use of regulatory insight to provide oversight and seek assurance from activities and sectors not currently regulated either by the HTA or other bodies.

14. In preparation for the 2022 strategy session, these emerging themes and other entries generated over the next 3 months will be used to inform and develop a series of strategic questions to explore and test past and future strategies, decisions and positions and set future strategic direction. The discussion will also seek to support and develop our narrative for change be that in models of delivery, existing and alternative funding or opportunities for partnership working.

15. A further update on horizon scanning will be reported to the Board in May 2022.

HTA 6a/22 Annex 1 Horizon Scanning Log

Issue ID	Issue	Linked log issue	Date added to log dd/mm/year	Date last updated dd/mm/year	Business Area	Action to be taken	Status of issue
1	Common SAEARs reported and similar standards identified during routine visits				Regulation	No further actions	Ongoing
2	Body donation and body donation cards				Anatomy	No further actions	No further actions required
3	Taphonomy and regulation of Taphonomy			transferred from old log	Anatomy	No further actions	No further actions required
4	Effective regulation of Living Organ Donation			transferred from old log	Living Donation		Ongoing
5	Regulators Pioneer Fund			transferred from old log	All	No further actions	No further actions required
6	Scotland opt-out law change March 2021 Human Tissue (Authorisation) (Scotland) Act 2019				Regulation	No further actions	No further actions required
7	Coroners Service inquiry			29/04/2021	Post Mortem	No further actions	No further actions required
8	Partnership working and strategic relationships		transferred from old log		All areas		On Business Plan
9	Proportionate licensing model		transferred from old log	29 July 2021	Regulation		On Business Plan
10	Review of Code D: Public Display		04 February 2021		Public Display	No further actions	No further actions required
11	Increase in reporting of HHV8 cases				ODT	Watching brief	Ongoing
12	Increase in QUOD biopsy cases			10 September 2021	ODT	Watching brief	Ongoing
13	Increase use of machine perfusion			29 April 2021	ODT	Watching brief	Ongoing
14	Future of Death - Contingency planning (Cabinet Office)			29 April 2021	Post Mortem	Watching brief	No further actions required
15	Health Building Notes 16-01 - in review			29 April 2021	Post Mortem	Watching brief	No further actions required
16	**Regulation of aesthetic treatments and products/BEIS**		10 April 2021	29 December 2021	Human Application	Transfer to HS register	On HS Register
17	**NI moving to system of deemed consent for deceased organ and tissue donation**	56	10 November 2021	01 October 2022	Regs/Policy	Update/revision to guidance required	On Business Plan
18	**Travelling for transplant**	45	01 July 2021	05 January 2021	ODT	Transfer to HS register	On HS Register
19	**Assessment and Reconditioning Centres**			01 October 2022	ODT	Transfer to HS register	On HS Register
20	**Statistical Process Control**		transferred from old log	02 November 2021	Authority	Watching brief	Ongoing

HTA 6a/22 Annex 1 Horizon Scanning Log

21	**Regulatory oversight in NI and responsibilities for informing DH/EU if there are internal operational and licence changes**			10 January 2022	Human Application	Watching brief	Ongoing
22	**Living donor lung transplant**		02 November 2021	01 October 2022	ODT	Watching brief	Ongoing
23	**Ethnicity reporting**		29 July 2021		HR	Watching brief	Review required
24	**Regulatory approaches to licensing establishments where the control of operations is based outside the UK**		29 July 2021	10 January 2022	Human Application	Watching brief	Watching brief
25	**Ongoing need to monitor for regulatory divergence from the EU**		11 February 2021	10 January 2022	Human Application	Watching brief	Watching brief
26	**Monitor for any EU legislation changes that will impact the Northern Ireland Protocol**			10 January 2022	Human Application	Watching brief	Watching brief
27	**Definition of 'storage' in the 'Guide' appears to differ from the definition that is contained within the Q&S Regs.**			10 January 2022	Human Application	Update/revision to guidance required	Watching brief
28	**Fees for IMPORT as a result of UK Exit from EEA**			01 October 2022	Finance	Watching brief	Watching brief
29	**Request for HTA to take over Regulation from CQC of matching and allocation of organs for transplantation.**		29 July 2021	01 October 2022	Regulation	Watching brief	Ongoing
30	**Extracorporeal Liver Perfusion/Support**			10 January 2022	ODT	No further actions	On Business Plan
31	**Licensing for cardiac vessels procured and stored to support coronary bypass**			10 January 2022	Human Application	Watching brief	Ongoing
32	**To what extent reimbursement is permissible for voluntary unpaid donation**			10 January 2022	Human Application	Watching brief	Ongoing
33	**Possible shift in existing licensing position for amniotic membrane products**			10 January 2022	Human Application	Watching brief	Ongoing
34	**Consent requirements for storage and use of PM tissue blocks and slides (BMA)**	46	21 June 2021	02 November 2021	Post Mortem	Watching brief	Ongoing
35	**Regulation of organs/tissues and cells that move between the ODT and HA framework**			10 January 2022	Human Application	Watching brief	Ongoing
36	**Licensing of Funeral Directors - Storage of bodies for a scheduled purpose**	44, 37, 38	21 June 2021	10 January 2022	Post Mortem	Transfer to HS register	Ongoing
37	**Licensing of Funeral Directors - Storage of bodies for a scheduled purpose**	36, 38, 44	30 September 2021	02 November 2021	Finance	Watching brief	

HTA 6a/22 Annex 1 Horizon Scanning Log

38	**Licensing of Funeral Directors - Storage of bodies for a scheduled purpose**	36, 37, 44	30 September 2021	30 September 2021	HR	Watching brief	Ongoing
39	**Professional registration of Anatomical Pathology Technologists**		30 September 2021	10 January 2022	Post Mortem	Watching brief	Ongoing
40	**Clarity of one-off import arrangements**		30 September 2021	08 December 2021	Human Application	No further actions	Ongoing
41	**HTA Regulatory support to Isle of Man**		02 November 2021	07 January 2021	Policy	Watching brief	Ongoing
42	**Increased number of incidents in PM sector relating to social media**	43	27 October 2021	07 January 2022	Post Mortem	No further actions	No further actions required
43	**Increased number of incidents in PM sector relating to social media**	42	02 November 2021	07 January 2022	HR	No further actions	No further actions required
44	**Funeral director - public health surveillance**	36, 37, 38	24 November 2021	15 December 2021	Post Mortem	escalate to HMT/SMT	Ongoing
45	**Cadavers on Display and Organ Tourism**	18	24 November 2021	05 January 2022	Policy	Transfer to HS register	Ongoing
46	**Roundtables**	34	02 November 2021		Policy	Watching brief	Ongoing
47	**Code updates and Accessibility**	17	02 November 2021		Comms	Watching brief	Ongoing
48	**Mid and Long term implications of O/S**		24 November 2021	05 January 2021	Policy	Transfer to HS register	Ongoing
49	**Increased number of enquiries relating activities that can fall under both the HTA and MHRA's oversight**		10 December 2021	01 October 2022	Human Application	Watching brief	Ongoing
50	**Delivery of tissues/cells by drone - contribution to discussions between the MHRA and CAA about associated risks**		10 December 2021	10 January 2022	Human Application	Watching brief	Ongoing
51	**Institute of Regulation**		10 December 2021	05 January 2022	Policy	Watching brief	Ongoing
52	**Health and Care Bill**		07 January 2022	07 January 2022	All	Watching brief	Ongoing
53	**Social media mentions on issues outside of our remit**		10 January 2022	10 January 2022	Comms	Watching brief	Ongoing
54	**DHSC review into staff working internationally**		10 January 2022	10 January 2022	All	Watching brief	Ongoing
55	**COVID vaccinations**		10 January 2022	10 January 2022	HR	Watching brief	Ongoing
56	**NI Assembly elections**	17	12 January 2022	12 January 2022	Policy	Watching brief	Ongoing

HTA 6b/22 Annex 2 Horizon Scanning Register

Item Number	Linked issue ID on HS log	Issue	Date transferred to register dd/mm/year	Last updated dd/mm/year	Potential risks	Potential opportunities	Action required
1	**16**	**Regulation of aesthetic treatments and products/BEIS**	01/08/2021	14/12/2021	Public confidence risk		Further consideration required
2	**19**	**Assessment and reconditioning centres**	15/10/2021	14/12/2021	Public confidence risk		Further consideration required
3	**18, 45, 48**	**Travelling for transplant and cadavers on display**	01/08/2021	14/12/2021	Political/Business risk		Further consideration required
4	**36, 37, 38, 44**	**Licensing of funeral directors - storage of bodies for a scheduled purpose**	24/11/2021	14/12/2021	Public confidence risk	To increase standards of those seeking to be licensed.	Further consideration required
5	**36, 37, 38, 44**	**Licensing of funeral directors - public health surveillance scheme**	24/11/2021	14/12/2021	Public confidence risk		Further consideration required
6	**48**	**Mid and long term implications of O/S**	14/12/2021	14/12/2021	Public confidence/Business risk		Further consideration required

Human Tissue Authority

Board meeting

Date: 10 February 2022

Paper reference: HTA 7/22

Agenda item: 10

Author: Julie Edgeworth

OFFICIAL

Deemed Consent Northern Ireland

Code of Practice for Deemed Consent in Northern Ireland

Purpose of paper

1. To update the Board on the request from the Department of Health Northern Ireland to amend our Code of Practice in preparation for the introduction of deemed consent for deceased organ and tissue donation in Northern Ireland (NI).

2. To provide the Board with information on the proposed amendments to Code of Practice F.

3. To seek the Board's approval to amend the code of practice.

Decision-making to date

4. Since July 2021 the HTA has been engaging with the NI office on proposals to introduce Deemed Consent in NI. As part of this engagement it is proposed that

minor amendments are made to the existing Code of Practice F (part two) to include Northern Ireland where it may be currently excluded.

5. We are proposing minimal revisions are made to the Code, to include Northern Ireland where it is currently excluded, so it accurately reflects the proposed introduction of deemed consent in NI. We propose no additional changes are made to the wider content of the Code, unless factually inaccurate.

6. The communications and engagement plan supporting the revision of the code will need to deliver:

   - Assurance to stakeholders that the revision supports an alignment of Deemed Consent practice.
   - Active engagement and consultation on the revision with stakeholders in Northern Ireland.
   - Information to stakeholders in England and in Wales on limited scope of the proposed amendments.

7. It has been agreed with the NI Parliamentary Bill Team on Deemed consent that an initial version of the revised Code will be shared in May 2022, with a final version being shared by the end of October 2022. This will allow time to undertake training and preparations for the implementation of the legislation in Spring 2023.

8. SMT approved this paper on 20 January 2022 for submission to the Board.

Action required

9. Members are asked to agree the proposed review of the Code of Practice F. Members will be invited to review and provide comments on the specific changes by correspondence during Q4.

Background

Legislative update

10. The Organ and Tissue Donation (Deemed Consent) Bill (the Bill) will amend the interpretation of 'appropriate consent' set out in the Human Tissue Act 2004 (HT Act) for NI. This will mean that if a potential adult donor in NI had neither made a

decision nor appointed a nominated representative/s who had given consent under that appointment, their consent to organ and tissue donation may be deemed.

11. The Bill completed the committee stage on 16 December 2021.

12. Following the Parliamentary process, the Bill is expected to receive Royal Assent in March 2022. The NI Government consultation tool website states the Bill incorporates a 12-month transition period between the legislation being passed and implementation, to allow time for an extensive awareness and education campaign to ensure all members of the public are fully aware of the implications of the legislative change. The awareness and education campaign will continue as the new system is being implemented.

13. The Bill, the amended Codes of Practice and regulations, which will set out material for which consent cannot be deemed, will also come into force in Spring 2023.

Code of Practice F

14. Code F provides practical guidance to professionals working in organ and tissue donation in England and NI. It is intended that amendments will be as minimal as possible.

15. The proposed approach to amending the Code of Practice is targeted to specifically address the introduction of deemed consent for deceased organ and tissue donation in NI. The proposed scope of the amendments is to remove references that imply deemed consent is not applicable in NI. Where possible, the amendments will be limited to removing phrases such as ‘excludes Northern Ireland’ or ‘in England’ and replacing them with ‘includes Northern Ireland’ or ‘in England and Northern Ireland’.

16. In addition, minor amendments will be required to Codes of Practice A, B, C, D, E and G to reflect the introduction of deemed consent in NI. Minor updates will also be needed to the Code of Practice on the Human Transplantation (Wales) Act 2013.

Stakeholder Engagement

17. We plan to hold a targeted consultation on the specific changes that are being made to the Code to reflect the change in legislation.

18. The targeted consultation will be supported by clear messaging and information in relation to the scope and purpose of the amendments. A Policy Briefing will be produced in liaison between the Policy and Communications teams that clearly and in plain English describes the background and intent of the amended Code.

19. Roundtable events will be established to present the proposed changes to key stakeholders. Communications on the proposed revisions will be shared more widely with other stakeholders to ensure transparency is maintained. This will likely be for six-eight weeks between May and June 2022.

20. We will engage the Organ Donation Clinical Advisory Group. This is a group of experts originally convened by the Department of Health in NI to provide a mechanism for clinicians and other stakeholders to advise on the development and implementation of the Bill. Members of the group include representatives from:
    - NHSBT – Clinical Leads for Organ Donation, Clinical Lead for Organ Utilisation, Specialist Nurses for Organ Donation and National Clinical Lead for Organ Donation
    - Public Health Agency
    - British Medical Association
    - Belfast Health and Social Care Trust

21. We will liaise with counterparts in the Department of Health NI and NHSBT to ensure that all messaging is accurate and aligned.

22. We will ensure non-NI stakeholders are also kept informed and assured of the purpose and progress of the revisions to the Code of Practice.

23. Targeted consultation and engagement events on proposed changes to Code of Practice F (part two), based on the Bill receiving Royal Ascent in March 2022, will be conducted between May and June. The revised Code and feedback from the consultation and engagement period will be shared with NI Department of Health prior to sharing with Board members for approval to lay before Parliament.

Process

24. The Code must be laid before both Houses of Parliament in Westminster for 40 days. If no objections to the amends are received, the HTA will issue Directions to bring the revised Code into force in line with the new law.

25. Separately the NI Department of Health must lay the draft Revised Code before the NI Assembly. The NI Department of Health will meet the 'laying' requirement simply by delivering the draft Revised Code it has received from the Secretary of State to the Business Office of the NI Assembly. There is no requirement for the NI Assembly to debate or approve the Revised Code, once it has been laid.

26. The tentative timeline and plan for preparing the Code has been developed on the assumption that the Bill receives Royal Assent in March 2022. This plan will need to be flexible and take into account progress and feedback at each of the key stages.

Next Steps

27. Following the Board's agreement to review the code, a revision to the code will be drafted and engagement (for information, awareness and assurance) will commence. The HTA will be working to a timeline that will bring an update to the Board in May and a revised code for agreement in July.

Human Tissue Authority
Board meeting

Date: 10 February 2022

Paper reference: HTA 8/22

Agenda item: 11

Author: Richard Sydee

OFFICIAL

Audit and Risk Assurance Committee update

Purpose of paper

1. This paper provides an overview of the business of the Audit, Risk and Assurance Committee (ARAC) meeting held on 27 January 2022.

Action required

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

Background

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

Internal Audit

4. The Committee noted one report from the 2021/22 audit plan. This report provided a finding of moderate assurance from an audit undertaken of the HTA approach to producing its Annual Governance Statement. The committee noted that the approach was felt to be proportionate and provide sufficient time for

review and challenge of the supporting evidence; but that it could be further improved through review against current best practice.

5. The Committee received assurance that the remainder of the audit plan for the 2021/22 business year was on track to be complete by year end and that planning for the 2022/23 audit plan would start soon, with a proposed audit plan agreed by the HTA SMT to be approved out of committee by ARAC in March.

6. The Committee noted the further improvement in clearing outstanding recommendations from previous Audit reports and welcomed the assurances provided from Dr Colin Sullivan that this would be an area of focus ahead of the next ARAC meeting.

External Audit

7. The National Audit Office engagement Director for the HTA, Mike Surman, and Dean Gibbs, Audit Director at KPMG, set out the proposed plan for the 2021/22 audit of HTA's Annual Report and Accounts. The Committee noted the change in the areas of focus this business year and welcomed assurance from Dean Gibbs that the HTA's approach to changes to the reporting of leases in financial statements, also tabled at this meeting, were appropriate.

Strategic Risk Register

8. The Strategic Risk Register was presented, and the committee informed that the scoring for two risks, risk 2 – failure to manage an incident and risk 4 – failure to utilise our capabilities effectively, had been reduced to reflect the reducing burden of responding to the Sandpiper case and incoming permanent and interim resources.

9. The committee welcomed this and discussed with the executive how these two risks, and risk 5 relating to finances, could be reduced further to be at tolerance.

Other items

10. The Committee were pleased to note further progress in relation to cyber security reporting and management. The ongoing success in meeting training requirements for all staff in this area and the greater clarity in reporting was welcomed. The Committee asked that reporting in this area continue to be

developed and simplified given the significance of cyber security to this organisation.

11. The Committee noted updated HTA policies on Ant Fraud, Bribery & Corruption and Whistleblowing Policy and Procedure. The Committee also discussed both the ARAC handbook and the proposed changes to the ARAC Terms of Reference that were to be presented to the Board for approval.

12. Under any other business the committee noted the HTA response to a Parliamentary Accounts Committee request to review contingent liabilities; it also noted the appointment of Dr Sullivan as the HTA's Accounting Officer and handover letter sent to him from the interim Accounting Officer.

13. The committee then thanked Dr Stuart Dollow for his active and diligent participation as an ARAC member as his appointment comes to an end

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

Date: 4 November 2021

Time: 10.00 – 12.00

Venue: Zoom Meeting

Protective Marking: OFFICIAL

Attendees:

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

HTA attendees
Louise Dineley, Director of Data, Technology and Development
Nicolette Harrison, Director of Regulation, HTA
Richard Sydee, Director of Resources
Jessica Porter, Head of Regulation
TJ O'Conner, Executive Assistant
Alison Margrave, Board Support (minutes)

Apologies
Glenn Houston
Maria Nyberg, Deputy Director Health Ethics, DHSC

Observers
Dr Colin Sullivan, incoming HTA Chief Executive
Jacky Cooper, Team Leader Human Tissue Policy and Ethics of Consent

Tom Billins, Policy Manager, HTA

Item 1 – Welcome and apologies

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

2. The Chair welcomed HTA's incoming Chief Executive, Dr Colin Sullivan, who was observing the meeting. Thanks were expressed to the Food Standards Agency for releasing Dr Sullivan to attend this meeting, and others, as part of his induction process.

Item 2 – Declarations of interest

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

Item 3 – Minutes of 15 July 2021 meeting [HTA 19/21]

4. The Chair stated that no comments on the factual accuracy of the minutes from the last meeting had been received. The minutes were adopted.

Item 4 – Matters arising from 15 July 2021 meeting [HTA20/21]

5. The Chair introduced the report, and the Board noted the actions which had been completed.

6. The Chair noted that due to changes in Ministerial responsibilities the work to develop further the strategic vision for the regulation of the Life Sciences sector was in abeyance at the moment.

Item 5 – Chair's Report

7. The Chair provided an oral update on the following points:

Recruitment of CEO. Dr Colin Sullivan had been appointed as HTA's Chief Executive and would officially take up this position on 1 January 2022. She thanked those Board members who had been involved in the recruitment process and the support received from the Department. Confirmation had been received from DHSC appointing Richard Sydee as acting Interim Accounting Officer. The Chair also noted comments from DHSC's Remuneration Committee suggesting the HTA undertakes a review of the process of recruiting to the most senior roles as it is not something the HTA does very often. This matter will be considered by the newly restructured HTA Remuneration Committee.

Recruitment of Board Members. Shortlisting of candidates is taking place with interviews planned for December and any recommendations will be considered by Ministers, probably in the New Year.

HTA Standing Orders. The Board had agreed the revised standing orders via correspondence and the Board noted their approval.

Department of Health and Social Care. The Board noted that there had been correspondence regarding HTA Board Member recruitment, potential meetings in the New Year and the confidential matter.

Confidential Matter. The Board noted meetings involving the Chair, the Senior Management Team, and representatives from the Department on this matter.

Board/SMT Strategic Away Day. SMT is looking at the possibility of organising an event in 2022 once the new Chief Executive has arrived.

Item 6 – Chief Executive's Report [HTA21/21]

8. Louise Dineley introduced the report to the Board.

9. She provided updates on communications, the successful pilot of roundtables and provided clarification around the staff vacancies where recruitment had been paused to allow for further scoping of the roles.

10. Nicolette Harrison provided updates on regulatory matters including whether guidance might be updated to consider what other organisations might call "never events". She also spoke about UK transition projects and Freedom of Information Act training which was held for HTA staff.

11. Richard Sydee spoke to the financial information provided in the report and provided an update, especially with regard to debtors noting that one million pounds had been received in fees since writing this report.

12. The Board asked about resilience and confidence around staffing levels and whether there was a need to adjust workplans during the transition period without a CEO. SMT assured the Board that this was in hand.

13. The Board asked about the evaluation of Virtual Regulatory Assessments and whether HTA's findings were being communicated to other regulatory bodies to share learning and best practice. SMT assured the Board that learning from the experience of on-line regulation is considered by the joint group of regulators in the health and social care family.

14. The Board sought assurance that HTA would be able to respond to the DHSC's Covid-19 Inquiry without further strain being placed on leadership and staff.

15. The Board noted the report with thanks to the SMT.

Item 7 – Audit and Risk Assurance Committee Update [HTA22/21]

16. Professor Gary Crowe introduced the report and provided updates on a number of key items.

17. The Audit and Risk Assurance Committee had conducted a deep dive on risk four - *failure to utilise capabilities effectively* and assurance had been given that plans had been put in place to mitigate any resource stretch. The Board sought assurance regarding the recruitment of Head of Technology position, which was given by the SMT.

18. The role of the Remuneration Committee providing additional people and human resources oversight to the Board was discussed.

19. The Board noted the report.

Item 8 – Development Programme Update [HTA23/21]

20. Louise Dineley introduced the report.

21. Updates were provided on capacity and resources and the reframing of a number of deliverables for Q3.

22. The Board sought further information on business mapping, engagement and commitment of staff and the future skill set for staff with relation to digital awareness.

23. The Board noted the report.

Item 9 – HTA Fees – proposals for 2022/223 [HTA24/21]

24. Richard Sydee introduced the report and stated that the Senior Management Team had discussed proposals in September and October. Following the Budget announcements SMT recommends a 2% increase on fees and the

introduction of two new fees for 2022/23, to be charged on Import and Export of relevant material moved between Great Britain and Northern Ireland under the UK transition protocols.

25. In response to a question, he confirmed that HTA has the authority to make fee increases in line with inflation and does not need DHSC approval for this.

26. The Board sought further information about the process which would be used to communicate the fee increases.

Action One

27. The Board approved the recommendation to increase HTA's fees by 2% and the introduction of two new fees for 2022/23, to be charged on Import and Export of relevant material moved between Great Britain and Northern Ireland under the UK transition protocols.

Item 10 – Living Donation – 12-month review of panel process [HTA25/21]

28. Nicolette Harrison introduced the report which provides an evaluation of the process and details the quality assurance mechanism in place. She thanked the Board for their feedback and welcomed the addition of any additional feedback direct to the transplant team.

29. The Board discussed the quality assurance process, expressed their satisfaction with it and some asked whether occasional quality assurance and reinstitution of the Panel review meetings for Members might be helpful

30. The Board noted that, at present, there was no recommendation to change the timeframe allowed for approving panel decisions.

31. The Board noted the report.

Item 11 – Police Referral Policy [HTA26/21]

32. Nicolette Harrison introduced the report and spoke to the proposed amendments to the police referral policy.

33. A member of the Board suggested that expertise within the Board could be used to help formulate any changes.

Action Two

34. It was agreed that Professor Penney Lewis would work with the HTA Team, and a revised policy would be brought to the Board for approval via correspondence.

Item 12 – Any other business

35. There was no other business raised.

36. The Chair thanked the HTA staff who had prepared papers and attended the meeting.

Date of Next Meeting

10 February 2022

Meeting actions

Action One

The Board approved the recommendation to increase HTA's fees by 2% and the introduction of two new fees for 2022/23, to be charged on Import and Export of relevant material moved between Great Britain and Northern Ireland under the UK transition protocols.

Action Two

It was agreed that Professor Penney Lewis would work with the HTA Team, and a revised policy would be brought to the Board for approval via correspondence.

Human Tissue Authority
Board meeting

Date: 10 February 2022

Paper reference: HTA 10/22

Agenda item: 13

Author: Alison Margrave

OFFICIAL

Matters Arising from HTA Board meeting 4 November 2021

Date Added	Action	Target date	Revised date	Status
Nov 21	The Board approved the recommendation to increase HTA's fees by 2% and the introduction of two new fees for 2022/23, to be charged on Import and Export of relevant material moved between Great Britain and Northern Ireland under the UK transition protocols.	Dec 21		Completed
Nov 21	Professor Penney Lewis to would work with the HTA Team. Revised policy would be brought to the Board for approval via correspondence.	Feb 22		In progress

Human Tissue Authority Board meeting

Date: 10 February 2022

Paper reference: HTA 11/22

Agenda item: 14

Author: Louise Dineley

OFFICIAL

Development Programme Update

Purpose of paper

1. The purpose of this paper is to provide the Board with:
   i. A look back over the quarter of progress against the Programme plan
   ii. A forward look at Programme deliverables in the next quarter

Decision making to date

2 This paper was approved by SMT (Senior Management Team) on 20 January 2022.

Action required

3 The Board is asked to:
   i. Note the update on the Q3 deliverables.
   ii. Note the deliverables and dependencies for Q4.

Background

4. In 2021/22 we have identified three priority projects. 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 adopt a more risk-based approach to oversight and regulatory action.
    - The implementation of a Target Operating Model.

5. In addition to these priority projects, there are a number of projects and targeted pieces of work that will support the developments and progress. 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.

Q3 2021/22 – update on deliverables

6. The deliverables for the three priority projects and the programme overall in the quarter are outlined below along with a current assessment.

7. *An updated version of the Regulatory Insight Model & Index (RIMI).*
Status: GREEN
The development of the Regulatory Insight Model & Index has been hampered in quarters two and three by a dependence on outputs from other areas of work. This dependency has necessitated a reframing of the delivery and product for "go live". By the end of Q3, version one of the HTA's Data Model has been produced and is ready for roll out. Planning is underway for its implementation and most importantly setting the context of this model as an initial model with plans for incremental and continuous development. Interest and opportunities for further development of the data model and the adoption of its underlying principles to strengthen the use of information and intelligence has been shown by other functions. This extended use will continue to be explored and progressed over the quarter.

8. *The design phase of the transition architecture for the Enterprise Content Management System (ECMS) with development progressing and delivered in full by the end of quarter four*.
   Status: AMBER
   The design phase of the transition architecture is dependent on the mapping of a future state and "to be" process and data flow maps. The delay (referenced in paragraph seven) in the delivery of this product means that this work has progressed as far as it can and is currently paused. In the absence of the "to be" model work has continued in the planning of the next phase of this work with requirements gathered and specifications drafted. This approach facilitates the ability to move at pace to the design phase once the modelled processes are completed.

9. *A package of "as is" and "to be" process maps, data flow maps and narratives that form the basis of our operating manual and operating system*
   Status: AMBER / RED
   The mapping of the "as is" process mapping was completed at the end of October 2021. Previous reports to ARAC had highlighted challenges with the commissioning and delivery of the work. The intention had been to move to an initial round of "to be" mapping in quarter three. This was delayed and has now been confirmed as a priority in Q4 along with the required resources.

   The completion of the "as is" and "to be" processing mapping and its outputs is significant given the dependencies with other projects across the Development Programme. As a result, the pausing and delays to this work experienced in Q2 and Q3 have had an impact on the progress of other development projects such as the next iteration of the Target Operating Model, development of the regulatory insight model as intended and in the identification of future skills requirements and subsequent organisational design. The work scoped and commissioned in quarter four will take account of these requirements and deliverables.

10. *Future workforce skills map to inform workforce development and future operating model*
    Status: AMBER (dependency based)
    The progress of the future workforce skills map has been delayed due to the dependency on the process mapping. As with other projects planning for what needs to be done has continued including the approach to a skills audit and alignment with a future operating model. This work and its delivery will be

reframed once a schedule of outputs from the business process mapping has been confirmed.

11. Engagement with stakeholders (internal and external)
    Status: AMBER
    It has been necessary in Q3 to prioritise and deploy the communications and engagement team's resource to other projects. Most notable has been the Website redevelopment project and the HTA's management and response to Operation Sandpiper. Despite pressure on resources work has continued to update the stakeholder map and trial new and additional communication routes.

Deliverables in Q4 2021/22

12. Following the agreement of the business priorities and resource deployment for Q4, the Development programme's priorities and deliverables for the quarter are to:
    - Roll out the HTA Data model version one.
    - To commission and complete the "to be" process mapping and data flows to a standard and with the outputs that support dependencies with other projects.
    - To commence engagement with stakeholders on proposed changes as part of the development programme.

These priorities and the associated outputs will support recovery of the programme and progress in all projects.

13. Progress against each of the three deliverables has already been with the approval of resources in quarter, providing confidence in the achievement of the required deliverables and in setting the foundations for the next phases of development of each of these projects and in providing outputs to progress work on future capacity and capability needs and IT requirements.

14. An annual report will be shared with ARAC and the Board at the Q1 meetings for information and to agree strategic priorities.